340B DRUG DISCOUNT PROGRAM

Agency Oversight Has Improved, but Actions Needed to Address Weaknesses

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Testimony

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U.S. Senate

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GAO Highlights

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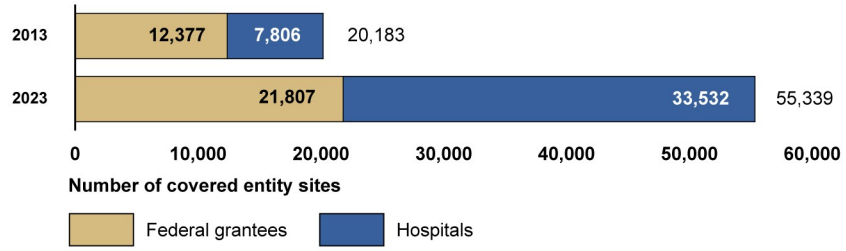
What GAO Found

The 340B Drug Pricing Program (340B Program) requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—certain federal grantees and hospitals—to have their drugs covered by Medicaid. In the 10-year period between 2013 and 2023—when we last reported on the program—the number of covered entity sites more than doubled.

340B Program Covered Entity Sites by Type, 2013 and 2023



Source: GAO analysis of Health Resources and Services Administration data. | GAO-26-108784

Accessible Data for 340B Program Covered Entity Sites by Type, 2013 and 2023

Number of covered entity sites	2013	2023
Federal grantees	12,377	21,807
Hospitals	7,806	33,532
Total	20,183	55,339

Source: GAO analysis of Health Resources and Services Administration data. I GAO-26-108784

Note: Numbers are as of January 1 of each year and represent the number of covered entities and associated sites.

GAO has identified numerous weaknesses in the Health Resources and Services Administration's (HRSA) oversight of the 340B Program. HRSA has taken steps to address some of these weaknesses, including implementing five of 20 GAO recommendations. Most notably, in fiscal year 2012, in response to a GAO recommendation, HRSA implemented a systematic approach to auditing covered entities and now audits 200 covered entities a year. Over time, HRSA has made other changes to strengthen its oversight by establishing an annual recertification process and other program integrity checks.

However, other weaknesses that GAO identified in HRSA's audits and oversight remain unaddressed. For example:

- HRSA's process for closing audits does not ensure covered entities have fully addressed any noncompliance identified.

- HRSA's audits do not fully assess compliance with the program requirement that prohibits covered entities from subjecting manufacturers to duplicate discounts, in which drugs are subject to 340B discounted prices and rebates under the Medicaid program.
- HRSA's oversight does not ensure only eligible hospitals participate in the program.

HRSA did not concur with six of the 15 unimplemented recommendations GAO made to address weaknesses in HRSA's oversight. HRSA concurred with the remaining nine recommendations, but the agency has expressed concerns that it lacks the necessary enforcement capability to implement some of them. HRSA has requested that Congress provide it with additional regulatory authority for the 340B Program.

Why GAO Did This Study

Covered entities can realize substantial savings through 340B Program price discounts and, according to HRSA, these savings can enable them to stretch federal resources to reach more eligible patients and provide more comprehensive services. Covered entities can provide 340B drugs to eligible patients regardless of income or insurance status and can generate revenue under the program when insurance reimbursement exceeds the 340B price paid for the drugs.

HRSA is responsible for administering the program and overseeing covered entities' compliance with program requirements. Program requirements include that covered entities must (1) prevent diversion of 340B drugs to individuals who are not eligible patients of the covered entities, and (2) avoid subjecting manufacturers to duplicate discounts.

This statement provides an overview of GAO's assessment of HRSA's oversight of the 340B Program.

This statement is primarily based on four GAO reports issued from 2011 through 2020 and on steps HRSA has taken to address GAO recommendations from those reports, as of February 2025. See GAO-11-836, GAO-18-480, GAO-20-108, and GAO-20-212. Those reports provide further details on our scope and methodology.

Chair Cassidy, Ranking Member Sanders, and Members of the Committee:

I am pleased to be here today as you examine the 340B Drug Pricing Program (340B Program), including its oversight. The program, created in 1992, and named for the statutory provision authorizing it in the Public Health Service Act, requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—certain hospitals and recipients of federal grants—in order to have their drugs covered by Medicaid.[1] The purpose of the 340B Program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services, according to the Health Resources and Services Administration (HRSA), the Department of Health and Human Services (HHS) agency that administers and oversees the program.[2]

Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to HRSA. In addition, covered entities can provide 340B drugs to eligible patients regardless of income or insurance status and can generate revenue under the program when insurance reimbursement exceeds the 340B price paid for the drugs. The 340B Program does not dictate how covered entities should use this revenue or require that these drug discounts be passed on to patients.

Covered entities must maintain compliance with 340B Program statutory requirements in three areas to continue participating in the program. First, covered entities must maintain compliance with program eligibility requirements outlined in law.[3] Second, covered entities are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.[4] Finally, covered entities cannot subject manufacturers to duplicate discounts, in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.[5]

In a September 2011 report, we identified shortcomings in HRSA's oversight of the 340B Program and recommended actions to improve oversight and ensure appropriate use of the program.[6] Since then, we have

[1]42 U.S.C. § 256b. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations.

[2]Because the statute does not explicitly state the purpose of the 340B Program, HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the Public Health Service Act. See H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). See also Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act).

[3]42 U.S.C. § 256b(a)(4).

[4]42 U.S.C. § 256b(a)(5)(B).

[5]42 U.S.C. § 256b(a)(5)(A). The Medicaid Drug Rebate Program, established under the Omnibus Budget Reconciliation Act of 1990, requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

[6]See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Washington, D.C.: Sept. 23, 2011).

monitored HRSA's progress in addressing our recommendations and conducted new work, which resulted in additional recommendations to improve program oversight.[7]

My statement today provides an overview of our assessment of HRSA's oversight of the 340B Program.

My remarks are based on our body of work examining the 340B Program. This includes reports issued and recommendations made from 2011 through 2023, as well as information on steps HRSA has taken to implement these recommendations. Those reports provide further details on our scope and methodology.[8] The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities. Entities eligible to participate in the program must submit applications to and be approved by HRSA prior to providing 340B drugs to eligible patients. Once registered for the program, covered entities must maintain compliance with program requirements, including those related to eligibility, diversion, and duplicate discounts.

Entities Eligible for the 340B Program

Entities eligible to participate in the 340B Program include federal grantees that receive one of 10 types of federal grants, as specified in statute.[9] These include federally qualified health centers, which provide comprehensive community-based primary and preventive care services to medically underserved populations, and other grantees that serve vulnerable populations.[10] Other entities eligible to participate include six types of hospitals that generally perform a government function to provide care to low-income, medically underserved individuals. This includes critical access hospitals—small, rural hospitals with no more than 25 inpatient beds, and disproportionate share hospitals—general acute care hospitals that serve a disproportionate number of low-income patients. (See fig. 1.) As of 2023—the last time we reported on the program—there were about 14,000 covered entities participating in the program, including about 11,400 grantees and 2,600 hospitals.

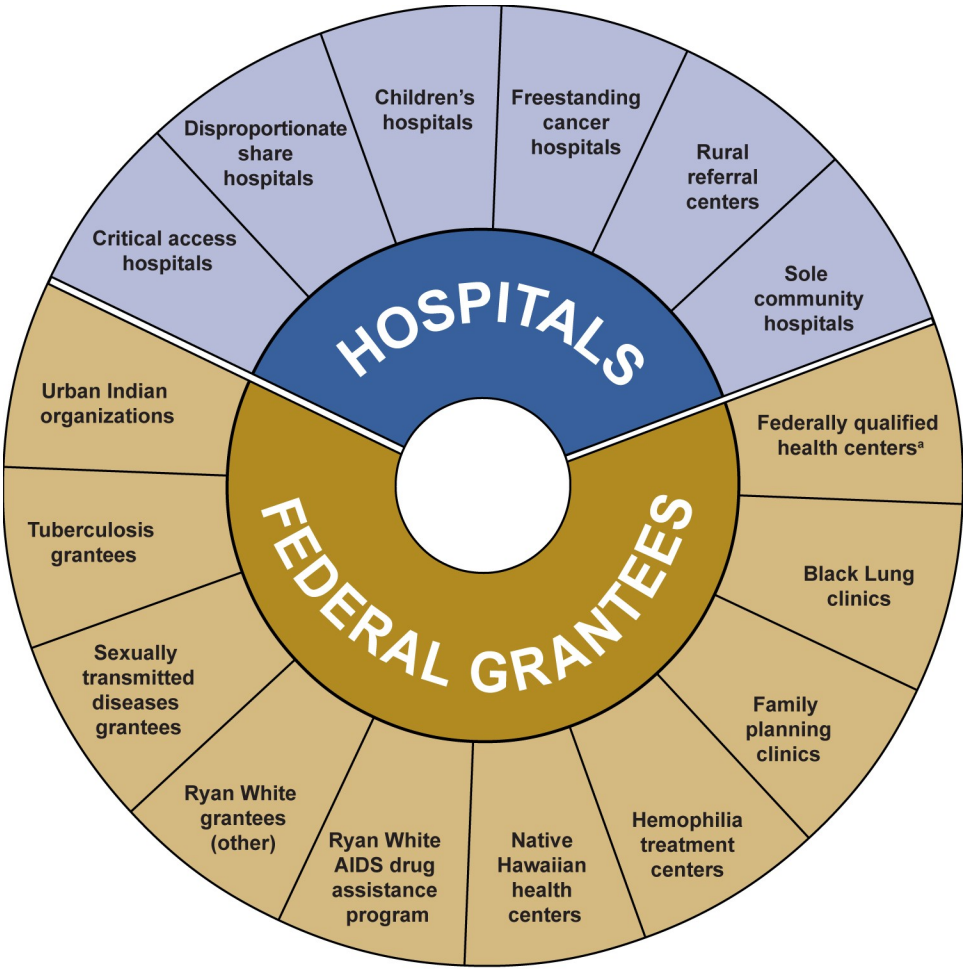
[7]See for example, GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480 (Washington, D.C.: June 21, 2018); GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements,* GAO-20-108 (Washington, D.C.: Dec. 11, 2019); GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 (Washington, D.C.: Jan. 21, 2020). A list of other related GAO products is included at the end of this statement.

[8]See, for example, GAO-11-836, GAO-18-480, GAO-20-108, and GAO-20-212.

[9]See 42 U.S.C. §§ 256b(a)(4)(A)-(K). All such grant programs are administered by agencies within HHS.

[10]Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the federally qualified health center program, but do not receive federal grants are referred to as federally qualified health center look-alikes and a relatively small number of them participate in the 340B Program.

Figure 1: Types of Entities Eligible to Participate in the 340B Program



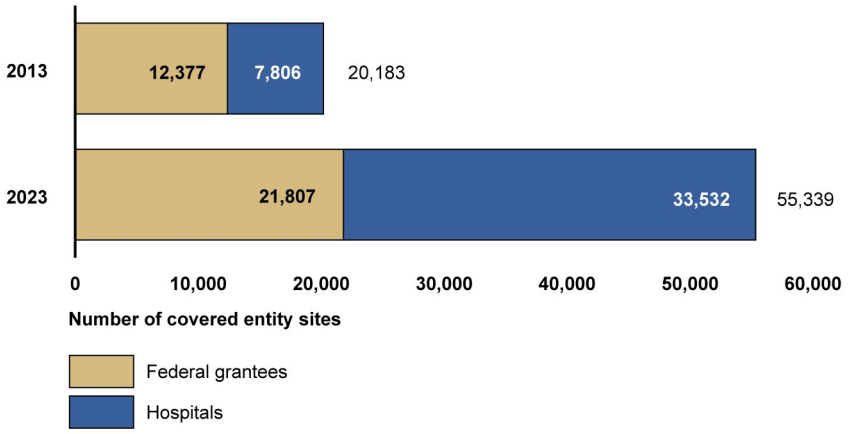
Source: GAO analysis of section 340B of the Public Health Service Act. | GAO-26-108784

[a]Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the federally qualified health center program, but do not receive federal grants, are referred to as federally qualified health center look-alikes, and a relatively small number of them participate in the 340B Program.

Some entities, typically federally qualified health centers and hospitals, have a main site (referred to as the parent site) and one or more associated sites (referred to as child sites), which can include satellite clinics, off-site outpatient facilities, hospital departments, and other facilities. Such associated sites must maintain compliance with program requirements to participate in the 340B Program and be considered part of the covered entity, according to HRSA.

According to data from HRSA, in the 10-year period between 2013 and 2023—when we last reported on the program—the number of covered entity sites more than doubled, from about 20,000 sites to more than 55,000 sites (see fig. 2). Much of the growth is due to increased hospital participation. Hospitals and associated sites increased from almost 8,000 in 2013 to more than 33,000 in 2023.

Figure 2: Covered Entity Sites by Type, 2013 and 2023



Source: GAO analysis of Health Resources and Services Administration data. | GAO-26-108784

Accessible Data for Figure 2: Covered Entity Sites by Type, 2013 and 2023

Number of covered entity sites	2013	2023
Federal grantees	12,377	21,807
Hospitals	7,806	33,532
Total	20,183	55,339

Source: GAO analysis of Health Resources and Services Administration data. I GAO-26-108784

Note: Numbers are as of January 1 of each year and represent the number of covered entities and associated sites.

340B Program Registration

To register for the 340B Program as covered entities, an eligible entity must first submit an application through an online database, the 340B Office of Pharmacy Affairs Information System. Entities must provide specific information about themselves, their associated sites, and their affiliated pharmacies. Once approved by HRSA and registered for the program, covered entities can begin purchasing drugs from manufacturers at 340B discounted prices.

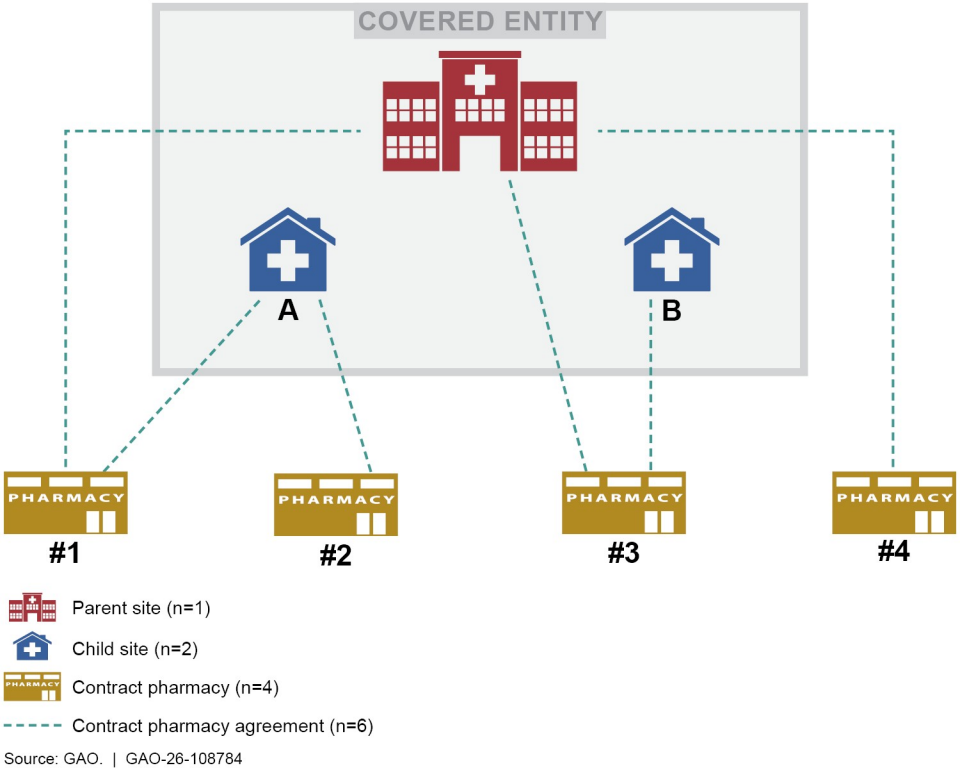
Covered entities may provide 340B drugs to patients through one or more dispensing methods. Specifically, covered entities may dispense these drugs through pharmacies—either through in-house pharmacies they own; through the use of contract pharmacy arrangements, in which they contract with outside retail pharmacies (contract pharmacies) and pay them to dispense drugs on their behalf; or both. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance, and in March 2010, HRSA issued final guidance allowing covered entities to have an unlimited number of contract pharmacies.[11]

According to HRSA guidance, a covered entity is required to have a written contract in place with each pharmacy through which it intends to dispense 340B drugs, but is not generally required to submit those contracts to HRSA.[12] A covered entity that has more than one site at which it provides health care may enter into separate pharmacy contracts for the parent site and each child site, or one comprehensive pharmacy

[11]See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[12]HRSA's guidance specifies that contracts must be provided to HRSA upon request.

contract including all sites intending to use the pharmacy.[13] It is up to the covered entity to determine which of its sites will be included in a contract with a pharmacy, and thus have what is referred to as a contract pharmacy arrangement with that pharmacy. Figure 3 provides an illustration of a covered entity with four contract pharmacies but a total of six contract pharmacy arrangements, as not all of the entity's sites have contracts with each of the pharmacies.

Figure 3: Illustrative Example of a 340B Program Contract Pharmacy Arrangement



Source: GAO. | GAO-26-108784

Covered entities that choose to have contract pharmacies are required to register with HRSA the names of each of the pharmacies with which they contract. As part of this registration, HRSA guidance specifies that covered entities must certify that they have signed and have in effect an agreement with each contract pharmacy and have a plan to ensure compliance with 340B Program requirements.

340B Program Requirements

Covered entities must maintain compliance with 340B Program statutory requirements in three areas to continue participating in the program: they must be eligible, they cannot divert discounted drugs to non-eligible patients, and they cannot subject drug manufacturers to duplicate discounts.

Eligibility of covered entities. As previously noted, entities are generally eligible for the 340B Program if they receive one of 10 federal grants or are one of six types of hospital. Hospitals must also meet additional

[13]Similarly, a contract can include multiple pharmacies from the same company, or a covered entity could have a separate contra ct with each pharmacy.

requirements. In order to participate, hospitals must be (1) owned or operated by a unit of state or local government; (2) nonprofit corporations that have been formally granted state or local governmental powers; or (3) private, nonprofit hospitals that have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid, which we refer to as nongovernmental hospitals. Additionally, hospitals generally must treat a disproportionate number of low-income Medicare and Medicaid patients, as measured by the hospital's disproportionate share hospital adjustment percentage.[14] Covered entities—both hospitals and grantees—must ensure that contact and eligibility-related information for themselves, their associated sites, and their contract pharmacies is accurate and up to date in the 340B Office of Pharmacy Affairs Information System.

Prohibition on diversion of 340B Program drugs to ineligible patients. Covered entities cannot divert any drugs purchased at the 340B price to an individual who is not eligible to receive them. The 340B statute does not define an eligible patient of a covered entity. In the absence of a statutory definition, HRSA guidance generally defines a patient as an individual whose health care records are maintained by the covered entity, for whom the covered entity maintains responsibility for care, and who is receiving services that are consistent with the type of services for which the covered entity qualified for 340B eligibility.[15]

Prohibition on duplicate discounts. Covered entities cannot subject drug manufacturers to duplicate discounts, which may occur when drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. In 2020, we reported that state Medicaid programs varied in whether they allowed covered entities to use 340B drugs for Medicaid beneficiaries.[16]

To prevent duplicate discounts, states need to know whether covered entities provided 340B drugs to Medicaid fee-for-service and managed care beneficiaries in order to exclude those drugs from the rebate requests they submit to manufacturers.[17] HHS's Centers for Medicare & Medicaid Services (CMS), which oversees the Medicaid Drug Rebate Program, provides states the flexibility to determine procedures for identifying and excluding 340B drugs from their Medicaid rebate requests. For example, covered entities and their contract pharmacies may be required by some states to use codes on drug claims (claim identifiers) to indicate drugs that were purchased at the 340B discounted price. In addition, some states use a file maintained by HRSA to

[14]A hospital's disproportionate share hospital adjustment percentage is generally based on its disproportionate share hospital patient percentage, which is determined by a calculation of the sum of two other percentages: (1) the low-income Medicare patient percentage, calculated as the ratio of Medicare Supplemental Security Income inpatient days to total Medicare inpatient days; and (2) the Medicaid patient percentage, calculated as the ratio of Medicaid, non-Medicare inpatient days to total inpatient days.

[15]See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996).

[16]See GAO-20-212.

[17]States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. Under a capitated managed care model, states typically contract with managed care organizations to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pay each organization a set amount per beneficiary per month to provide or arrange those services.

determine which covered entities use 340B drugs for Medicaid beneficiaries and thus have claims that should be excluded from rebate requests to manufacturers.[18]

GAO Identified Weaknesses in HRSA's Oversight, Many of Which Remain Unaddressed

Since 2011, when we first reviewed the 340B Program, we have identified numerous weaknesses in HRSA's oversight and made 20 recommendations for HRSA to address them. While HRSA has taken steps to address some of these weaknesses, including by implementing five of our recommendations, many of the weaknesses remain unaddressed.

In 2011, we found HRSA's oversight of the program was weak because it relied primarily on covered entities and manufacturers to police themselves to ensure compliance with program requirements.[19] We recommended that HRSA conduct audits of covered entities. HRSA agreed with our recommendation, and in fiscal year 2012, implemented it by establishing a systematic approach to conducting audits of covered entities. The agency now audits 200 entities—a combination of hospitals and federal grantees—per year.

HRSA's audits include

- assessments of covered entities' 340B eligibility status;
- assessments of covered entities' policies and procedures, including those for overseeing contract pharmacies and preventing duplicate discounts and diversion; and
- reviews of a sample of prescriptions filled during a 6-month period to identify instances of noncompliance by covered entities.

In addition to audits, over time HRSA has strengthened its oversight by establishing an annual recertification process and other program integrity checks on hospitals and contract pharmacies. For example, in fiscal year 2015, HRSA began conducting quarterly checks to make sure hospitals still treated a disproportionate number of low-income Medicare and Medicaid patients; that is, that hospitals' disproportionate share hospital adjustment percentages continued to meet the statutory thresholds for program eligibility. In January 2020, HRSA began checks for all newly registering nongovernmental hospitals to ensure hospitals were in compliance with the statutory requirement to have contracts with state or local governments to provide health care services to low-income individuals not eligible for Medicaid or Medicare. Additionally, HRSA began conducting quarterly checks in fiscal year 2017 of a randomly selected 5 percent of new contract pharmacy arrangements to verify there were signed contracts in effect for each arrangement that listed all entity sites and pharmacy locations, as required, among other things.

[18]In 1993, HRSA and CMS collaborated to establish the Medicaid Exclusion File as a mechanism to assist in the identification of 340B drugs provided to Medicaid fee-for-service beneficiaries. The file is intended to provide Medicaid provider numbers for covered entities that choose to use 340B drugs for these Medicaid beneficiaries to the state Medicaid agencies on a regular basis.

When the Medicaid Exclusion File was created, Medicaid drug rebates were provided only under fee-for-service. According to HRSA, the Medicaid Exclusion File is not to be used for Medicaid managed care. HRSA has not created a mechanism for covered entities to use to identify 340B drugs provided to Medicaid managed care beneficiaries but encourages covered entities to work with states to develop strategies to prevent duplicate discounts for drugs reimbursed through managed care.

[19]See GAO-11-836.

However, since our 2011 report, we have conducted additional reviews of the program. Throughout this body of work, we have identified weaknesses in HRSA's oversight that remain unaddressed, including weaknesses related to the agency's audit process, as well as its oversight of program eligibility, contract pharmacy use, and duplicate discount prevention.

Audits of 340B covered entities. When HRSA audits of covered entities result in findings of noncompliance, covered entities are required to 1) submit corrective action plans to HRSA that indicate that the entities will determine the full scope of any noncompliance (beyond the sample of prescriptions reviewed during an audit); 2) outline the steps they plan to take to correct findings of noncompliance, including any necessary repayments to manufacturers; and 3) specify the timelines for implementing the corrective action plans. Under its procedures, HRSA closes the audit when a covered entity submits a letter attesting that its corrective action plan, including its assessment of the full scope of noncompliance, has been implemented and any necessary repayments to manufacturers have been completed.

However, in our June 2018 report, we found that the process for closing audits does not ensure all covered entities have fully addressed any noncompliance identified.[20] First, although HRSA requires that covered entities determine the full scope of noncompliance found in audits, it does not provide guidance as to how entities should make this assessment. Specifically, HRSA does not specify how far back in time covered entities must look to see if any related noncompliance occurred and instead, relies on each entity to make this determination. Second, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity is now in compliance with 340B Program requirements. It does not require most audited covered entities to provide documentation that they implemented their corrective action plans prior to HRSA closing the audits.[21]

After our 2018 report, HRSA made changes to its audit process that limited the findings of noncompliance that the agency issues. Specifically, as noted in our December 2020 report, HRSA officials told us that, beginning in fall 2019, the agency started issuing audit findings only when audit information presented a clear and direct violation of the requirements outlined in the 340B Program statute.[22] For example, HRSA officials reported that in its fiscal year 2019 audits, there were instances in which the agency did not issue findings for 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 clear statutory violations. HRSA also did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility. As a result of these changes, of the 199 fiscal year 2019 audits that HRSA had finalized as of September 2020, there were 36

[20]See GAO-18-480.

[21]HRSA audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), and covered entities that are targeted based on information from stakeholders such as drug manufacturers (10 percent of the audits conducted). HRSA requires covered entities subject to targeted audits to document their methodology for assessing the full scope of noncompliance and provide evidence that their corrective action plan has been implemented. However, it does not require this from the other covered entities that are audited, which represent the majority of audited entities.

[22]See GAO, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements.* GAO-21-107. (Washington, D.C.: December 14, 2020).

Specifically, following a covered entity's 2019 legal challenge, HRSA evaluated its ability to require and enforce corrective action, and it concluded that in the absence of binding and enforceable regulations, the agency would no longer issue findings based solely on noncompliance with guidance.

instances in which the information gathered in these audits did not result in a finding, but would have resulted in one in the past, according to HRSA officials.

Eligibility. Our work also identified weaknesses in HRSA's oversight to ensure only eligible hospitals participate in the 340B Program. Specifically, our December 2019 report found HRSA's processes to assess the eligibility of participating nongovernmental hospitals did not provide reasonable assurance that these hospitals met eligibility requirements.[23] For example, HRSA primarily relies on self-reported information from cost reports on whether hospitals operate as nonprofit—information that has not been determined reliable for this purpose. After we issued our report, HRSA began requiring all newly registering nongovernmental hospitals to submit documentation of their nonprofit status; however, this requirement does not affect nongovernmental hospitals that were already participating in the program.

Additionally, we found that HRSA primarily relies on hospitals' self-attestations to verify the existence of contracts with state and local governments.[24] HRSA does collect and review contracts with state or local governments for a sample of nongovernmental hospitals through its audit and contract integrity check processes, and in 2020, the agency began requiring all newly registering nongovernmental hospitals to submit their state or local government contracts at registration. However, audit and integrity check reviews are limited in number, and as previously mentioned, collecting contracts from newly registering hospitals does not capture hospitals already registered for the program. In addition, we found that guidance for auditors on how to assess the documents lacks detailed instructions.

As we highlighted in our report, these weaknesses in oversight of hospital eligibility are concerning as they may allow noneligible hospitals to participate in the 340B Program.[25] We found that contracts for 13 hospitals reviewed did not appear to require hospitals to serve low-income individuals not eligible for Medicaid or Medicare, as required by statute. Despite this, these 13 hospitals were permitted to participate in the program.[26]

Contract pharmacy use. Our June 2018 report identified weaknesses in HRSA's oversight of contract pharmacy use by covered entities.[27] For example, we found HRSA did not have complete data on the total number of contract pharmacy arrangements in the 340B Program because it did not require covered entities to register contract pharmacies for each site of the entity for which a contract exists.[28] Additionally, while HRSA has said that covered entities are responsible for overseeing their contract pharmacies to ensure that drugs the entity distributes through them comply with 340B Program requirements, we found that HRSA's guidance to covered entities lacks specificity as it relates to the scope and frequency of such oversight. Due, at least in

[23]See GAO-20-108. Nongovernmental hospitals are private, nonprofit hospitals that have contracts with state and local governments to serve low-income individuals not eligible for Medicaid or Medicare.

[24]See GAO-20-108.

[25]See GAO-20-108.

[26]See GAO-20-108. Our review also found hospitals that had submitted documents that did not appear to be contracts (i.e., mutually binding agreements to provide services or supplies in exchange for something of value.) For example, one hospital submitted an unsigned document listing presentations on health education topics, such as managing lower back pain, that the hospital offered in collaboration with a local library.

[27]See GAO-18-480.

[28]Covered entities may register their contract pharmacies in one of two ways: 1) only in relation to the parent site (use by child sites would be allowed as long as the sites were included in a comprehensive contract between the entity and the contracted pharmacies); or 2) separately for each site (parent and child) involved in a contractual arrangement with the pharmacy.

part, to the lack of specific guidance, we found that some covered entities we contacted performed minimal contract pharmacy oversight.

Duplicate discount prevention. We found that HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, covered entities are prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. However, as explained in our June 2018 report, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care, even though the majority of Medicaid enrollees, prescriptions, and spending for drugs were in managed care.[29]

Moreover, as we reported in January 2020, when duplicate discounts in Medicaid managed care claims are identified, HRSA does not require covered entities to address them or work with manufacturers to repay them, as it does when duplicates are identified in Medicaid fee-for-service.[30] As a result, manufacturers may be subject to duplicate discounts for drugs provided under managed care.

Furthermore, we found that audits of covered entities do not include reviews of state Medicaid programs' policies and procedures for the use and identification of 340B drugs.[31] As a result, the audits are unable to determine whether covered entities are following state requirements and taking the necessary steps to comply with the prohibition on subjecting manufacturers to duplicate discounts.

Across multiple reports, we made 20 recommendations to HRSA to address these and other weaknesses. HRSA agreed with and has implemented five recommendations, while 15 recommendations remain unimplemented as of February 2025. (See app. I.) HRSA did not concur with six of the unimplemented recommendations, such as our recommendations to (1) require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, and (2) incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs into its audit process.[32]

While HRSA concurred with the remaining nine unimplemented recommendations, it has expressed concerns that it does not have the necessary enforcement capability to implement some recommendations, specifically recommendations related to issuing or clarifying guidance. Over the past decade, the agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget

[29]See GAO-18-480.

[30]See GAO-20-212.

[31]See GAO-20-212.

[32]HRSA indicated that requiring all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits would create a significant burden on covered entities. However, entities are already required to develop and implement these plans; therefore, providing HRSA with evidence of successful implementation should not impose a significant burden for covered entities.

HRSA did not agree with our recommendation that it should incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures into its audit process because it does not have authority to enforce covered entities' compliance with state policies and procedures. While we understand that HRSA does not have authority to enforce compliance with state Medicaid programs' policies and procedures, covered entities' compliance with those policies and procedures is fundamental to preventing duplicate discounts and thus ensuring covered entities' compliance with the 340B Program's prohibition on duplicate discounts.

requests. According to HRSA, this authority would allow it to set clear, enforceable standards of participation on all aspects of the 340B Program and help ensure compliance with 340B Program requirements.

Chair Cassidy, Ranking Member Sanders, and Members of the Committee, this concludes my statement. I would be pleased to respond to any questions you may have.

GAO Contact and Staff Acknowledgments

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Appendix I: Status of 340B Program Recommendations to the Health Resources and Services Administration (HRSA)

GAO has made 20 prior recommendations related to HRSA's oversight of the 340B Program. Five of these recommendations have been fully implemented, and 15 have not. Table 1 describes the 15 recommendations that have yet to be implemented and any actions HRSA has taken to implement them as of February 2025.

Table 1: Status of 15 GAO Recommendations Related to the Health Resources and Services Administration's (HRSA) Oversight of the 340B Program That Had Not Been Fully Implemented, as of February 2025

Recommendations from: ***Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*** (GAO-11-836) Published: Sept. 23, 2011	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 2: The Secretary of Health and Human Services should instruct the administrator of HRSA to finalize new, more specific guidance on the definition of a 340B patient.	Y	Subsequent to the issuance of GAO-11-836, the Department of Health and Human Services (HHS) indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. The agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget requests over the past decade. HRSA officials have told us that they believe having this authority would ensure the agency's ability to implement this recommendation.
Recommendation 4: The Secretary of Health and Human Services should instruct the Administrator of HRSA to issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.	Y	Subsequent to the issuance of GAO-11-836, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. The agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget requests over the past decade. HRSA officials have told us that they believe having this authority would ensure the agency's ability to implement this recommendation.

Recommendations from: *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (GAO-18-480) Published: June 21, 2018	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 1: The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists.	N	As of February 2025, HRSA reiterated that it did not agree with this recommendation and noted that as long as the contract with a pharmacy says it includes all of the covered entities' sites, HRSA does not require the entity to register the pharmacy for each individual site. If HRSA audits a covered entity, its draft audit protocols call for the auditor to verify if the pharmacy contract specifies it includes all entity sites, and, if it does not, the auditor is to verify whether the pharmacy is registered for each entity site that is included in the contract. However, since HRSA only audits 200 covered entities per year, such procedures do not provide HRSA with complete data on entities' contract pharmacy arrangements. Complete data on contract pharmacy arrangements are also important for manufacturers to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site. Thus, we continue to believe that HRSA needs more complete information on contract pharmacy arrangements to best target its oversight of covered entities with the most complex 340B programs.
Recommendation 2: The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with the Centers for Medicare & Medicaid Services (CMS) as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.[a]	Y	Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. The agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget requests over the past decade. HRSA officials have told us that they believe having this authority would ensure the agency's ability to implement this recommendation. As of February 2025, HHS reported that new regulations finalized by CMS in September 2024 included Medicaid policies that impact 340B covered entities and the prevention of duplicate discounts in Medicaid managed care. Specifically, the regulations require the use of identifiers on Medicaid managed care plan pharmacy identification cards that would allow pharmacies to identify a patient as being enrolled in a Medicaid managed care plan.[b] While this will not assist in identifying which drugs were purchased under the 340B Program, the rule noted that it may help states and their Medicaid managed care plans avoid claiming Medicaid rebates for drugs that would lead to duplicate discounts. HHS noted that in the absence of explicit statutory authority for HRSA itself to issue regulations on this topic, HRSA plans to leverage this rule to strengthen efforts to prevent duplicate discounts, such as through the provision of technical assistance to covered entities.

Recommendations from: *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (GAO-18-480) Published: June 21, 2018	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 3: The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.[a]	Y	Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. The agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget requests over the past decade. HRSA officials have told us that they believe having this authority would ensure the agency's ability to implement this recommendation. As of February 2025, HHS reported that new CMS regulations finalized in September 2024 included Medicaid policies that impact 340B covered entities and the prevention of duplicate discounts in Medicaid managed care.[b] It also noted that in the absence of explicit statutory authority for HRSA itself to issue regulations on this topic, HRSA plans to leverage this rule to strengthen efforts to prevent duplicate discounts, such as through the provision of technical assistance to covered entities.
Recommendation 4: The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit.	Y	Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. The agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget requests over the past decade. HRSA officials have told us that they believe having this authority would ensure the agency's ability to implement this recommendation.
Recommendation 5: The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance.	N	As of February 2025, HRSA reiterated that it did not agree with this recommendation. As noted in our published report, HRSA requires covered entities with audit findings to determine the full scope of noncompliance, and requires certain entities—those subject to targeted audits (which includes reaudits)—to provide to HRSA their methodology for such assessments.[c] However, targeted audits represent a small portion of the audits HRSA conducts. To implement this recommendation, HRSA should require all audited covered entities—not just those subject to targeted audits—to provide a written description of methodologies for HRSA review. HRSA stated that such requirements would create a significant burden for covered entities. However, these entities are already required to formulate and implement these methodologies; therefore, providing HRSA with documentation of the methodologies should not impose a significant burden for covered entities. Without this information, HRSA does not have reasonable assurance that the majority of covered entities have adequately identified all instances of noncompliance.

Recommendations from: ***Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*** (GAO-18-480) **Published: June 21, 2018**	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 6: The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit.	N	As of February 2025, HRSA reiterated that it did not agree with this recommendation. As noted in our published report, HRSA requires certain covered entities—those subject to targeted audits (which includes reaudits)—to provide evidence that their corrective action plans have been successfully implemented.[c] However, targeted audits represent a small portion of the audits HRSA conducts. To implement this recommendation, HRSA should require all audited covered entities—not just those subject to targeted audits—to provide evidence that their corrective action plans have been successfully implemented. HRSA stated that such requirements would create a significant burden for covered entities. However, these entities are already required to develop and implement these plans; therefore, providing HRSA with evidence of successful implementation should not impose a significant burden for covered entities. Without such evidence, HRSA does not have reasonable assurance that the majority of covered entities audited have corrected the issues identified in the audit and are not continuing practices that could lead to noncompliance.
Recommendation 7: The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.	Y	Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. The agency has requested that Congress provide it additional regulatory authority for the 340B Program as part of many of its budget requests over the past decade. HRSA officials have told us that they believe having this authority would ensure the agency's ability to implement this recommendation.

Recommendations from: ***340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*** (GAO-20-108) **Published: Dec. 11, 2019**	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 1: The Administrator of HRSA should ensure that the information it uses to verify nonprofit status for all nongovernmental hospitals that participate in the 340B Program is reliable—for example, by requiring and reviewing the submission of official documentation hospitals must already maintain or by ensuring the reliability of the data the agency uses.	Y	As of February 2025, HHS reiterated that HRSA believes that the information it uses to determine nonprofit status is reliable because hospital administrators attest to its accuracy, and the department requested that the recommendation be closed as implemented. However, as noted in our published report, neither HRSA nor the agency that collects the data has evaluated the reliability of the data for verifying nonprofit status. In addition, although HRSA requires newly registering nongovernmental hospitals to submit documentation of their nonprofit status, such as Internal Revenue Service forms, this does not affect the nongovernmental hospitals that are already participating in the 340B Program, for which it continues to rely on Medicare cost report data. Without ensuring it is using reliable information, HRSA cannot effectively determine if nongovernmental hospitals participating in the 340B Program meet the statutory eligibility requirements.
Recommendation 2: The Administrator of HRSA should implement a process to verify that every nongovernmental hospital that participates in the 340B Program has a contract with a state or local government as required by statute.	N	As of February 2025, HRSA stated that it requires nongovernmental hospitals to certify the existence of such contracts and reviews contracts from certain nongovernmental hospitals—those that are newly registering, changing classification during recertification, or undergoing program audits. To implement this recommendation, HRSA should verify the existence of such contracts for all nongovernmental hospitals. As noted in our published report, HRSA stated that such requirements would create a burden for both the agency and covered entities. While we understand that verifying the existence of such contracts for all participating nongovernmental hospitals would require additional effort on HRSA's part, we maintain that relying on hospitals' attestations is not sufficient to ensure hospitals' eligibility. In addition, nongovernmental hospitals are already required to maintain copies of their state or local government contracts; therefore, HRSA's verification of such contracts should not impose a significant burden for covered entities. Without this information, HRSA does not have reasonable assurance that nongovernmental hospitals have the statutorily required contracts to participate in the 340B Program.

Recommendations from: ***340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*** (GAO-20-108) **Published: Dec. 11, 2019**	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 4: The Administrator of HRSA should provide more specific guidance for 340B Program auditors on how to determine if nongovernmental hospitals' contracts with state and local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare.	Y	As of February 2025, HHS reiterated that HRSA updated its audit guidance and procedures to more clearly specify that contracts must contain requirements for the provision of health care services to low-income individuals, and the department requested that GAO close this recommendation as implemented. Specifically, in October 2019, prior to the issuance of our report and its associated recommendation, HRSA added language to its audit guidance directing auditors who had questions concerning nongovernmental hospitals' contracts to contact HRSA. However, to implement this recommendation, HRSA should update its audit guidance to include information on how auditors are to determine whether contracts include any kind of requirement to provide services to low-income individuals not eligible for Medicaid or Medicare. For example, the guidance could provide examples of population and service descriptions that would likely meet, or not meet, the statutory requirement. Without more specific guidance for auditors' review of contracts, HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals' contracts with state or local governments.
Recommendation 6: The Administrator of HRSA should require nongovernmental hospitals participating in the 340B Program to demonstrate that they have contracts with state or local governments in effect prior to the beginning of their audits' periods of review and should apply consistent and appropriate consequences for hospitals that are unable to do so.	Y	As of February 2025, this recommendation had been partially implemented as HRSA had updated its draft audit procedures to specify that auditors should ensure that the contract effective dates cover the entire audit period. In addition, HRSA stated that it collects, reviews, and confirms that contracts are active for certain nongovernmental hospitals—those that are newly registering or changing classification during recertification. However, to fully implement this recommendation, HRSA also must show that it has ceased accepting retroactive contract documentation, and it has applied consistent and appropriate consequences when auditors find that nongovernmental hospitals did not have contracts in effect prior to the beginning of their audit periods. Allowing hospitals that are unable to demonstrate that they have contracts in place that cover their audits' periods of review to continue to participate without consequences undermines the effectiveness of HRSA's audit process, and it increases the risk that ineligible hospitals will receive discounts under the program.

Recommendations from: *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (GAO-20-212) Published: Jan. 21, 2020[d]	Agency concurrence with recommendation (Y/N)	Progress toward implementation
Recommendation 2: The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs into its audit process, working with CMS as needed to obtain states' policies and procedures.	N	As of February 2025, HRSA reiterated that it did not agree with this recommendation. HRSA stated that through its audit process, if the agency finds that a hospital is not compliant with the state's Medicaid billing requirements and thus creating the potential for a duplicate discount, it issues an area for improvement (as opposed to an audit finding). However, as we previously reported, covered entities are not required to address areas for improvement. In addition, as noted in our report, HRSA does not require its auditors to review state Medicaid programs' actual policies but instead relies on covered entities' descriptions of these policies if available, which are not always accurate. Without considering states' actual policies and procedures and ensuring that covered entities are following them, HRSA's audits cannot effectively identify compliance. Our recommendation suggests that HRSA work with CMS to obtain states' policies and procedures.
Recommendation 3: The Administrator of HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care.	N	As of February 2025, HRSA reiterated that it did not agree with this recommendation. When duplicate discounts are identified in Medicaid fee-for-service, HRSA requires covered entities to work with manufacturers to remedy them. HRSA has stated that covered entities' obligations for preventing duplicate discounts are the same for Medicaid fee-for-service and managed care. Thus, as noted in our published report, we believe the steps for addressing identified duplicate discounts in managed care should be similar. As a result, to implement this recommendation, HRSA should require—not just encourage—covered entities to work with manufacturers to remedy any duplicate discounts related to managed care as they do for those related to fee-for-service.

Source: GAO analysis of information received from HRSA. | GAO-26-108784

[a]This is a priority recommendation, which is a recommendation that GAO believes warrants priority attention from heads of key departments or agencies. They are highlighted because, upon implementation, they may significantly improve government operation —for example, by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a high-risk or duplication issue.

[b]See 89 Fed. Reg. 79,020, 79,081 (Sept. 26, 2024) (codified in relevant part at 42 C.F.R. § 438.3(s)(7)).

[c]HRSA audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), and covered entities that are targeted based on information from stakeholders such as drug manufacturers (10 percent of the audits conducted). These targeted audits also include covered entities selected for a follow-up audit by HRSA as a result of findings from a prior audit (referred to as reaudits).

[d]GAO-20-212 also included one recommendation (Recommendation 1) to CMS.

Related GAO Products

340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19. GAO-23-106095. Washington, D.C.: May 11, 2023.

Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements. GAO-21-107. Washington, D.C.: December 14, 2020.

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