



December 2020

DRUG PRICING PROGRAM

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

Accessible Version

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.

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Abbreviations

340B OPAIS	340B Office of Pharmacy Affairs Information System
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration

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December 14, 2020

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Michael C. Burgess
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Brett Guthrie
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The 340B Drug Pricing Program (340B Program), 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 for their drugs to be covered by Medicaid.¹ Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program. These savings allow covered entities to generate revenue under the program when purchasing 340B drugs for eligible patients whose insurance reimbursement exceeds the 340B price

¹42 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.

paid for the drugs. According to HRSA, the purpose of the 340B Program is to enable covered entities to use these gains to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.²

Entities eligible to participate in the 340B Program include certain types of federal grantees and nonprofit hospitals that provide care to the medically underserved and meet other criteria, such as being owned by a unit of state or local government.³ Participation in the 340B Program has grown from nearly 9,700 covered entities in 2010 to 12,700 covered entities in 2020. According to HRSA, about 80 percent of covered entities are grantees (e.g., a family planning clinic), and 20 percent are hospitals. However, a covered entity may have multiple sites of operation, and about three-quarters of the approximately 37,500 covered entity sites participating in the program are affiliated with hospitals.

Since the establishment of the 340B Program, participation of these covered entities has been contingent on compliance with statutory program requirements; HRSA has issued interpretive guidance and statements of policy to assist covered entities in complying. For example, covered entities must maintain compliance with the statutory definitions pertaining to eligibility to continue participating in the program.⁴ Covered entities are also prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.⁵ Finally, covered entities cannot subject manufacturers to

²The Public Health Service Act does not explicitly state the purpose of the 340B program; thus, HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became the statute. 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).

³See 42 U.S.C. § 256b(a)(4)(L)(i) (incorporated by reference into 42 U.S.C. §§ 256b(a)(4)(M)-(O)).

⁴See 42 U.S.C. § 256b(a)(4). For an example of relevant guidance, see *Statutory Prohibition on Group Purchasing Organization Participation* (Feb. 7, 2013).

⁵42 U.S.C. § 256b(a)(5)(B). For an example of relevant guidance, see Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

For our prior work on this topic, see 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).

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.⁶

To oversee covered entities' continued compliance with these requirements, HRSA implemented in fiscal year 2012 a systematic approach for auditing covered entities. HRSA issues findings for noncompliance with 340B Program requirements based on information gathered through its audit process. Covered entities must address findings to avoid termination from the program. As of September 2020, HRSA finalized over 1,240 audits conducted from fiscal years 2012 through 2019, and almost 900 of them resulted in at least one finding.

In prior reports, we raised concerns about the oversight of the 340B Program and made recommendations to strengthen HRSA's audit process and guidance to covered entities regarding compliance with 340B Program requirements. (Appendix I provides information on the status of these recommendations.) You asked us to review HRSA's efforts to oversee covered entity compliance with 340B Program requirements. This report describes (1) the audit findings HRSA issued to address covered entity noncompliance with 340B Program requirements, and (2) other efforts HRSA has undertaken to help ensure that covered entities comply with 340B Program requirements.

To describe the audit findings HRSA issued to address covered entity noncompliance with 340B Program requirements, we reviewed relevant federal laws and regulations, as well as HRSA's policies, procedures, and guidance related to 340B Program audits. We also reviewed HRSA-provided information on the number and type of audit findings finalized from fiscal years 2012 through 2019.⁷ At the time of our review in September 2020, HRSA had finalized 199 of 200 fiscal year 2019 audits. Additionally, we interviewed HRSA officials about the audit process and

⁶42 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). For an example of relevant guidance, see *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

⁷We did not include audit findings from fiscal year 2020 because the vast majority of audits conducted in that year were not finalized at the time of our review. For updated information about audit findings issued by HRSA, see Health Resources and Services Administration, *Program Integrity*, accessed September 24, 2020, www.hrsa.gov/opa/program-integrity/index.html.

findings issued since fiscal year 2012 and reviewed related documentation. Finally we spoke with the contractor that has conducted audits on HRSA's behalf since fiscal year 2017.⁸

To describe other efforts HRSA has undertaken to help ensure that covered entities comply with 340B Program requirements, we reviewed relevant HRSA policies and procedures related to 340B Program oversight. We also reviewed HRSA-provided information on the number of covered entities that were found through efforts other than audits to be noncompliant from fiscal year 2012 through June 2020. We interviewed officials from HRSA, the 340B Prime Vendor, trade organizations that represent covered entities, and other stakeholders that provide covered entities with 340B compliance assistance such as organizations that conduct independent audits of covered entities' 340B Programs.⁹

We conducted this performance audit from January 2020 to December 2020 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 an application to and be approved by HRSA. Once registered for the program, covered entities must maintain compliance with program requirements related to eligibility, diversion, and duplicate discounts. As of September 2020, there were nearly 12,700 covered entities participating in the program.

⁸Beginning in fiscal year 2017, HRSA has contracted with The Bizzell Group to perform 340B Program audits.

⁹The 340B Prime Vendor's role includes supporting the distribution of covered outpatient drugs through the 340B Program and serving as a resource to covered entities and other 340B stakeholders. Apexus, a pharmacy solutions provider, began serving as the 340B Prime Vendor in 2004.

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.¹⁰ These include federally qualified health centers (which provide comprehensive community-based primary and preventive care services to medically underserved populations), as well as family planning clinics and Ryan White HIV/AIDS program grantees (see fig. 1).¹¹ 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. These types of hospitals include 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).¹² In addition, eligible hospitals fall under one of three classifications: (1) hospitals 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 (referred to as nongovernmental hospitals) that have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare.¹³ Proprietary, for-profit hospitals are not eligible to participate in the program.

¹⁰See 42 U.S.C. §§ 256b(a)(4)(A)-(K). All such grant programs are administered by agencies within HHS.

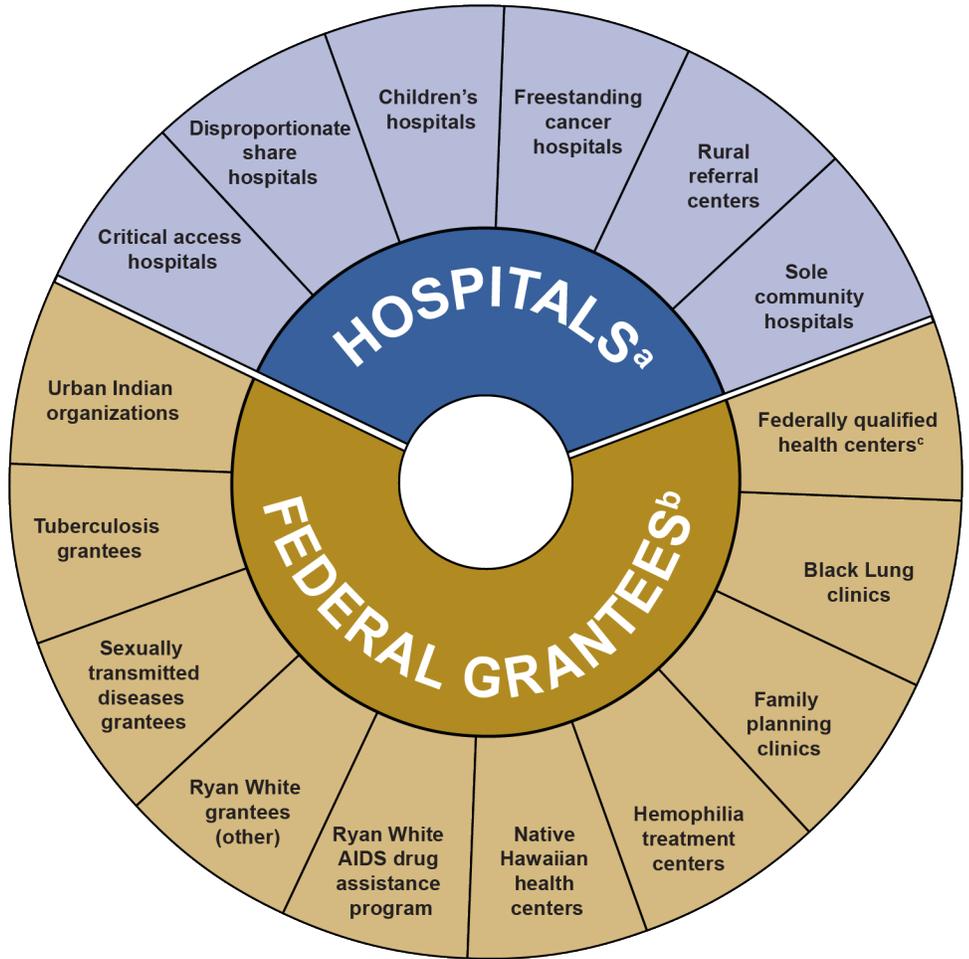
¹¹Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the federally qualified health center program, but do not receive federal grants are referred to as federally qualified health center look-alikes and a relatively small number of them participate in the 340B program.

¹²See 42 U.S.C. §§ 256b(a)(4)(L)-(O).

¹³See 42 U.S.C. § 256b(a)(4)(L)(i) (incorporated by reference into 42 U.S.C. §§ 256b(a)(4)(M)-(O)). Medicare is the federal program that provides coverage of health care services for individuals age 65 and older, certain individuals with disabilities, and individuals with end-stage renal disease.

For our prior work on this topic, see GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, [GAO-20-108](#) (Washington, D.C.: Dec. 11, 2019).

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-21-107

^aEligible hospitals are (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income and medically needy populations. Medicare is the federal health care program for the elderly, disabled, and individuals with end-stage renal disease. With the exception of critical access hospitals, 340B hospitals are required to meet specified disproportionate share adjustment percentages by treating a disproportionate number of low-income Medicare and Medicaid patients.

^bEligible grantees are typically eligible for the program because they receive some type of federal support, such as a federal grant.

^cNot 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 and one or more associated sites, which can include satellite clinics, off-site outpatient facilities, hospital departments, and other facilities. According to HRSA officials, to participate in the 340B Program and be considered part of the covered entity, the associated sites must also be registered and maintain compliance with program requirements.

340B Program Registration

To register for the 340B Program as covered entities, eligible entities must first submit an application through an online database, the 340B Office of Pharmacy Affairs Information System (340B OPAIS). Entities must provide specific information about themselves, their associated sites, and their affiliated pharmacies. Entities may also be asked to provide other supporting documentation when completing their registration. For example, federal grantees must provide information about the grant that makes them eligible for program participation.

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. A covered entity may register an unlimited number of contract pharmacy arrangements with HRSA.¹⁴

340B Program Requirements

Covered entities must maintain compliance with 340B Program statutory requirements in three areas to continue participating in the program. HRSA historically has issued interpretive guidance and statements of

¹⁴See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

For our prior work on this topic, see GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, [GAO-18-480](#) (Washington, D.C.: June 21, 2018).

policy (such as the definition of a patient eligible to receive 340B Program drugs, which is not defined in statute) to assist covered entity compliance.

Eligibility of covered entities. Covered entities must ensure that they have contracts in place for all contract pharmacy locations and maintain auditable records. Covered entities must ensure that contact and eligibility-related information for themselves, their associated sites, and their contract pharmacies in 340B OPAIS is accurate and kept up to date. Generally, hospitals must meet specified disproportionate share hospital adjustment percentages by treating a disproportionate number of low-income Medicare and Medicaid patients.¹⁵ Certain types of hospitals that participate in the 340B Program are also prohibited from procuring outpatient drugs through a group purchasing organization.¹⁶

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 states that diversion occurs when 340B drugs are given to individuals who are not “patients” of the covered entity. It generally defines such patients as individuals whose health care records are not maintained by the covered entity, for whom the covered entity does not maintain responsibility for care, or who are receiving services that are not consistent with the type of services for which the covered

¹⁵A hospital's disproportionate share hospital adjustment percentage is generally based on its disproportionate share hospital patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicaid and Medicare patients. To be eligible for the 340B program, disproportionate share hospitals, free-standing cancer centers, and children's hospitals must maintain a disproportionate share hospital adjustment percentage of greater than 11.75 percent. Sole community hospitals and rural referral centers must maintain a disproportionate share hospital adjustment percentage greater than or equal to 8 percent. Critical access hospitals are eligible without a disproportionate share hospital adjustment percentage. See 42 U.S.C. § 256b(a)(4)(L)(ii) (incorporated by reference into 42 U.S.C. §§ 256b(a)(4)(M)), 42 U.S.C. § 256b(a)(4)(O).

¹⁶Hospitals buy drugs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations, which pool the purchasing power of multiple providers to bargain for lower prices from manufacturers. Disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals participating in the 340B Program may not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. See 42 U.S.C. §§ 256b(a)(4)(L)(iii) (incorporated by reference into 42 U.S.C. § 256b(a)(4)(M)).

entity qualified for 340B eligibility.¹⁷ In order to comply with this requirement, covered entities must, among other actions, have adequate controls in place to ensure that 340B drugs are only distributed to eligible patients with outpatient status. These controls include ensuring that any software used by the covered entity to determine the eligibility of patients is effective and that oversight of the entity's 340B drug inventory guarantees that drugs are properly distributed and replenished.

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. 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.¹⁸ There are several different procedures used to identify and exclude 340B drugs from Medicaid rebate requests. For example, covered entities and their contract pharmacies may be required by states to use codes on drug claims (claim identifiers) to indicate drugs that were purchased at the 340B discounted price. Covered entities that purchase and dispense 340B drugs for Medicaid fee-for-service patients are required by HRSA to ensure that their billing information is correctly listed on HRSA's Medicaid Exclusion File, which is used by certain states to determine which covered entities' claims should be excluded from rebate requests to manufacturers.¹⁹ If a state is not aware that a covered entity provided

¹⁷See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

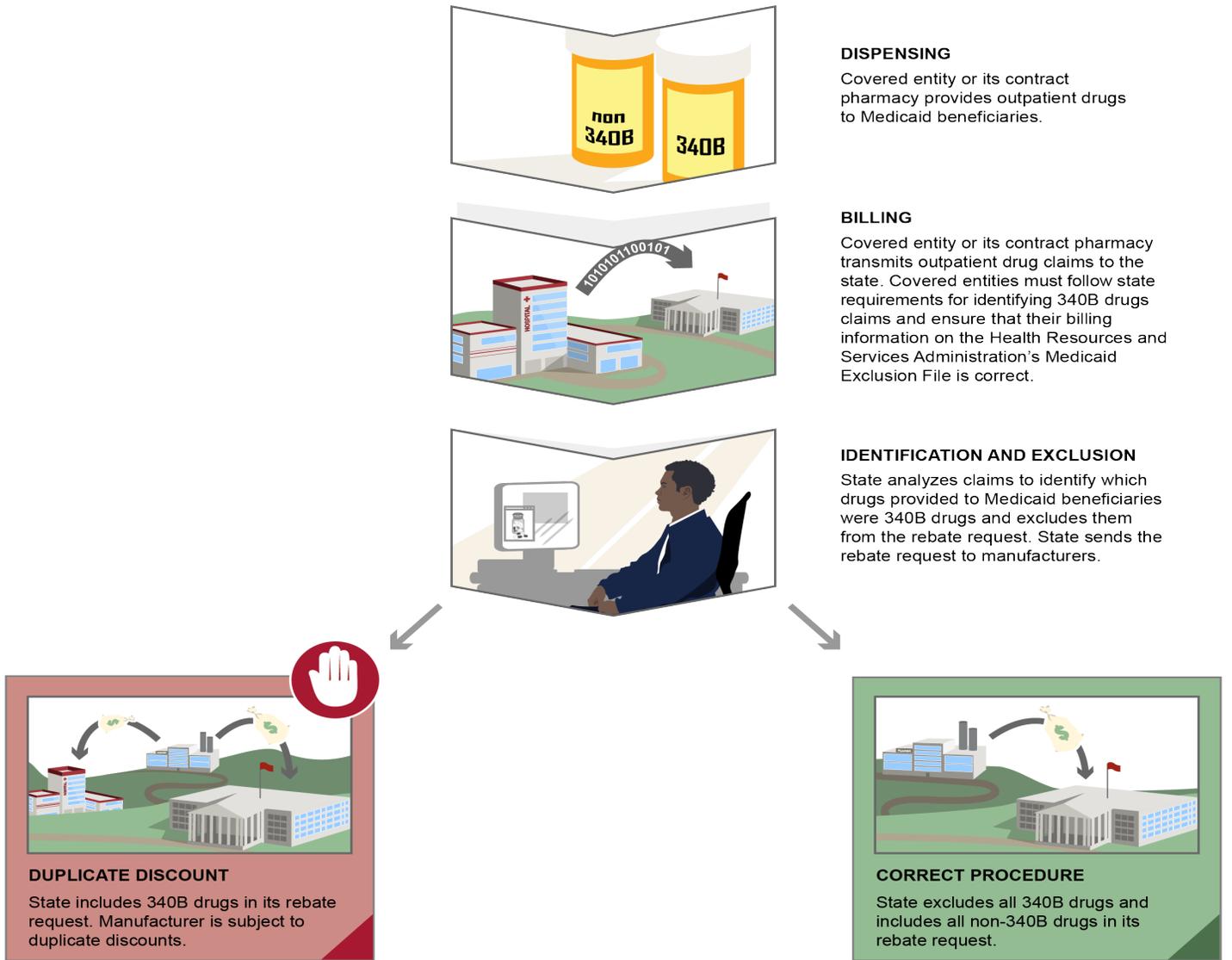
¹⁸States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. Under a capitated managed care model, states typically contract with managed care organizations to provide a specific set of services 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.

¹⁹In 1993, HRSA established the Medicaid Exclusion File by issuing guidance for the prevention of duplicate discounts in Medicaid fee-for-service, specifying that HHS provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis. See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (Jun. 23, 1993).

340B drugs to Medicaid fee-for-service beneficiaries, it would not know to exclude those drugs claims from its rebate requests, which could lead to duplicate discounts (see fig. 2).

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. See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

Figure 2: Example of How Covered Entities Prevent Duplicate Discounts for 340B Program Drugs in Medicaid Fee-for-Service



Source: GAO. | GAO-21-107

Note: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. 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. This graphic does not reflect the role of managed care organizations in preventing duplicate discounts in Medicaid managed care.

When the Medicaid Exclusion File was created in 1993, 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. See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

HRSA is responsible for overseeing the 340B Program, including covered entities' compliance with the statutory requirements applicable to eligibility, diversion, and duplicate discounts. A federal district court ruled in 2014 that HRSA had limited rulemaking authority to carry out the 340B Program, and agency rulemaking authority was limited to specified purposes, such as the establishment of an administrative process to resolve claims by covered entities and manufacturers.²⁰ That court has also acknowledged the agency's authority to interpret the 340B statute and to issue guidance documents interpreting statutory provisions.²¹ According to HRSA, such authority does not provide it with appropriate enforcement capability. Beginning with fiscal year 2017, HRSA has requested the provision of general authority to issue regulations in each of its annual budget 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.

HRSA's Audit Process

HRSA has increased the number of covered entities audited since fiscal year 2012, and in fiscal year 2015 began its current practice of auditing 200 entities per year.²² Beginning in fiscal year 2017, HRSA contracted with an outside organization to perform audits on its behalf. These audits include reviews of each covered entity's policies and procedures, an

²⁰Other specific agency rulemaking authority includes defining standards of methodology to calculate 340B ceiling prices for covered outpatient drugs and imposition of civil monetary penalties for manufacturers that knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug. See *Pharm. Research & Mfrs. of Am. v. United States HHS*, 43 F. Supp. 3d 28, 39-45 (D.D.C. May 23, 2014).

²¹See *Pharm. Research & Mfrs. of Am. v. United States HHS*, No. 14-1685, p. 12 (D. D.C. Oct., 14, 2015).

²²HRSA conducted 51 audits in fiscal year 2012, 94 audits in fiscal year 2013, and 99 audits in fiscal year 2014.

HRSA's audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year) and those that are targeted based on information from stakeholders such as drug manufacturers about potential noncompliance (10 percent of the audits conducted). The criteria for risk-based audits include a covered entity's volume of 340B drug purchases, number of contract pharmacies, time in the 340B Program, and complexity of its program.

assessment of overall compliance with respect to 340B Program requirements, and reviews of a sample of prescriptions filled during a 6-month period to identify any instances of noncompliance (such as diverting 340B drugs to ineligible patients or failing to prevent duplicate discounts by not applying state-required claim identifiers).

Once the audit is completed, HRSA's contractor provides the agency with the results. HRSA officials then determine whether the covered entity should receive any findings of noncompliance with program requirements in the areas of eligibility, diversion, and duplicate discounts, which must be addressed by the entity using a corrective action plan.²³ Since the agency began conducting audits in fiscal year 2012, HRSA officials have also determined whether to recommend areas for improvement based on a failure to follow best practices that may reflect applicable guidance but not statutory requirements. These do not require a corrective action plan by the entity, but they encourage the entity to follow best practices related to compliance with 340B Program requirements.

After HRSA issues a final letter to the covered entity indicating the agency's decision to issue any findings of noncompliance and areas for improvement, covered entities may submit a disagreement letter to dispute the agency's decision. Based on HRSA's review of the disagreement letter, which may be accompanied by evidence provided by the entity, HRSA issues a second final letter that either reverses or upholds the findings being disputed and the audit is considered final.²⁴ Findings of noncompliance from all finalized audits are permanently made public on HRSA's website; areas for improvement are not made public. To avoid termination from the 340B Program, covered entities must address and correct all audit findings through corrective action plans. HRSA closes out the audit once the entity attests that the corrective action plan has been fully implemented and any necessary repayments have been made to affected manufacturers.

²³The audits review covered entities' policies and practices to see if the potential for duplicate discounts exists. However, in order to determine whether duplicate discounts have actually occurred, a covered entity must then check with its state Medicaid agency to see if it has received rebates for the same drugs for which the entity received a discounted price.

²⁴From fiscal year 2012 through February 2020, covered entities disagreed with 672 findings, and based on their disagreements, HRSA reversed 192 of these (29 percent).

As of September 2020, HRSA Had Issued Over 1,500 Findings of Noncompliance in Finalized Audits of Covered Entities since Fiscal Year 2012

HRSA reported that the agency issued a total of 1,536 findings to address covered entity noncompliance found in the 1,242 finalized audits conducted from fiscal years 2012 through 2019 as of September 2020.²⁵ These findings, which address violations of statutory requirements and a failure to follow guidance that HRSA developed to clarify these requirements, were in the areas of eligibility (561), diversion (546), and duplicate discounts (429) (see table 1).

²⁵HRSA conducted one audit in fiscal year 2019 that we did not include because it had not been finalized at the time of our review in September 2020.

Table 1: Eligibility, Diversion, and Duplicate Discount Findings of Noncompliance Issued by the Health Resources and Services Administration (HRSA) for 340B Program Audits Conducted from Fiscal Years 2012–2019, as of September 2020

Audit findings in three areas of 340B Program requirements	Number issued
Eligibility of covered entities	
Incorrect record in HRSA’s 340B Office of Pharmacy Affairs Information System	457
Obtaining covered outpatient drugs through a group purchasing organization ^a	54
Failure to oversee 340B Program compliance at contract pharmacies	40
Other eligibility-related violations (e.g., maintaining auditable records)	10
Total eligibility-related findings	561
Diversion of 340B Program drugs to ineligible patients	
Dispensing 340B drugs to ineligible individuals (e.g., individuals prescribed drugs at an ineligible site, individuals who did not meet eligibility definition set in HRSA guidance) ^b	463
Failure to ensure proper inventory management of 340B drugs	76
Systematic errors in the software used to determine 340B eligibility ^c	7
Total diversion-related findings	546
Duplicate discounts	
Inaccurate information on the Medicaid Exclusion File ^d	264
Billing contrary to information on the Medicaid Exclusion File ^d	108
Failure to follow state Medicaid requirements (e.g., omitting codes on drug claims known as claim identifiers to indicate drugs purchased at the 340B discounted price)	34
Duplicate discount-related errors at contract pharmacies	23
Total duplicate discount-related findings	429
Total	1,536

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

Note: The table shows findings for the 1,242 audits that HRSA has conducted and finalized since it began conducting audits in fiscal year 2012, as of September 2020. This includes findings for the 199 audits finalized for fiscal year 2019 (out of 200 conducted). These findings address both violations of statutory requirements and a failure to follow guidance that HRSA developed to clarify these requirements. Covered entities must maintain compliance with 340B Program requirements in the three areas shown in this table to continue participating in the program. See 42 U.S.C. §§ 256b(a)(4), (5)(A),(B).

^aHospitals buy drugs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations. Disproportionate share hospitals, children’s hospitals, and free-standing cancer hospitals participating in the 340B Program may not obtain covered outpatient drugs through a group purchasing organization. See 42 U.S.C. §§ 256b(a)(4)(L)(iii)(incorporated by reference into 42 U.S.C. § 256b(a)(4))(M)).

^bAccording to HRSA guidance, in general, an eligible patient is an individual who (1) has health records that are maintained by the covered entity, (2) receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care remains with the covered entity, and (3) receives services consistent with the range of services for which grant funding or federally qualified health center look-alike status has been provided. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

^cThis finding could be issued if HRSA found that the covered entity failed to ensure that the patient eligibility verification systems used by the entity or its contract pharmacies accurately screened for

patient eligibility by, for example, not affording an accurate evaluation of the prescribing provider when determining 340B eligibility.

⁴In 1993, HRSA issued final guidance for the prevention of duplicate discounts in Medicaid fee-for-service, establishing that the Department of Health and Human Services will provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis through a mechanism known as the Medicaid Exclusion File. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (Jun. 23, 1993). According to HRSA, the Medicaid Exclusion File does not apply to the prevention of duplicate discounts under Medicaid managed care. See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

HRSA officials told us that, beginning in fall 2019, the agency started issuing findings, which require covered entities to take corrective action, only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that 340B Program 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. Following a covered entity's 2019 legal challenge to HRSA's authority to enforce audit findings, 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.²⁶ For example, HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency:

- 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;²⁷ and
- did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other

²⁶See *Genesis Health Care v. Azar*, No. 19-cv-01531 (D.S.C. Dec. 18, 2019) (granting defendant's motion to dismiss). Genesis contended that, absent judicial review, HRSA would continue to incorporate its allegedly unlawful and narrower definition of "patient" into its audit standards, so Genesis, as well as other covered entities, would continue to be subject to the same standards. However, the court indicated that the proper time to challenge this allegedly narrower definition of "patient" is when the definition is used in an audit that marks the completion of the agency's decision-making process and affects the legal rights of the relevant actors and has appreciable legal consequences.

²⁷For the statutory requirements related to diversion of 340B drugs, see, for example, 42 U.S.C. § 256b(a)(5)(B). For relevant guidance, see 59 Fed. Reg. 47884 (Sep. 19, 1994) and 61 Fed. Reg. 55156 (Oct. 24, 1996).

measures as set forth in guidance because the 340B statute does not address contract pharmacy use.²⁸

HRSA officials also said that there were instances among fiscal year 2019 audits in which the agency also did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements, including billing the state Medicaid office for a 340B drug without using a claim identifier to indicate a drug purchased at the 340B discounted price. HRSA officials said that these findings were not issued because the agency does not have statutory authority to enforce state Medicaid requirements.²⁹

While HRSA issued 164 findings to covered entities for the 199 fiscal year 2019 audits that were finalized as of September 2020, there were 36 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. HRSA officials noted that, in certain instances in which an audit reveals that a covered entity failed to follow program guidance or best practices, the agency may issue an area for improvement, which does not require corrective action. However, HRSA officials noted that the full extent to which audits will be affected by the agency's increased focus on clear and direct violations of statute is not yet certain.

HRSA Has Undertaken Multiple Efforts to Prevent and Correct Noncompliance

In addition to the audits, HRSA uses several educational resources to promote covered entities' compliance with 340B Program requirements. HRSA also implemented program integrity checks on hospitals and contract pharmacies, an annual recertification process, and a self-disclosure process to identify noncompliance.

Education on 340B Program requirements. HRSA and the 340B Prime Vendor, Apexus, provide covered entities with educational resources to promote compliance with 340B Program requirements. HRSA's website

²⁸For the statutory requirements related to 340B Program eligibility, see 42 U.S.C. § 256b(a)(4). For relevant guidance, see, for example, 75 Fed. Reg. 10272 (Mar. 5, 2010).

²⁹For the statutory requirements related to duplicate discounts, see 42 U.S.C. § 256b(a)(5)(A). HRSA officials noted that they share information related to a covered entity's failure to follow a state's Medicaid requirements with the Centers for Medicare & Medicaid Services, which oversees the Medicaid Drug Rebate Program.

features 340B Program guidance, peer-to-peer webinars on complying with program requirements, and a frequently asked questions section that addresses topics such as 340B OPAIS database management and proper Medicaid Exclusion File use. Since fiscal year 2004, HRSA has entered into an agreement with Apexus to provide covered entities with educational opportunities. Specifically, Apexus maintains a website with educational resources and answers to frequently asked questions about program compliance. It also administers courses on 340B Program compliance, which trained nearly 11,000 participants in fiscal year 2019, according to Apexus officials. Additionally, Apexus officials said their national call center, which received 27,800 inquiries in fiscal year 2019, serves as an information resource for covered entities. Officials from Apexus and HRSA told us that they plan to implement a new, proactive approach for working with covered entities that will include emailing compliance-boosting tips beginning in December 2020.

Program integrity checks of 340B hospitals to assess eligibility.

HRSA conducts program integrity checks of specific requirements of hospitals, both during registration and on a quarterly basis, to assess their eligibility to participate in the 340B Program. Specifically:

- **Hospital Medicare cost report checks during registration.** In calendar year 2017, HRSA began conducting Medicare cost report checks for a random sample of 10 percent of hospitals registering for the 340B Program.³⁰ The agency uses the documentation to verify that the data provided to HRSA during registration are consistent with the information in the latest Medicare cost report. Specifically, HRSA officials said that they use this information to confirm that the hospital can demonstrate that it recorded outpatient charges as the 340B Program only applies to outpatient drugs. According to HRSA, from calendar years 2017 through 2019, 750 hospitals attempted to register for the 340B Program, and three of the 75 hospitals that HRSA randomly selected for its review had their registration denied because the information in their Medicare cost reports indicated that they were ineligible to participate in the program.
- **Nongovernmental hospital contract reviews during registration.** In calendar year 2017, HRSA began conducting contract integrity checks for a random sample of 20 percent of nongovernmental

³⁰Hospitals—and other institutional providers—that render services to Medicare beneficiaries are required to submit Medicare cost reports to the Centers for Medicare & Medicaid Services annually. Among other things, these reports contain information on facility characteristics, utilization data, and financial statement data.

hospitals during registration. To participate in the 340B Program, these private, nonprofit hospitals must have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare. For the selected hospitals, HRSA requests a copy of the contract, which the agency reviews to verify that it is signed by both hospital and government officials, is in effect, and does not expire before program participation would begin. According to HRSA, from calendar years 2017 through 2019, 610 nongovernmental hospitals attempted to register for the 340B Program, and three of the 122 hospitals HRSA selected for review had their registration denied because they did not have a contract in place prior to attempting to register for the 340B Program.

HRSA officials told us that they recently made changes to this review. Specifically, in January 2020, HRSA began to include all nongovernmental hospitals registering for the program, as opposed to reviewing contracts from a sample of hospitals. Additionally, in July 2020, HRSA officials implemented an additional analysis of the contracts to determine whether they provided for the provision of health care services to low-income individuals not eligible for Medicare or Medicaid as required for 340B Program eligibility.

- **Quarterly disproportionate share hospital adjustment percentage checks.** In fiscal year 2015, HRSA began conducting quarterly checks of the Medicare cost reports of all hospitals for which 340B Program eligibility is dependent on maintaining a disproportionate share hospital adjustment percentage that does not fall below the statutory thresholds defining program eligibility.³¹ From fiscal years 2015 through 2019, HRSA officials told us that they conducted this check more than 25,000 times and identified 86 hospitals that appeared not to have met the requirement. Nearly one-third (27) of those 86 hospitals were not able to provide documentation supporting their eligibility, thus were terminated from the 340B Program.
- **Quarterly hospital classification reviews.** In fiscal year 2019, HRSA began conducting quarterly checks of Medicare cost report data for all hospitals participating in the program to identify those that list themselves as proprietary for further review, as this designation

³¹This integrity check applies to enrolled disproportionate share hospitals, free standing cancer centers, children's hospitals, sole community hospitals, and rural referral centers based on their particular disproportionate share hospital adjustment percentage. Critical access hospitals are eligible without a disproportionate share hospital adjustment percentage.

could identify for-profit hospitals that are not eligible for the 340B program. Hospitals that listed themselves as proprietary on their most recent Medicare cost report may be required to submit documentation confirming their nonprofit status. HRSA conducted this check in fiscal year 2019, and of the 2,521 hospitals reviewed, 14 were identified as ineligible for program participation based on being listed as proprietary. According to HRSA, all 14 hospitals subsequently provided official documentation supporting their eligibility, thus were not terminated from the program.

Quarterly program integrity checks of contract pharmacy arrangements. Beginning in fiscal year 2017, HRSA began conducting quarterly checks of a randomly selected 5 percent of new contract pharmacy arrangements, which covered entities are required to register with HRSA. HRSA verifies that each contract is in effect, signed by officials from the covered entity and the pharmacy, lists all entity sites and pharmacy locations, and corresponds with the information in 340B OPAIS. If the covered entity fails to produce a contract, HRSA will terminate the contract pharmacy from the 340B Program and review the entity's other contract pharmacy arrangements. According to HRSA, from fiscal years 2017 through 2019, less than 2 percent of the 589 contract pharmacy arrangements that HRSA reviewed were terminated.

Annual recertification of eligibility. Covered entities are statutorily required to complete an annual recertification process to continue participating in the 340B Program.³² Prior to the beginning of the recertification period, HRSA alerts covered entity officials of the upcoming requirement and disseminates daily notifications until the covered entity completes the process. To recertify, covered entities must ensure that their basic information—including contact information for entity officials and contract pharmacy addresses—is updated and accurate in 340B OPAIS and self-attest to being in compliance with all 340B Program requirements. HRSA officials told us that the agency may request supporting documentation if a covered entity makes changes to statutorily required data or other key elements of its records during recertification. Failure to recertify will result in a covered entity being terminated from the 340B Program. From fiscal years 2012 through 2019, nearly 2,000 covered entities have been terminated through the recertification process due to loss of a qualifying grant, a disproportionate share hospital

³²42 U.S.C. § 256b(a)(7)(E)).

adjustment percentage falling below the statutory threshold, or failing to recertify, among other reasons.

Self-disclosure to identify noncompliance. Following the implementation of HRSA’s audit process in fiscal year 2012, officials said that the agency began a self-disclosure initiative to allow covered entities to report and correct self-identified instances of noncompliance with 340B Program requirements. As of June 2020, covered entities made 521 self-disclosures to HRSA, with nearly half (232) of these being related to diversion. For example, in fiscal year 2019, one disproportionate share hospital reported that it mistakenly purchased outpatient covered drugs through a group purchasing organization, violating the group purchasing organization prohibition. In fiscal year 2020, another disproportionate share hospital reported its ineligibility for the 340B Program based on its disproportionate share hospital adjustment percentage falling below the statutory threshold.

According to HRSA, covered entities that self-disclose compliance breaches have to prepare and submit corrective action plans, which must include a description of the breach and the entity’s plan to remedy the cause of the issue, disclose the breach to manufacturers, and make any necessary repayments. Corrective action plans are expected to be completed within 6 months of approval.

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reproduced in app. II, and technical comments, both of which we have incorporated as appropriate. In its written comments, HHS responded to our characterization of its implementation efforts in app. I of this report, which includes a table with the status of our previous recommendations related to HRSA oversight of the 340B Program. Specifically, HRSA addressed the implementation of two recommendations made in our 2019 report on nongovernmental hospitals participating in the 340B Program.³³

First, we previously recommended that 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

³³GAO-20-108.

eligible for Medicaid or Medicare.” HHS concurred with this recommendation, and in June 2020, the agency indicated that HRSA had updated its audit guidance to specify that auditors should contact HRSA if any required contract elements, including this provision, are not easily identified.

However, this updated guidance does not describe how auditors are to identify whether contracts actually require these services. Rather, it cautions them not to “dive too [deeply]” to identify such information. Reliance on the initiative of individual auditors to contact HRSA with questions does not ensure uniform or adequate application of this statutory eligibility requirement. Therefore, we remain concerned that HRSA lacks reasonable assurance that the audits are appropriately identifying nongovernmental hospitals that may be participating in the 340B Program based on contracts that are inconsistent with program requirements or HRSA’s guidance. Thus, we consider this recommendation open.

Second, we previously recommended that 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.” As noted in the 2019 report, HRSA updated its draft audit procedures for fiscal year 2020 audits in September 2019 to specify that auditors should look for effective dates that cover the entire audit period.

While this is an important step, HRSA must also demonstrate that it has ceased accepting retroactive contract documentation and applies consistent and appropriate consequences when auditors find that nongovernmental hospitals did not have contracts in effect prior to the beginning of their audit periods. In its written comments, HHS indicated that HRSA had not taken these actions. We continue to believe that allowing hospitals that fail to demonstrate that they meet the statutory requirement of having contracts in place that cover the audit’s period of review to continue to participate in the 340B Program without consequences undermines the effectiveness of HRSA’s audit process and increases the risk that ineligible hospitals will receive discounts under the program. Thus, we consider this recommendation open.

We are sending copies of this report to the appropriate congressional committees, the Secretary of HHS, the Administrator of HRSA, and other

interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at DraperD@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.

A handwritten signature in black ink, appearing to read 'Debra A. Draper', with a stylized flourish at the end.

Debra A. Draper
Director, Health Care

Appendix I: Prior GAO Recommendations Related to Oversight of the 340B Program

The 340B Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities. The Health Resources and Services Administration (HRSA) is the agency within the Department of Health and Human Services (HHS) that is responsible for administering and overseeing the 340B Program. Since 2011, we have reported on HRSA’s oversight of the program and made a number of recommendations. See table 2 for our previous recommendations and the status of their implementation.

Table 2: Status of Prior GAO Recommendations Related to the Health Resources and Services Administration’s (HRSA) Oversight of the 340B Program, as of July 2020

Recommendations from:	Concur (Yes/No)	Status
<p><i>Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (GAO-11-836)</i> Published: Sept. 23, 2011</p>		
<p>Recommendation 1: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of Health and Human Services (HHS) should instruct the administrator of HRSA to conduct selective audits of 340B covered entities to deter potential diversion.</p>	Yes	This recommendation has been implemented.
<p>Recommendation 2: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to finalize new, more specific guidance on the definition of a 340B patient.</p>	Yes	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
<p>Recommendation 3: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted.</p>	Yes	This recommendation has been implemented.

**Appendix I: Prior GAO Recommendations
Related to Oversight of the 340B Program**

Recommendation 4: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS 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.	Yes	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendation 5: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.	Yes	This recommendation has been implemented.
Recommendations from:	Concur (Y/N)	Status
<i>Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (GAO-18-480)</i> Published: June 21, 2018		
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.	No	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.
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 as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs. ^a	Yes	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
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	Yes	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
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.	Yes	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
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.	No	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.

**Appendix I: Prior GAO Recommendations
Related to Oversight of the 340B Program**

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.	No	As of July 2020, HRSA did not plan to take any actions to implement this recommendation.
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.	Yes	In July 2020, HRSA said that, having determined that its authority to issue guidance does not provide appropriate enforcement capability, it is not pursuing new guidance under the program at this time. HRSA has requested the provision of general authority to issue regulations in its fiscal year 2021 budget request.
Recommendations from: <i>340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements (GAO-20-108)</i> Published: Dec. 11, 2019	Concur (Y/N)	Status
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.	Yes	In June 2020, HHS reiterated that HRSA believes that the information it uses to determine nonprofit status is reliable, and HRSA is not taking steps to implement this recommendation at this time.
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.	No	As of June 2020, HRSA did not plan to take any actions to implement this recommendation.
Recommendation 3: The Administrator of HRSA should amend its contract integrity check procedures for the 340B Program to include a review of whether hospitals' contracts with state and local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare as required by statute, and procedures should provide guidance for staff to conduct these reviews.	Yes	This recommendation has been implemented.
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.	Yes	In June 2020, HHS indicated that HRSA had 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. However, these documents do not contain any specific guidance on how auditors are to evaluate whether contracts require these services. Without more specific guidance, HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals' contracts with state or local governments.

**Appendix I: Prior GAO Recommendations
Related to Oversight of the 340B Program**

<p>Recommendation 5: The Administrator of HRSA should revise its 340B Program audit procedures to require auditors to document their assessments of whether nongovernmental hospitals' contracts with state and local governments are appropriately signed, cover the time periods under review, and require hospitals to serve low-income individuals not eligible for Medicaid or Medicare, such as by requiring auditors to separately affirm and record their review of each of these elements.</p>	<p>Yes</p>	<p>This recommendation has been implemented.</p>
<p>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.</p>	<p>Yes</p>	<p>In June 2020, HHS indicated that HRSA has taken certain steps to address this recommendation. However, HRSA still 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.</p>

<p>Recommendations from:</p>	<p>Concur (Yes/No)</p>	<p>Status</p>
<p><i>340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement</i> (GAO-20-212) Published: Jan. 21, 2020</p>		
<p>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 Centers for Medicare & Medicaid Services as needed to obtain states' policies and procedures.</p>	<p>No</p>	<p>As of July 2020, HRSA did not plan to take any actions to implement this recommendation.</p>
<p>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.^b</p>	<p>No</p>	<p>As of July 2020, HRSA did not plan to take any actions to implement this recommendation.</p>

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

^aThis is a priority recommendation, which are those that GAO believes warrant 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.

^bThis report included one recommendation (Recommendation 1) to the Centers for Medicare & Medicaid Services and two recommendations to HRSA.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

November 16, 2020

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*340B DRUG PRICING PROGRAM: HRSA Uses Multiple Mechanisms to Help Ensure Compliance with Program Requirements*" (Job code 104047/GAO-21-107).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C.
Arbes -S

Digitally signed by
Sarah C. Arbes -S
Date: 2020.11.16
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Sarah C. Arbes
Assistant Secretary for Legislation

Attachment

**Appendix II: Comments from the Department
of Health and Human Services**

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, 340B DRUG PRICING PROGRAM: HRSA USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH PROGRAM REQUIREMENTS (GAO-21-107)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

HHS places the highest priority on the integrity of the 340B Drug Pricing Program (340B Program) and continually works to strengthen oversight of the Program. In this report, the GAO sought to review the Health Resources and Services Administration's (HRSA) efforts to oversee covered entity compliance with 340B Program requirements by examining (1) 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. The GAO had no recommendations in this report.

HHS appreciates the GAO's work in this area as it informs HHS' program integrity efforts. During the course of the study, HRSA took the opportunity to make improvements to the program and has worked to enhance some of its program integrity efforts.

The GAO report includes specific statements related to HRSA's issuance of audit findings only when information obtained from a covered entity during an audit presents a clear and direct violation of the 340B statute, as guidance does not provide appropriate enforcement capability. On the page titled "GAO Highlights," the GAO characterizes HRSA officials stating that there were instances in FY 2019 when HRSA did not issue audit findings for failure to comply with guidance related to contract pharmacies because the 340B statute does not address contract pharmacies. HRSA would like to clarify the following statement to ensure accuracy:

"...HRSA officials reported that, *in the absence of a clear statutory violation*, there were instances among fiscal year 2019 audits 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."

Guidance does not provide HRSA appropriate enforcement capability, and HRSA has requested regulatory authority in the President's Budget each year since fiscal year (FY) 2017. Binding and enforceable regulations for all aspects of the 340B Program would provide HRSA the ability to more clearly define and enforce policy and would significantly strengthen HRSA's oversight of the Program.

In addition, Appendix I of the Draft Report includes a table listing recommendations from previous GAO reports on the 340B Program since 2011. The table also includes the status of each recommendation. For the report titled "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements," HRSA would like to clarify the explanation provided by GAO regarding the implementation efforts for recommendations four and six.

Recommendation four states "...HRSA should provide more specific guidance for 340B Program auditors on how to determine if nongovernmental hospitals' contracts with state and

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, 340B DRUG PRICING PROGRAM: HRSA USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH PROGRAM REQUIREMENTS (GAO-21-107)

local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare.” In Appendix I of the Draft Report, the GAO asserts that HRSA has not provided specific guidance on how auditors are to evaluate whether contracts require these services and that HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals’ contracts with state or local governments.

In June 2020, HRSA provided GAO with additional information to indicate that HRSA considered recommendation four to be implemented. Specifically, HRSA provided documentation to the GAO, including updated audit documents that detail that auditors are required to contact HRSA if there are any concerns with the contract or if there are elements that are not easily identified or questionable in nature. Such elements include whether the contract has a statement that the hospital is to provide health care services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under Medicaid.

As part of its response to recommendation four in June 2020, HRSA also stated that the 340B statute does not specify what constitutes the type or amount of service that must be provided to low-income individuals who are not eligible for Medicare and Medicaid. Without additional rulemaking authority from Congress, HRSA cannot issue legally binding regulations that would interpret existing statutory provisions. Therefore, absent this additional rulemaking authority, HRSA believes that it has implemented this provision by updating its guidance documents. HRSA continues to request that the GAO close the recommendation.

Similarly, recommendation six in the same report states “...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.” In the June 2020 response, HRSA stated that as part of the proposed process of collecting contracts at registration, HRSA implemented this recommendation prospectively for newly registering hospitals. Through this process, HRSA reviews the contracts for hospitals to ensure that they include the name of the hospital, the name of the government agency, the dates to ensure that the contract is active, and signatures from both the covered entity and the government official. While this collection of contracts only applies to newly registering hospitals, HRSA continues to collect contract documentation for hospitals that change their eligibility classification during the annual recertification process. Additionally, HRSA also updated its audit procedures to include specific elements that the HRSA auditor must confirm, including that there is a contract in place and that it includes effective dates that cover the entire audit period.

HRSA’s ability to impose consistent and appropriate consequences for hospitals that are unable to provide a contract that covers a certain period of time depends on the facts and circumstances of a particular case. While HRSA has authority to require that a contract exists, the 340B statute does not specify the details related to what those contracts must entail. As previously mentioned in this document, HRSA cannot issue legally binding regulations interpreting the existing

**Appendix II: Comments from the Department
of Health and Human Services**

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED, 340B DRUG PRICING PROGRAM: HRSA USES MULTIPLE MECHANISMS TO HELP ENSURE COMPLIANCE WITH PROGRAM REQUIREMENTS (GAO-21-107)

statutory provisions without additional rulemaking authority from Congress. HRSA has requested regulatory authority in every President's Budget since FY 2017 and has again requested this in the FY 2021 President's Budget. Therefore, enforcement related to this recommendation is challenging and will require evaluation on a case-by-case basis.

Based on the updated audit procedures as detailed and the implementation of this recommendation for new hospitals, HRSA believes that this recommendation is implemented. HRSA continues to request that the GAO close this recommendation.

Agency Comment Letter

Text of Appendix II: Comments from the Department of Health and Human Services

Page 1

November 16, 2020

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office 441
G Street NW
Washington, DC 20548 Dear

Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "340B DRUG PRICING PROGRAM: HRSA Uses Multiple Mechanisms to Help Ensure Compliance with Program Requirements" (Job code 104047/GAO-21-107).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah C. Arbes
Assistant Secretary for Legislation

Attachment

Page 2

**General Comments from the Department of Health & Human Services on the
Government Accountability Office's Draft Report Entitled, 340B Drug Pricing
Program: HRSA Uses Multiple Mechanisms to Help Ensure Compliance with
Program Requirements (GAO-21-107)**

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

HHS places the highest priority on the integrity of the 340B Drug Pricing Program (340B Program) and continually works to strengthen oversight of the Program. In this report, the GAO sought to review the Health Resources and Services Administration's (HRSA) efforts to oversee covered entity compliance with 340B Program requirements by examining (1) 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. The GAO had no recommendations in this report.

HHS appreciates the GAO's work in this area as it informs HHS' program integrity efforts. During the course of the study, HRSA took the opportunity to make improvements to the program and has worked to enhance some of its program integrity efforts.

The GAO report includes specific statements related to HRSA's issuance of audit findings only when information obtained from a covered entity during an audit presents a clear and direct violation of the 340B statute, as guidance does not provide appropriate enforcement capability. On the page titled "GAO Highlights," the GAO characterizes HRSA officials stating that there were instances in FY 2019 when HRSA did not issue audit findings for failure to comply with guidance related to contract pharmacies because the 340B statute does not address contract pharmacies. HRSA would like to clarify the following statement to ensure accuracy:

"...HRSA officials reported that, in the absence of a clear statutory violation, there were instances among fiscal year 2019 audits 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."

Guidance does not provide HRSA appropriate enforcement capability, and HRSA has requested regulatory authority in the President's Budget each year since fiscal year (FY) 2017. Binding and enforceable regulations for all aspects of the 340B Program would provide HRSA the ability to more clearly define and enforce policy and would significantly strengthen HRSA's oversight of the Program.

In addition, Appendix I of the Draft Report includes a table listing recommendations from previous GAO reports on the 340B Program since 2011. The table also includes the status of each recommendation. For the report titled "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements," HRSA would like to clarify the explanation provided by GAO regarding the implementation efforts for recommendations four and six.

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Recommendation four states "...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." In Appendix I of the Draft Report, the GAO asserts that HRSA has not provided specific guidance on how auditors are to evaluate whether contracts require these services and that HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals' contracts with state or local governments.

In June 2020, HRSA provided GAO with additional information to indicate that HRSA considered recommendation four to be implemented. Specifically, HRSA provided documentation to the GAO, including updated audit documents that detail that auditors are required to contact HRSA if there are any concerns with the contract or if there are elements that are not easily identified or questionable in nature. Such elements include whether the contract has a statement that the hospital is to provide health care services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under Medicaid.

As part of its response to recommendation four in June 2020, HRSA also stated that the 340B statute does not specify what constitutes the type or amount of service that must be provided to low-income individuals who are not eligible for Medicare and Medicaid. Without additional rulemaking authority from Congress, HRSA cannot issue legally binding regulations that would interpret existing statutory provisions. Therefore, absent this additional rulemaking authority, HRSA believes that it has implemented this provision by updating its guidance documents.

HRSA continues to request that the GAO close the recommendation.

Similarly, recommendation six in the same report states "...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." In the June 2020 response, HRSA stated that as part of the proposed process of collecting contracts at registration, HRSA implemented this recommendation prospectively for newly registering hospitals. Through this process, HRSA reviews the contracts for hospitals to ensure that they include the name of the hospital, the name of the government agency, the dates to ensure that the contract is active, and signatures from both the covered entity and the government official. While this collection of contracts only applies to newly registering hospitals, HRSA continues to collect contract documentation for hospitals that change their eligibility classification during the

annual recertification process. Additionally, HRSA also updated its audit procedures to include specific elements that the HRSA auditor must confirm, including that there is a contract in place and that it includes effective dates that cover the entire audit period.

HRSA's ability to impose consistent and appropriate consequences for hospitals that are unable to provide a contract that covers a certain period of time depends on the facts and circumstances of a particular case. While HRSA has authority to require that a contract exists, the 340B statute does not specify the details related to what those contracts must entail. As previously mentioned in this document, HRSA cannot issue legally binding regulations interpreting the existing statutory provisions without additional rulemaking authority from Congress. HRSA has requested regulatory authority in every President's Budget since FY 2017 and has again requested this in the FY 2021 President's Budget. Therefore, enforcement related to this recommendation is challenging and will require evaluation on a case-by-case basis.

Based on the updated audit procedures as detailed and the implementation of this recommendation for new hospitals, HRSA believes that this recommendation is implemented. HRSA continues to request that the GAO close this recommendation.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A Draper (202) 512-7114 or DraperD@gao.gov

Acknowledgments

In addition to the contact named above, Hernán Bozzolo (Assistant Director), Amanda Cherrin (Analyst-in-Charge), and Michael Alleyne made key contributions to this report. Also contributing were George Bogart, Vikki Porter, and Caitlin Scoville.

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