



## Testimony

Before the Committee on Health,  
Education, Labor & Pensions, U.S.  
Senate

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# DRUG DISCOUNT PROGRAM

## Status of Agency Efforts to Improve 340B Program Oversight

Statement of Debra A. Draper  
Director, Health Care

Accessible Version

# GAO Highlights

Highlights of [GAO-18-556T](#), a testimony before the Committee on Health, Education, Labor & Pensions, U.S. Senate

## Why GAO Did This Study

According to HRSA, the purpose of the 340B Program, which was created in 1992, is to enable covered entities to stretch scarce 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 generate revenue by receiving reimbursement from patients' insurance. The program does not specify how this revenue is to be used or whether discounts are to be passed on to patients. The number of participating covered entity sites—currently about 38,000—has almost doubled in the past 5 years and the number of contract pharmacies increased from about 1,300 in 2010 to around 18,700 in 2017. In recent years, questions have been raised regarding oversight of the 340B Program, particularly given the program's growth over time.

In September 2011, GAO identified inadequacies in HRSA's oversight of the 340B Program and made recommendations for improvement. Among other things, this statement describes HRSA actions in response to GAO recommendations to improve its program oversight.

For this statement, GAO obtained information and documentation from HRSA officials about any significant program updates and steps they have taken to implement the 2011 GAO recommendations. More detailed information on the objectives, scope, and methodology can be found in GAO's September 2011 report.

View [GAO-18-556T](#). For more information, contact Debra A. Draper at (202) 512-7114 or [draperd@gao.gov](mailto:draperd@gao.gov).

May 15, 2018

## DRUG DISCOUNT PROGRAM

### Status of Agency Efforts to Improve 340B Program Oversight

## What GAO Found

The 340B Drug Pricing Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—eligible clinics, hospitals, and others—in order to have their drugs covered by Medicaid. Covered entities are only allowed to provide 340B drugs to certain eligible patients. Entities dispense 340B drugs through in-house pharmacies or contract pharmacies, which are outside pharmacies entities contract with to dispense drugs on their behalf. The number of contract pharmacies has increased significantly in recent years.

In its September 2011 report, GAO found that the Health Resources and Services Administration's (HRSA) oversight of the 340B Program was inadequate to ensure compliance with program rules, and GAO recommended actions that HRSA should take to improve program integrity, particularly given significant growth in the program in recent years. HRSA has taken steps to address two of GAO's four recommendations:

- **HRSA initiated audits of covered entities.** GAO found that HRSA's oversight of the 340B Program was weak because it primarily relied on covered entities and manufacturers to ensure their own compliance with program requirements and HRSA engaged in few oversight activities. GAO recommended that HRSA conduct audits of covered entities and in fiscal year 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities. HRSA now audits 200 covered entities a year, which is less than 2 percent of entities participating in the 340B Program. Audits conducted to date have identified instances of non-compliance with program requirements, including the dispensing of drugs to ineligible patients. GAO currently has work underway reviewing HRSA's efforts to ensure compliance at contract pharmacies, which includes an examination of HRSA's audits of covered entities.
- **HRSA clarified guidance for manufacturers.** GAO found a lack of specificity in guidance for manufacturers for handling cases in which distribution of drugs is restricted, such as when there is a shortage in drug supply. GAO recommended that HRSA refine its guidance. In May 2012, HRSA clarified its policy for manufacturers that intend to restrict distribution of a drug and provided additional detail on the type of information manufacturers should include in their restricted distribution plans.
- **HRSA has not clarified guidance on two issues.** GAO also found that HRSA guidance on (1) the definition of an eligible patient and (2) hospital eligibility criteria for program participation lacked specificity and recommended that HRSA clarify its guidance. HRSA agreed that clearer guidance was necessary and, in 2015, released proposed guidance that addressed both issues. However, in January 2017, the agency withdrew that guidance in accordance with recent directives to freeze, withdraw, or postpone pending federal guidance. In March 2018, HRSA indicated it was in the process of determining next steps related to guidance on the patient definition, but would need additional authority to further clarify guidance on hospital eligibility; rulemaking authority for the 340B Program was requested in the administration's fiscal year 2019 budget proposal.

Chairman Alexander, Ranking Member Murray, and Members of the Committee:

I am pleased to be here today as you examine the 340B Drug Pricing Program (340B Program), including issues concerning its oversight. The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA), requires drug manufacturers to sell outpatient drugs at discounted prices to eligible clinics, hospitals, and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid.<sup>1</sup> 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, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.<sup>2</sup> In recent years, questions have been raised regarding HRSA's oversight of the 340B Program, particularly given growth in the program over time. According to HRSA, as of January 2017, covered entities had more than 38,000 sites participating in the 340B Program—almost double the number reported just 5 years earlier.<sup>3</sup>

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate:

- 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 generate 340B revenue. For example, they can purchase drugs at 340B prices for all eligible patients regardless of the patients' income or insurance status and generate revenue, such as by receiving reimbursement from a patient's insurance that may exceed the 340B price paid for the drugs.

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<sup>1</sup>42 U.S.C. § 256b.

<sup>2</sup>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 PHSA. 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 PHSA).

<sup>3</sup>Data represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there were 12,340 unique organizations participating in the program as of January 1, 2017.

The 340B Program does not dictate how covered entities should use this revenue or require that discounts on the drugs be passed on to patients.

- Incentives for participation by drug manufacturers also are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA also requires program participants to meet certain conditions set forth both in law and agency guidance. For example, covered entities are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the entities.<sup>4</sup> Similarly, to help ensure covered entities receive discounts to which they are entitled, HRSA has issued guidance (referred to as “HRSA’s nondiscrimination guidance” throughout this statement) prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to non-340B health care providers, such as by imposing minimum purchase requirements or other restrictive conditions.<sup>5</sup>

In a September 2011 report, we identified inadequacies in HRSA’s oversight of this program and recommended actions that should be taken to improve oversight and ensure appropriate use of the program.<sup>6</sup> Since then, we have been monitoring HRSA’s progress in addressing our recommendations and have testified about this at hearings before the House Committee on Energy and Commerce on March 24, 2015, and July 18, 2017.<sup>7</sup> My statement today will describe HRSA actions in response to GAO recommendations to address (1) weaknesses in oversight of the 340B Program and (2) the lack of clarity in program guidance. The statement will also (3) describe ongoing GAO work regarding the 340B Program and HRSA oversight.

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<sup>4</sup>42 U.S.C. § 256b(a)(5)(B).

<sup>5</sup>Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

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

<sup>7</sup>See GAO, *Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight*, [GAO-15-455T](#) (Washington, D.C.: March 24, 2015) and GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight*, [GAO-17-749T](#) (Washington, D.C.: July 18, 2017).

For this statement, we obtained information and documentation from HRSA officials about any significant program updates, and steps they have taken to implement our 2011 recommendations. More detailed information on the objectives, scope, and methodology for our 2011 report can be found in that report.<sup>8</sup> We conducted our work for the 2011 report from September 2010 to September 2011, and updated this work in February and March 2015, in June and July 2017, and again in March 2018. 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.

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## Background

The 340B Program was created following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to state Medicaid agencies.<sup>9</sup> HRSA is responsible for administering and overseeing the 340B Program.

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## Program Participants

Eligibility for the 340B Program, which is defined in the PHS Act, has expanded over time, most recently through the Patient Protection and Affordable Care Act (PPACA), which extended eligibility to additional types of hospitals.<sup>10</sup> Entities generally become eligible by receiving certain federal grants or by being one of six hospital types. Eligible grantees include clinics that offer primary and preventive care services, such as

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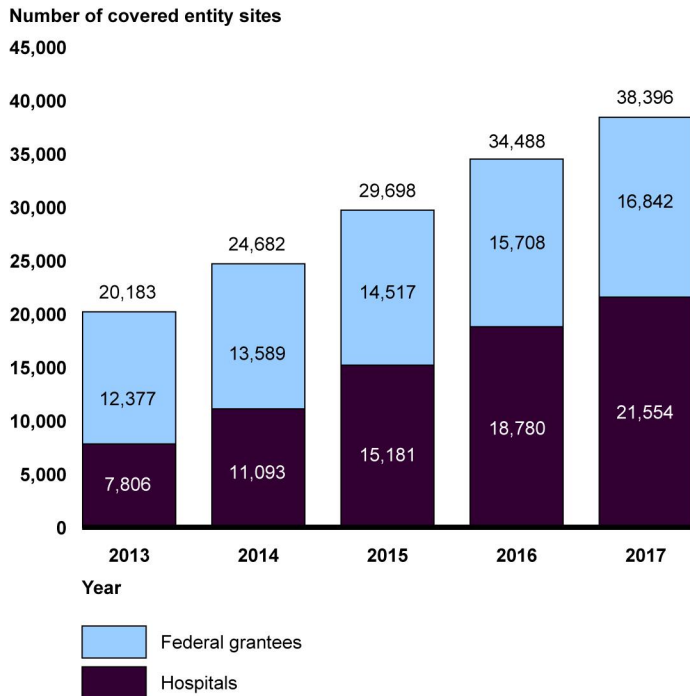
<sup>8</sup>[GAO-11-836](#).

<sup>9</sup>The Medicaid Drug Rebate Program was established through the *Omnibus Budget Reconciliation Act of 1990* and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508 § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

<sup>10</sup>See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

Federally Qualified Health Centers, clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, and AIDS Drug Assistance Programs, which serve as a “payer of last resort” to cover the cost of providing HIV-related medications to certain low-income individuals. Eligible hospitals include certain children’s hospitals, free-standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and general acute care hospitals that serve a disproportionate number of low-income patients, referred to as disproportionate share hospitals (DSH).<sup>11</sup> To become a covered entity and participate in the program, eligible entities must register with HRSA and be approved. Entity participation in the 340B Program has grown over time to include more than 38,000 entity sites, including more than 21,000 hospital sites and nearly 17,000 federal grantee sites (see fig. 1).

**Figure 1: Growth in Covered Entity Sites, 2013 to 2017**



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-556T

<sup>11</sup>Medicare DSH hospitals receive an additional Medicare payment based on their DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

Note: Numbers are as of January 1 of each year.

**Data Table for Figure 1: Growth in Covered Entity Sites, 2013 to 2017**

	2013	2014	2015	2016	2017
<b>Hospitals</b>	7,806	11,093	15,181	18,780	21,554
<b>Federal grantees</b>	12,377	13,589	14,517	15,708	16,842
<b>Total</b>	20,183	24,682	29,698	34,488	38,396

To be eligible for the 340B Program hospitals must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify.<sup>12</sup> Additionally, they must be (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.<sup>13</sup>

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B Program and must participate in order to have their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions.

## Program Structure, Operation, and Key Requirements

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a participating drug manufacturer may charge covered entities.<sup>14</sup> Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example

<sup>12</sup>Critical access hospitals are exempt from this requirement.

<sup>13</sup>According to HRSA, a hospital is said to be “formally granted governmental powers” when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

<sup>14</sup>Manufacturers may sell a drug at a price that is lower than the ceiling price. As such, covered entities may negotiate prices below the ceiling price.

- 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.<sup>15</sup>
- covered entities are also prohibited from diverting any drug purchased at the 340B price to an individual who does not meet HRSA’s definition of a patient. This definition, issued in 1996, outlines three criteria that generally state that diversion occurs when 340B discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services.<sup>16</sup> (See table 1 for more information on HRSA’s definition of an eligible patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the 340B Program definition of a patient regardless of whether they are low-income, uninsured, or underinsured.

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**Table 1: Health Resources and Services Administration’s (HRSA) Definition of a Patient Eligible for Discounted Drugs under the 340B Program**

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**Criteria for patient eligibility:<sup>a</sup>**

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1. The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual’s health care.
  2. The individual 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 (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.<sup>b</sup>
  3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided.<sup>c</sup>
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Source: GAO analysis of HRSA guidance. | GAO-18-556T

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B Program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

<sup>a</sup>These criteria do not apply to AIDS Drug Assistance Programs; rather an individual enrolled in an AIDS Drug Assistance Programs will be considered a patient of that program.

<sup>b</sup>An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

<sup>c</sup>According to HRSA, hospitals are exempt from this requirement. Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the health center

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<sup>15</sup>42 U.S.C. § 256b(a)(5)(A).

<sup>16</sup>See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).



program but do not receive federal grants are referred to as look-alikes and are eligible to participate in the 340B Program.

A covered entity typically purchases and dispenses 340B drugs through pharmacies—either through an in-house pharmacy, or through the use of a contract pharmacy arrangement, in which the covered entity contracts with an outside pharmacy to dispense drugs on its behalf. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance. HRSA’s original guidance permitting the use of contract pharmacies limited their use to covered entities that did not have in-house pharmacies and allowed each covered entity to contract with only one outside pharmacy.<sup>17</sup> However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.<sup>18</sup> Since that time, the number of unique contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to around 18,700 in 2017 (see fig. 2); and, according to HRSA data, in 2017, there were more than 46,000 contract pharmacy arrangements.<sup>19</sup> HRSA guidance requires a written contract between the covered entity and each contract pharmacy. Covered entities are responsible for overseeing contract pharmacies to ensure compliance with prohibitions on drug diversion and duplicate discounts. HRSA guidance indicates that covered entities are “expected” to conduct annual independent audits of contract pharmacies, leaving the exact method of ensuring compliance up to the covered entity.

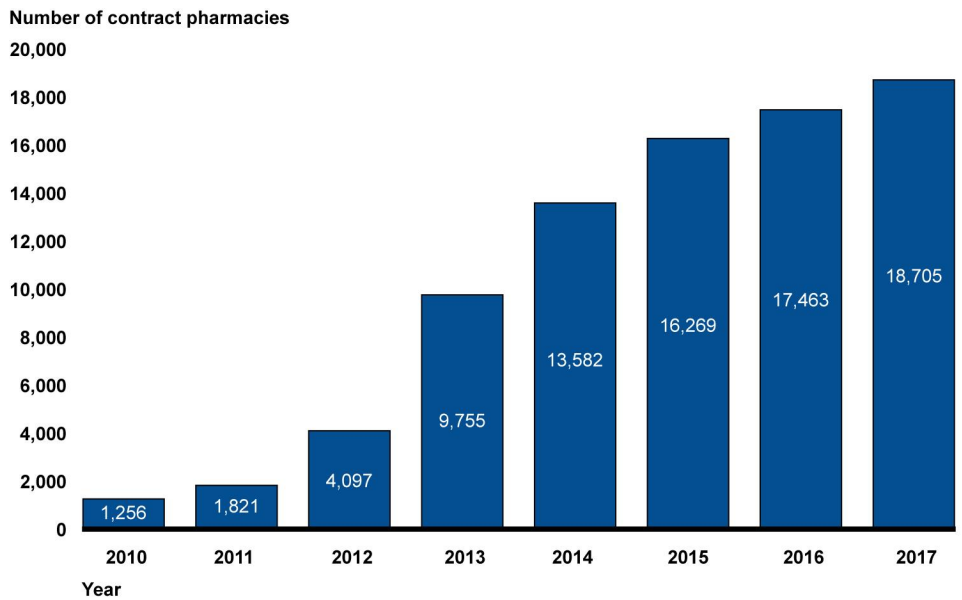
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<sup>17</sup>Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996).

<sup>18</sup>Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

<sup>19</sup>Contract pharmacies may have arrangements to dispense drugs for more than one entity. HRSA data indicates that there were 46,174 contract pharmacy arrangements—arrangements between a covered entity site and a pharmacy—as of January 1, 2017. However, the total number of contract pharmacy arrangements is likely higher, as HRSA does not require entities to report all arrangements to the agency.

**Figure 2: Growth in Contract Pharmacy Participation, 2010 to 2017**



Source: Health Resources and Services Administration. | GAO-18-556T

Note: Data represent the number of unique contract pharmacies participating in the program as of January 1 of each year. Contract pharmacies may have arrangements to dispense drugs for more than one entity.

**Data Table for Figure 2: Growth in Contract Pharmacy Participation, 2010 to 2017**

	2010	2011	2012	2013	2014	2015	2016	2017
<b>Contract Pharmacies</b>	1,256	1,821	4,097	9,755	13,582	16,269	17,463	18,705

Drug manufacturers also must follow certain 340B Program requirements. For example, HRSA’s nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same channels that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the program.

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## HRSA Has Implemented GAO's Recommendation to Improve Its Oversight of the 340B Program by Conducting Audits

In our September 2011 report, we found that HRSA's oversight of the 340B Program was weak because it primarily relied on covered entities and manufacturers to police themselves and ensure their own compliance with program requirements.<sup>20</sup> Upon enrollment into the program, HRSA requires participants to self-certify that they will comply with applicable 340B Program requirements and any accompanying agency guidance, and expects participants to develop the procedures necessary to ensure and document compliance, informing HRSA if violations occur. HRSA officials told us that covered entities and manufacturers could also monitor each other's compliance with program requirements, but we found that, in practice, participants could face limitations to such an approach.

Beyond relying on participants' self-policing, we also found that HRSA engaged in few activities to oversee the 340B Program and ensure its integrity, which agency officials said was primarily due to funding constraints. Further, although HRSA had the authority to conduct audits of program participants to determine whether program violations had occurred, at the time of our 2011 report, the agency had never conducted such an audit.

In our 2011 report, we concluded that changes in the settings where the 340B Program was used may have heightened the concerns about the inadequate oversight we identified. In the years leading up to our report, the settings where the 340B Program was used had shifted to more contract pharmacies and hospitals than in the past, and that trend has continued in recent years. We concluded that increased use of the 340B Program by contract pharmacies and hospitals may have resulted in a greater risk of drug diversion to ineligible patients, in part because these facilities were more likely to serve patients that did not meet the definition of a patient of the program.

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<sup>20</sup>[GAO-11-836](#).

To address these oversight weaknesses, we recommended that the Secretary of HHS instruct the Administrator of HRSA to conduct selective audits of covered entities to deter potential diversion. In response to that recommendation, in fiscal year 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities that is outlined on its website.<sup>21</sup> HRSA audits include entities that are randomly selected based on risk-based criteria (approximately 90 percent of the audits conducted each year), and entities that are targeted based on information from stakeholders (10 percent of the audits conducted). HRSA currently audits a total of 200 entities per year, which accounts for less than 2 percent of covered entities. (See table 2.)

**Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), fiscal years 2012-2017**

Fiscal year	Number of audits	Percent of covered entities audited <sup>a</sup>
2012	51	0.5%
2013	94	0.9%
2014	99	0.9%
2015	200	1.7%
2016	200	1.7%
2017	200	1.6%

Source: HRSA. | GAO-18-556T.

<sup>a</sup>Determined using the number of covered entities as of January 1 of each fiscal year. As a result of the audits already conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion and the potential for duplicate discounts. The agency has developed a process to address non-compliance through corrective action plans. The results of each year’s audits are available on HRSA’s website, and we currently have work underway reviewing HRSA’s efforts to ensure compliance with 340B Program requirements at contract pharmacies that includes an examination of HRSA’s audits of covered entities.

<sup>21</sup>See <https://www.hrsa.gov/opa/programintegrity/index.html>, accessed May 2, 2018.

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## HRSA Implemented One of Three GAO Recommendations to Clarify Program Guidance

In our 2011 report, we found that HRSA’s guidance on three key program requirements lacked the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others’ compliance, and raising concerns that the guidance could be interpreted in ways that were inconsistent with its intent.<sup>22</sup>

First, we found that HRSA’s nondiscrimination guidance was not sufficiently specific in detailing practices manufacturers should follow to ensure that drugs were equitably distributed to covered entities and non-340B providers when distribution was restricted.<sup>23</sup> Some stakeholders we interviewed for the 2011 report, such as covered entities, raised concerns about the way certain manufacturers interpreted and complied with the guidance in these cases. We recommended that HRSA further clarify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers’ plans to restrict distribution of drugs at 340B prices in such cases. In response, HRSA issued a program notice in May 2012 that clarified HRSA’s policy for manufacturers that intend to restrict distribution of a drug and provided additional detail on the type of information manufacturers should include in such restricted distribution plans.<sup>24</sup>

In addition, we found a lack of specificity in HRSA’s guidance on two other issues—the definition of an eligible patient and hospital eligibility for program participation. Specifically, we found that

- HRSA’s guidance on the definition of an eligible patient lacked the necessary specificity to clearly define the various situations under which an individual was considered eligible for discounted drugs through the 340B Program. As a result, covered entities could interpret the definition either too broadly or too narrowly. At the time of

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<sup>22</sup>[GAO-11-836](#).

<sup>23</sup>Restricted distribution may occur when there is a shortage in drug supply or when shortages are anticipated.

<sup>24</sup>HRSA Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012).

our report, agency officials told us they recognized the need to provide additional clarity around the definition of an eligible patient, in part because of concerns that some covered entities may have interpreted the definition too broadly to include non-eligible individuals, such as those seen by providers who were only loosely affiliated with a covered entity.

- HRSA had not issued guidance specifying the criteria under which hospitals that were not publicly owned or operated could qualify for the 340B Program.<sup>25</sup> For example, we found HRSA guidance lacking on one of the ways hospitals could qualify for the program, namely by executing a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. Specifically, we found that HRSA did not outline any criteria that must be included in such contracts, such as the amount of care a hospital must provide to these low-income individuals, and did not require the hospitals to submit their contracts for review by HRSA.<sup>26</sup> As a result, hospitals with contracts that provided a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not have been what the agency intended.

Given the lack of specificity in these areas, we recommended that HRSA (1) finalize new, more specific guidance on the definition of an eligible patient, and (2) issue guidance to further specify the criteria that hospitals not publicly owned or operated must meet to be eligible for the 340B Program. HRSA agreed with these recommendations and had planned to address them in a comprehensive 340B Program regulation that it submitted to the Office of Management and Budget for review in April 2014. However, HRSA withdrew this proposed regulation in November 2014 following a May 2014 federal district court ruling that the agency had not been granted broad rulemaking authority to carry out all the provisions of the 340B Program.<sup>27</sup> After this ruling, the agency issued a proposed Omnibus Guidance in August 2015 to interpret statutory requirements for

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<sup>25</sup>We use the term “hospitals that are not publicly owned or operated” to refer to public and private nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B Program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B Program.

<sup>26</sup>HRSA officials we interviewed for the September 2011 report told us that contracts were selectively reviewed if further clarification was necessary.

<sup>27</sup>See *Pharm. Research & Mfrs. of Am. v. United States HHS*, No. 13-1501, 2014 U.S. Dist. LEXIS 70894 (D.D.C. May 23, 2014).

the 340B Program in areas where it did not have explicit rulemaking authority, including further specificity on the definition of a patient of a covered entity and hospital eligibility for 340B Program participation.<sup>28</sup> However, in January 2017, the agency withdrew the guidance following the administration's January 20 memorandum directing agencies to withdraw or postpone regulations and guidance that had not yet taken effect.<sup>29</sup> In March 2018, HRSA indicated that it was working with HHS to determine next steps regarding the proposed Omnibus Guidance, which included the patient definition, but that it was unable to further clarify guidance on hospital eligibility without additional authority. HRSA also noted that the administration's fiscal year 2019 budget proposal requests rulemaking authority, which, if enacted, would provide the agency with the authority to regulate hospital eligibility for the 340B Program.

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## GAO Has Ongoing Work Related to the 340B Program

GAO has ongoing work related to 340B contract pharmacies and the characteristics of hospitals participating in the program. Specifically, given the increase in the number of contract pharmacies in the 340B Program and concerns that contract pharmacy arrangements present an increased risk to the integrity of the program, we were asked to review contract pharmacy use under the 340B Program. In our forthcoming report, we plan to

- describe the extent to which covered entities contract with pharmacies to distribute 340B drugs, and the characteristics of these pharmacies;
- describe financial arrangements selected covered entities have with contract pharmacies and third-party administrators related to the administration and dispensing of 340B drugs;<sup>30</sup>

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<sup>28</sup>See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).

<sup>29</sup>See Memorandum for the Heads of Executive Departments and Agencies, Regulatory Freeze Pending Review, 82 Fed. Reg. 8346 (Jan. 24, 2017).

<sup>30</sup>Third-party administrators are private companies that some covered entities contract with to manage systems for patient eligibility, program finances, and 340B inventory.

- describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and
- examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies.

In addition, with the growth in the number of hospitals participating in the 340B Program and Medicaid coverage expansions as a result of PPACA, we were asked to review how hospitals that participate in the 340B Program compare to other hospitals. In our forthcoming report, we plan to address

- how hospitals that participate in the 340B Program compare to non-340B hospitals in terms of certain characteristics; and
- how, if at all, the characteristics of 340B and non-340B hospitals changed after state Medicaid coverage was expanded under PPACA.

We expect to issue these reports this summer.

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

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## GAO Contacts and Staff Acknowledgments

For further information about this statement, please contact Debra A. Draper at (202) 512-7114 or [draperd@gao.gov](mailto:draperd@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Key contributors to this statement were Michelle Rosenberg, Assistant Director; Amanda Cherrin, Sandra George, and David Lichtenfeld.



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