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Report to Congressional Requesters

January 2020

340B DRUG DISCOUNT PROGRAM

Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement

GAO-20-212

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GAO Highlights

Highlights of GAO-20-212, a report to congressional requesters

Why GAO Did This Study

Covered entities can receive substantial discounts on outpatient drugs through the 340B Program, an estimated 25 to 50 percent of the cost of the drugs, according to HRSA. Additionally, Medicaid drug rebates are an important source of savings for states and the federal government, saving more than $36 billion in fiscal year 2018. However, ensuring that manufacturers are not subject to both discounts requires coordination within HHS, and between covered entities and states. GAO was asked to provide information on the prevention of duplicate discounts. Among other things, this report examines HHS's efforts to ensure compliance with the prohibition on duplicate discounts. GAO reviewed documentation, including federal policies and those from all 50 states and Washington, D.C. on preventing duplicate discounts. GAO also interviewed officials from CMS, HRSA, and 16 covered entities from four states selected to obtain variation in the types of entities and other factors.

What GAO Recommends

GAO is making three recommendations, namely that: 1) CMS ensure that state Medicaid programs have written policies and procedures that are designed to prevent duplicate discounts and forgone rebates; and that HRSA 2) incorporate covered entities' compliance with state policies into its audits, and 3) require covered entities to work with manufacturers regarding repayment of identified duplicate discounts in managed care. HHS agreed with the recommendation to CMS, but disagreed with those to HRSA. GAO continues to believe these are needed to improve oversight and the integrity of the 340B Program, as explained in the report.

View GAO-20-212. For more information, contact Debra A. Draper at (202) 512-7114 or DraperD@gao.gov

What GAO Found

The 340B Drug Pricing Program (340B Program) and the Medicaid Drug Rebate Program require manufacturers to provide discounts on outpatient drugs in order to have their drugs covered by Medicaid. These discounts take the form of reduced sales prices for covered entities participating in the 340B Program—eligible hospitals and federal grantees—and rebates on drugs dispensed to Medicaid beneficiaries, shared by states and the federal government. However, federal law prohibits subjecting manufacturers to "duplicate discounts" in which drugs provided to Medicaid beneficiaries are subject to both 340B Program discounted prices (i.e., are 340B drugs) and Medicaid rebates. To prevent duplicate discounts, state Medicaid programs must know when covered entities dispense 340B drugs to Medicaid beneficiaries, so the state programs can exclude those drugs from their Medicaid rebate requests.

GAO found that limitations in the Department of Health and Human Services's (HHS) oversight of the 340B and Medicaid Drug Rebate Programs may increase the risk that duplicate discounts occur.

- HHS's Centers for Medicare & Medicaid Services (CMS) conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts. CMS does not track or review states' policies or procedures for preventing duplicate discounts, and GAO found that the procedures states used to exclude 340B drugs are not always documented or effective at identifying these drugs. As a result, CMS does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests. CMS also does not have a reasonable assurance that states are seeking rebates for all eligible drugs, potentially increasing costs to state and federal governments due to forgone rebates.
- HHS's Health Resources and Services Administration's (HRSA) audits of covered entities do not include reviews of states' policies and procedures for the use and identification of 340B drugs. As a result, the audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply with the prohibition on subjecting manufacturers to duplicate discounts.
- GAO reported in 2018 that HRSA had not issued guidance on, and did not audit for, duplicate discounts in Medicaid managed care and recommended the agency do so as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care. HRSA is working to determine next steps to address these recommendations. In this report, GAO found that, unlike Medicaid fee-for-service, when duplicate discounts in Medicaid managed care claims are identified, HRSA does not require covered entities to address them or work with manufacturers to repay them. As a result, manufacturers may be subject to duplicate discounts for drugs provided under managed care.

Given these limitations in federal oversight, HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
FFS	fee-for-service
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
MEF	Medicaid Exclusion File

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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January 21, 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) and the Medicaid Drug Rebate Program require drug manufacturers to provide discounts on outpatient drugs in order to have their drugs covered by Medicaid.[1] For the 340B Program, administered by the U.S. Department of Health and Human Services's (HHS) Health Resources and Services Administration (HRSA), these discounts take the form of reduced sales prices for participating covered entities—eligible hospitals and federal grantees. The discounts, which HRSA estimates to be 25 to 50 percent of the cost of the drugs, are comparable to the rebates made available to state Medicaid programs through the Medicaid Drug Rebate Program, overseen by HHS's Centers for Medicare & Medicaid Services (CMS). While both covered entities and state Medicaid programs are eligible for

[1]42 U.S.C. §§ 256b, 1396r-8. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations. Outpatient prescription drug coverage is an optional benefit in Medicaid but all states have elected to cover it.

these discounts, federal law prohibits subjecting drug manufacturers to duplicate discounts in which drugs provided to Medicaid beneficiaries are subject to both the 340B Program discounted price and a Medicaid rebate.[2]

To prevent duplicate discounts, covered entities and states must work together to identify when covered entities provide drugs purchased at discounted prices through the 340B Program to Medicaid beneficiaries so states can exclude those purchases from rebate requests sent to drug manufacturers. (In this report, we refer to the discounted price through the 340B Program as the 340B price, and to drugs purchased by covered entities at that price as 340B drugs.) States also need to know when the drugs provided to Medicaid beneficiaries by covered entities were not purchased at 340B prices, so they do not forgo rebates for which they are legally entitled, which may increase their costs, as well as that of federal taxpayers.

In recent years, the potential for duplicate discounts has increased due to substantial growth in the 340B Program and the expansion of the Medicaid Drug Rebate Program. Specifically, from 2010 to 2019, the number of covered entities participating in the 340B Program increased from nearly 9,700 to nearly 13,000. In addition, since a change in HRSA guidance allowed covered entities to have an unlimited number of contract pharmacies, there also has been a large increase in the number of contract pharmacies—outside pharmacies that covered entities contract with and pay to dispense 340B drugs on their behalf.[3] Specifically, the number of contract pharmacies increased from about 1,300 at the beginning of 2010 to around 23,000 in 2019. Furthermore, while the Medicaid Drug Rebate Program had historically been limited to drugs provided under Medicaid fee-for-service (FFS), in 2010, the Patient Protection and Affordable Care Act expanded the program by also requiring drug manufacturers to provide rebates for drugs provided under

[2]42 U.S.C. §§ 256b(a)(5)(A), 1396r-8(j)(1).

[3]The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance, and in March 2010, HRSA issued final guidance allowing covered entities to have an unlimited number of contract pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

Medicaid managed care.[4] Since that time, total Medicaid drug rebates more than doubled from about $15 billion in fiscal year 2011 to more than $36 billion in fiscal year 2018.

In recent years, the HHS Office of Inspector General and others have identified challenges covered entities and states face in identifying 340B drugs provided to Medicaid beneficiaries, and thus in preventing duplicate discounts.[5] In addition, in a June 2018 report, we identified weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements, including the prohibition on duplicate discounts.[6] We reported that HRSA had not issued guidance as to how covered entities should prevent duplicate discounts in Medicaid managed care and thus, did not include reviews of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care in its audits of the entities. As a result, we found that drug manufacturers were at risk of providing duplicate discounts. We recommended that HRSA address these issues. HRSA concurred with our recommendations, and as of October 2019, reported that it was continuing to work to determine next steps to address them.

You asked us to examine stakeholders' efforts to prevent duplicate discounts under the 340B and Medicaid Drug Rebate Programs. In this report, we

[4]Pub. L. No. 111-148, § 2501(c), 124 Stat. 119, 308 (2010) (codified at 42 U.S.C. §§ 1396b(m)(2)(A)(xiii), 1396r-8(b)(1)). States provide Medicaid services through either FFS or managed care. Under FFS, states reimburse providers directly for each service delivered. Under managed care, states typically contract with managed care plans using a capitated payment model to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pays each plan a set amount per beneficiary per month to provide or arrange those services.

[5]See, for example, Department of Health and Human Services, Office of Inspector General, *State Efforts To Exclude 340B Drugs From Medicaid Managed Care Rebates*, Report Number OEI-05-14-00430 (Washington, D.C.: June 2016); National Association of Medicaid Directors, NAMD Working Paper Series, *Medicaid and the 340B Program: Alignment and Modernization Opportunities*, (Washington, D.C.: May 13, 2015); and Medicaid and CHIP Payment and Access Commission, Issue Brief, *The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact,* (Washington, D.C.: May 2018).

[6]GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480 (Washington, D.C.: June 21, 2018).

1. describe state Medicaid programs' policies on the use and identification of 340B drugs provided to their beneficiaries to prevent duplicate discounts; and
2. examine HHS's efforts, specifically those of CMS and HRSA, to ensure compliance with the prohibition on duplicate discounts in the Medicaid Drug Rebate and 340B Programs.

To describe state Medicaid programs' policies on the use and identification of 340B drugs provided to their beneficiaries to prevent duplicate discounts, we collected information from states and covered entities. Specifically, in January 2019, we sent a data collection instrument to all 50 states and the District of Columbia requesting documentation of, and information about, their policies related to 340B drugs.[7] The data collection instrument requested the states' policies related to the use and identification of 340B drugs in both Medicaid FFS and managed care for three different methods in which outpatient drugs can be dispensed to Medicaid beneficiaries.[8] We received responses from all states, and reviewed their available policies to determine whether they allowed covered entities to provide 340B drugs to beneficiaries covered under Medicaid FFS or managed care for each dispensing method, and how the state identified and excluded 340B drugs provided to such beneficiaries from rebate requests sent to drug manufacturers. For states that indicated they did not have written policies or procedures for using or identifying 340B drugs, we asked for a description of how they prevented duplicate discounts in practice.

In order to gain a more in-depth understanding of how states worked with covered entities to implement policies and procedures to prevent duplicate discounts, we also interviewed Medicaid officials from a nongeneralizable sample of four states. We selected the four states—Michigan, Oregon, Pennsylvania, and Texas—to obtain variation in factors such as the amount of Medicaid expenditures and rebates on outpatient drugs under both Medicaid FFS and managed care, and geographic location. In addition, we interviewed officials from a nongeneralizable sample of four covered entities located in each of the

[7]In this report, the term states refers to the 50 states and the District of Columbia.

[8]The three methods for dispensing outpatient drugs for which we requested information are (1) covered entities' in-house pharmacies, (2) contract pharmacies, and (3) provider-administered drugs—drugs that doctors and nurses administer to patients directly, such as during office visits.

four selected states (for a total of 16 covered entities) about their understanding of their individual states' policies and the covered entities' actions to prevent duplicate discounts.[9] We selected covered entities of various types that had either high quantities or dollar amounts of 340B drug purchases and that varied as to whether or not they were providing these drugs to Medicaid FFS beneficiaries.[10]

To examine HHS's efforts, specifically those of CMS and HRSA, to ensure compliance with the prohibition on duplicate discounts in the Medicaid Drug Rebate and 340B Programs, we reviewed relevant laws, policies, procedures, and guidance, including HRSA's audit procedures. In addition, we interviewed CMS and HRSA officials responsible for overseeing and administering the Medicaid Drug Rebate and 340B Programs, respectively, about their oversight of duplicate discounts, and any potential actions or initiatives the agencies were undertaking, such as updating or clarifying guidance for covered entities, states, and manufacturers. Additionally, as part of the interviews with the states and covered entities described earlier, we asked officials for their perspectives on federal guidance related to preventing duplicate discounts, and whether they believed any clarifications were needed. We also contacted and obtained information about federal oversight, including CMS's and HRSA's efforts to resolve disputes about duplicate discounts, from three drug manufacturers that had high 340B Program participation based on either total 340B drug sales in dollars or in units sold, as well as consultants that research duplicate discount issues on behalf of manufacturers, and a trade organization that represents drug manufacturers. (Appendix I provides information on manufacturers' efforts to detect and avoid duplicate discounts.) Finally, we evaluated CMS's and HRSA's guidance and oversight against federal internal control standards related to information and communication and monitoring.[11]

[9]Thirteen of the 16 covered entities we interviewed also provided us with their policy and procedure manuals on the use and identification of 340B drugs for Medicaid beneficiaries, and we reviewed these manuals to gain a better understanding of the entities' efforts to comply with state policies.

[10]HRSA has information on whether covered entities report using 340B drugs for Medicaid FFS beneficiaries, but does not have similar information related to Medicaid managed care.

[11]See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

We conducted this performance audit from July 2018 to January 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 Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states on outpatient drugs as a condition of having their drugs covered by Medicaid.[12] The 340B Program, named for the statutory provision authorizing it in the Public Health Service Act, was created in 1992 following the enactment of the Medicaid Drug Rebate Program and allows covered entities to purchase outpatient drugs at discounted prices.[13] HRSA and CMS both have roles in overseeing compliance with the prohibition on duplicate discounts.

The Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. Under the rebate program, drug manufacturers pay rebates to states as a condition for the federal contribution to Medicaid spending for the manufacturers' outpatient drugs. State Medicaid programs generally must cover all of the drugs of manufacturers that participate in the rebate program. Originally, rebates were available only for drugs paid for by the state on a FFS basis, but the Patient Protection and Affordable Care Act extended the program to outpatient drugs paid for under Medicaid managed care; there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than FFS.[14] The rebates received for both FFS and managed care are shared by the federal government and states.

[12]See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (1990) (codified, as amended, at 42 U.S.C. § 1396r-8).

[13]42 U.S.C. § 256b.

[14]According to analysis from the Medicaid and CHIP Payment and Access Commission, in fiscal year 2018, 61 percent of Medicaid gross spending for drugs and 71 percent of Medicaid drug prescriptions were in managed care. Additionally, as of July 2017, about 69 percent of Medicaid enrollees received their medical care services through managed care.

The amount of Medicaid rebates for a drug is based on a statutory formula.[15] Using that formula CMS calculates a unit rebate amount for each drug and provides that amount to states so they can determine the amount of rebates to request.[16] Every quarter, each state multiplies the number of units of each drug it either paid for on a FFS basis or provided through its managed care plans by the CMS-provided unit rebate amount. For drugs provided under FFS, the state calculates the number of units based on drug claims it reimbursed, while states use drug utilization data provided by managed care plans to determine the number of units of each drug that were provided by the plans to Medicaid beneficiaries. Each state then sends rebate requests to each manufacturer reflecting the total quarterly amount of rebates owed for each of the manufacturer's drugs.[17] States are to exclude claims for 340B drugs from their rebate requests.

340B Program

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives for both to do so. Covered entities can realize substantial savings through the program's price discounts. In addition, covered entities can generate revenue to the extent that they can purchase 340B drugs for eligible patients whose insurance reimbursement exceeds the price paid. Incentives for participation by drug manufacturers are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs.

Covered entities generally become eligible for the 340B Program by qualifying as certain federal grantees or as one of six specified types of hospitals. Eligible federal grantees include federally qualified health centers, which provide comprehensive community-based primary and preventive care services to medically underserved populations, as well as certain other federal grantees, such as family planning clinics and Ryan

[15]See 42 U.S.C. § 1396r-8(c). See also 42 C.F.R. § 447.509 (2018).

[16]CMS uses drug pricing data provided by drug manufacturers to calculate the unit rebate amount for each drug.

[17]For each drug, the rebate request specifies, among other things, the unit rebate amount, the number of units Medicaid paid for, the amount of rebates claimed, and the number of prescriptions. The request does not have to separately list each prescription or drug claim for which the state is seeking a rebate.

White HIV/AIDS program grantees, among others.[18] Eligible hospitals include critical access hospitals—small, rural hospitals with no more than 25 inpatient beds; disproportionate share hospitals—general acute care hospitals that serve a disproportionate number of low-income patients; and four other types of hospitals.[19]

To participate in the 340B Program, covered entities must register with HRSA and annually recertify their continuing eligibility. Once their eligibility is approved by HRSA, covered entities can begin purchasing drugs from manufacturers at the 340B discounted prices. Covered entities may provide drugs, including 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 pharmacies and pay them to dispense drugs on their behalf; or both. In addition, providers who work at covered entities, such as doctors and nurses, may administer 340B drugs to patients directly, such as during office visits. These are known as provider-administered drugs.

As a condition of participating in the 340B Program, covered entities must follow certain requirements. For example, they are prohibited from diverting a 340B drug to an individual who is not a patient of the covered entity. Covered entities are also prohibited from subjecting manufacturers to duplicate discounts.

Preventing Duplicate Discounts and Forgone Rebates

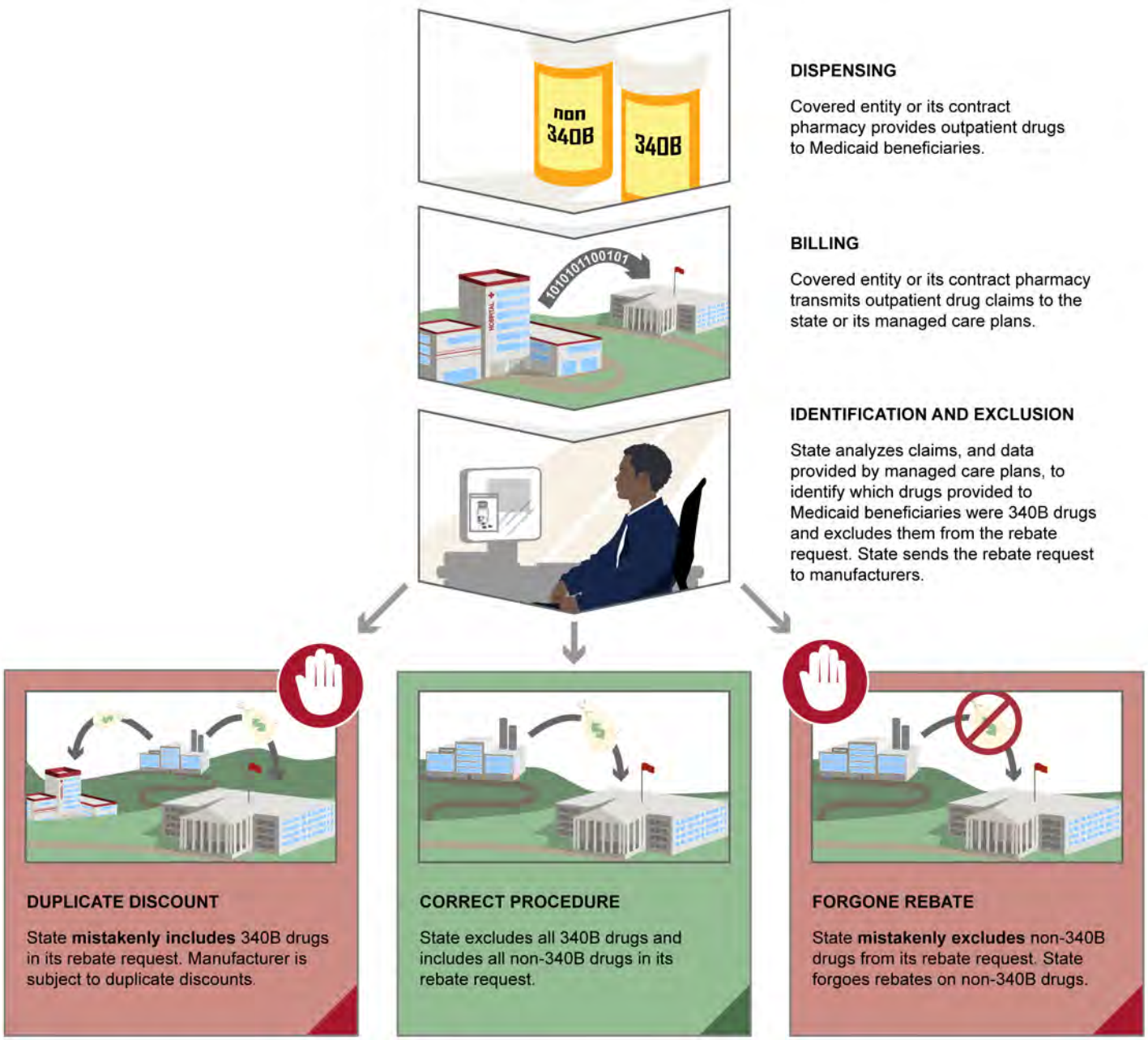
Both states and covered entities play key roles in preventing duplicate discounts and forgone rebates. States must know whether covered entities provided 340B drugs to Medicaid beneficiaries in order to exclude those drugs from the rebate requests they submit to manufacturers. When covered entities provide 340B drugs to Medicaid beneficiaries, it is known as “carving in;” if covered entities do not dispense these drugs to Medicaid beneficiaries, it is known as “carving out.” As shown in figure 1, if a state is not aware that a covered entity provided 340B drugs to Medicaid beneficiaries, it would not know to exclude those drugs from its

[18]The other types of federal grantees are Black Lung clinics, hemophilia treatment centers, Native Hawaiian health centers, sexually transmitted diseases grantees, tuberculosis grantees, and Urban Indian organizations.

[19]The other types of hospitals are children’s hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals.

rebate requests, which could lead to duplicate discounts. In contrast, if a state mistakenly believes the entity used 340B drugs when it did not, it might exclude those drugs from its rebate requests and would forgo eligible rebates.

Figure 1: Example of How Covered Entities and State Medicaid Programs Must Work Together to Prevent Duplicate Discounts and Forgone Rebates



Source: GAO. | GAO-20-212

Note: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

To help prevent duplicate discounts, in 1993, HRSA and CMS collaborated to establish the Medicaid Exclusion File (MEF) as a mechanism to assist in the identification of 340B drugs provided to Medicaid FFS beneficiaries. The MEF lists the covered entities that reported to HRSA that they choose to use or "carve in" 340B drugs for their Medicaid FFS patients. Specifically, HRSA requires that covered entities that decide to carve in these drugs for Medicaid provide the agency with the provider number or numbers that the entities use to bill the state for those drugs.[20] The entity and the provider number or numbers it specifies are then listed on the MEF. HRSA guidance specifies that all drugs billed with the provider numbers listed on the MEF should be 340B drugs so a state that choses to use the MEF knows the drugs should be excluded from rebate requests; there is no requirement for states to use the MEF to identify 340B drugs. If a covered entity wants its contract pharmacy to dispense 340B drugs to patients covered under Medicaid FFS, HRSA guidance requires the covered entity, the contract pharmacy, and the state Medicaid program to have an arrangement to prevent duplicate discounts; any such arrangement must be reported to HRSA.[21]

When the MEF was created, Medicaid drug rebates were only required for drugs provided under FFS. As such, in a 2014 policy release, HRSA clarified that the MEF is only intended for use for Medicaid FFS, that is, only covered entities that elect to carve in 340B drugs for Medicaid FFS are required to provide the provider numbers used for billing Medicaid FFS for inclusion on the MEF.[22] The MEF is not intended to capture whether covered entities have decided to carve in 340B drugs for Medicaid managed care and, if so, what provider numbers they use for billing for those drugs. 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.

[20]The provider number can either be a national provider identifier for the covered entity or for a provider at the covered entity, such as a pharmacy or doctor. In addition, it could be a Medicaid billing number that the covered entity uses when submitting claims for 340B drugs to a state.

[21]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services , 75 Fed. Reg. at 10278.

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

While HRSA requires covered entities to use the MEF, there is no similar requirement for state Medicaid programs. CMS provides states the flexibility to determine procedures for identifying and excluding 340B drugs from their Medicaid rebate requests. Under a May 2016 final rule, states' contracts with Medicaid managed care plans that provide coverage of outpatient drugs must require the plans to provide the states with drug utilization data that is necessary for the states to claim Medicaid rebates.[23] In addition, the contracts must require the plans to establish procedures for excluding 340B drugs from the drug utilization data provided to states for purposes of rebate collection.[24]

Federal Oversight

To oversee covered entities' compliance with 340B Program requirements, in fiscal year 2012, HRSA implemented a systematic approach to conducting audits of a small sample of covered entities, and began conducting audits of 200 entities per year in fiscal year 2015.[25] HRSA audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), or targeted based on information from stakeholders such as drug manufacturers about potential noncompliance (10 percent of the audits conducted). HRSA's criteria for risk-based audits include a covered entity's volume of 340B drug purchases, number of contract pharmacies, time in the program, and complexity of its program.

Among other things, HRSA's audits include reviews of each covered entity's policies and procedures, an assessment of the entity's compliance with respect to 340B Program requirements, including the prevention of duplicate discounts in Medicaid FFS, and reviews of a

[23]The rule specifies that the utilization data must, at a minimum, include the number of units of each outpatient drug dispensed by, or covered by, the managed care plan.

[24]Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Final Rule, 81 Fed. Reg. 27498, 27857 (May 6, 2016) (codified at 42 C.F.R. § 438.3(s)(3)). This requirement does not apply to states that require submission of managed care claims data from covered entities directly.

[25]HRSA began conducting audits in response to a recommendation we made in September 2011 for the agency to conduct selective audits of covered entities to deter the diversion of 340B drugs to individuals who are not patients of the entities. See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,* GAO-11-836 (Washington, D.C.: Sep 23, 2011). In addition to audits, HRSA also has a self-disclosure process, whereby entities can report any material compliance breaches, and steps to address the breach, to HRSA.

sample of prescriptions filled during a 6-month period to identify any instances of noncompliance. Under HRSA's audit procedures, a covered entity with audit findings is required to 1) submit a corrective action plan to HRSA that indicates it will determine the full scope of any noncompliance (beyond the sample of prescriptions reviewed during an audit) and 2) outline the steps it plans to take to correct findings of noncompliance, including any necessary repayments to manufacturers, among other things. If the HRSA audit shows that duplicate discounts may have occurred, the covered entity must, as part of its corrective action plan, contact the state Medicaid program to determine whether duplicate discounts actually occurred—namely, whether the state requested a rebate on the claims in question, and if so, contact the drug manufacturer to offer repayment. HRSA closes the audit when a covered entity submits a letter attesting that its corrective action plan, including its assessment of the full scope of noncompliance, has been implemented and any necessary repayments to manufacturers have been resolved. In addition, HRSA may re-audit a covered entity (i.e. subject it to a targeted audit) to determine whether it has implemented its corrective action plan.

To oversee the Medicaid Drug Rebate Program, CMS receives copies of states' Medicaid rebate requests each quarter. States are required to submit this data to manufacturers for FFS and managed care drugs, which should not include drugs purchased through the 340B Program, within 60 days of the end of the quarterly rebate period. Specifically, states provide drug utilization data that includes the drug name, national drug code (a unique identifier for each drug), the unit rebate amount, the number of units reimbursed, the rebate amount claimed, and the number of prescriptions, among other things. CMS has a system that reviews this information for errors, such as the inclusion of drugs from manufacturers that no longer participate in the Medicaid Drug Rebate Program, and generates a discrepancy report for the state. CMS also has a system in place to identify, for state review, cases in which the utilization data reflect a substantial increase or decrease in the number of FFS records submitted compared to prior quarters; such a review is not currently performed for managed care. In addition, CMS reviews state Medicaid programs' contracts with managed care plans using a checklist to ensure that the contracts include elements required by statute or regulation.

State Medicaid Programs' Policies on the Use and Identification of 340B Drugs Vary, Are Not Always Documented, and May Not Prevent Duplicate Discounts

State Medicaid Programs' Policies for Use and Identification of 340B Drugs Vary

State Medicaid programs' policies varied in whether they allowed covered entities to use 340B Program drugs for Medicaid beneficiaries. Most states allowed covered entities to decide whether to use, or "carve in," 340B drugs for Medicaid beneficiaries at their in-house pharmacies and for provider-administered drugs. Fewer states allowed covered entities to dispense these drugs to Medicaid beneficiaries at contract pharmacies, particularly beneficiaries whose drugs were covered under FFS. Table 1 below summarizes states' policies on covered entities' use of 340B drugs for Medicaid beneficiaries for both FFS and managed care by dispensing method.

Table 1: Count of State Medicaid Programs' Policies Regarding Covered Entities' Use of 340B Drugs for Fee-for-Service and Managed Care by Dispensing Method, 2019

Policy on use of 340B drugs	Fee-for-Service			Managed Care		
	In-house pharmacies n=51	Provider-administered drugs n=51	Contract pharmacies n=51	In-house pharmacies n=36	Provider-administered drugs n=38	Contract pharmacies n=36
Covered entity decision	45	45	12	25	27	11
Carve out[a]	2	1	37	1	1	19
Carve in[b]	2	2	0	2	2	0
Other[c]	2	2	2	8	8	6
No policy	0	1	0	0	0	0

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: Not all state Medicaid programs covered outpatient drugs through managed care. Specifically, 38 of 51 states covered at least some outpatient drugs through managed care; managed care plans in two of the 38 states covered only provider-administered drugs. The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

[a]States that required covered entities to "carve out" 340B drugs did not allow covered entities to provide these drugs to Medicaid beneficiaries. This also includes states that allowed 340B drugs to

be dispensed to Medicaid beneficiaries at contract pharmacies if there was an established arrangement to prevent duplicate discounts between the state, the covered entity, and the contract pharmacy, but no such arrangements existed at the time of our review.

[b]States that required covered entities to "carve in" required covered entities to provide 340B drugs to eligible Medicaid beneficiaries.

[c]Other includes, for example, states that required covered entities to seek approval to provide 340B drugs, did not allow covered entities to bill the state for these drugs provided to Medicaid beneficiaries, or states in which policies regarding use were made by the managed care plans.

In addition to varying by state, policies on the use of 340B drugs sometimes varied within a state; that is, some states had different policies depending on whether the drugs were provided to Medicaid FFS or managed care beneficiaries, the dispensing method used, or both. For example, Oregon allowed covered entities to decide whether to dispense 340B drugs at contract pharmacies to Medicaid managed care beneficiaries, but required covered entities to carve out (not use) these drugs at contract pharmacies under Medicaid FFS. Illinois required covered entities to carve in 340B provider-administered drugs and those dispensed at in-house pharmacies for Medicaid beneficiaries in both FFS and managed care, but prohibited their use for Medicaid beneficiaries at contract pharmacies. See appendix II for information on each state Medicaid program's policies regarding covered entities' use of 340B drugs.

The states that allowed or required covered entities to carve in 340B drugs for Medicaid beneficiaries used several different procedures to identify and exclude those drugs from Medicaid rebate requests. These procedures included relying on the MEF, requiring covered entities to use a 340B claim identifier—a code on the claim that indicates that the drug used was purchased at the 340B discounted price, or using other state-developed procedures to identify and exclude 340B drugs from rebate requests.[26] The procedures states used varied between Medicaid FFS and managed care, and among dispensing methods. For example, states were more likely to use HRSA's MEF to identify and exclude provider-administered drugs in both Medicaid FFS and Medicaid managed care and to use a 340B claim identifier to identify and exclude drugs dispensed

[26]There are industry-accepted transaction standards that states can direct covered entities to use on their drug claims to identify them as 340B drugs. For pharmacy drugs, the National Council on Prescription Drug Programs has created a "submission clarification code" field that can be populated with a value of "20" to identify a 340B drug. For provider-administered drugs, the American National Standards Institute has created a "UD" modifier value that can be added to identify a relevant claim.

at in-house pharmacies. Some states used a combination of procedures or created their own state-specific procedures. For example,

- 11 states required that covered entities inform them of their decisions to carve in 340B drugs for Medicaid beneficiaries. The states then maintained a list of these covered entities or their providers, which they used to exclude 340B drugs from rebate requests.[27]
- Oregon required covered entities to provide the state with a list of each 340B drug dispensed to a Medicaid managed care beneficiary at a contract pharmacy so that the state could exclude those drugs from its rebate requests.
- Vermont required covered entities, on a monthly basis, to send the state a file listing each 340B drug provided to a Medicaid beneficiary; the state used this information to exclude those drugs from rebate requests.

See table 2 for a summary of the procedures used by states to identify 340B drugs provided to Medicaid beneficiaries, and appendix III for a listing of the procedures by state.

Table 2: Number of State Medicaid Programs That Allow Covered Entities to Use 340B Drugs, by Procedure for Identifying Those Drugs, Medicaid Fee-for-Service or Managed Care, and Dispensing Method, 2019

Procedure	Fee-for Service			Managed care		
	In-house pharmacies n=49	Provider-administered drugs n=50	Contract pharmacies n=14	In-house pharmacies n=35	Provider-administered drugs n=37	Contract pharmacies n=17
Medicaid Exclusion File[a]	13	18	2	8	13	1
340B claim identifiers	17	12	9	15	11	11
Medicaid Exclusion File and 340B claim identifiers	7	5	0	6	5	1
Other[b]	10	14	2	5	7	3
None[c]	1	1	0	0	1	0
Not applicable[d]	1	0	1	1	0	1

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: This table only includes state Medicaid programs that covered outpatient drugs through the specified delivery system and allowed covered entities to provide 340B drugs to Medicaid beneficiaries for the specified dispensing method. In other words, for each dispensing method, the table excludes states that required covered entities to “carve out” or not use 340B drugs for Medicaid

[27]Six of these 11 states used their state-developed provider list to exclude 340B drugs from rebate requests in conjunction with another procedure, usually the MEF.

beneficiaries. Additionally, states are not included in the managed care columns if they did not cover outpatient drugs under managed care. The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

[a]The Medicaid Exclusion File is a list of provider numbers of covered entities that elected to use, or carve in, 340B drugs for Medicaid fee-for-service beneficiaries; the list is maintained by the Health Resources and Services Administration.

[b]Other procedures used by states include, for example, state-developed lists of providers that provide 340B drugs to Medicaid beneficiaries and a covered entity-provided list of relevant claims. We also included states that delegate the identification of 340B drugs to managed care plans as other.

[c]None represents states that allowed covered entities to provide 340B drugs to Medicaid beneficiaries but did not have any procedures to identify those drugs.

[d]Not applicable represents a state which allows covered entities to dispense 340B drugs at in-house and contract pharmacies but prohibits them from billing the state for such drugs.

State Medicaid Programs' Policies on the Use and Identification of 340B Drugs Are Not Always Documented and May Not Prevent Duplicate Discounts

State Medicaid programs' policies related to 340B drugs were not always documented and some states' policies may not prevent duplicate discounts. Some states had written policies for the use of 340B drugs, and procedures to identify them, for some dispensing methods, but not for others, such as states that had documented policies for in-house pharmacies but not contract pharmacies. Without written policies, covered entities in those states may not be aware of requirements for dispensing and identifying 340B drugs, increasing the risk of duplicate discounts. Specifically, we found that nine states did not have written policies or procedures on the use or identification of 340B drugs for all dispensing methods. Seven of the nine states had policies or procedures regarding the use and identification of 340B drugs that were used in practice, but these policies and procedures were not always documented. For example:

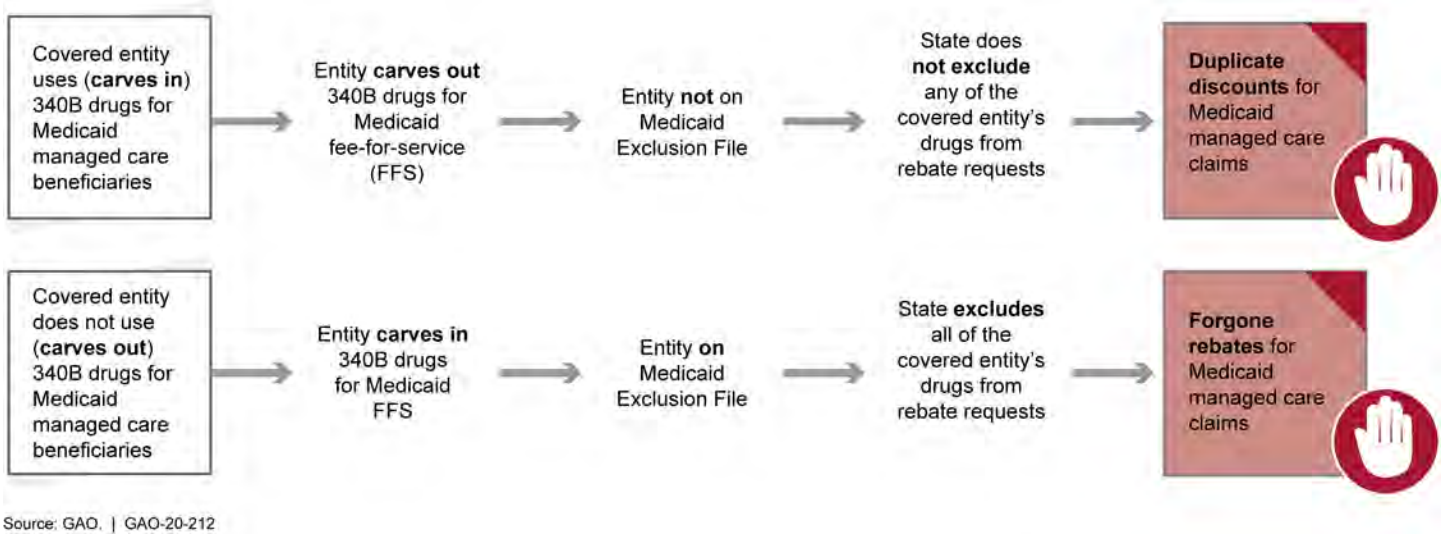
- Connecticut did not have documented policies on the use and identification of 340B drugs, but officials from the state reported that it allowed covered entities to provide these drugs to Medicaid beneficiaries and relied on the MEF to identify and exclude them from rebate requests.
- While Pennsylvania and Ohio had written policies regarding the use of 340B drugs in Medicaid FFS and for some dispensing methods under managed care, the states' policies requiring covered entities to carve out these drugs for Medicaid managed care beneficiaries at contract pharmacies were not documented.

The remaining two states did not have policies or procedures, documented or otherwise, for all dispensing methods:

- Officials from Washington, D.C. reported that D.C. did not have a policy regarding the use of provider-administered 340B drugs nor did it have procedures to identify and exclude those drugs from its Medicaid drug rebate requests.
- A Rhode Island Medicaid official told us that the state did not have written policies regarding the identification of 340B drugs dispensed to Medicaid FFS beneficiaries at in-house pharmacies, and that the state did not have procedures, written or otherwise, by which to exclude such drugs from rebate requests. Additionally, while the state had a written policy for identifying and excluding 340B drugs administered by providers at hospitals, officials told us that they had no policy or exclusion procedures for drugs administered by providers at other types of covered entities.

In addition, we found that states' policies may not prevent duplicate discounts. For example, some states used the MEF to identify and exclude 340B drugs from their rebate requests in a manner contrary to the MEF's purpose as set forth by HRSA. As noted previously, HRSA guidance specifies that the MEF is not intended to be used to identify and exclude 340B drugs provided to Medicaid managed care beneficiaries from Medicaid drug rebate requests. Covered entities are only required to be listed on the MEF if they carve in 340B drugs for Medicaid FFS. Since the MEF may not accurately reflect covered entities' use of 340B drugs for Medicaid managed care, states' use of the MEF in this instance may increase the risk of duplicate discounts or forgone rebates unless states require covered entities to make the same decisions on the use of 340B drugs for FFS and managed care. For example, as shown in figure 2, a state's use of the MEF for managed care would likely result in a duplicate discount if covered entities carve out 340B drugs for Medicaid FFS, but carve in these drugs for managed care, as those entities would not be listed on the MEF. Consequently, the state would not know to exclude drugs provided by those entities from the managed care plans' utilization data that are used for requesting rebates. If covered entities did the opposite—carved in for FFS and carved out for Medicaid managed care—then the state would likely forgo Medicaid rebates as it would exclude drugs from its rebate request that were not purchased through the 340B Program.

Figure 2: Depiction of How the Use of the Medicaid Exclusion File for Medicaid Managed Care Could Result in Duplicate Discounts or Forgone Rebates



Source: GAO. | GAO-20-212

Note: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

Seven of the 13 states that used the MEF exclusively to identify and exclude Medicaid managed care drugs from rebate requests for at least one dispensing method did not require covered entities to make the same carve-in decisions for both FFS and managed care. Additionally, while the six remaining states required covered entities to make the same decision regarding use of 340B drugs in FFS and managed care, that requirement was not always clearly explained in the states' policies. For example, an official from Arkansas, which used the MEF for identifying and excluding 340B drugs from rebate requests, told us that covered entities are required to make the same carve-in decisions for both Medicaid FFS and managed care. However, it is unclear how covered entities would be aware of that requirement, as it was not documented in the state's policy manuals at the time of our information request.

Finally, states that rely on the MEF or state-developed lists of providers carving in 340B drugs for Medicaid beneficiaries may not be able to identify instances where covered entities are unable to purchase drugs at the 340B Program discounted price, and instead need to purchase drugs outside of the 340B Program. For example, orphan drugs are excluded

from the discounted 340B Program price for some covered entities.[28] In these situations, states that rely on the MEF or other state-developed lists of providers may be forgoing rebates. For example, if covered entities do not have a separate provider number for billing Medicaid for these non-340B drugs, the states would be excluding both 340B and non-340B drugs from their rebate requests. State Medicaid officials in Oregon and Pennsylvania acknowledged that their states were likely forgoing rebates when covered entities listed on the MEF were unable to purchase drugs at the 340B Program price. While these state officials indicated that they did not consider the lost rebates financially significant, the loss of these rebates would also increase federal Medicaid expenditures, since rebates are shared between the state and the federal government.

Limitations in HHS Oversight Increase the Risk of Duplicate Discounts

CMS Oversight of State Medicaid Programs' Efforts to Prevent Duplicate Discounts Is Limited

CMS oversight of state Medicaid programs' efforts to prevent duplicate discounts is limited. States have the flexibility to select the procedures used for identifying and excluding 340B drugs from rebate requests. Although CMS collaborated with HRSA to establish the MEF as a tool for identifying 340B drugs in Medicaid FFS, CMS does not require states to use the MEF in their duplicate discount prevention efforts. Instead, CMS has provided states with options of procedures they could consider for identifying and excluding 340B drugs from rebate requests. For example, CMS's February 2016 final rule on covered outpatient drugs, which detailed requirements for Medicaid reimbursement of covered outpatient drugs, included in its preamble examples of procedures that states could use to identify and exclude 340B drugs in FFS without prescribing any specific required procedure.[29] Additionally, as noted earlier, the final rule CMS issued in May 2016 on Medicaid managed care included a provision relating to duplicate discounts for Medicaid managed care drugs. Specifically, it mandated that state Medicaid programs' contracts with

[28]42 U.S.C. § 256b(e). Orphan drugs are drugs designated by the Secretary of HHS as treating a rare disease or condition.

[29]See Medicaid Program; Covered Outpatient Drugs, Final Rule, 81 Fed. Reg. 5170, 5320 (Feb. 1, 2016).

managed care plans that provide outpatient drugs require the plans to establish procedures for excluding 340B drugs from utilization data provided to states for use in seeking rebates, but did not specify what procedures plans should use.[30] Most recently, in January 2020, CMS released a bulletin to state Medicaid programs on best practices for preventing duplicate discounts.

CMS has some visibility into state Medicaid programs' 340B-related policies and procedures through its oversight activities, but these activities are not intended to, and do not enable CMS to, assess compliance with the duplicate discount prohibition. For example, CMS has a system in place that reviews copies of states' quarterly Medicaid drug rebate requests; however, CMS officials told us that these requests do not contain detailed, claim-level information that could be used to determine if specific drugs purchased through the 340B Program were incorrectly included. Additionally, CMS reviews states' contracts with Medicaid managed care plans to ensure that they include language requiring the plans to have procedures to exclude 340B drugs from Medicaid rebate data provided to states, but CMS officials told us that the contract language does not have to specify or describe those mechanisms, limiting the information available regarding duplicate discount prevention efforts. CMS also required states to submit their plans for reimbursing covered entities for 340B drugs provided under Medicaid FFS to ensure that the states' payment methodologies complied with federal requirements, but these reviews were not focused on ensuring that such drugs were excluded from rebate requests.[31]

CMS officials told us that they do not track which procedures states use to prevent duplicate discounts; review states' policies or procedures for identifying and excluding 340B drugs from rebate requests for deficiencies or to ensure effectiveness; or audit states' compliance with the prohibition on duplicate discounts. This is problematic because, as

[30]Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care; CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. at 27,857 (codified at 42 C.F.R. § 438.3(s)).

[31]Federal regulations generally require states to pay for drugs covered under their FFS programs, including 340B drugs, at actual acquisition costs plus a professional dispensing fee. See 42 CFR § 447.512(b) (2018). According to CMS officials, states that require covered entities to carve out 340B drugs provided under Medicaid FFS would need to include this in the plans submitted to CMS describing their payment methodologies for outpatient drugs.

noted previously, we found that not all state Medicaid programs have written policies and procedures that specify the extent to which covered entities can use 340B drugs for Medicaid beneficiaries, or how they are to identify these drugs so the state can exclude them from Medicaid rebate requests. If states do not have written policies, covered entities may not be aware of whether, or under what circumstances, they are permitted to provide 340B drugs to Medicaid beneficiaries or how to properly inform the state of their use, which could result in errors that lead to duplicate discounts and forgone rebates. We found some evidence of confusion from covered entities about state policies. For example, officials from Apexus, which manages HRSA's 340B Prime Vendor Program, told us that Apexus's call center, which fields questions from covered entities and other stakeholders about the 340B Program, most frequently receives questions related to clarifying states' duplicate discount-related policies.[32] These inquiries about state requirements indicate that there is currently confusion among covered entities.[33]

CMS's limited oversight of state Medicaid programs' efforts to prevent duplicate discounts is also problematic because we found that states' policies and procedures were not always effective at preventing duplicate discounts, or in line with federal guidance. For example, the MEF is only intended to be used for Medicaid FFS. CMS officials told us that, while the agency was not aware of any states using the MEF for Medicaid managed care, such use would be concerning because it is not an accurate tool for that purpose. However, as previously shown in table 2, we found that eight states relied on the MEF to identify and exclude Medicaid managed care drugs dispensed at in-house pharmacies from rebate requests and 13 states used the MEF to identify and exclude managed care drugs administered by providers.

The lack of CMS oversight of state Medicaid programs' policies and procedures related to duplicate discount prevention is inconsistent with federal standards for internal control for information and communication, which state that management should obtain relevant data from reliable internal and external sources in a timely manner based on the identified information requirements so that data can be used for effective

[32]HRSA awarded a contract to Apexus to manage its Prime Vendor Program. As the prime vendor, Apexus provides 340B Program education to stakeholders, and helps support program integrity through technical assistance, among other things.

[33]Apexus officials told us that these questions include: "Does my state require carve in/out?" and "What are the Medicaid billing requirements for my state?"

monitoring.[34] Without reviewing states' policies and procedures, CMS does not have the information needed to effectively oversee states' compliance with the Medicaid drug rebate statute, which exempts 340B drugs from Medicaid rebate requirements, and ensure that states have effective policies and procedures for preventing duplicate discounts. The lack of oversight of states' policies and procedures also results in CMS not having reasonable assurance that states are seeking rebates for all eligible drugs, and since Medicaid rebates are shared by the states and the federal government, forgoing rebates increases Medicaid costs for both states and the federal government.

Oversight Weaknesses Impede HRSA's Ability to Ensure That Duplicate Discounts Are Prevented or Remedied

We identified several areas of weaknesses in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied:

Covered entities' compliance with state policies and procedures is not assessed. HRSA's auditors are instructed to look for the potential for duplicate discounts in Medicaid FFS by assessing whether the covered entity's information on the MEF is correct; whether the entity is following its policies and procedures to prevent duplicate discounts; and whether a sample of claims reveals any noncompliance.[35] Auditors are also instructed to use information provided by the covered entity to determine if the covered entity is following state policies. However, HRSA officials told us that its auditors are not expected to independently identify or verify state Medicaid programs' policies to determine whether the covered entity is actually following what the state requires. Instead, HRSA officials stated that it is a best practice for covered entities to include a description of state Medicaid programs' policies related to the 340B Program, such as how relevant drugs are to be identified, in their policy and procedure

[34]See GAO, *Standards for Internal Control in the Federal Government,* GAO-14-704G (Washington, D.C.: September 2014).

[35]If covered entities carve out Medicaid FFS, auditors are to review the sample of claims to make sure that no drugs purchased through the 340B Program were dispensed to Medicaid FFS beneficiaries. If covered entities carve in, auditors are to look to see that the covered entities are listed on the MEF and review a sample of claims to see that covered entities are following their outlined policies and procedures.

manuals.[36] In addition, HRSA told us that its auditors interview covered entity staff about the controls in place to prevent duplicate discounts, and may discuss state requirements during these interviews. The auditor is then required to use this information to determine whether the covered entity is following state policy. For example, if the covered entity says that the state requires a 340B claim identifier, the auditor is to look to see if the covered entity used that identifier in the sample of claims that are reviewed. However, the auditor is not expected to determine if the state actually requires a claim identifier, or allows covered entities to use 340B drugs.

The fact that HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries is inconsistent with federal standards for internal control related to information and communication. Those standards state that management should obtain relevant data from reliable internal and external sources in a timely manner based on the identified information requirements and evaluate both internal and external sources of data for reliability so that it can be used for effective monitoring.[37]

This lack of HRSA oversight is especially concerning because we found that the covered entities we interviewed did not always have a correct understanding of their states' policies. For example, officials from two of the four Pennsylvania covered entities we spoke with told us they were dispensing 340B drugs to Medicaid managed care beneficiaries at contract pharmacies, despite state officials telling us the state does not allow that practice. As a result of this confusion, duplicate discounts may have occurred as the state was not excluding drugs dispensed by contract pharmacies from its Medicaid rebate requests. Additionally, of the 13 covered entity policy and procedure manuals we reviewed, only four had descriptions of their states' policies and two of those descriptions were incorrect. If HRSA were to audit the majority of those 13 covered entities, its auditors would likely be unable to appropriately assess the entities' compliance with state requirements. Without fully assessing

[36]Covered entities are expected to have policy and procedure manuals that, among other things, specify their procedures for preventing duplicate discounts. HRSA officials also told us that covered entities' policy and procedure manuals should, among other things, address whether the covered entity uses 340B drugs for Medicaid patients, and how the covered entity's billing information is reflected on the MEF.

[37]GAO-14-704G.

compliance with state policy, HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts. As a result, drug manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid drugs.

Not all identified duplicate discounts are repaid. HRSA officials told us that covered entities' obligations for preventing duplicate discounts are the same for Medicaid FFS and managed care. However, as we reported in 2018, HRSA audits do not assess for the potential for duplicate discounts in Medicaid managed care despite the fact that the potential for duplicate discounts related to Medicaid managed care has existed since 2010, when manufacturers were required to begin paying Medicaid rebates under managed care in addition to FFS. As we noted in 2018, HRSA indicated that it does not audit for duplicate discounts in managed care because the agency has not issued guidance on how covered entities should prevent this.[38] As a result, we recommended that HRSA issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care and incorporate into its audit process an assessment of covered entities' compliance with the prohibition on duplicate discounts as it relates to Medicaid managed care claims. HHS concurred with these recommendations and, as of October 2019, HRSA reported that it was working to determine next steps related to these recommendations. However, HRSA has noted that the agency lacks explicit general regulatory authority to issue regulations on most aspects of the 340B Program, and also told us, in October 2019, that guidance does not provide the agency with appropriate enforcement capability.[39] As a result, HRSA requested authority in the President's

[38]GAO-18-480. Although HRSA audits do not include assessments of potential duplicate discounts in Medicaid managed care, in April 2018, HRSA updated its audit process to require its auditors to determine if a covered entity has policies and procedures related to the prevention of duplicate discounts in managed care if, during the audit, the auditor learns that the covered entity is carving in Medicaid managed care claims. If such a check determines that the covered entity does not have policies and procedures related to the prevention of duplicate discounts in managed care, then the audit report is to include an area for improvement for the covered entity to develop these policies and procedures. According to HRSA officials, from April 2018 to August 2019, the agency identified this area for improvement for 37 audits.

[39]A May 2014 federal district court decision found that Congress granted HRSA limited rulemaking authority to carry out the 340B Program. See *Pharm. Research & Mfrs. of Am. v. United States HHS*, 43 F. Supp. 3d 28, 45 (D.D.C. 2014). Notably, however, in a subsequent decision, the court acknowledged the agency's authority to issue guidance documents interpreting the statute. See *Pharm. Research & Mfrs. of Am. v. United States HHS*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015).

budget request for fiscal year 2020 to issue regulations on all aspects of the 340B Program, as the agency believes that binding and enforceable regulations would provide it with the ability to more clearly define and enforce policy. In addition, the agency is not pursuing additional guidance under the 340B Program at this time. We note, however, that the law prohibits the payment of duplicate discounts and requires HRSA to issue guidance to covered entities describing methodologies and options for avoiding duplicate discounts.[40] In the absence of federal guidance, HRSA instructs covered entities to work with their states on duplicate discount prevention.

HRSA requires covered entities to work with affected drug manufacturers regarding the repayment of duplicate discounts in FFS that are identified through HRSA or manufacturer audits. However, HRSA officials told us that the agency does not require covered entities to take the same actions to address duplicate discounts for managed care claims that HRSA learns about through its audits or other means. For example, HRSA officials told us that they did not follow up on a letter from a state that confirmed a duplicate discount occurred on a Medicaid managed care claim, because the agency did not yet have guidance for covered entities related to Medicaid managed care claims. Additionally, HRSA officials told us they would not require a covered entity to develop a corrective action plan or make offers of repayment to a manufacturer if a drug manufacturer's audit of that covered entity identified a duplicate discount in managed care. Although HRSA officials told us that they expect covered entities to work in good faith with all parties involved to resolve potential duplicate discounts in managed care, HRSA does not require these actions if a duplicate discount is identified in managed care, as it does in FFS. This is particularly problematic as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care, and the drug manufacturers we contacted believe that duplicate discounts are more prevalent in Medicaid managed care than FFS.

HRSA expecting but not requiring covered entities to address identified duplicate discounts related to Medicaid managed care is contrary to federal law, which provides that covered entities are liable to drug manufacturers for duplicate discounts that are identified through HRSA or manufacturer audits.[41] It is also inconsistent with federal internal control

[40]42 U.S.C. § 256b(d)(2)(B)(iii).

[41]42 U.S.C. § 256b(a)(5)(D).

standards related to monitoring, which state that management should oversee the prompt remediation of deficiencies and the audit resolution process, which begins when the results of an audit or other review are reported to management, and is completed only after action has been taken that corrects identified deficiencies. Without HRSA requiring covered entities to address identified duplicate discounts in Medicaid managed care as they would duplicate discounts in FFS, drug manufacturers may erroneously provide both 340B discounts and Medicaid rebates on the same drug claim.

Conclusions

The prevention of duplicate discounts in the 340B and Medicaid Drug Rebate Programs requires extensive coordination between state Medicaid programs and covered entities, and among agencies within HHS. Similar levels of coordination are required to ensure that states are not forgoing rebates on drugs not purchased at the 340B price, which would result in increased costs for both state and federal governments.

Limitations in federal oversight impede CMS's and HRSA's ability to ensure compliance with the prohibition on duplicate discounts. CMS does not assess whether states have 340B policies and procedures and, if so, whether they are documented, effective, and accessible to stakeholders. As a result, it is unable to proactively identify and correct problematic policies and procedures, and prevent duplicate discounts and forgone rebates. Additionally, without knowing state Medicaid programs' 340B policies, HRSA is unable to perform a comprehensive review of whether covered entities are taking the necessary actions to prevent duplicate discounts. In addition, HRSA's audits are not assessing compliance with the prohibition against duplicate discounts in managed care because the agency has yet to put forth guidance on this issue. While HRSA is not currently pursuing 340B-related guidance, the agency continues to work on determining next steps to respond to our 2018 recommendations on the issue. In the meantime, however, HRSA still must ensure that covered entities are complying with 340B Program requirements, including the prohibition on duplicate discounts in managed care. Failure to do so not only puts drug manufacturers at risk of providing duplicate discounts, but also compromises the integrity of the 340B Program.

Recommendations for Executive Action

We are making a total of three recommendations, including one to CMS and two to HRSA. Specifically:

- The Administrator of CMS should ensure that state Medicaid programs have written policies and procedures that specify the extent to which covered entities can use 340B drugs for Medicaid beneficiaries, are designed to effectively identify if 340B drugs were used, and if so, how they should be excluded from Medicaid rebate requests. The policies and procedures should be made publically available and cover FFS, managed care, and all of the dispensing methods for outpatient drugs. (Recommendation 1)
- The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs into its audit process, working with CMS as needed to obtain states' policies and procedures. (Recommendation 2)
- The Administrator of HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care. (Recommendation 3)

Agency Comments and Our Evaluation

HHS provided written comments, which are reproduced in app. IV, and technical comments, which we have incorporated as appropriate. In its written comments, HHS concurred with one of our three recommendations and did not concur with the remaining two recommendations.

HHS concurred with our recommendation that CMS ensure that state Medicaid programs have written policies and procedures for identifying 340B drugs and excluding them from Medicaid rebate requests and stated that it will work with states to strengthen policies and procedures related to 340B drugs for Medicaid beneficiaries.

HHS did not concur with our recommendation that HRSA incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures into its audit process. HHS stated that HRSA does not have authority to determine whether state Medicaid policies and procedures are "accurate and appropriate." We agree that HRSA is not the appropriate party for reviewing and assessing state Medicaid programs' policies and procedures, which is why we recommended that CMS, not HRSA, strengthen its oversight of states' 340B-related policies and procedures, a recommendation with which HHS

concurred. We recommended that HRSA update its 340B Program audits to include assessments of whether covered entities are following state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs. HHS stated that HRSA does not have authority to enforce covered entities' compliance with state Medicaid programs' policies and procedures and that doing so would be "beyond the scope of the 340B Program" and would require additional training for HRSA auditors, who currently "do not have this level of expertise." While we understand that HRSA does not have authority to enforce compliance with state Medicaid programs' policies and procedures, covered entities' compliance with state Medicaid programs' policies and procedures is fundamental to preventing duplicate discounts and assessing compliance with state policies and procedures is essential to ensuring covered entities' compliance with the 340B Program's prohibition on duplicate discounts.

Further, HRSA already audits for compliance with certain aspects of states' 340B-related Medicaid policies for preventing duplicate discounts. Specifically, HHS states that covered entities are expected to include a description of state policy in their policy and procedure manuals. If such descriptions exist, HRSA auditors are required to review those descriptions and determine if covered entities are following them. Thus, HRSA auditors already interpret state Medicaid policies and procedures when performing audits and the agency already enforces compliance with state policies by issuing audit findings when covered entities are not following them. However, as noted in our report, HRSA does not require its auditors to review state Medicaid programs' actual policies and procedures. Instead, the auditors currently rely on covered entities' descriptions of those policies and procedures, which we found were not always accurate. Additionally, knowledge of state policies would allow HRSA to incorporate an assessment of compliance into all audits as opposed to only those of covered entities that have such descriptions in their manuals. Finally, without considering states' actual policies and procedures and ensuring that covered entities are following them, HRSA's audits cannot effectively identify the potential for duplicate discounts. For example, simply checking covered entities' actions against information on the MEF does not provide useful information if the covered entities are in one of the many states that do not use the MEF and instead direct entities to identify 340B drugs dispensed to Medicaid beneficiaries via a different mechanism, such as 340B identifiers.

HHS states that implementing this recommendation would be burdensome and difficult to operationalize because HRSA would need to

be notified of any changes to states' policies and procedures. We understand that the lack of knowledge of state Medicaid programs' policies related to duplicate discount prevention at the federal level complicates the ability of HRSA and its auditors to determine what state-level requirements exist and to apply them to audits. This is, in part, why we recommended that CMS ensure that state Medicaid programs' policies are publicly available—a recommendation that, as noted above, HHS concurred with—and that HRSA work with CMS to obtain these policies as needed. Though we understand that this creates an additional step in HRSA's audit process, we continue to believe that including an assessment of covered entities' compliance with state Medicaid programs' policies and procedures related to 340B drugs is necessary to identify potential duplicate discounts and to ensure covered entities' compliance with 340B Program requirements.

HHS also did not concur with our recommendation that HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care. In its response, HHS noted that because HRSA does not have guidance related to preventing duplicate discounts in Medicaid managed care, "it is difficult to assess compliance in this area." However, our recommendation is not asking HRSA to assess compliance related to duplicate discounts in Medicaid managed care; instead, we are recommending that, when actual duplicate discounts have been identified, HRSA require covered entities to remedy those duplicate discounts. As noted in the report, actual duplicate discounts may be identified and confirmed by state Medicaid agencies through audits or other means. Given that HRSA officials told us that covered entities' obligations for preventing duplicate discounts are the same for Medicaid FFS and managed care, the steps for addressing identified noncompliance should be similar, and thus, the agency should require and not just "encourage" covered entities to work with manufacturers to remedy any duplicate discounts related to managed care as they do for those related to FFS.

Additionally, the potential for duplicate discounts related to Medicaid managed care has existed since 2010, when manufacturers were required to begin paying Medicaid rebates under managed care in addition to FFS. Ten years later, HRSA still has not issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care and has indicated that it is not pursuing new guidance at this time. This inaction continues to leave the 340B Program vulnerable to noncompliance with federal law. HHS concurred with our 2018

recommendations that HRSA issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care and incorporate into its audit process an assessment of covered entities' compliance with the prohibition on duplicate discounts as it relates to Medicaid managed care claims.[42] Until these recommendations are implemented, HRSA must, at a minimum, ensure that covered entities work with manufacturers regarding any identified duplicate discounts in managed care to help ensure compliance with 340B Program requirements.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Administrator of HRSA, the Administrator of CMS, 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 V.

Debra A. Draper
Director, Health Care

[42]GAO-18-480.

Appendix I: Drug Manufacturers' Efforts to Prevent and Detect Duplicate Discounts

Officials from all three drug manufacturers and the organizations that work on their behalf that we contacted reported challenges preventing and detecting duplicate discounts due to a lack of information. For example, officials from drug manufacturers told us that state Medicaid programs do not always provide data on the individual claims for which they were requesting rebates. Specifically, to obtain rebates, states submit requests to participating manufacturers for all drug purchases made that quarter; these requests contain the total quarterly amount owed for each of the manufacturers' drugs, but not information detailing each claim for which rebates are being sought. Although the Centers for Medicare & Medicaid Services (CMS) encourages states to respond to reasonable manufacturer requests for claim-level data, the provision of such data is not required.[1] Without this claim-level data, manufacturers reported that it is difficult to determine if rebate requests include claims for drugs purchased at the 340B discounted price. Additionally, manufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries. This is because the Medicaid Exclusion File (MEF), a list maintained by the Health Resources and Services Administration (HRSA) to assist in the prevention of duplicate discounts, is only required to reflect the provider numbers used by covered entities that choose to use (carve in) 340B drugs provided directly by the covered entity to Medicaid fee-for-service (FFS) beneficiaries. The MEF does not include information on whether covered entities are using 340B drugs for Medicaid managed care beneficiaries and may not include information on contract pharmacies that are dispensing these drugs to Medicaid beneficiaries on covered entities' behalf.

Despite these limitations, the drug manufacturers we contacted reported that when claim-level data is available they review that data to detect potential duplicate discounts before they issue rebate payments. For example, officials from one drug manufacturer told us that they compare the provider numbers on the claim-level data obtained from states with the information on the MEF and dispute rebate requests for any claims from a provider number listed on the MEF. However, officials from some drug manufacturers told us that this approach is ineffective for preventing duplicate discounts for drugs dispensed at contract pharmacies because, as noted above, the MEF may not include information on contract

[1]See Medicaid Drug Rebate Program Notice Release No. 173.

pharmacies, and the claim-level data may only list the provider number for the dispensing pharmacy, not the prescribing covered entity.

The drug manufacturers we contacted also reported trying to identify duplicate discounts after rebates have been paid by looking at 340B purchasing patterns. For example, officials from one drug manufacturer told us they look at covered entities' purchases and assess whether the proportion of 340B purchases is consistent with their carve-in status. Specifically, these officials explained that if a covered entity is not listed on the MEF, then the entity should not be using 340B drugs for Medicaid FFS patients. Therefore, if all or nearly all of the purchases made by that covered entity were at the discounted price, it could indicate the presence of duplicate discounts. While the MEF is only intended to indicate covered entities that are using 340B drugs for Medicaid FFS beneficiaries, officials reported that drug manufacturers also rely on the MEF as a proxy for covered entities' carve-in practices for Medicaid managed care since there is no equivalent data source.

If there are concerns that duplicate discounts occurred, officials from the drug manufacturers we contacted indicated that they may conduct what is referred to as a "good faith inquiry," in which the manufacturer, or a consultant working on the manufacturer's behalf, requests data from covered entities on a specific set of drug claims for which they have paid rebates to determine if those claims involved 340B drugs.[2] If drug manufacturers confirm that a duplicate discount did occur, officials reported that they may work to negotiate a repayment from the state or covered entity, depending on which party was responsible for the error. Additionally, one official who works on behalf of manufacturers told us that manufacturers also will work with covered entities to remedy the cause of the duplicate discount to prevent future occurrences. Drug manufacturers told us that it is not always clear whether states or covered entities are responsible for duplicate discounts, and thus, which party should be contacted regarding repayment. Additionally, drug manufacturers reported that some states refer them directly to covered entities to resolve all inquiries. Medicaid program officials in Michigan and Texas, for example, said that their states refer manufacturers to the covered entities because they believe that the covered entities would

[2]Officials from nine of the 16 covered entities we spoke with said that they had been contacted by drug manufacturers or their representatives regarding their use of 340B drugs and, in one case, these inquiries determined that duplicate discounts had occurred, and resulted in the covered entity repaying a manufacturer.

most likely be responsible for any duplicate discounts that occurred due to a failure to correctly apply the required claim identifiers.

If drug manufacturers need assistance resolving their concerns or obtaining repayment for duplicate discounts, they can access options made available by HRSA and CMS. Specifically, drug manufacturers can request approval from HRSA to audit a covered entity to investigate suspicions of duplicate discounts in both Medicaid FFS and managed care. To receive approval from HRSA to conduct an audit, a drug manufacturer must document reasonable cause and provide an audit plan. In addition, HRSA requires the drug manufacturer to use an independent auditor who follows government auditing standards.[3] According to HRSA, from October 2011 through August 2019, 45 audits were requested by drug manufacturers and 26 requests were approved. Of the 26 audits approved by HRSA, the agency received 13 final audit reports, six of which had duplicate discount-related findings.[4] However, while audits can be a tool for identifying duplicate discounts and obtaining repayment, some drug manufacturers we spoke with indicated that the cost of audits may outweigh the benefits received in the form of repayments. Additionally, as noted previously, HRSA does not require covered entities to repay manufacturers for duplicate discounts that occur in managed care. Drug manufacturers also may use the state hearing process or pursue a dispute resolution in conjunction with states through CMS if their issues with state Medicaid programs cannot be resolved through inquires. According to CMS officials, through the dispute resolution process, the agency provides drug manufacturers and states with guidance to assist in determining responsibilities and identifying next steps to work through conflicts. CMS officials said that, in general, they have received five to 10 Medicaid drug rebate disputes per year, about half of which are related to 340B duplicate discount issues.

[3]See Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996). Although HRSA requires manufacturer's audits of covered entities to be conducted in accordance with government auditing standards, HRSA's audits of covered entities do not follow such standards.

[4]Not all of the audits may have been specifically focused on, or included, a review related to duplicate discounts.

Appendix II: State Medicaid Programs' Policies on Covered Entities' Use of 340B Drugs, by Dispensing Method

Table 3: State Medicaid Programs' Policies Regarding Covered Entities' Use of 340B Drugs in Medicaid Fee-For-Service, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Alabama	Covered entity decision	Covered entity decision	Covered entity decision
Alaska	Covered entity decision	Covered entity decision	Carve out
Arizona	Covered entity decision	Covered entity decision	Carve out
Arkansas	Covered entity decision	Covered entity decision	Carve out
California	Carve in	Carve in	[a]
Colorado	Covered entity decision	Covered entity decision	Carve out
Connecticut	Covered entity decision	Covered entity decision	Covered entity decision
Delaware	Covered entity must obtain approval from state to dispense 340B drugs	Covered entity must obtain approval from state to dispense 340B drugs	Carve out
District of Columbia	Covered entity decision	No policy	Carve out
Florida	Covered entity decision	Covered entity decision	Covered entity decision
Georgia	Covered entity decision	Covered entity decision	Carve out
Hawaii	Covered entity decision	Covered entity decision	Covered entity decision
Idaho	Covered entity decision	Covered entity decision	Carve out
Illinois	Carve in	Carve in	Carve out
Indiana	Covered entity decision	Covered entity decision	Carve out
Iowa	Covered entity decision	Covered entity decision	Carve out
Kansas	Covered entity decision	Covered entity decision	Carve out
Kentucky	Covered entity decision	Covered entity decision	Carve out
Louisiana	Covered entity decision	Covered entity decision	Carve out
Maine	Carve out	Covered entity decision	Carve out
Maryland	Covered entity decision	Covered entity decision	Covered entity decision
Massachusetts	Covered entity decision	Covered entity decision	Covered entity decision
Michigan	Covered entity decision	Covered entity decision	Covered entity decision
Minnesota	Covered entity decision	Covered entity decision	Carve out
Mississippi	Covered entity decision	Covered entity decision	Carve out
Missouri	Covered entity decision	Covered entity decision	Carve out
Montana	Covered entity decision	Covered entity decision	Carve out[b]
Nebraska	Covered entity decision	Covered entity decision	Carve out
Nevada	Covered entity decision	Covered entity decision	Carve out
New Hampshire	[c]	[c]	[c]
New Jersey	Covered entity decision	Covered entity decision	Carve out
New Mexico	Covered entity decision	Covered entity decision	Covered entity decision
New York	Covered entity decision	Covered entity decision	Covered entity decision

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
North Carolina	Covered entity decision	Covered entity decision	Covered entity decision
North Dakota	Covered entity decision	Covered entity decision	Carve out
Ohio	Covered entity decision	Covered entity decision	Carve out[b]
Oklahoma	Covered entity decision	Covered entity decision	Carve out[b]
Oregon	Covered entity decision	Covered entity decision	Carve out
Pennsylvania	Covered entity decision	Covered entity decision	Carve out
Rhode Island	Covered entity decision	Covered entity decision	Carve out
South Carolina	Covered entity decision	Covered entity decision	Covered entity decision
South Dakota	Carve out	Carve out	Carve out
Tennessee	Covered entity decision	Covered entity decision	Carve out
Texas	Covered entity decision	Covered entity decision	Covered entity decision
Utah	Covered entity decision	Covered entity decision	Carve out[b]
Vermont	Covered entity decision	Covered entity decision	Carve out
Virginia	Covered entity decision	Covered entity decision	Carve out
Washington	Covered entity decision	Covered entity decision	Carve out
West Virginia	Covered entity decision	Covered entity decision	Carve out
Wisconsin	Covered entity decision	Covered entity decision	Carve out
Wyoming	Covered entity decision	Covered entity decision	Carve out

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. Carve out means that the state does not allow covered entities to provide 340B drugs to Medicaid beneficiaries. Carve in means that the state requires covered entities to provide 340B drugs to eligible Medicaid beneficiaries.

[a]California allows covered entities to dispense 340B drugs at contract pharmacies if there is an approved arrangement between the state, the covered entity, and the contract pharmacy. At the time of our information request, California officials indicated that they only had approved arrangements for certain hemophilia centers and had no approved arrangements with other types of covered entities.

[b]State allows covered entities to dispense 340B drugs at contract pharmacies if there is an approved arrangement between the state, the covered entity, and the contract pharmacy. At the time of our information request, the state had no such arrangements, and thus covered entities would have to carve out 340B drugs.

[c]New Hampshire allows covered entities to provide 340B drugs to Medicaid beneficiaries, but generally does not allow them to bill Medicaid for these drugs. The one exception is that the state does allow covered entities that are approved family planning clinics to bill Medicaid for 340B drugs administered by providers to Medicaid beneficiaries.

Table 4: State Medicaid Programs' Policies Regarding Covered Entities' Use of 340B Drugs in Medicaid Managed Care, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Arizona	Covered entity decision	Covered entity decision	Carve out
Arkansas	Covered entity decision	Covered entity decision	Carve out
California	Carve in	Carve in	Covered entity decision
Colorado	Covered entity decision	Covered entity decision	Carve out
Delaware	Covered entity must obtain approval from state to dispense 340B drugs	Covered entity must obtain approval from state to dispense 340B drugs	Carve out
District of Columbia	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
Florida	Covered entity decision	Covered entity decision	Covered entity decision
Georgia	Covered entity decision	Covered entity decision	Carve out
Hawaii	Covered entity decision	Covered entity decision	Covered entity decision
Illinois	Carve in	Carve in	Carve out
Indiana	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
Iowa	Covered entity decision	Covered entity decision	Carve out
Kansas	Covered entity decision	Covered entity decision	Carve out
Kentucky	Covered entity decision	Covered entity decision	Carve out
Louisiana	Covered entity decision	Covered entity decision	Carve out
Maryland	Covered entity decision	Covered entity decision	Covered entity decision
Massachusetts	Covered entity decision[a]	Covered entity decision	Covered entity decision[a]
Michigan	Covered entity decision	Covered entity decision	Covered entity decision
Minnesota	Covered entity decision	Covered entity decision	Carve out
Mississippi	Covered entity decision	Covered entity decision	Carve out
Nebraska	Policies determined by each managed care plan	Policies determined by each managed care plan	Carve out
Nevada	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
New Hampshire	[b]	[b]	[b]
New Jersey	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
New Mexico	Covered entity decision	Covered entity decision	Covered entity decision
New York	Covered entity decision	Covered entity decision	Covered entity decision
North Dakota	Carve out	Carve out	Carve out
Ohio	Covered entity decision	Covered entity decision	Carve out[c]
Oregon	Covered entity decision	Covered entity decision	Covered entity decision
Pennsylvania	Covered entity decision	Covered entity decision	Carve out

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Rhode Island	Covered entity decision	Covered entity decision	Covered entity decision
South Carolina	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
Tennessee	[d]	Covered entity decision	[d]
Texas	Covered entity decision	Covered entity decision	Covered entity decision
Utah	Covered entity decision	Covered entity decision	Carve out[c]
Virginia	Covered entity decision	Covered entity decision	Carve out
Washington	Covered entity decision	Covered entity decision	Carve out
West Virginia	[d]	Covered entity decision	[d]

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: Not all state Medicaid programs covered outpatient drugs through managed care. As such, this table only includes the 38 states that covered at least some outpatient drugs through managed care.

The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. Carve out means that the state did not allow covered entities to provide 340B drugs to Medicaid beneficiaries. Carve in means that the state required covered entities to provide 340B drugs to eligible Medicaid beneficiaries.

[a]While Massachusetts allows most types of covered entities to decide whether or not to dispense 340B drugs to Medicaid managed care beneficiaries at in-house or contract pharmacies, the state requires federally qualified health centers to carve out these drugs for Medicaid managed care for these dispensing methods.

[b]New Hampshire allows covered entities to provide 340B drugs to Medicaid beneficiaries, but generally does not allow them to bill Medicaid for these drugs. The one exception is that the state does allow covered entities that are approved family planning clinics to bill Medicaid for 340B drugs administered by providers to Medicaid beneficiaries.

[c]State allows covered entities to dispense 340B drugs at contract pharmacies if there is an approved arrangement between the state, the covered entity, and the contract pharmacy. At the time of our information request, the state had no such arrangements, and thus covered entities would have to carve out 340B drugs.

[d]Managed care plans in this state do not cover outpatient drugs dispensed at pharmacies; they only cover provider-administered drugs.

Appendix III: State Medicaid Programs' Procedures for Identifying 340B Drugs, by Dispensing Method

Table 5: State Medicaid Programs' Procedures for Identifying 340B Drugs Dispensed to Medicaid Fee-For-Service Beneficiaries, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Alabama	Medicaid Exclusion File	Medicaid Exclusion File	Medicaid Exclusion File
Alaska	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Arizona	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
Arkansas	340B claim identifiers	Medicaid Exclusion File	[a]
California	340B claim identifiers	340B claim identifiers	340B claim identifiers
Colorado	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Connecticut	Medicaid Exclusion File	Medicaid Exclusion File	Medicaid Exclusion File
Delaware	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
District of Columbia	340B claim identifiers	No procedure	[a]
Florida	340B claim identifiers	Medicaid Exclusion File	340B claim identifiers
Georgia	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File	[a]
Hawaii	State-developed exclusion process[b]	State-developed exclusion process[b]	340B claim identifiers
Idaho	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Illinois	340B claim identifiers	340B claim identifiers	[a]
Indiana	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Iowa	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Kansas	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Kentucky	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Louisiana	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Maine	[a]	State-developed list of providers using 340B drugs	[a]
Maryland	340B claim identifiers	State-developed list of providers using 340B drugs	340B claim identifiers
Massachusetts	State-developed list of providers using 340B drugs	State-developed list of providers using 340B drugs	[c]
Michigan	340B claim identifiers	340B claim identifiers	340B claim identifiers
Minnesota	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Mississippi	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Missouri	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
Montana	State-developed list of providers using 340B drugs	State-developed list of providers using 340B drugs	[a]
Nebraska	Medicaid Exclusion File and 340B claims identifiers	Medicaid Exclusion File	[a]
Nevada	Medicaid Exclusion File	Medicaid Exclusion File	[a]
New Hampshire	[d]	State-developed list of providers using 340B drugs	[d]
New Jersey	340B claim identifiers	Medicaid Exclusion File	[a]
New Mexico	340B claim identifiers	340B claim identifiers	340B claim identifiers
New York	340B claim identifiers	340B claim identifiers	340B claim identifiers
North Carolina	340B claim identifiers	340B claim identifiers	340B claim identifiers
North Dakota	340B claim identifiers	340B claim identifiers	[a]
Ohio	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Oklahoma	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
Oregon	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Pennsylvania	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Rhode Island	No procedure	[e]	[a]
South Carolina	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs
South Dakota	[a]	[a]	[a]
Tennessee	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Texas	340B claim identifiers	340B claim identifiers	340B claim identifiers
Utah	340B claim identifiers	340B claim identifiers	[a]
Vermont	State-developed exclusion process[f]	State-developed exclusion process[f]	[a]
Virginia	340B claim identifiers	340B claim identifiers	[a]
Washington	Medicaid Exclusion File	Medicaid Exclusion File	[a]
West Virginia	340B claim identifiers	340B claim identifiers	[a]
Wisconsin	340B claim identifiers	340B claim identifiers	[a]
Wyoming	Medicaid Exclusion File and State-developed list of providers using 340B drugs	Medicaid Exclusion File and State-developed list of providers using 340B drugs	[a]

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. The Medicaid Exclusion File is a list of provider numbers used to bill Medicaid for covered entities that elected to use, or carve in, 340B drugs for Medicaid fee-for-service beneficiaries. The list is maintained by the Health Resources and Services Administration.

[a]State does not allow covered entities to use 340B drugs for Medicaid fee-for-service beneficiaries for this dispensing method, and thus does not need a procedure to identify these drugs.

[b]Hawaii requires covered entities, on a quarterly basis, to identify for the state drugs provided to Medicaid beneficiaries that were not purchased under the 340B Program.

[c]Massachusetts requires contract pharmacies to include the covered entities' National Provider Identifier on claims using 340B drugs, which the state then uses to exclude those claims from its rebate request.

[d]New Hampshire allows covered entities to provide 340B drugs through this dispensing method, but does not allow them to bill Medicaid for these drugs.

[e]Rhode Island uses a 340B claim identifier to identify and exclude associated drugs administered by providers at hospitals, but does not have any procedures to identify these drugs administered by providers at other types of covered entities.

[f]Vermont requires covered entities, on a monthly basis, to identify for the state 340B drugs provided to Medicaid beneficiaries so they may be excluded from the state's rebate request.

Table 6: State Medicaid Programs' Procedures for Identifying 340B Drugs Dispensed to Medicaid Managed Care Beneficiaries, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Arizona	Medicaid Exclusion File and State-developed list of providers using 340B drugs	Medicaid Exclusion File and State-developed list of providers using 340B drugs	[a]
Arkansas	340B claim identifiers	Medicaid Exclusion File	[a]
California	340B claim identifiers	340B claim identifiers	340B claim identifiers
Colorado	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Delaware	Medicaid Exclusion File and State-developed list of providers using 340B drugs	Medicaid Exclusion File and State-developed list of providers using 340B drugs	[a]
District of Columbia	340B claim identifiers	No procedure	340B claim identifiers
Florida	340B claim identifiers	Medicaid Exclusion File	340B claim identifiers
Georgia	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File	[a]
Hawaii	State-developed exclusion process[b]	State-developed exclusion process[b]	340B claim identifiers
Illinois	340B claim identifiers	340B claim identifiers	[a]
Indiana	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers
Iowa	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Kansas	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Kentucky	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Louisiana	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Maryland	340B claim identifiers	State-developed list of providers using 340B drugs	340B claim identifiers
Massachusetts	340B claim identifiers	340B claim identifiers	340B claim identifiers
Michigan	340B claim identifiers	340B claim identifiers	340B claim identifiers
Minnesota	340B claim identifiers	340B claim identifiers	[a]
Mississippi	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Nebraska	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Nevada	Medicaid Exclusion File	Medicaid Exclusion File	Medicaid Exclusion File
New Hampshire	[c]	State-developed list of providers using 340B drugs	[c]
New Jersey	340B claim identifiers	Medicaid Exclusion File	340B claim identifiers
New Mexico	340B claim identifiers	340B claim identifiers	340B claim identifiers
New York	340B claim identifiers	340B claim identifiers	340B claim identifiers

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
North Dakota	[a]	[a]	[a]
Ohio	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Oregon	Medicaid Exclusion File	Medicaid Exclusion File	State-developed exclusion process[d]
Pennsylvania	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Rhode Island	Managed care plans are responsible for excluding 340B drugs from data they send to the state	Managed care plans are responsible for excluding 340B drugs from data they send to the state	Managed care plans are responsible for excluding 340B drugs from data they send to the state
South Carolina	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs
Tennessee	[e]	Medicaid Exclusion File	[e]
Texas	340B claim identifiers	340B claim identifiers	340B claim identifiers
Utah	340B claim identifiers	340B claim identifiers	[a]
Virginia	340B claim identifiers	340B claim identifiers	[a]
Washington	Medicaid Exclusion File	Medicaid Exclusion File	[a]
West Virginia	[e]	340B claim identifiers	[e]

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: Not all state Medicaid programs covered outpatient drugs through managed care. As such, this table only includes the 38 states that covered at least some outpatient drugs through managed care. The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. The Medicaid Exclusion File is a list of provider numbers used to bill Medicaid for covered entities that elected to use, or carve in, 340B drugs for Medicaid fee-for-service beneficiaries. The list is maintained by the Health Resources and Services Administration.

[a]State does not allow covered entities to use 340B drugs for Medicaid managed care beneficiaries for this dispensing method and thus does not need a procedure to identify these drugs.

[b]Hawaii requires covered entities, on a quarterly basis, to identify for the state drugs provided to Medicaid beneficiaries that were not purchased under the 340B Program. The state also requires managed care plans to submit to the state, on a monthly basis, data that identifies 340B drugs at the claim level.

[c]New Hampshire allows covered entities to provide 340B drugs through this dispensing method, but does not allow them to bill Medicaid for these drugs.

[d]Oregon requires covered entities, on at least a quarterly basis, to identify for the state 340B drugs provided to Medicaid beneficiaries so they may be excluded from the state's rebate request.

[e]Managed care plans in this state do not cover outpatient drugs dispensed at pharmacies; they only cover provider-administered drugs.

Appendix IV: 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

Debra 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 DISCOUNT PROGRAM: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*" (GAO-20-212).

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

Sincerely,

Sarah Arbes
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED- 340 B DRUG DISCOUNT PROGRAM: OVERSIGHT OF THE INTERSECTION WITH THE MEDICAID DRUG REBATE PROGRAM NEEDS IMPROVEMENT (GAO-20-212)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

The Medicaid Drug Rebate Program was established by the Omnibus Budget Reconciliation Act of 1990 to help offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. It requires that, for covered outpatient drugs to be eligible for Federal financial participation through Medicaid, manufacturers must pay rebates to states on these drugs when dispensed to Medicaid beneficiaries and paid for by Medicaid. States are responsible for determining the amount of rebates owed and send invoices to manufacturers for each quarter. In addition, the 340B Drug Pricing Program, established by the Veterans Health Care Act of 1992, requires drug manufacturers to provide outpatient drugs to eligible health care providers, known as covered entities, at significantly reduced prices if those drugs are to be eligible for Federal financial participation through Medicaid. The covered entities generally bill their patients' insurance for 340B purchased drugs. Together, these programs serve as an increasingly important source of savings for both states and the Federal government. HHS places the highest priority on the integrity of these programs and continually works to strengthen oversight of the programs within its limited authority.

HHS appreciates the GAO's work in this area as it informs HHS' program integrity efforts. In its report, the GAO examines stakeholders' efforts to prevent duplicate discounts under the 340B and Medicaid Drug Rebate Programs. HHS recognizes the importance of avoiding duplicate discounts and has processes in place to ensure that duplicate discounts do not occur under these two programs. HHS regulations require that Medicaid Managed Care Organizations (MCOs) include an identifier on a prescription claim filled with a 340B-purchased drug so that these claims are excluded from the state quarterly rebate billings. The Health Resources and Services Administration provides the "Medicaid Exclusion File", which identifies covered entities that participate in the 340B Program specifically for fee-for-service drugs. States are also required to submit copies of their Medicaid rebate requests to HHS within 60 days of the end of each quarter. These data should exclude drugs that have been filled with drugs purchased through the 340B Program.

In addition, states are required to submit Medicaid State Plan Amendments (SPAs) to HHS when they change their Medicaid 340B drug program coverage policies. A SPA must be submitted to HHS if the state requires covered entities and/or contract pharmacies to "carve out" 340B drugs, meaning these entities will not use drugs purchased under the 340B Program for Medicaid patients. Rather, these drugs will be subject to Medicaid drug rebates. States may decide to carve-out 340B drugs as a mechanism to prevent duplicate discounts from occurring. If the covered entity or contract pharmacy is not able to use 340B drugs for Medicaid beneficiaries, the pharmacy can remain a Medicaid provider and drugs can be purchased outside of the 340B Program and dispensed to Medicaid patients.

As the GAO notes, states play a key logistic role in preventing duplicate discounts because they invoice manufacturers for rebates. The states rely on the information provided by covered entities and the MCOs to exclude prescription claims filled with 340B drugs before sending manufacturers' a rebate invoice. States use both provider-level and/or claim-level methods to exclude 340B drugs from invoices and have significant flexibility to use a variety of methods to prevent duplicate discounts. In some cases, states may place certain requirements on covered entities regarding the prevention of duplicate discounts. HHS will continue to work with the states to make sure that utilization data excludes any claims for 340B drugs and address any issues, if necessary.

The GAO's first recommendation for HRSA is related to HRSA's covered entity audit process. HRSA is currently evaluating its covered entity audit process and other program integrity efforts as they relate to HRSA's ability to enforce and require corrective action in the 340B Program, which is primarily administered by guidance. Guidance does not provide HRSA appropriate enforcement capability; therefore, HRSA is not pursuing new guidance under the program at this time. HRSA notes that it does not have regulatory authority related to the prevention of duplicate discounts for covered entities. The agency has requested regulatory authority in every President's Budget since fiscal year (FY) 2017 and has again requested this in FY 2020. 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.

As discussed in more detail below, HHS has concerns with how the GAO characterizes its findings in the report. Specifically, the GAO asserts "covered entities' compliance with state policies and procedures is not assessed." HRSA notes that its audits of covered entities focus on ensuring that covered entities' 340B Program operations are meeting all 340B Program requirements. The program audits also help HRSA and covered entities identify and mitigate program risks, as well as identify best practices regarding 340B Program compliance. As such, these program audits emphasize having strong controls and involve an in-depth review of auditable records, system compliance, and the covered entities' policies and procedures to prevent diversion and duplicate discounts. While HRSA does not have the statutory authority to require covered entities to comply with state laws and requirements aimed at preventing duplicate discounts, it is HRSA's expectation that covered entities comply with all applicable laws and requirements and include a description of any applicable state Medicaid policies related to the 340B Drug Pricing Program in their 340B policies and procedures manual. HRSA auditors are expected to review the covered entities' policies and procedures for information related to state requirements to prevent a duplicate discount.

In addition, the GAO asserts that "not all identified duplicate discounts are repaid" and that HRSA does "not require a covered entity to develop a corrective action plan or make offers of repayment to a manufacturer" regarding identified duplicate discounts in Medicaid managed care organizations (MCOs). As the GAO explains, HRSA does not yet have guidance for covered entities related to Medicaid managed care claims; therefore, it is difficult to assess compliance in

this area absent policy on the issue. As noted in a 2014 policy release,[1] however, HRSA provides examples of best practices related to ways covered entities working with MCOs and state partners can develop models for the prevention of duplicate discounts. Some covered entities report using a variety of methods including, but not limited to, Bank Identification Numbers and/or Processor Control Numbers to identify patients of MCOs, National Council for Prescription Drug Programs codes at the individual claim level for claims submitted through a point of sale system at a retail or clinic pharmacy (contract pharmacy), and UD Modifiers for physician administered claims or drug costs submitted as part of a bundled or capitated rate. States may place certain requirements on covered entities regarding the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their states to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs. HRSA also encourages parties to work in good faith to resolve any issues.

Recommendation 1

The Administrator of CMS should ensure that state Medicaid programs have written policies and procedures that specify the extent to which covered entities can use 340B drugs for Medicaid beneficiaries, are designed to effectively identify if 340B drugs were used, and if so, how they should be excluded from Medicaid rebate requests. The policies and procedures should be made publically available and cover FFS, managed care, and all of the dispensing methods for outpatient drugs.

HHS Response

HHS concurs with this recommendation. HHS will continue to partner with states to ensure Medicaid drug rebates that are applied do not coincide with 340B discounts. HHS will work with states to strengthen policies and procedures related to 340B drugs for Medicaid beneficiaries. In addition, HHS plans to provide guidance to states on best practices for preventing duplicate discounts, especially in Medicaid managed care.

Recommendation 2

The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid policies and procedures regarding the use and identification of 340B drugs into its audit process, working with CMS as needed to obtain states' policies and procedures.

HHS Response

HHS non-concurs with the GAO's recommendation.

HRSA does not have the authority to determine if state Medicaid policies and procedures are adequate or appropriate to prevent duplicate discounts. It also does not have the authority to enforce covered entities' compliance with those policies and procedures. However, as previously stated, HRSA does expect that covered entities include a description of their states' Medicaid policies related to 340B in their 340B policies and procedures manual. In addition, HRSA coordinates with CMS on any issues that may surface regarding state policy matters.

[1] See: https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf

Although it is HRSA's view that interpreting state policies and billing requirements for the purpose of assessing covered entity compliance with state mandates is beyond the scope of the 340B Program, we note that even if this legal obstacle could be addressed, implementing this recommendation would still present significant challenges. For example, to incorporate an assessment of covered entities' compliance with state policies and procedures in its audit process, HRSA would first need to verify and interpret 50 varying state policies and procedures with respect to the identification of 340B drugs. HRSA notes that this degree of analysis would add tremendous burden and complexity to the audit process. HRSA auditors do not currently have this level of expertise and would need extensive training to be able to do so. To the extent that this recommendation is implemented, it would be further difficult to operationalize, as it is unclear how often state policies and procedures are updated. In addition, states would need to notify HRSA of any changes to policies and procedures, and covered entity audits would need to consider the policy at the time the 340B drug was purchased and dispensed, which would be extremely difficult to operationalize.

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.

HHS Response
HHS non-concurs with the GAO's recommendation.

As previously stated, HRSA does not have guidance for covered entities related to Medicaid managed care claims; therefore, it is difficult to assess compliance in this area absent policy on the issue. For any issues that arise, HRSA encourages parties to work in good faith to resolve issues.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Michelle Rosenberg (Assistant Director), David Lichtenfeld (Analyst-in-Charge), Amanda Cherrin, and Sarah Tempel made key contributions to this report. Also contributing were Jennie Apter, Ethiene Salgado-Rodriguez, and Jennifer Whitworth.

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United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
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DRUG DISCOUNT PROGRAM

Update on Agency Efforts to Improve 340B Program Oversight

Statement of Debra A. Draper
Director, Health Care

July 18, 2017

DRUG DISCOUNT PROGRAM

Update on Agency Efforts to Improve 340B Program Oversight

GAO Highlights

Highlights of GAO-17-749T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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 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. This statement describes (1) HRSA actions in response to GAO recommendations to improve its program oversight, and (2) ongoing GAO work regarding the 340B program and HRSA 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-17-749T. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

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—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 conducts 200 audits a year, which have identified instances of non-compliance with program requirements, including the dispensing of drugs to ineligible patients.
- **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 when manufacturers restricted 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, earlier this year, the agency withdrew that guidance in accordance with recent directives to freeze, withdraw, or postpone pending federal guidance.

Given particular concerns that the significant escalation in the number of contract pharmacies poses a potential risk to the integrity of the 340B Program, GAO was asked to examine this issue and expects to issue a future report, in which it plans to address the extent to which covered entities use contract pharmacies; financial arrangements between covered entities and pharmacies; the provision of discounts on drugs dispensed by contract pharmacies to low-income, uninsured patients; and how covered entities and HRSA ensure compliance with 340B program requirements at contract pharmacies.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:

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.[1] 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.[2] 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.[3]

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. The 340B Program does not dictate how covered entities should use

[1]42 U.S.C. § 256b.

[2]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).

[3]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.

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.[4] 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.[5]

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.[6] Since then, we have been monitoring HRSA's progress in addressing our recommendations, including at a March 24, 2015, hearing before your Subcommittee on Health.[7] 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.

For this statement, we obtained information and documentation from HRSA officials about any significant program updates, and steps they

[4]42 U.S.C. § 256b(a)(5)(B).

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

[6]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).

[7]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).

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.[8] We conducted our work for the 2011 report from September 2010 to September 2011, and updated this work in February and March 2015 and again in June and July 2017. The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program 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.[9] HRSA is responsible for administering and overseeing the 340B Program.

Program Participants

Eligibility for the 340B Program, which is defined in the PHSA, has expanded over time, most recently through the Patient Protection and Affordable Care Act, which extended eligibility to additional types of hospitals.[10] 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 Federally Qualified Health Centers, clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, and state-operated 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

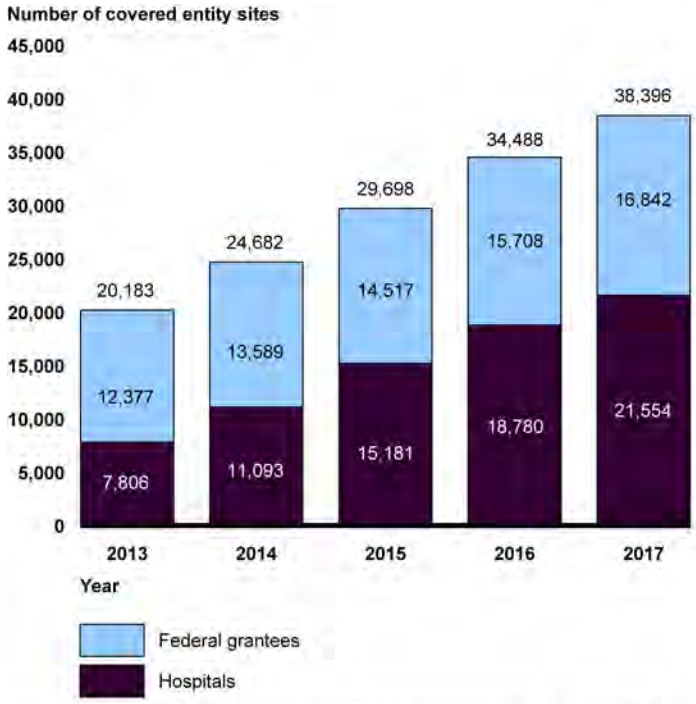
[8]GAO-11-836.

[9]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).

[10]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.

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).[11] 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-17-749T

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

[11]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.

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.[12] 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.[13]

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.[14] Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example

- 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.[15]
- 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

[12]Critical access hospitals are exempt from this requirement.

[13]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.

[14]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.

[15] 42 U.S.C. § 256b(a)(5)(A).

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.[16] (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.

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

	Criteria for patient eligibility:[a]
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.[b]
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.[c]

Source: GAO analysis of HRSA guidance. | GAO-17-749T

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)

[a]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.

[b]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.

[c]Disproportionate share 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 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 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

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

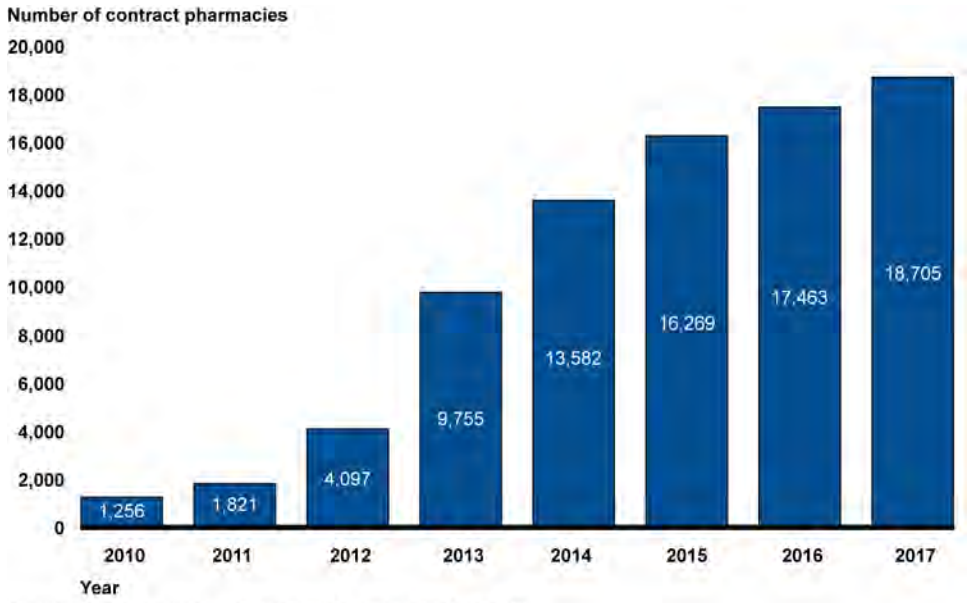
allowed each covered entity to contract with only one outside pharmacy.[17] However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.[18] Since that time, the number of unique contract pharmacies has increased significantly, from about 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.[19] 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 of 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.

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

[18]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

[19]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-17-749T

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.

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.

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.[20] 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.

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 (FY) 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities that

[20]GAO-11-836.

is outlined on its website.[21] Now numbering 200 per year, 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). (See table 2 for the number of audits conducted by HRSA from FY 2012-2017.)

Table 2: Audits of Covered Entities by the Health Resources and Services Administration (HRSA), FY 2012-2017

Fiscal year	Total audits
2012	**51**
2013	**94**
2014	**99**
2015	**200**
2016	**200**
2017 (planned)	**200**
Total	**844**

Source: HRSA. | GAO-17-749T.

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.

[21]See https://www.hrsa.gov/opa/programintegrity/index.html, accessed June 30, 2017.

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.[22]

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.[23] 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.[24]

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 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

[22]GAO-11-836.

[23]Restricted distribution may occur when there is a shortage in drug supply or when shortages are anticipated.

[24]HRSA Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012).

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.[25] 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.[26] 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.[27] After this ruling, the agency issued a proposed omnibus guidance in August 2015 to interpret statutory requirements for the 340B program in areas where it did not have explicit rulemaking authority, including further specificity on the definition of a patient of a

[25]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.

[26]HRSA officials we interviewed for the September 2011 report told us that contracts were selectively reviewed if further clarification was necessary.

[27]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).

covered entity and hospital eligibility for 340B program participation.[28] 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.[29] In July 2017, 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.

GAO Has Ongoing Work Examining HRSA Oversight of 340B Contract Pharmacies

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. For this review, we are planning to address the following four questions.

- To what extent do the various types of covered entities use contract pharmacies and where are the pharmacies located?
- What, if any, financial arrangements do covered entities have with contract pharmacies and third-party administrators related to the administration and dispensing of 340B drugs, and how, if at all, this varies by entity type?[30]
- To what extent do covered entities provide low-income, uninsured patients with discounts on drugs dispensed by contract pharmacies?
- How, if at all, do covered entities and HRSA ensure compliance with 340B program requirements at contract pharmacies?

We are in the early stages of this work, and we expect to issue a future report on 340B contract pharmacies.

[28]See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).

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

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

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

GAO Contacts and Staff Acknowledgments

For further information about this statement, please contact Debra A. Draper at (202) 512-7114 or 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; Rotimi Adebonojo, Jennie Apter; and Amanda Cherrin.

United States Government Accountability Office

Report to Congressional Requesters

June 2018

DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

GAO-18-480

June 2018

DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

GAO Highlights

Highlights of GAO-18-480, a report to congressional requesters

Why GAO Did This Study

Covered entities can provide 340B drugs to eligible patients and generate revenue by receiving reimbursement from patients' insurance. The number of pharmacies covered entities have contracted with has increased from about 1,300 in 2010 to nearly 20,000 in 2017. GAO was asked to provide information on the use of contract pharmacies. Among other things, this report: 1) describes financial arrangements selected covered entities have with contract pharmacies; 2) describes the extent that selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and 3) examines HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies. GAO selected and reviewed a nongeneralizable sample of 30 contracts between covered entities and pharmacies, 20 HRSA audit files, and 55 covered entities to obtain variation in the types of entities and other factors. GAO also interviewed officials from HRSA and 10 covered entities.

What GAO Recommends

GAO is making seven recommendations, including that HRSA's audits assess for duplicate discounts in Medicaid managed care, and HRSA require information on how entities determined the scope of noncompliance and evidence of corrective action prior to closing audits. HHS agreed with four of the recommendations, but disagreed with three recommendations, which GAO continues to believe are warranted to improve HRSA's oversight as explained in the report.

View GAO-18-480. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

The 340B Drug Pricing Program (340B Program), which is administered by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), requires drug manufacturers to sell outpatient drugs at a discount to covered entities so that their drugs can be covered by Medicaid. Covered entities include certain hospitals and federal grantees (such as federally qualified health centers). About one-third of the more than 12,000 covered entities contract with outside pharmacies—contract pharmacies—to dispense drugs on their behalf. GAO's review of 30 contracts found that all but one contract included provisions for the covered entity to pay the contract pharmacy a flat fee for each eligible prescription. The flat fees generally ranged from $6 to $15 per prescription, but varied by several factors, including the type of drug or patient's insurance status. Some covered entities also agreed to pay pharmacies a percentage of revenue generated by each prescription.

Thirty of the 55 covered entities GAO reviewed reported providing low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies. Of the 30 covered entities that provided discounts, 23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs. Additionally, 14 of the 30 covered entities said they determined patients' eligibility for discounts based on whether their income was below a specified level, 11 reported providing discounts to all patients, and 5 determined eligibility for discounts on a case-by-case basis.

GAO found weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies, such as:

- HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, manufacturers cannot be required to provide both the 340B discount and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement for the majority of Medicaid prescriptions, which occur under managed care.
- HRSA requires covered entities that have noncompliance issues identified during an audit to assess the full extent of noncompliance. However, because HRSA does not require all the covered entities to explain the methodology they used for determining the extent of the noncompliance, it does not know the scope of the assessments and whether they are effective at identifying the full extent of noncompliance.
- HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing the audit. Instead, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity came into compliance with 340B Program requirements.

Given these weaknesses, HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements.

Contents

Figures

Abbreviations

CMS	Centers for Medicare & Medicaid Services
FQHC	federally qualified health center
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
TPA	third-party administrator

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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June 21, 2018

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

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
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—to have their drugs covered by Medicaid.[1] 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 340B Program is to enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.[2] In 2017, there were more than 12,000 covered entities and more than 38,000 total sites participating in the 340B Program.

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 revenue as they can purchase 340B drugs for eligible patients whose insurance

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

[2]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the Public Health Service Act. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act).

reimbursement exceeds the 340B price paid for the drugs. The statute authorizing the 340B Program does not dictate how covered entities should use this revenue or require discounts on the drugs to be passed along to patients. Incentives for participation by drug manufacturers are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs.

A covered entity typically purchases and dispenses 340B drugs through pharmacies—either through an in-house pharmacy; through the use of a contract pharmacy arrangement, in which the entity contracts with an outside pharmacy and pays it to dispense drugs on its behalf; or both. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance, and in March 2010, HRSA issued final guidance allowing covered entities to have an unlimited number of contract pharmacies.[3] Since that time, the number of contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to around 20,000 in 2017.

Covered entities are required to meet certain conditions set forth both in law and interpretive agency guidance.[4] For example, they are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.[5] They are also 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.[6] Covered entities that use contract pharmacies are responsible for overseeing those pharmacies to ensure compliance with 340B Program prohibitions on drug diversion and duplicate discounts. Some covered entities hire and pay a private company, referred to as a third-party administrator (TPA), to help determine patient eligibility and manage 340B inventory as a means to ensure compliance with 340B Program requirements at contract pharmacies.

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

[4]Since the establishment of the 340B Program, HRSA has used interpretive guidance and statements of policy to provide guidance to covered entities regarding compliance with program requirements, including statutory prohibitions on duplicate discounts and diversion. See, for example, 75 Fed. Reg. 10273 (Mar. 5, 2010).

[5]42 U.S.C. § 256b(a)(5)(B).

[6]42 U.S.C. § 256b(a)(5)(A).

In a September 2011 report, we identified inadequacies in HRSA's oversight of the 340B Program and recommended ways for HRSA to improve oversight and ensure appropriate use of the program.[7] In response, HRSA has taken action to improve its oversight of covered entities, including implementing a systematic approach to conducting audits of covered entities.[8] Given the growth in the 340B Program, there has been continued interest in program oversight, and how the increase in contract pharmacies affects the integrity of the program. You asked us to review the use of contract pharmacies in the 340B Program. In this report we

1. describe the extent to which covered entities contract with pharmacies to distribute 340B drugs, and characteristics of these pharmacies;
2. describe financial arrangements selected covered entities have with contract pharmacies and TPAs related to the administration and dispensing of 340B drugs;
3. describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and
4. examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies.

To examine the extent to which covered entities contract with pharmacies to distribute 340B drugs and the characteristics of these pharmacies, we analyzed HRSA's 340B Program database to identify the covered entities registered to participate in the 340B Program and the contract pharmacies registered to dispense 340B drugs for each entity, as of July 1, 2017—the most current data available when we began our analysis.[9] The pharmacy characteristics we reviewed included the type of pharmacy and the distance between the pharmacy and the covered entities with which it had a contract. To determine the types of pharmacies that participated as contract pharmacies, we matched the pharmacies included in the 340B database with data from the National Council for

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

[8]See GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight*, GAO-17-749T (Washington, D.C.: July 18, 2017).

[9]According to the data we received from HRSA, at the time of our analysis, there were more than 12,000 covered entities registered to participate in the 340B Program.

Prescription Drug Programs' DataQ—a database used by health care payers and claims processors across the country to identify pharmacies, which contains information reported by pharmacies on their pharmacy type and ownership, among other items.[10] We used the addresses included in the 340B database to determine the location of each covered entity, its affiliated sites, and its contract pharmacies and used this information to determine the distance between the entity and its contract pharmacies.[11] We calculated the distance (in miles) from the pharmacy to the nearest site of the covered entity. To assess the reliability of the 340B and DataQ databases, we obtained information from officials who are knowledgeable about them regarding steps taken to ensure the accuracy of the information contained in each, and performed checks to identify missing or incorrect data. Based on these steps, we determined that the data were sufficiently reliable for the purposes of our reporting objective.

To describe financial arrangements selected covered entities have with contract pharmacies and TPAs, we reviewed a sample of contracts between entities and pharmacies and collected information from selected entities and TPAs. We selected a nongeneralizable sample of 30 pharmacy contracts from among those that HRSA had collected—contracts the agency obtained during audits of covered entities from fiscal years 2014 through 2016.[12] We selected contracts to obtain variation in the type of covered entity (15 hospitals and 15 federal grantees) and geographic location. For these selected contracts, we identified the types and amounts of fees that covered entities agreed to pay contract pharmacies for dispensing and managing 340B prescriptions, as well as

[10]We matched the contract pharmacies in the 340B database to DataQ using the pharmacy's Drug Enforcement Agency number, which is a unique identifier used for tracking prescribers of controlled substances. About 1 percent of the 340B contract pharmacies (162 pharmacies) did not have a Drug Enforcement Agency number in the 340B database, and an additional 2 percent of the 340B contract pharmacies (405 pharmacies) for which a number was available in the 340B database did not have a corresponding record in DataQ, and thus their pharmacy types are unknown.

[11]We excluded 26 contract pharmacies that categorized themselves as mail order pharmacies from our distance calculations. In addition, we also excluded 103 covered entities (less than 3 percent of entities with contract pharmacies) and 644 contract pharmacies (about 3 percent of contract pharmacies) from our distance analysis because we were unable to determine their physical locations based on their addresses.

[12]HRSA collects copies of contracts between covered entities and their contract pharmacies as part of its audit process. Fiscal years 2014 through 2016 were the most recent period for which HRSA completed audits, and thus, the most recent time period of contracts HRSA had on file at the time we began our analysis.

determined factors that may have impacted the fee amounts. To describe financial arrangements covered entities have with TPAs, beginning in September 2017, we sent a data collection instrument—which we refer to as a questionnaire in this report—to a nongeneralizable sample of 60 covered entities that had contract pharmacies to obtain information about the arrangements they had with TPAs.[13] We received responses from 55 of the covered entities—28 hospitals and 27 federal grantees. In addition, we interviewed 10 of the 55 covered entities that responded to our questionnaire to obtain more detailed information about the fees they pay their TPAs. We selected covered entities to receive the questionnaire and for interviews to achieve variation in terms of their type, geographic location, and number of contract pharmacies. Finally, we interviewed two TPAs to gain insights about the types of financial arrangements they have with covered entities.

To describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients, we used the same questionnaire as previously noted to collect information about any discounts provided. This included information on the proportion of pharmacies at which discounts on 340B drugs were available, how covered entities determined which patients were eligible for those discounts, the prices these patients generally paid to obtain the drugs, and how covered entities inform patients and contract pharmacies about the availability of discounts. Additionally, we asked officials from the 10 covered entities we interviewed for additional information about discounts provided on 340B drugs dispensed to low-income, uninsured patients at contract pharmacies.

To examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies, we reviewed relevant policies, procedures, and guidance, including HRSA's 2010 guidance on contract pharmacy services and documentation of the agency's audit procedures. We also analyzed summaries of HRSA's audits of covered entities for fiscal years 2012 through 2017, posted on its website as of February 8,

[13]Four covered entities that received our questionnaire informed us that although they had contract pharmacies registered in HRSA's 340B database, they did not use them and thus, would not be able to answer our questionnaire. As a result, we sent the questionnaire to four additional covered entities.

2018.[14] We conducted an in-depth review of a nongeneralizable sample of 20 audits that were conducted from fiscal years 2014 through 2016 for covered entities that had contract pharmacies at the time of the audit.[15] We selected this sample from among audits that were closed by HRSA to obtain variation in terms of covered entity type and audit findings.[16] We also interviewed HRSA officials about their oversight activities, including their audit process, and spoke with the contractor that has conducted audits on HRSA's behalf since fiscal year 2017.[17] Additionally, we asked officials from the 10 covered entities interviewed about their practices for overseeing contract pharmacies. Finally, we evaluated HRSA's contract pharmacy guidance, covered entity oversight, and audit process against federal internal control standards related to control activities, information and communication, and monitoring.[18]

We conducted this performance audit from January 2017 to June 2018 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 was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to

[14]As of that date, audit results were available for all audits conducted through fiscal year 2016 and 169 of the 200 audits conducted in fiscal year 2017.

[15]At the time we began our review, fiscal year 2017 audits were ongoing, so we reviewed selected audits from the prior three years.

[16]If the audit contains findings, HRSA closes the audit once the covered entity attests that all required corrective actions to address the findings have been addressed and any necessary repayments have been made to affected manufacturers.

[17]Beginning in fiscal year 2017, HRSA contracted with The Bizzell Group to perform the audits on its behalf. The Bizzell Group provides a completed audit protocol to HRSA, which the agency then uses to determine the audit findings and issue a final audit report. HRSA spent $3.8 million in fiscal year 2017 for 340B Program audit services.

[18]See GAO, *Standards for Internal Control in the Federal Government,* GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

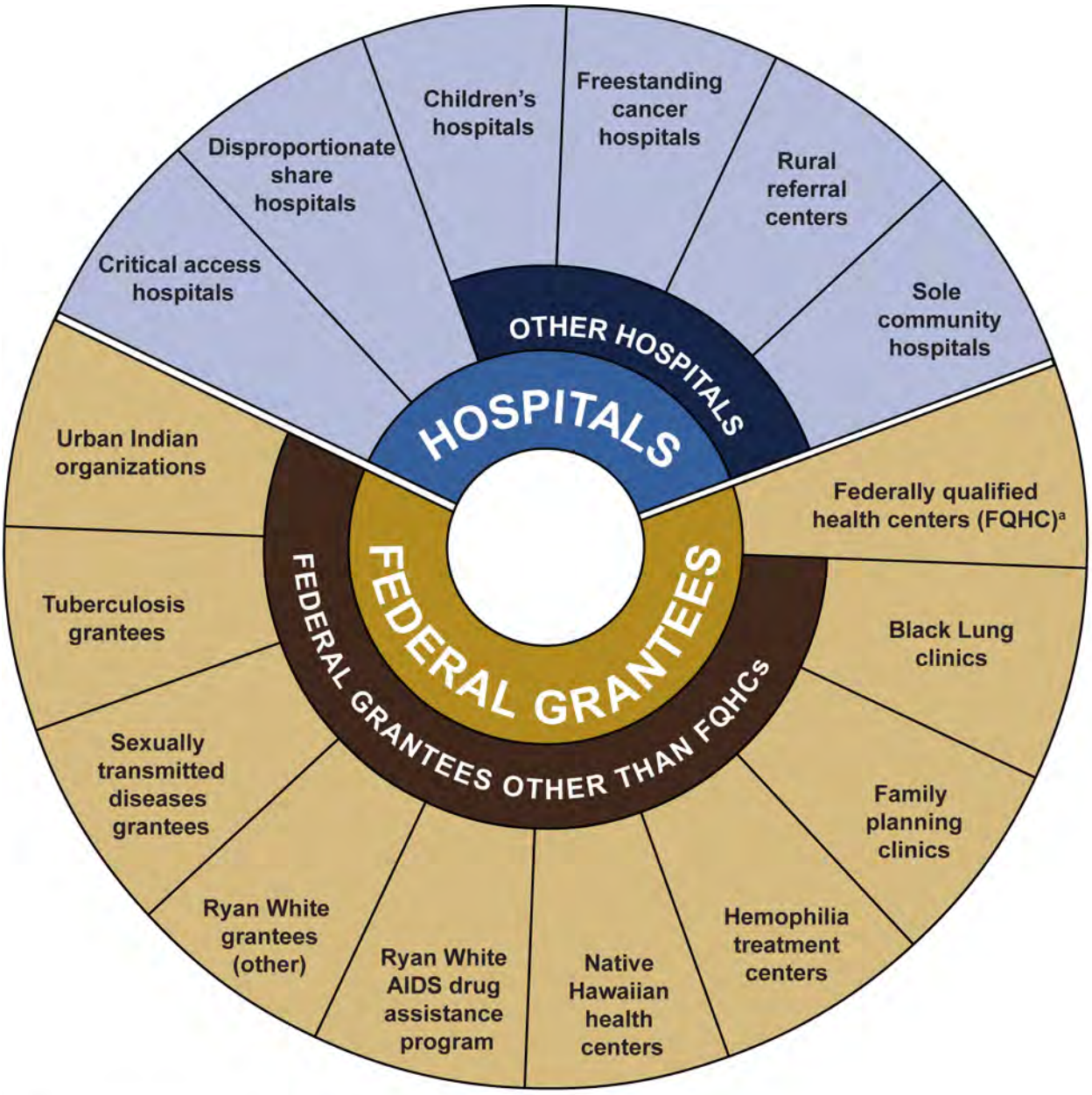
state Medicaid agencies.[19] HRSA is responsible for administering and overseeing the 340B Program.

340B Program Eligibility

Eligibility for the 340B Program, which is defined in the Public Health Service Act, has expanded over time. Covered entities generally become eligible for the 340B Program by qualifying as certain federal grantees or as one of six specified types of hospitals. Eligible federal grantees include federally qualified health centers (FQHCs), which provide comprehensive community-based primary and preventive care services to medically underserved populations, as well as certain other federal grantees, such as family planning clinics and Ryan White HIV/AIDS program grantees. Eligible hospitals include critical access hospitals—small, rural hospitals with no more than 25 inpatient beds; disproportionate share hospitals—general acute care hospitals that serve a disproportionate number of low-income patients; and four other types of hospitals (see fig. 1).

[19]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. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding Social Security Act § 1927; codified as amended at 42 U.S.C. § 1396r-8).

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-18-480

[a]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program, but do not receive federal grants, are referred to as FQHC look-alikes and are eligible to participate in the 340B Program.

Some covered entities, typically hospitals and FQHCs, have multiple sites: the main site, which HRSA refers to as the parent site, and one or more other associated sites referred to as child sites. Child sites 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 meet program requirements and be registered with HRSA as a child site.

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.[20] Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example, 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.[21]
- diverting any drug purchased at the 340B price to an individual who is not a patient of the covered entity. Under HRSA guidance defining this term, diversion generally occurs when 340B drugs are given to individuals who are not receiving health care services from covered entities or are receiving services that are not consistent with the type of services for which the covered entity qualified for 340B status. (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 their financial or insurance status.

[20]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.

[21]The Patient Protection and Affordable Care Act expanded the Medicaid Drug Rebate Program to include drugs dispensed to Medicaid beneficiaries through managed care plans. Pub. L. No. 111-148, § 2501(c)(1), 124 Stat. 119, 308 (2010). Prior to the effective date of this expansion (Mar. 23, 2010), manufacturers' responsibility to pay Medicaid rebates for outpatient drugs covered was limited to drugs covered under Medicaid fee-for-service.

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

Criteria for patient eligibility[a]
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.[b]
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.[c]

Source: GAO analysis of HRSA guidance. | GAO-18-480

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).

[a]These criteria do not apply to Ryan White 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. Rather an individual enrolled in a Ryan White AIDS drug assistance program is considered a patient of the covered entity if registered as such by the state program.

[b]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.

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

Contract Pharmacies

Covered entities may choose to dispense 340B drugs they purchase through contract pharmacies. 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 entities that did not have in-house pharmacies and allowed each entity to contract with only one outside pharmacy.[22] However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.[23] Since that time, the number of contract pharmacies has increased more than fifteen-fold, from about 1,300 to approximately 20,000. According to HRSA guidance, a covered entity is required to have a written contract in place with each pharmacy through which it intends to dispense 340B drugs, but is not

[22]See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43551, 43555 (Aug. 23, 1996).

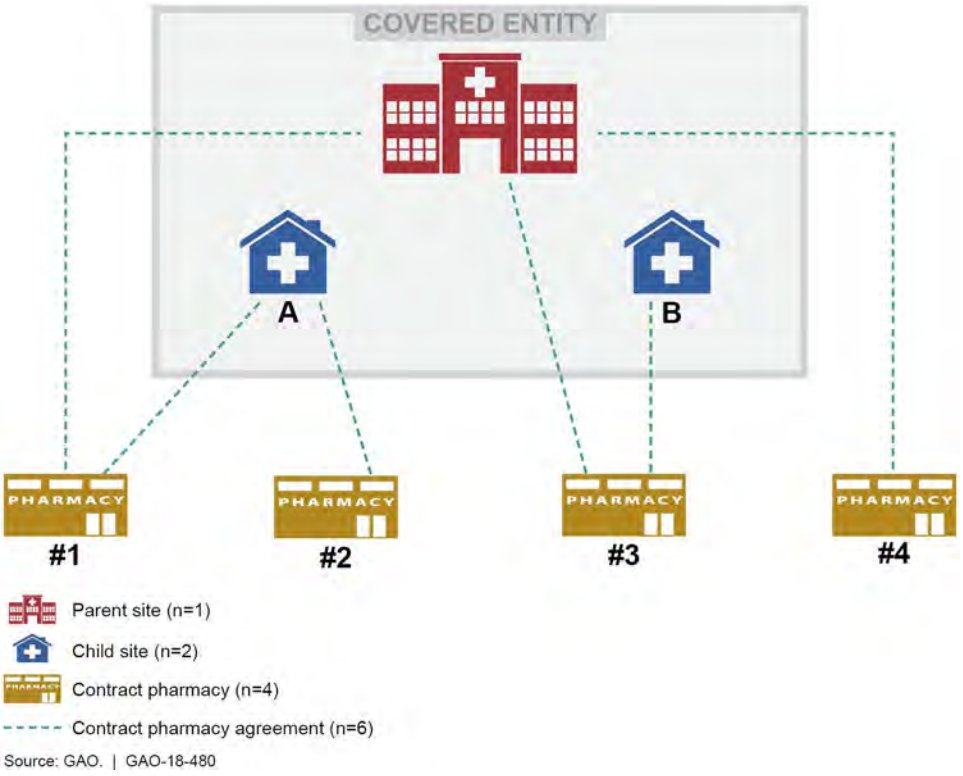
[23]See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272, 10277 (Mar. 5, 2010).

generally required to submit its pharmacy contracts to HRSA.[24] A covered entity that has more than one site at which it provides health care may enter into separate pharmacy contracts for the parent site and each child site, or one comprehensive pharmacy contract including all sites intending to use the pharmacy.[25] It is up to the covered entity to determine which of its sites will be included in a contract with a pharmacy, and thus have what is referred to as a contract pharmacy arrangement with that pharmacy. Figure 2 provides an illustration of a covered entity that has four contract pharmacies but a total of six contract pharmacy arrangements, as not all of the entity's sites have contracts with each of the pharmacies.

[24]HRSA's guidance specifies that contracts must be provided to HRSA upon request. HRSA obtains copies of a small number of covered entities' pharmacy contracts. Specifically, HRSA collects contracts for covered entities that are audited, and in fiscal year 2017, began collecting contracts for 5 percent of new pharmacy registrations.

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

Figure 2: Illustrative Example of a 340B Program Contract Pharmacy Arrangement



Covered entities that choose to have contract pharmacies are required to register with HRSA the names of each of the pharmacies with which they contract. Covered entities may register their contract pharmacies in one of two ways: 1) only in relation to the parent site (use by child sites would be allowed as long as the sites were included in a comprehensive contract between the entity and the contracted pharmacies); or 2) separately for each site (parent and child) involved in a contractual arrangement with the pharmacy. As part of this registration, HRSA guidance specifies that covered entities must certify that they have signed and have in effect an agreement with each contract pharmacy and have a

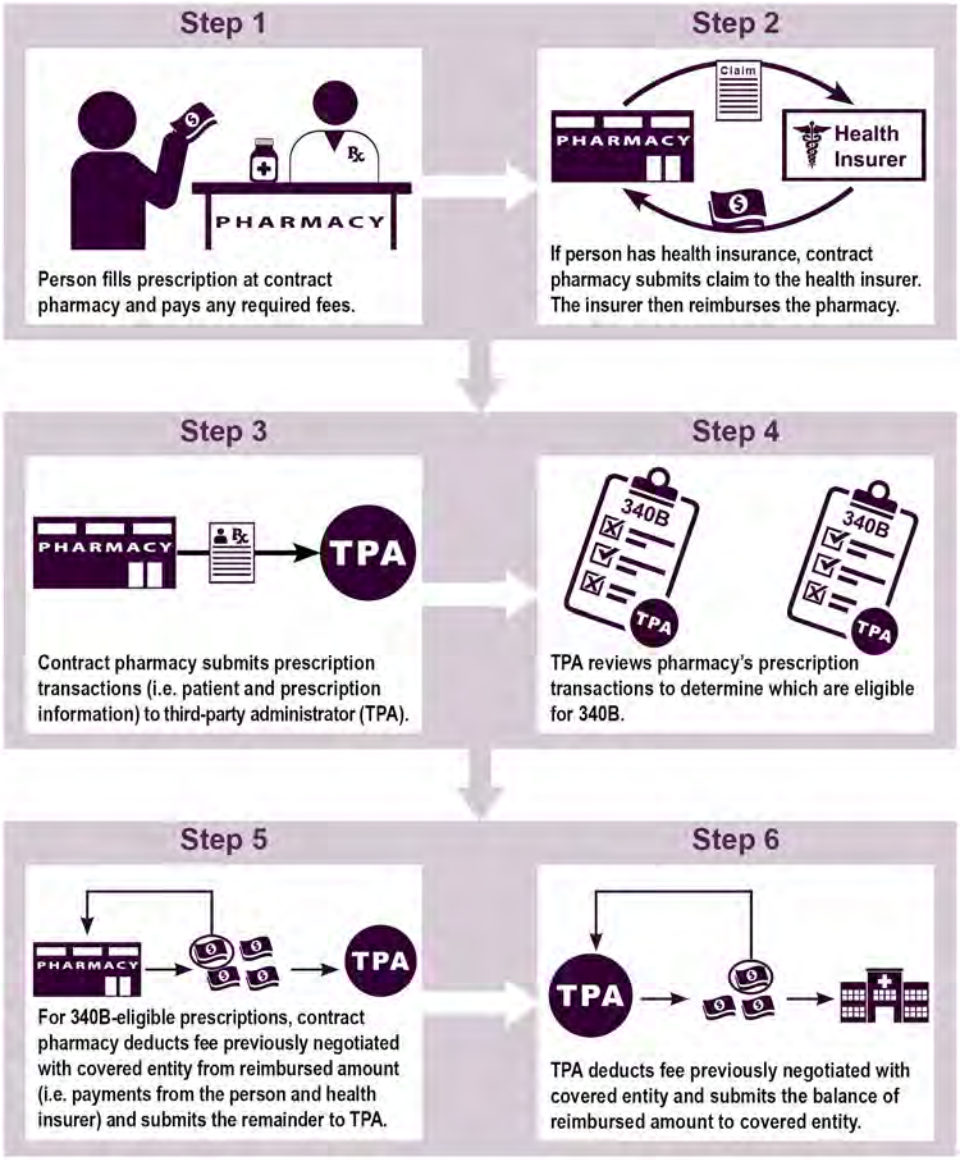
plan to ensure compliance with the statutory prohibitions on 340B drug diversion and duplicate discounts at their contract pharmacies.[26]

Like other pharmacies, when contract pharmacies fill prescriptions, they collect payments from the patient; if the patient has health insurance, the pharmacy will bill the insurer for the drug. In addition, each covered entity must determine which prescriptions are for eligible patients of the entity, and thus, can be filled with 340B drugs. One way that a covered entity could choose to do this is to employ a TPA to review all the prescriptions filled by a contract pharmacy to determine which, if any, prescriptions were issued by the covered entity to an eligible patient, and thus are eligible for the 340B discount. The covered entity then pays both the contract pharmacy and the TPA fees that they have negotiated for their roles in managing and distributing 340B drugs.[27] These fees are typically deducted from the reimbursed amounts received from patients and their health insurers by the pharmacy and TPA, and then the balance is forwarded to the covered entity. (See fig. 3 for an example of how covered entities work with contract pharmacies and TPAs to dispense 340B drugs.)

[26]For a contract pharmacy to dispense 340B drugs to patients covered under Medicaid fee-for-service, HRSA guidance requires that the covered entity, the contract pharmacy, and the state Medicaid agency have an agreement in place to prevent duplicate discounts and report the agreement to HRSA. 75 Fed. Reg. 10278 (Mar. 5, 2010).

[27]The 340B Program statute does not impose any requirements or limitations on the fees that covered entities may pay their contract pharmacies or TPAs.

Figure 3: Example of How Covered Entities, Contract Pharmacies, and Third-Party Administrators Work Together to Dispense 340B Drugs



Source: GAO. | GAO-18-480

Note: Not all covered entities employ a TPA to help manage the dispensing of 340B drugs at contract pharmacies; entities that do not may have their own staff perform the TPA duties depicted in the illustration.

HRSA's Oversight of Covered Entities

In fiscal year 2012, HRSA implemented a systematic approach to conducting audits of covered entities that is outlined on its website. HRSA has increased the number of covered entities audited since it began audits in fiscal year 2012, and now audits 200 entities per year. (See table 2.) 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 covered entities that are targeted based on information from stakeholders such as drug manufacturers (10 percent of the audits conducted).[28] 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, complexity of its program, and history of violations or allegations of noncompliance associated with diversion and duplicate discounts.

Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year

Fiscal year	Number of audits	Percent of covered entities audited[a]
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: GAO analysis of HRSA data. | GAO-18-480

[a]Determined using the number of covered entities as of January 1 of each fiscal year.

Among other things, HRSA's audits include reviews of each covered entity's policies and procedures, including those for overseeing contract pharmacies; an assessment of the entity's compliance with respect to 340B eligibility status, the prevention of duplicate discounts and diversion, and other program requirements; and reviews of a sample of prescriptions filled during a 6-month period, including prescriptions dispensed by contract pharmacies, to identify instances of non-compliance. As a result of the audits conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion and the potential for duplicate

[28]Targeted audits also include covered entities selected for a follow-up audit by HRSA as a result of findings from a prior audit. These are referred to as re-audits.

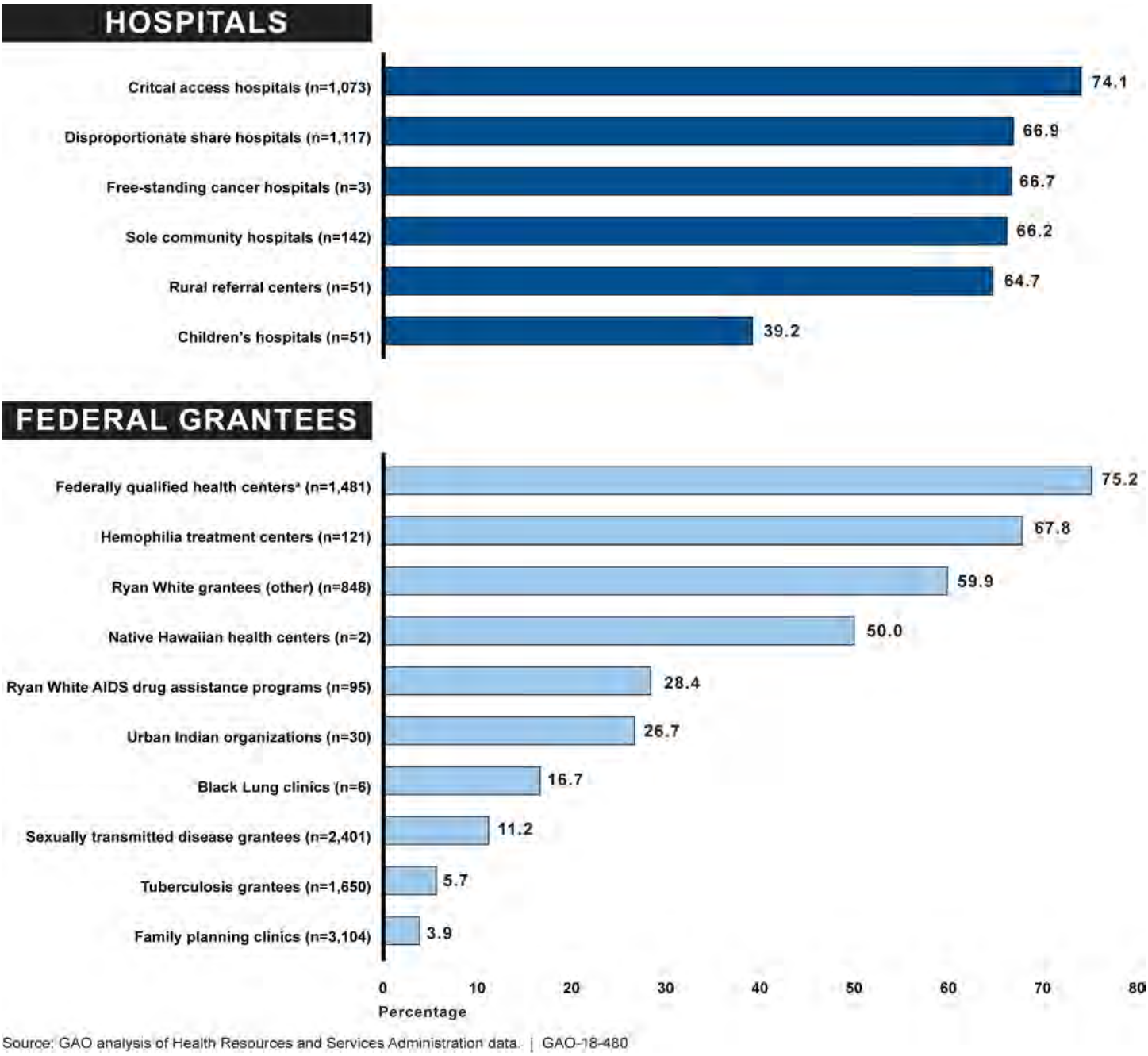
discounts.[29] Based on the audits for which results were posted on HRSA's website as of February 8, 2018, 72 percent of the covered entities audited in fiscal years 2012 through 2017 had one or more findings of noncompliance. When an audit of a covered entity has a finding of noncompliance, covered entities are required to submit a corrective action plan within 60 days of the audit being finalized for HRSA approval. 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.

About One-Third of Covered Entities Had One or More Contract Pharmacies, and Pharmacy Characteristics Varied

As of July 1, 2017, about one-third of the more than 12,000 covered entities in the 340B Program had contract pharmacies, but the extent to which covered entities had contract pharmacies varied by type of entity. Overall, a higher percentage of hospitals (69.3 percent) had at least one contract pharmacy compared to federal grantees (22.8 percent). Among the six types of hospitals, the percentage that had at least one contract pharmacy ranged from 39.2 percent of children's hospitals to 74.1 percent of critical access hospitals. Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9 percent of family planning clinics to 75.2 percent of FQHCs (see fig.4).

[29]The 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 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.

Figure 4: Percent of Covered Entities That Had at Least One Contract Pharmacy as of July 1, 2017, by Entity Type



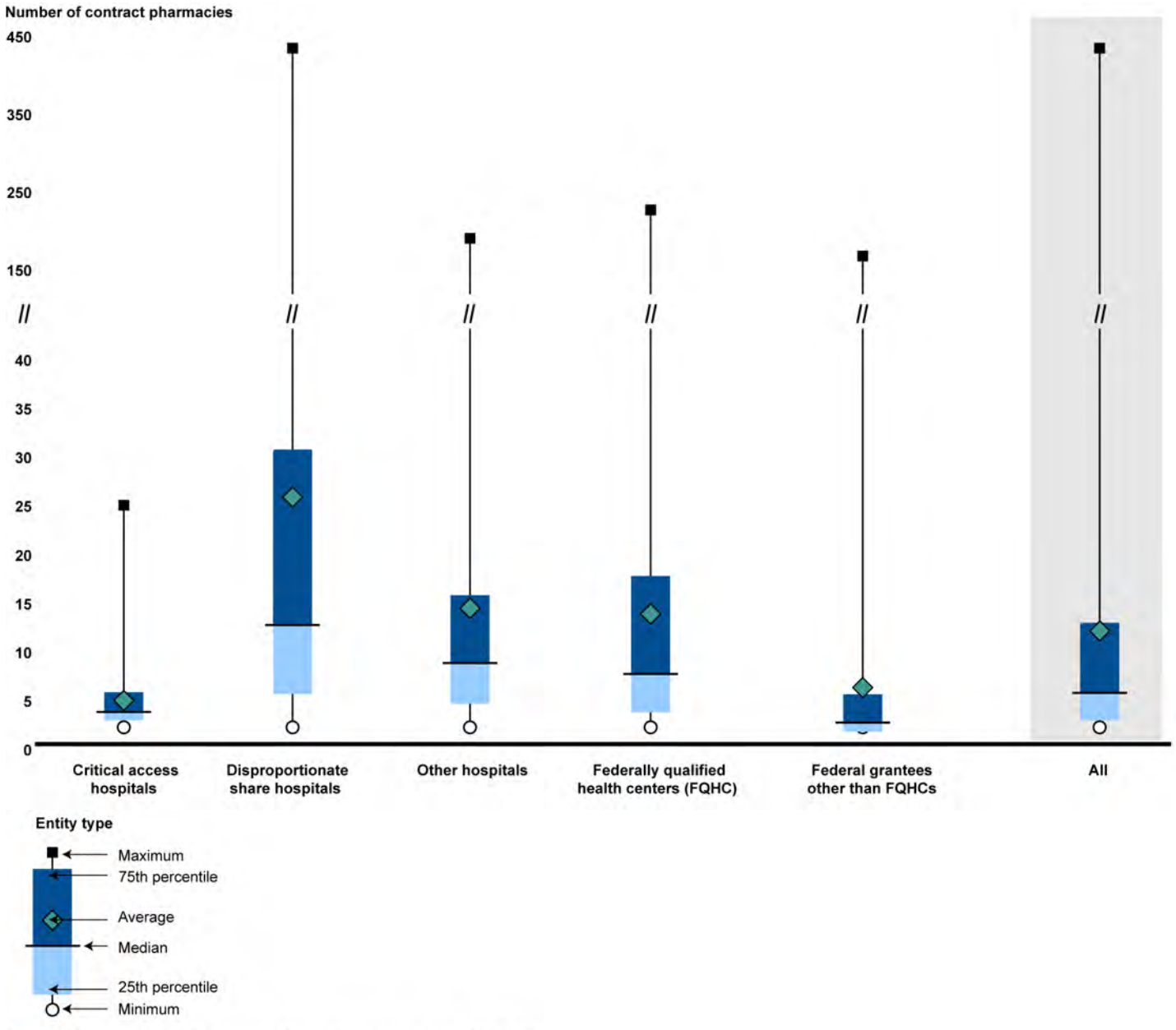
Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

[a]Not all federally qualified health centers (FQHCs) receive federal grants. Providers that meet all of the requirements for the FQHC program, but do not receive federal grants, are referred to as FQHC look-alikes and are eligible to participate in the 340B Program.

Among covered entities that had at least 1 contract pharmacy, the number of contract pharmacies ranged from 1 to 439, with an average of 12 contract pharmacies per entity. However, the number of contract pharmacies varied by covered entity type, with disproportionate share hospitals having the most on average (25 contract pharmacies), and critical access hospitals having the least (4 contract pharmacies).[30] (See fig. 5 for the distribution of contract pharmacies by covered entity type.) However, we found that a covered entity that contracts with a pharmacy may not actually use the pharmacy to dispense 340B drugs. For example, three covered entities that received our questionnaire told us that although they had one or more contract pharmacies registered with HRSA, they did not use those pharmacies to dispense 340B drugs. Moreover, officials from a covered entity we interviewed reported that while the entity maintained a contract with a specialty pharmacy, it had not dispensed 340B drugs through that pharmacy in several years. Officials explained that the covered entity maintained its contract and continued to register this pharmacy with HRSA because it would be financially beneficial should it have a patient fill a 340B-eligible specialty drug at this pharmacy in the future.

[30]Covered entities that are hospitals or FQHCs may register multiple sites as part of the entity. Across these types of covered entities, the average number of contract pharmacies per entity site ranged from a minimum of about two per critical access hospital site to a maximum of about four per disproportionate share hospital site.

Figure 5: Distribution of Contract Pharmacies as of July 1, 2017, by Covered Entity Type



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

The actual number of 340B contract pharmacy arrangements—the number of contractual arrangements between contract pharmacies and the sites of a covered entity—is unknown because HRSA does not

require a covered entity to register pharmacies with each of its child sites. Rather, HRSA gives covered entities the option to register contract pharmacies only in relation to the parent site: child sites may use that pharmacy if included in the written contract between the entity and the pharmacy.[31] Based on our analysis of HRSA data, 1,645 covered entities that had at least one child site registered their contract pharmacies only with their parent sites. These 1,645 covered entities had a total of 25,481 registered contract pharmacy arrangements.[32] However, if the pharmacies were contracted to work with all of the covered entities' sites—the parents and all the child sites—then these 1,645 entities could have as many as 866,388 contract pharmacy arrangements.[33] Therefore, the number of contract pharmacy arrangements is likely higher than what is reported in HRSA's database.

Nearly 93 percent of the approximately 20,000 pharmacies that 340B covered entities contracted with as of July 1, 2017, were classified as community/retail pharmacies, less than 1 percent were classified as specialty pharmacies, and about 7 percent were other types of pharmacies including institutional and mail order pharmacies.[34] Furthermore, the majority (75 percent) of 340B contract pharmacies were chain pharmacies, while 20 percent were independent pharmacies and 5

[31]As previously noted, HRSA does not require covered entities to submit copies of all of their pharmacy contracts.

[32]Since the same pharmacy may have a contract to work with multiple covered entities, the number of contract pharmacy arrangements is more than the number of pharmacies that serve as 340B contract pharmacies.

[33]To determine the total possible number of arrangements, for each of the 1,645 covered entities that had multiple sites and registered their contract pharmacies only with their parent sites, we multiplied the number of sites by the number of contract pharmacies each covered entity registered with HRSA. We then summed the numbers for the 1,645 covered entities. For example, a covered entity that had five sites and 10 contract pharmacies registered only with the parent site (for a total of 10 registered contract pharmacy arrangements) could actually have a total of 50 possible arrangements.

[34]Community/retail pharmacies are defined by DataQ as those where pharmacists prepare and dispense drugs for a local patient population, counsel patients, administer vaccinations, and provide other professional services associated with pharmaceutical care such as health screenings. Specialty pharmacies are defined as pharmacies that dispense low-volume and high-cost drugs to patients undergoing intensive therapies for illnesses that are generally chronic, complex and potentially life threatening. Some of the pharmacies categorized as community/retail pharmacies may also dispense such high-cost drugs. Other pharmacies also include those where the type is unknown. About one-tenth of one percent of all contract pharmacies (26 pharmacies) were mail order pharmacies.

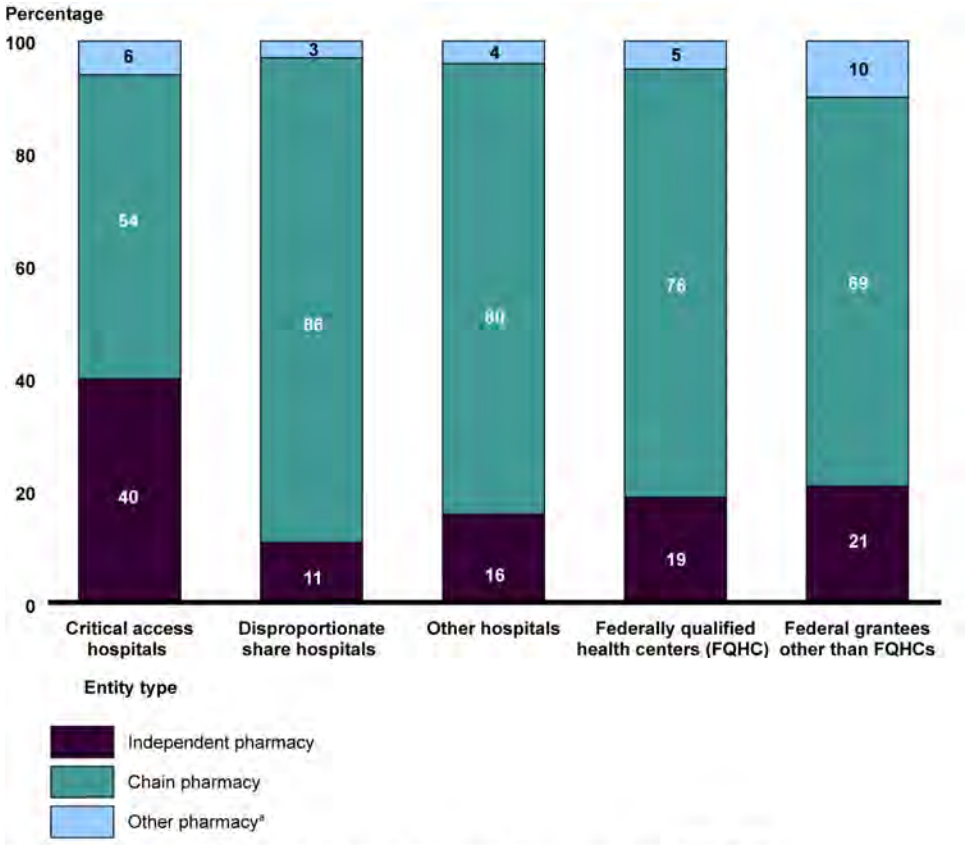
percent were other pharmacies.[35] In contrast, slightly over half of all pharmacies nationwide are chain pharmacies and about one-third are independent. The five biggest pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—represented a combined 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide.[36] Figure 6 shows how the types of pharmacies varied by type of covered entity. Critical access hospitals had a higher proportion of independent contract pharmacies (40 percent of their pharmacies) compared to other covered entity types (which ranged from 11 percent for disproportionate share hospitals to 21 percent for other federal grantees). Our analysis suggests that this is likely due, in part, to a larger proportion of critical access hospitals compared to other types of covered entities being located in rural areas; independent contract pharmacies are also more likely than other contract pharmacies to be located in rural areas.[37]

[35]Chain pharmacies are defined by DataQ as those in which four or more pharmacies are under common ownership, while independent pharmacies have three or less locations under the same ownership or are independent pharmacies that have signed a franchisor agreement. Other pharmacies include government pharmacies, alternative dispensing sites such as physician's offices, and pharmacies for which the type of pharmacy was unknown.

[36]Walgreens alone accounted for 31 percent of 340B contract pharmacies. Walgreens pharmacies account for only about 10 percent of all pharmacies nationwide.

[37]We used the addresses from the 340B database, along with the Rural Urban Commuting Area—a system for geographic classification, to determine whether covered entities and pharmacies were located in rural or urban areas.

Figure 6: Percent of 340B Program Contract Pharmacies by Pharmacy and Covered Entity Type, as of July 1, 2017



Source: GAO analysis of Health Resources and Services Administration data and DataQ data. | GAO-18-480

Note: We used the National Council for Prescription Drug Programs' DataQ to identify pharmacy type. DataQ is a database from the National Council for Prescription Drug Programs, which contains information reported by pharmacies that is used by health care payers and claims processors across the country to identify pharmacies.

[a]"Other pharmacy" includes government pharmacies, alternative dispensing sites—such as physician offices, and pharmacies for which the type of pharmacy was unknown.

Across all covered entities, the distance between the entities and their contract pharmacies ranged from 0 miles (meaning that the contract pharmacy and entity were co-located) to more than 5,000 miles; the

median distance was 4.2 miles.[38] Table 3 shows the distribution of distances between covered entities and their pharmacies overall and by entity type.

Table 3: Distance (in Miles) between Covered Entities and Their Contract Pharmacies as of July 1, 2017, by Entity Type

Entity type	Minimum	25th percentile	Median	75th percentile	Maximum
Disproportionate share hospitals	0	1.5	4.7	25.4	5,052
Critical access hospitals	0	0.6	3.6	28.7	2,495
Other hospitals	0	1.5	5.9	35.7	3,422
Federally qualified health centers (FQHC)	0	0.8	2.4	7.0	4,666
Federal grantees other than FQHCs	0	4.6	19.9	123.7	2,711
All entities	0	1.2	4.2	20.7	5,052

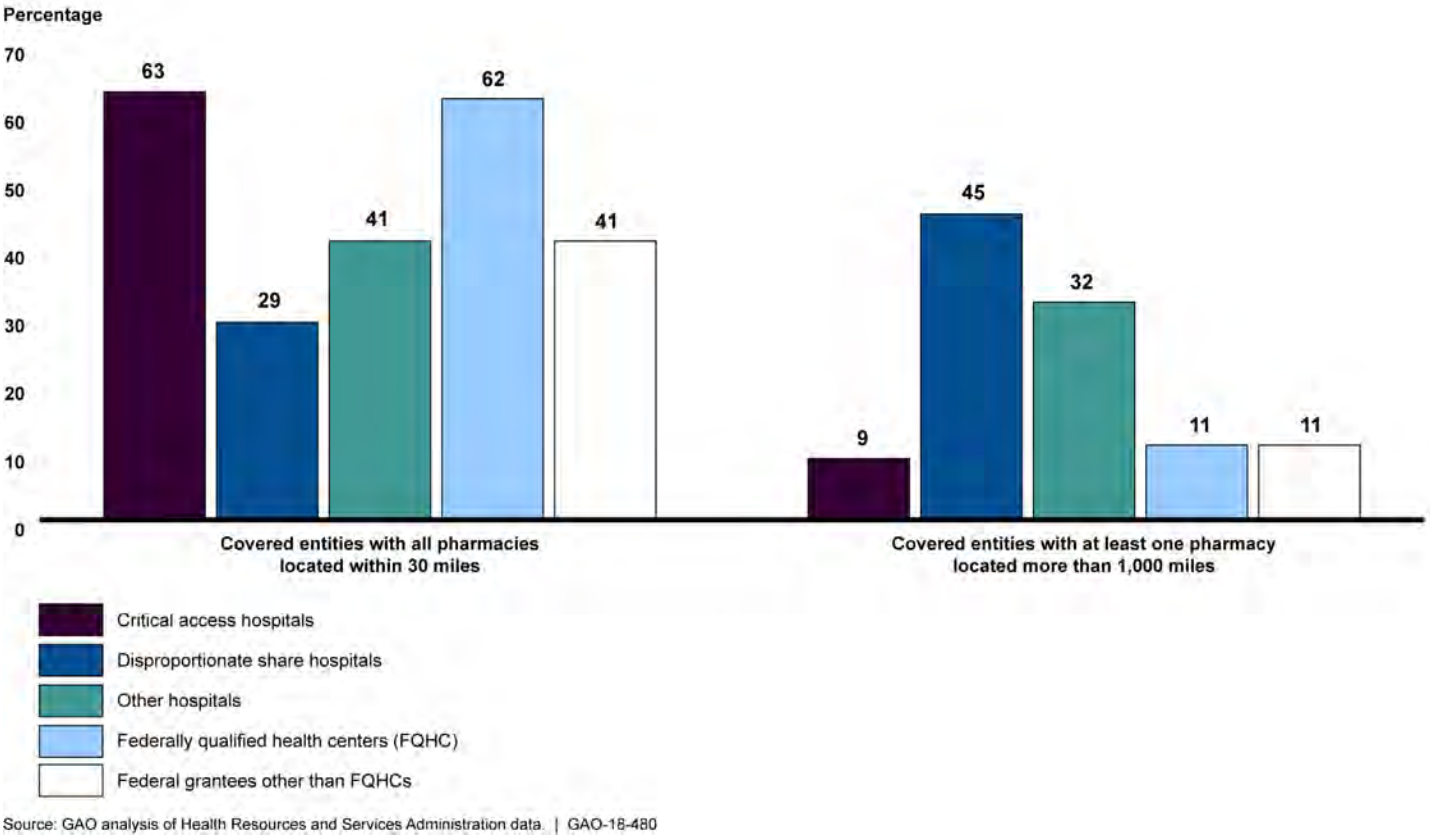
Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

Note: Distance was measured from the contract pharmacy to the closest site of the entity. Mail order pharmacies were excluded from distance calculations.

While there was a range in distances between covered entities and each of their pharmacies, about half of the entities had all their contract pharmacies located within 30 miles, but this varied by entity type. Specifically, more than 60 percent of critical access hospitals and FQHCs had all of their contract pharmacies within 30 miles. In contrast, 45 percent of disproportionate share hospitals had at least one pharmacy that was more than 1,000 miles away compared to 11 percent or less for grantees and critical access hospitals. (See fig. 7.)

[38]Distance between a covered entity and its contract pharmacies was measured from the pharmacy to the closest site of the entity. We excluded mail order pharmacies from distance calculations. The maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut that contracted with a pharmacy in Hawaii. The 340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away. When asked why contract pharmacies may be located many miles away from the covered entity, HRSA officials indicated that the pharmacies may provide prescriptions by mail (even if they are not classified as mail order pharmacies) or dispense specialty drugs. In addition, HRSA officials noted that some covered entities may serve patients who live far away from the entity and thus have contracts with pharmacies located close to where their patients reside.

Figure 7: Percent of Covered Entities with Contract Pharmacies within Given Distances as of July 1, 2017, by Entity Type



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-480

Note: Distance was measured from the contract pharmacy to the closest site of the covered entity. Mail order pharmacies were excluded from distance calculations.

Selected Covered Entities Used Various Methods to Pay Contract Pharmacies and TPAs

Contracts we reviewed between selected covered entities and contract pharmacies showed that entities generally agreed to pay their contract pharmacies a flat fee per 340B prescription, with some entities also paying additional fees based on a percentage of revenue. Selected covered entities and TPAs included in our review indicated two main methods entities use to pay for TPA services: 1) per prescription processed, or 2) per contract pharmacy.

Contracts Reviewed Showed Covered Entities Agreed to Pay Contract Pharmacies a Fee per 340B Prescription; Some Also Agreed to Additional Fees

Twenty-nine of the 30 contracts we reviewed between covered entities and contract pharmacies included provisions for the entities to pay flat fees for each eligible 340B prescription. For the remaining contract, the covered entity and the contract pharmacy were part of the same hospital system, and the contract provided that the entity would not pay fees for 340B prescriptions. In addition to payment of flat fees, 13 of the 29 contracts required the covered entity to pay the contract pharmacy a fee based on a percentage of revenue generated for each 340B prescription. Among the contracts we reviewed, more federal grantees than hospitals had contracts that included both flat fees and fees based on the percentage of revenue (see fig. 8).

Figure 8: Types of Fees Included in Selected Contracts between Covered Entities and Pharmacies, by Entity Type

Source: GAO review of selected 340B contracts. | GAO-18-480

Note: We reviewed a total of 30 contracts between covered entities and pharmacies that HRSA collected during audits of entities between fiscal years 2014 and 2016. One contract was between a covered entity and a pharmacy that were part of the same hospital system, which did not require the entity to pay fees for 340B prescriptions. As a result, the total number of contracts we reviewed with fees was 29.

Example of Fees between a Covered Entity and Contract Pharmacy

In the hypothetical example below, the contract pharmacy receives a total reimbursement of $100 for providing an eligible patient with a 340B drug. Pursuant to a contract with the covered entity, the contract pharmacy deducts its fee of $15, and forwards the remaining balance of $85 to the third-party administrator (TPA).

Source: GAO. | GAO-18-480

We found a wide range in the amount of flat fees covered entities agreed to pay pharmacies in the contracts we reviewed, though they generally ranged from $6 to $15 per 340B prescription.[39] (See Appendix I for a description of fees listed in each of the contracts we reviewed.) The amount of the flat fees per 340B prescription varied by several factors according to our review, including covered entity type, type of drug, and patient insurance status:

- **Flat fees were generally higher for hospitals than federal grantees.** In general, hospitals' flat fees were higher than those for grantees, with most flat fees ranging from $15 to $25 per 340B prescription for hospitals, compared to from $6 to $13 for grantees.
- **Flat fees were sometimes higher for brand drugs.** Three of the 29 contracts we reviewed specified different flat fees for brand and generic drugs. In 2 of these contracts flat fees were $5 or $7 higher for brand drugs. In the remaining contract, the fees for some brand drugs were substantially higher, ranging from $75 to $1,750 for brand drugs, compared to $0 for generic drugs. Additionally, some contracts we reviewed only specified a fee for brand drugs, and 4 of the contracts either excluded generic drugs from being purchased at the 340B price or limited the use of the 340B Program to brand drugs.
- **Flat fees were different or substantially higher for certain specialty drugs.** For 2 of the 29 contracts we reviewed, flat fees were for drugs to treat hemophilia.[40] Given the different nature of hemophilia treatment drugs, fees for these drugs were different than those in the other contracts for other types of drugs, and provided for payments of $.06 and $.09 per unit of blood clotting factor. Additionally, 2 contracts contained substantially higher flat fees for specialty medications. In 1 contract, the flat fees were $125 per prescription for brand and generic human immunodeficiency virus drugs, and $1,750 for brand hepatitis C drugs. In another contract the flat fees were $65 for all specialty drugs, compared to $13 for other drugs.

[39]Overall, the flat fees ranged from $0 to $1,750 per eligible 340B prescription. Both ends of this range came from the same contract, which provided for a flat fee of $0 for some generic drugs, but included higher fees for other drugs, including a fee of $1,750 for brand drugs used to treat hepatitis C.

[40]Hemophilia is a bleeding disorder in which the blood does not clot normally. The main treatment for the disease is to provide patients with infusions of blood clotting factor containing a protein to aid in clotting.

- **Flat fees were sometimes higher for 340B prescriptions dispensed to patients with insurance.** Seven of the 29 contracts we reviewed specified different flat fees for prescriptions provided to patients with health insurance than for patients paying with cash or through a drug discount card provided by the covered entity.[41] The flat fees entities would pay under these contracts ranged from $1 to $16 higher per 340B prescription dispensed to insured patients compared to patients not using insurance.

As previously noted, in addition to requiring flat fees for dispensing prescriptions, 13 of the 29 contracts we reviewed included provisions for the covered entity to pay the pharmacy a fee based on the percentage of revenue generated by each prescription. These percentage fees only applied to prescriptions provided to patients with insurance, and ranged from 12 to 20 percent of the revenue generated by the prescriptions. Generally there were two methods for determining the amount of revenue generated. The first method used the reimbursement the pharmacy received for the prescription, while the second method used the net revenue after subtracting the 340B cost of the drug from the reimbursement received by the pharmacy.[42]

Selected Covered Entities Use Two Main Methods to Pay TPAs

Officials from the two TPAs we interviewed and questionnaire respondents from the 39 covered entities that use TPAs described two main methods entities use to reimburse TPAs for 340B services: 1) a fee for each prescription processed by the TPA, and 2) a fee for each contract pharmacy for which the TPA processes 340B claims on behalf of the entity.

[41]Six of these contracts between grantees and a contract pharmacy had provisions for patients to use a drug discount card provided by the grantee to pay for prescriptions. When presented at the pharmacy, the pharmacy uses the discount card to verify the patient is 340B eligible and determine the amount the patient pays for the prescription.

[42]Some contracts included applicable patient copayments as part of the reimbursement, while others just used the reimbursement received from the patient's health insurance.

Example of Fees between a Covered Entity and Third-Party Administrator (TPA)

In the hypothetical example below, the TPA receives $85 from the contract pharmacy. This amount represents the total reimbursement for the 340B drug, less fees deducted by the contract pharmacy. Pursuant to an agreement with the covered entity, the TPA deducts a fee of $5, and forwards the remaining balance of $80 to the covered entity. This represents the total revenue the covered entity generated from the 340B drug.

Source: GAO. | GAO-18-480

Officials with the two TPAs we interviewed told us that their agreements with covered entities most frequently involve covered entities compensating them based on a fee for each prescription they process on behalf of the entity. Officials from one of these TPAs described three different fee-per-prescription options they offer to covered entities, with the amount of the fees varying based on the option selected:

- A small fee, for example, 20 cents, for every prescription filled by the covered entity's contract pharmacy, and reviewed and processed by the TPA. This includes prescriptions that may not have originated from the covered entity, and may not be 340B eligible, as contract pharmacies can also fill prescriptions for individuals who are not patients of the entity.
- A mid-sized fee, for example, $1.90, for each prescription filled by the covered entity's contract pharmacy that the TPA reviewed and determined originated from the covered entity. These prescriptions may or may not be 340B eligible.
- A larger fee, for example, $5 to $7, for each prescription filled by the covered entity's contract pharmacy that the TPA determined originated from the entity and is 340B eligible.

The 39 covered entities that responded to our questionnaire and reported using a TPA most frequently reported paying their TPAs a fee per each prescription processed, but the exact method varied. For example, some covered entities said they paid their TPAs for each prescription regardless of whether it was determined to be 340B eligible, others limited the fees to prescriptions that were 340B eligible, and some reported paying TPAs for 340B-eligible prescriptions dispensed to an insured patient. (See table 4.)

Table 4: Examples of Methods Used by 39 Covered Entities to Pay Third-Party Administrators (TPA) for Reviewing and Processing 340B Prescriptions

Method used to pay TPA	Number of entities reporting this method
Per prescription processed, regardless of whether the prescription was 340B-eligible	16
Per 340B-eligible prescription processed and dispensed, regardless of the patient's insurance status	15
Flat fee per contract pharmacy for which the TPA has administration responsibilities	11
Per 340B-eligible prescription processed and dispensed to an insured patient	8
Percentage of the difference between the 340B price and the reimbursement received for the drug	7
Per 340B-eligible prescription processed and dispensed to an insured patient and a percentage of the difference between the 340B price and the reimbursement received for the drug	2
Flat fee (e.g., fee per month)	3

Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, and 39 said they used TPAs to review and process 340B prescriptions. Several of the covered entities indicated that they used more than one method to pay TPAs for their services, thus the numbers in the table will not add to 39.

Among the 10 covered entities we interviewed, officials from 8 of these entities said they used TPAs; 5 said they pay their TPAs a fee per prescription, 1 reported paying a fee per contract pharmacy, and 2 reported using both options.[43] Among the covered entities that used fees per prescription and told us the amounts of the fees they pay, the fees ranged from $3.50 to $10.00 per 340B eligible prescription or $3.95 per prescription regardless of whether the prescription was 340B eligible.[44]

[43]For the two covered entities that reported using both methods to pay their TPAs, one had two TPAs, each of which they paid using a different method, while the other said it paid the TPA differently for each of its contract pharmacies.

[44]Five of the seven covered entities that reported paying their TPA a fee per prescription provided information on the amount of that fee, one of which said it paid a fee regardless of whether the prescription was 340B eligible.

For those that pay their TPA a fee per contract pharmacy, the fee was $25,000 a year per pharmacy.[45]

About Half of the Covered Entities Reviewed Provided Low-Income, Uninsured Patients Discounts on 340B Drugs at Some or All of Their Contract Pharmacies

Of the 55 covered entities responding to our questionnaire, 30 reported providing low-income, uninsured patients discounts on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies.[46] All 30 covered entities providing patients with discounts reported providing discounts on the drug price for some or all 340B drugs dispensed at contract pharmacies.[47] Federal grantees were more likely than hospitals to provide such discounts and to provide them at all contract pharmacies (see fig. 9).[48]

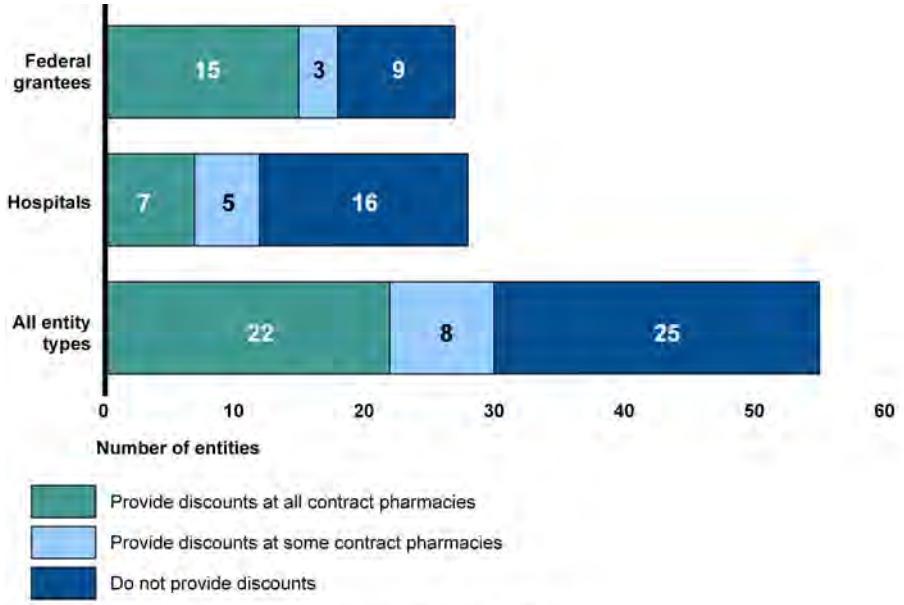
[45]Two of the three covered entities that reported paying their TPA a fee per pharmacy provided information on the amount of that fee. One of those covered entities split the fee with other covered entities that were part of the same hospital system, and thus was responsible for a smaller portion of the fee.

[46]In contrast, 17 of the 23 covered entities that had in-house pharmacies reported offering discounts at those pharmacies, including 4 entities that did not offer discounts at their contract pharmacies.

[47]In our questionnaire, a discount on the drug price was defined as charging the patient less than the wholesale price—the price that a wholesaler charges a pharmacy for a drug—or what a self-paying patient would pay.

[48]While not a requirement of the 340B Program, covered entities that became eligible for the program as a result of being federal grantees may have requirements as part of their grants related to the use of 340B revenue or the provision of discounts to patients.

Figure 9: Number of Selected Covered Entities that Reported Providing Discounts to Low-Income, Uninsured Patients on the Price of 340B Drugs Dispensed at Contract Pharmacies, by Entity Type

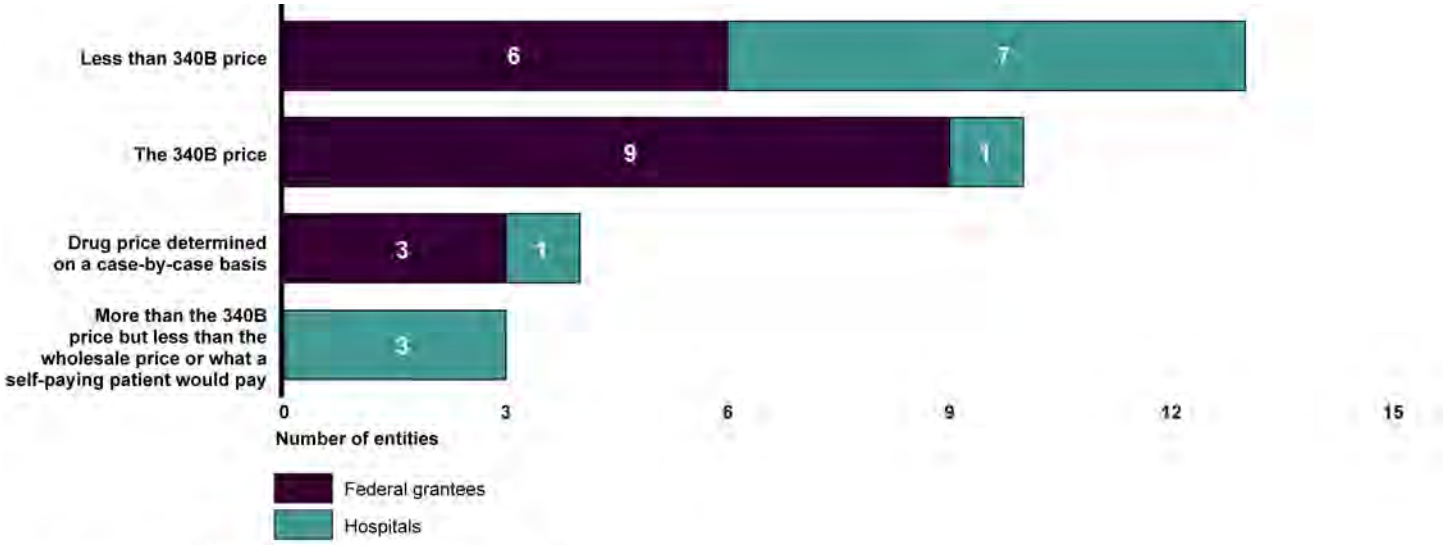


Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities; 55 entities responded.

Of the 30 covered entities that responded to our questionnaire that they provided discounts on the drug price, 23 reported providing patients the full 340B discount—the patients obtained drugs from contract pharmacies at the 340B price or less. In many cases, these covered entities indicated that patients received drugs at no cost. Some covered entities reported that patients would pay more than the 340B price, but less than the wholesale price of the drug or what a self-paying patient would pay, and others indicated they determined discounts for patients on a case-by-case basis. A larger number of federal grantees than hospitals (15 compared to 8) indicated their patients would pay the 340B price or less for their drugs at contract pharmacies where discounts were available. (See fig. 10.)

Figure 10: Prices Patients Pay for 340B Drugs for 30 Covered Entities That Reported Providing Discounts at Their Contract Pharmacies, by Entity Type



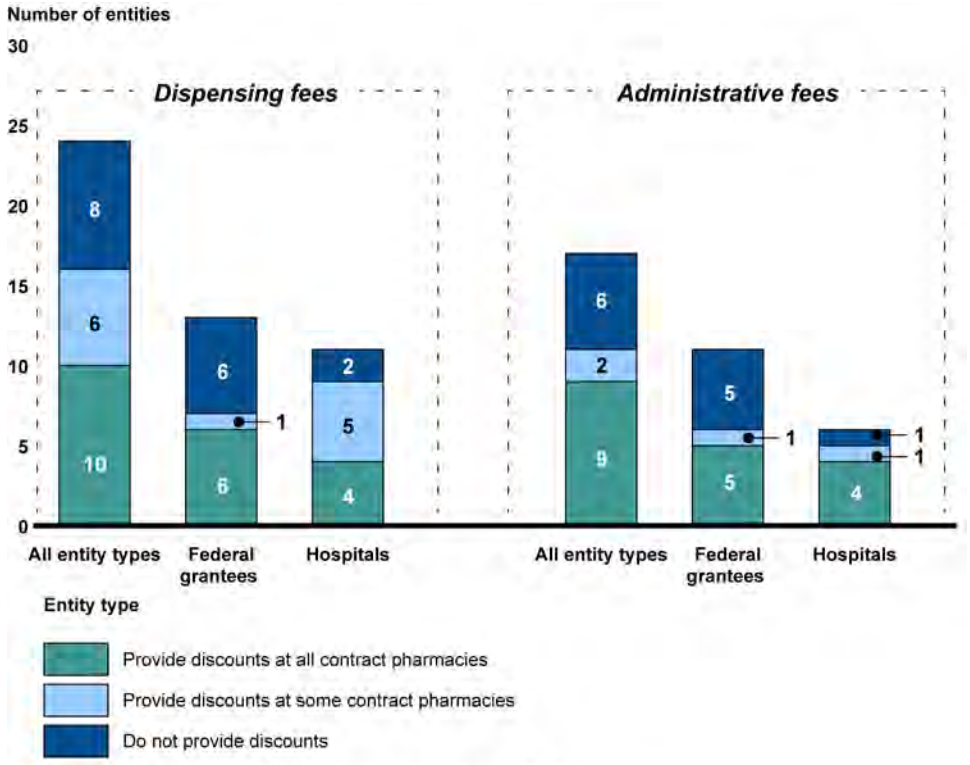
Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients.

In addition to providing discounts on the 340B drug price, some of the 30 covered entities also reported providing discounts on fees patients may pay to contract pharmacies for 340B drugs. Contract pharmacies may charge fees to dispense 340B drugs or cover administrative costs of participating in a covered entity's 340B program, including costs associated with tracking drug inventories and ordering new drugs.[49] In general, about two-thirds of the covered entities with patients who would be subject to dispensing or administrative fees at contract pharmacies reported providing discounts on the fees at some or all of their contract pharmacies. Hospitals were more likely than grantees to provide discounts on these fees when applicable. (See fig.11.)

[49]Six of the 30 covered entities indicated they did not charge patients dispensing fees through their contact pharmacies, and 13 did not charge administrative fees. Therefore, discounts on dispensing fees could be applicable to 24 covered entities (13 federal grantees and 11 hospitals), and discounts on administrative fees could be applicable to 17 covered entities (11 federal grantees and 6 hospitals).

Figure 11: Number of Selected Covered Entities That Reported Providing Discounts on Dispensing and Administrative Fees at Contract Pharmacies, by Entity Type



Source: Responses to GAO's questionnaire to covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities, and 55 provided responses. Data shown are for the 30 covered entities that reported providing discounts to low-income, uninsured patients at contract pharmacies. Six of the 30 covered entities indicated they did not charge patients dispensing fees through their contact pharmacies, and 13 did not charge administrative fees. Therefore, discounts on dispensing fees could be applicable to 24 covered entities, and discounts on administrative fees could be applicable to 17 covered entities.

The 30 covered entities providing 340B discounts to low-income, uninsured patients reported using a variety of methods to determine whether patients were eligible for these discounts. Fourteen of the covered entities said they determined eligibility for discounts based on whether a patient's income was below certain thresholds as a percentage of the federal poverty level, 11 reported providing discounts to all patients, and 5 said they determined eligibility for discounts on a case-by-case basis. For those 14 covered entities determining eligibility based on income as a percentage of the federal poverty level, the threshold used to determine who was eligible for discounts varied but most reported that

patients with incomes at or below 250 percent of the federal poverty level would be eligible for discounts. (See table 5.)

Table 5: Income Thresholds Used by Selected Covered Entities to Determine Eligibility for 340B Discounts, by Entity Type

Income threshold as a percent of the federal poverty level	Number of federal grantees	Number of hospitals	Total number of entities
100	2	0	2
200	4	1	5
225	0	1	1
250	0	2	2
300	1	1	2
350	0	1	1
500	1	0	1
Total	**8**	**6**	**14**

Source: Responses to GAO's questionnaire to 340B covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients. Of those 30 covered entities, 14 reported determining eligibility for discounts based on a patient's income as a percentage of the federal poverty level. In 2018, the federal poverty level in the continental United States was $25,100 a year for a family of four.

Covered entities reported making patients aware of the availability of discounts at contract pharmacies primarily through oral communication by staff located at either the entity or the pharmacy. In addition, the covered entities reported using a variety of methods to inform contract pharmacies about which patients were eligible for discounts, including through notes in patient medical records sent to the pharmacy or by placing codes on the patient's prescriptions sent to or presented at the pharmacy. (See table 6.) Officials from one covered entity we interviewed said that it provides patients eligible for discounts with an identification card (which they referred to as a drug discount card) that patients present at the contract pharmacy; this card informs pharmacy staff of the specific discount amount. Officials from another covered entity said they place codes on electronic prescriptions which informs the pharmacy about discounts.

Table 6: Examples of Methods Used by 30 Covered Entities to Inform Contract Pharmacies of Patients' Eligibility for Discounts

Method used by covered entity	Number of covered entities
Providing patient eligibility files or electronic medical records to pharmacy	11
Placing codes or annotations on electronic prescriptions with discount information	10
Relying on pharmacist familiarity with patients, providers and medications	8
Placing stamps or notations on paper prescription	6
Using identification cards with patient information	6
Providing patients with copayment assistance cards or debit cards to present at pharmacy	3

Source: Responses to GAO's questionnaire to 340B covered entities. | GAO-18-480

Note: We sent a questionnaire to 60 covered entities. Fifty-five covered entities responded to the questionnaire, 30 of which reported providing discounts to low-income, uninsured patients. Twelve of the 30 covered entities reported using two or more methods to inform pharmacies about patients' eligibility for discounts, thus the numbers in the table do not add to 30.

Some covered entities that did not provide discounts on 340B drugs at their contract pharmacies reported assisting patients with drug costs through other mechanisms. For example, 6 of the 10 covered entities we interviewed said that while they did not provide discounts on 340B drugs dispensed at their contract pharmacies, they provide charity care to low-income patients, including free or discounted prescriptions. Additionally, 4 of the 25 covered entities that reported on our questionnaire that they did not provide discounts at their contract pharmacies said they provided patients with discounts on 340B drugs at their in-house pharmacies.

Oversight Weaknesses Impede HRSA's Ability to Ensure Compliance at 340B Contract Pharmacies

HRSA does not have complete data on the total number of contract pharmacy arrangements in the 340B Program to inform its oversight efforts, including information that could be used to better target its audits. Additionally, weaknesses in HRSA's audit process compromise its oversight of covered entities. Finally, the lack of specificity in HRSA's guidance to covered entities potentially impedes covered entities' oversight of contract pharmacies.

HRSA Does Not Have Complete Data on Contract Pharmacy Arrangements to Use for Its Oversight

HRSA does not have complete data on all contract pharmacy arrangements in the 340B Program to inform its oversight efforts. HRSA requires covered entities to register their contract pharmacies with the agency and recertify that registration annually. Contract pharmacies registered to each covered entity are recorded in a publicly available database, which according to HRSA, is used by various stakeholders to validate the eligibility of entities and confirm shipping addresses for each contract pharmacy eligible to receive 340B drugs on an entity's behalf. However, because covered entities differ in the way they register their contract pharmacies, HRSA, and its publicly available database, does not have information on all of an entity's contract pharmacy arrangements. Specifically, because HRSA does not require covered entities to separately register contract pharmacies to each child site for which a contractual relationship exists, HRSA does not have complete information on which sites of an entity have contracted with a pharmacy to dispense 340B drugs. Our analysis of HRSA data showed that the registration of contract pharmacies for 57 percent of covered entities with child sites only specified relationships between contract pharmacies and the parent site; thus HRSA may only have information on a portion of the actual number of 340B contract pharmacy arrangements. Additionally, manufacturers do not have complete information on which covered entity sites have contracts with a pharmacy to dispense 340B drugs, according to HRSA officials. Manufacturers could use such information to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site.

HRSA officials told us that the number of contract pharmacy arrangements recorded in HRSA's database increases a covered entity's chance of being randomly selected for a risk-based audit. However, since HRSA gives covered entities multiple contract pharmacy registration options, the likelihood of an entity being selected for an audit is dependent, at least in part, on how an entity registers its pharmacies as opposed to the entity's actual number of pharmacy arrangements. Without more complete information on covered entities' contract pharmacy arrangements, HRSA cannot ensure that it is optimally targeting the limited number of risk-based audits done each year to entities with more contract pharmacy arrangements. Federal internal control standards related to information and communication state that management should use quality information to achieve the entity's objectives, such as by obtaining relevant data that are reasonably free from error and bias and represent what they purport to represent so that

they can be used for effective monitoring.[50] Without complete information on covered entities' use of contract pharmacies, HRSA does not have the information needed to effectively oversee the 340B Program, including information that could be used to better target its audits of covered entities.

Weaknesses in HRSA's Audit Process Impede Its Oversight of 340B Program Compliance at Contract Pharmacies

HRSA primarily relies on audits to assess covered entities' compliance with 340B Program requirements, including compliance at contract pharmacies, according to HRSA officials; however weaknesses in its audit process impede the effectiveness of its oversight.[51] As a result of its audits, HRSA has identified instances of diversion and the potential for duplicate discounts at contract pharmacies, among other findings of noncompliance. Specifically, through the audits conducted since fiscal year 2012, HRSA identified at least 249 instances of diversion at contract pharmacies and 15 instances of the potential for duplicate discounts for drugs dispensed at contract pharmacies, as of February 2018. HRSA had also identified 33 covered entities with insufficient contract pharmacy oversight. (See Table 7.)

[50]GAO-14-704G.

[51]In addition to audits, other mechanisms HRSA uses to oversee compliance at contract pharmacies include the agency's registration and annual recertification process; its collection of contracts for 5 percent of newly registered contract pharmacies; and its self-disclosure process, whereby covered entities can report any material compliance breaches, and steps to address the breach, to HRSA.

Table 7: Summary of Health Resources and Services Administration's (HRSA) Audit Findings Related to Contract Pharmacies, as of February 8, 2018

Fiscal Year	Diversion Findings			Duplicate Discount Findings			Contract pharmacy oversight findings
	Total	Number at contract pharmacies	Percent at contract pharmacies	Total	Number at contract pharmacies	Percent at contract pharmacies	
2012	**16**	9	56	**18**	3	17	0
2013	**52**	22	42	**25**	1	4	5
2014	**54**	38	70	**23**	1	4	9
2015	**95**	65	68	**46**	3	7	9
2016	**94**	64	68	**55**	6	11	7
2017[a]	**69**	51	74	**39**	1	3	3
Total	**380**	**249**	**66**	**206**	**15**	**7**	**33**

Source: GAO analysis of HRSA data. | GAO-18-480

Notes: A diversion finding indicates that a covered entity dispensed 340B drugs to an individual who did not meet HRSA's definition of a patient. A duplicate discount finding indicates the potential that drugs prescribed to Medicaid beneficiaries were subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. A contract pharmacy oversight finding indicates that a covered entity did not perform any type of oversight activities for its contract pharmacies.

[a]Data for fiscal year 2017 are not complete because not all audits had been closed at the time of our review—as of February 8, 2018. Therefore, the number of findings for that fiscal year could increase depending on the results of the remaining audits.

However, we identified two areas of weaknesses in HRSA's audit process that impede its oversight of covered entities' compliance with 340B Program requirements at contract pharmacies: 1) the process does not include an assessment of all potential duplicate discounts, and 2) the process for closing audits does not ensure all covered entities have fully addressed any noncompliance identified.

Medicaid Delivery Systems

States provide Medicaid services through either fee-for-service or managed care. Under fee-for-service, states reimburse providers directly for each service delivered. For example, a pharmacy would be paid by the state for each drug dispensed to a Medicaid beneficiary. 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 pays each organization a set amount per beneficiary per month to provide or arrange those services.

Source: GAO. | GAO-18-480

Not all potential duplicate discounts are assessed. HRSA's audits only assess the potential for duplicate discounts in Medicaid fee-for-service. They do not include a review of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care.[52] The potential for duplicate discounts related to Medicaid managed care has existed since 2010 when manufacturers were required to pay Medicaid rebates under managed care, and currently, there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than fee-for-service.[53]

HRSA officials told us that they do not assess the potential for duplicate discounts in Medicaid managed care as part of their audits because they have yet to issue guidance as to how covered entities should prevent duplicate discounts in Medicaid managed care.[54] They agreed that the lack of Medicaid managed care guidance for covered entities was problematic, and HRSA's December 2014 policy release stated, "HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with the Centers for Medicare & Medicaid Services (CMS) to develop policy in this regard."[55] According to HRSA, in the absence of formal guidance, covered entities should work with their states to develop strategies to prevent duplicate discounts in Medicaid managed care. However, 8 of the 10 covered entities we spoke with described challenges working with their

[52]While HRSA does not include an assessment for duplicate discounts related to Medicaid managed care claims as part of its audit process, beginning April 1, 2018, if the agency becomes aware of the potential for such duplicate discounts during the course of an audit, then it will note this in the audit report for the covered entity. If the audit of the covered entity results in findings, then the entity would be required to indicate how it will address the duplicate discounts.

[53]According to analysis from the Medicaid and CHIP Payment and Access Commission, in fiscal year 2016, almost 60 percent of Medicaid gross spending for drugs and almost 70 percent of Medicaid drug prescriptions were in managed care. Additionally, as of July 2015, about 65 percent of Medicaid enrollees received their medical care services through managed care.

[54]Federal law directs HRSA to provide guidance to covered entities regarding the prevention of duplicate discounts. 42 U.S.C. § 256b(d)(2)(B)(iii). In 1993, HRSA issued final guidance for the prevention of duplicate discounts in Medicaid fee-for-service, establishing that HHS will provide covered entity Medicaid provider numbers to the state Medicaid agencies on a regular basis. 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). This information is referred to as the Medicaid Exclusion File.

[55]See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014). CMS is the HHS agency responsible for overseeing state Medicaid programs.

states and local Medicaid managed care organizations to ensure that duplicate discounts were not occurring or expressed the need for more guidance from HRSA on how to comply with 340B requirements related to duplicate discount prevention. As a result of these challenges, some covered entities acknowledged that they did not have assurance that duplicate discounts were not occurring with their Medicaid managed care claims, while other entities told us that they did not seek discounts for the drugs of managed care patients due to compliance challenges.

Federal internal control standards related to control activities and monitoring state that agencies should 1) implement control activities through policies, such as by determining the necessary policies based on the objectives and related risks for the operational process; and 2) establish and operate monitoring activities to monitor the internal control system and evaluate results, such as by establishing and operating monitoring activities that are built into each entity's operations, performed continually, and responsive to change.[56] In addition, federal law directs the agency to develop detailed guidance describing methodologies and options for avoiding duplicate discounts.[57] Until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

Audit closure process does not ensure all identified issues of noncompliance are addressed. Under HRSA's audit procedures, covered entities with audit findings are required to 1) submit corrective action plans to HRSA that indicate that the entities will determine the full scope of any noncompliance (beyond the sample of prescriptions reviewed during an audit); 2) outline the steps they plan to take to correct findings of noncompliance, including any necessary repayments to manufacturers; and 3) specify the timelines for implementing the corrective action plans.[58] HRSA closes the audit when a covered entity

[56]GAO-14-704G.

[57]42 U.S.C. § 256b(d)(2)(B)(iii).

[58]As part of its audit, HRSA reviews a sample of prescriptions filled with 340B drugs during a 6-month period. In the 20 audit files we reviewed, HRSA sampled a total of 1,073 out of 2,286,862 prescriptions (0.05 percent). This included 511 out of 260,839 prescriptions filled at the selected covered entities' contract pharmacies during the audit time frame.

submits a letter attesting that its corrective action plan, including its assessment of the full scope of noncompliance, has been implemented and any necessary repayments to manufacturers have been completed.[59]

However, we identified two specific deficiencies in HRSA's approach. First, although HRSA requires that covered entities determine the full scope of noncompliance found in audits, it does not provide guidance as to how entities should make this assessment. Specifically, HRSA does not specify how far back in time covered entities must look to see if any related noncompliance occurred and instead, relies on each entity to make this determination. For example, a document from a fiscal year 2017 audit revealed that a covered entity that had participated in the 340B Program for 3 years only reviewed 5 months of claims to determine whether any other instances of diversion had occurred, diminishing the likelihood that its efforts identified the full scope of noncompliance. Additionally, until April 2018, HRSA did not require covered entities that were audited to communicate the methodology used to assess the full scope of noncompliance, or the findings of their assessments, including how many or which manufacturers were due repayment. Beginning April 1, 2018, HRSA requires covered entities subject to targeted audits to document their methodology for assessing the full scope of noncompliance. However, as previously noted, only 10 percent of the 200 audits HRSA currently conducts each year are targeted audits. Consequently, the vast majority of covered entities audited are not required to provide HRSA with information on their methodology for assessing the full scope of noncompliance. Furthermore, HRSA officials told us that they believe determining the scope of noncompliance is a matter between the covered entities and manufacturers. Thus, HRSA relies on manufacturers to determine the adequacy of a covered entity's effort to assess the full scope of noncompliance. However, covered entities only contact the manufacturers that they determine were affected by the noncompliance based on the methodology they choose to apply; thus, it is unclear how manufacturers not contacted would be in a position to negotiate an acceptable assessment of the scope of noncompliance and any applicable repayment.

Federal internal control standards related to control activities state that agencies should implement control activities through policies, such as by

[59]Beginning April 1, 2018, HRSA requires covered entities with audit findings to submit a copy of their revised policies and procedures that reflects changes made in response to the audit prior to HRSA closing the audit.

documenting policies in the appropriate level of detail to allow management to effectively monitor the control activity.[60] As HRSA does not provide guidance on how covered entities are to assess the full scope of noncompliance and does not review most entities' methodology for making such assessments, the agency does not have reasonable assurances that entities have adequately identified all instances of noncompliance.

Second, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity is now in compliance with 340B Program requirements. Beginning April 1, 2018, HRSA requires the 10 percent of covered entities that are subject to targeted audits to provide documentation that they implemented their corrective action plans prior to HRSA closing the audits. However, it still relies on the remaining 90 percent of audited covered entities to self-attest to their compliance with program requirements.

HRSA officials told us they believe that a covered entity providing a description of the corrective actions is sufficient, and that the self-attestation of corrective action plan implementation provides HRSA with the information necessary to close the audit. However, aside from the self-attestation, HRSA's only mechanism to ensure that the majority of audited covered entities have implemented their corrective action plans is to re-audit the entities—in other words, subject the entity to a targeted audit. To date, the agency told us that it has re-audited 21 covered entities, and based on those re-audits, determined that 1 entity did not fully implement its corrective action plan from the original audit. However, we found that of the 19 re-audited covered entities for which results were available, 12 had similar findings of noncompliance in their second audits, as were identified in their original audits (e.g., diversion findings in both audits), 3 of which were caused by the same issue, according to information provided to us by HRSA.

Federal internal control standards for monitoring specify that agencies should establish and operate monitoring activities to monitor the internal control system and evaluate the results, for example by using ongoing monitoring to obtain reasonable assurance of the operating effectiveness of the service organization's internal controls over the assigned process.[61]

[60]GAO-14-704G.

[61]GAO-14-704G.

By only reviewing evidence of corrective action plan implementation for the limited number of covered entities subject to targeted audits, HRSA does not have reasonable assurance that the majority of covered entities audited have corrected the issues identified in the audit, and are not continuing practices that could lead to noncompliance, thus increasing the risk of diversions, duplicate discounts, and other violations of 340B Program requirements.

HRSA's Guidance for Covered Entities' Oversight of Contract Pharmacies Lacks Specificity

HRSA guidance for covered entities on their oversight of contract pharmacies lacks specificity and thus provides entities with considerable discretion on the scope and frequency of their oversight practices. Specifically, HRSA's 2010 guidance on contract pharmacy services specifies that covered entities are responsible for overseeing their contract pharmacies to ensure that drugs the entity distributes through them comply with 340B Program requirements, but states that, "the exact method of ensuring compliance is left up to the covered entity."[62] The guidance also states that, "annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected," but HRSA officials told us that covered entities are not required to conduct independent audits and instead are expected to do some form of periodic oversight of their contract pharmacies.[63] Thus, according to HRSA officials, if a covered entity indicates that it has performed oversight in the 12 months prior to a HRSA audit, then HRSA considers the entity to have met HRSA's standards for conducting contract pharmacy oversight regardless of what the oversight encompassed.

Due, at least in part, to a lack of specific guidance, we found that some covered entities performed minimal contract pharmacy oversight.

- Officials from a grantee reported auditing claims of 5 randomly selected patients quarterly, despite treating approximately 900 patients each month.
- Officials from a critical access hospital that serves about 21,000 patients a year at its outpatient clinics reported that the annual independent audit of their hospital system reviewed five claims.

[62]75 Fed. Reg. 10278 (Mar. 5, 2010).

[63]75 Fed. Reg. 10278 (Mar. 5, 2010). HRSA indicated that it does not have statutory authority to require covered entities to conduct annual independent audits of their contract pharmacies.

- Officials from two entities reported that they did not contract for an independent audit of their 340B Program, despite HRSA's expectation to do so.

Additionally, of the 20 covered entities whose audits we reviewed, 6 had no documented processes for conducting contract pharmacy oversight.

The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices. Specifically, 66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies, and 33 of the 813 audits for which results were available had findings for lack of contract pharmacy oversight.[64] However, the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity. This is despite the fact that HRSA officials told us that the agency requires auditors to review documentation of covered entities' oversight activities.[65]

Federal internal control standards related to control activities state that agencies should implement control activities through policies, such as by documenting the responsibility for an operational process's objectives and related risks, and control activity design, implementation, and operating effectiveness. The standards also specify that management should periodically review policies, procedures, and related control activities for continued relevance and effectiveness in achieving its objectives or addressing related risks.[66] As a result of the lack of specific guidance and its numerous audit findings of noncompliance, HRSA does not have assurance that covered entities' contract pharmacy oversight practices are sufficiently detecting 340B noncompliance.

Conclusions

The 340B Program provides covered entities with discounts on outpatient drugs and the ability to generate revenue on drugs purchased under the

[64]These figures are based on the 813 audits conducted by HRSA from fiscal year 2012 to fiscal year 2017 for which results were posted on HRSA's website as of February 8, 2018.

[65]HRSA officials told us that they are updating their policy and protocols to more clearly define HRSA's expectations for its contracted auditor.

[66]GAO-14-704G.

program. Use of contract pharmacies enables covered entities to increase the use of 340B drugs by expanding their distribution networks, thereby increasing the volume of 340B drugs dispensed and generating associated savings and revenue. The expansion of contract pharmacies presents an opportunity for entities to fill more prescriptions with discounted 340B drugs, but it also increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts. Although covered entities and HRSA have taken steps to ensure that 340B Program requirements are being met at contract pharmacies, HRSA's audits continue to identify instances of noncompliance.

As currently structured, weaknesses in HRSA's oversight impede its ability to ensure compliance with 340B Program requirements at contract pharmacies. HRSA cannot ensure that its limited number of audits target covered entities with the most complex 340B programs, and thus the greatest risk of noncompliance, because the agency does not have complete data on entities' contract pharmacy arrangements. Additionally, HRSA's audit process does not adequately identify compliance issues, nor does it ensure that identified issues are corrected. HRSA's audits do not assess compliance with a key 340B Program requirement (the prohibition regarding duplicate discounts) as it relates to Medicaid managed care, and HRSA does not provide audited entities with guidance for determining the full scope of noncompliance, which reduces the effectiveness of HRSA's audits in identifying drug diversion and duplicate discounts. Moreover, where audits identify instances of noncompliance, HRSA's process does not confirm that all covered entities successfully correct the deficiencies and take steps to prevent future noncompliance. Although HRSA made improvements to its process for targeted audits during the course of our review, the agency does not require most covered entities subject to an audit to provide evidence of corrective actions taken.

Moreover, the lack of specificity in HRSA's guidance to covered entities on the methods through which they should ensure compliance may impede the effectiveness of entities' oversight. For example, without guidance instructing covered entities how to prevent duplicate discounts in Medicaid managed care, entities are left to individually navigate the policies and practices of states and private insurers. Furthermore, by not clearly communicating expectations for covered entities' oversight of their contract pharmacies, HRSA faces the risk that instances of noncompliance, such as diversion, at contract pharmacies will not be identified and addressed. As the 340B Program continues to grow, it is essential that HRSA address these shortcomings.

Recommendations for Executive Action

We are making the following seven recommendations to HRSA:

- The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists. (Recommendation 1)
- The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs. (Recommendation 2)
- 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. (Recommendation 3)
- 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. (Recommendation 4)
- 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. (Recommendation 5)
- 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. (Recommendation 6)
- The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight. (Recommendation 7)

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reproduced in app. II, and technical comments, which we have incorporated as appropriate. In its written comments, HHS concurred with four of our seven recommendations, did not concur with three of our

recommendations, and stated that it had concerns with some of the other information in our report.

In concurring with four of our recommendations, HHS stated that HRSA is making changes to its audit process to strengthen oversight of the 340B Program. Regarding our recommendation related to guidance on duplicate discounts, HHS concurred, but commented that the recommendation did not account for the critical role that CMS would play in its successful implementation. We agree that CMS would play an important role in ensuring compliance with the prohibition on duplicate discounts in Medicaid managed care, which is why we recommended that HRSA coordinate with CMS on the guidance. HHS indicated that HRSA and CMS are strategizing on effective ways to address this issue. HHS also concurred with our recommendations to issue guidance related to identifying the full scope of noncompliance and covered entities' oversight of their contract pharmacies, although it noted that HRSA would face challenges in issuing guidance related to areas where it does not have explicit regulatory authority. While we recognize that HRSA's authority to issue regulations governing the 340B Program may be limited, our recommendations were focused on HRSA clarifying certain program requirements through whatever format the agency deems appropriate. Since the establishment of the 340B Program, HRSA has used interpretative guidance and statements of policy to provide guidance to covered entities regarding compliance with program requirements. HRSA has also used certain of its audit procedures, such as the template provided to covered entities for the development of corrective action plans, to provide such clarifications. Our recommendations are intended to expand the availability of information HRSA provides to covered entities to help them improve compliance with existing program requirements. As such, we continue to believe that further clarification, whether provided as interpretive guidance, audit procedures, or another format, is necessary to help ensure compliance with program requirements.

Among the recommendations with which HHS did not concur was our recommendation to require covered entities to register contract pharmacies for each site of the entity for which a contract exists. HHS stated that its current registration process is responsive to our concerns for all covered entity types other than hospitals and health centers. However, as we note in the report, hospitals and FQHCs are typically the covered entity types that have multiple sites, and are generally more likely to have contract pharmacies. HHS cited administrative burden for both covered entities and HRSA as a reason not to require covered entities to

provide more complete information about contract pharmacy arrangements. However, given that HRSA requires covered entities to register both their sites and their contract pharmacies with the agency, it is unclear why there would be significant additional burden for covered entities to indicate which of the previously registered sites had contracts with which contract pharmacies. It is also important to note that contract pharmacy use by covered entities is voluntary, and covered entities that choose to have contract pharmacies are required to oversee those pharmacies to ensure compliance with 340B Program requirements. Therefore, the use of contract pharmacies inherently comes with additional administrative responsibilities for the covered entity, and we believe that the requirement to register each contract pharmacy arrangement with HRSA should present limited additional burden on covered entities.

Rather than implementing our recommendation, HHS stated that HRSA will make changes to its audit selection process; HRSA will assume that all contract pharmacies registered with the parent site would also be used by all sites of the covered entity prior to selecting entities for risk-based audits. Although this may be a good step forward, it does not provide information on the actual number of contract pharmacy arrangements for each covered entity. As such, we continue to believe that HRSA needs more complete information on contract pharmacy arrangements to best target its limited number of audits to covered entities with the most complex 340B programs. This is also important information to provide manufactures to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site.

HHS also did not concur with our two recommendations to require covered entities to specify their methodologies for identifying the full scope of noncompliance identified during their audits as part of their corrective action plans, and to provide evidence that these plans have been successfully implemented prior to HRSA closing audits. In its response, HHS noted that on April 1, 2018, HRSA implemented these requirements for entities subject to targeted audits (including re-audits), which represent 10 percent of all entities audited. However, HRSA indicated that implementing these requirements for all covered entities that are audited would create a significant burden for these entities. As we previously noted, HRSA already requires covered entities with audit findings to determine the full scope of noncompliance and to submit corrective action plans. Thus, it is unclear how requiring covered entities to include written descriptions of their methodologies for identifying the full

scope of noncompliance, which should already be formulated, and to provide evidence that the corrective actions that entities developed have been implemented, would create significant additional burden for these entities.

HHS also expressed concern that these additional steps would significantly delay the audit process and repayments to manufacturers. We recognize that reviewing these documents may create some additional work for HRSA and possibly require additional time to close audits. However, we believe this additional work and time is necessary for the audits to be effective at adequately identifying compliance issues and ensuring that those issues are corrected. Furthermore, these additional actions could reduce the need for re-audits which are burdensome in terms of cost and time, for both the covered entity and HRSA.

Finally, HHS also expressed concerns about some of the other information included in the draft report.

- HHS stated that disclosing actual fees paid by covered entities to pharmacies and TPAs could cause disruptions in the drug pricing market and fluctuations in fees entities pay. Our report provides fees for a small and nongeneralizable sample of contracts, covered entities, and TPAs. For example, we provide contract pharmacy fees for 30 of the thousands of contracts that exist between covered entities and pharmacies. It is unclear how this information could cause disruptions in the drug pricing market or lead to fluctuations in fees covered entities may pay, and HHS did not provide any evidence to support its assertion. Additionally, HHS has raised questions about the effect of the 340B Program on drug pricing.[67] As such, we believe that our discussion of fees brings enhanced transparency to the 340B Program, and provides Congress with important information it requested to gain a better understanding of the program and enhance its oversight.
- Regarding the distance between contract pharmacies and covered entities, HHS noted that the longest distance was for a specialty pharmacy that was registered for 17 days. As noted in our scope and methodology, our analysis was of covered entities and contract pharmacies participating as of July 1, 2017. Additionally, there were

[67]Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,* (Washington, D.C.: May 2018).

other contract pharmacy arrangements of similarly long distances. HHS also expressed concern that the draft report did not note that such specialty pharmacies may be needed due to restricted distribution by a manufacturer, which would be outside a covered entity's control. In our report, we noted that the 340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away. However, the report does include some potential reasons HRSA provided us as to why this may occur.

- HHS also commented that our table on the number and percent of covered entities audited does not fully reflect HRSA's auditing efforts because it does not include the number of entity sites and contract pharmacies included within each audit. However, HRSA's audits of covered entities generally do not include visits to multiple covered entity sites, or all contract pharmacies that distribute 340B drugs on a covered entity's behalf. Additionally, while the audits include a review of a sample of 340B drugs distributed, that sample may not include prescriptions written at, or dispensed from, all of the covered entity's sites or contract pharmacies. As a result, information in our report highlights the number of entities that were audited.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, 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.

Debra A. Draper
Director, Health Care

Appendix I: Summary of Fees Included in 340B Pharmacy Contracts Reviewed

Table 8 provides a brief description of the fees that covered entities pay pharmacies with which they contracted to dispense 340B drugs based on our review of 30 contracts.

Table 8: Fees That 30 Selected Covered Entities Pay to Contract Pharmacies for Dispensing 340B Drugs, by Entity Type

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Hospitals		
Critical access hospital	Chain	• Flat fee of $24 for each brand drug prescription • Flat fee of $15 for each prescription patient pays with cash • Generic drugs excluded
Critical access hospital	Chain	• Flat fee of $15 for each prescription
Critical access hospital	Chain	• Flat fee of $28 for each brand drug prescription for patients with insurance coverage • Limited to brand drugs
Critical access hospital	Independent	• Flat fee of $17 for each prescription
Critical access hospital	Independent	• Flat fee of $15 for each prescription
Critical access hospital	Not available[a]	• Flat fee of $24 for each brand drug prescription • Generic drugs excluded
Critical access hospital	Not available[a]	• Fee of $0 for each prescription
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • Up to 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments • The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • Up to 15 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments • The covered entity does not pay any fees if the patient does not have insurance coverage

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Disproportionate share hospital	Chain	• Flat fee of $15 for each prescription when patient has insurance coverage • 20 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Disproportionate share hospital	Chain	• Flat fee of $18 for each generic drug prescription • Flat fee of $25 for each brand drug prescription
Disproportionate share hospital	Chain	• Flat fee of $30 for each brand drug prescription
Disproportionate share hospital	Chain	• Flat fee of $22 for each brand and generic drug prescription
Disproportionate share hospital	Independent	• Flat fee of $5 for each generic drug prescription • Flat fee of $10 for each brand drug prescription
Federal grantees		
Federally qualified health center	Chain	• Flat fee of $28 for each brand drug prescription for patients using a drug discount card[b] or insurance • Limited to brand drugs
Federally qualified health center	Chain	• Flat fee of $6 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $7 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Federally qualified health center	Chain	• Flat fee of $6 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $7 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Federally qualified health center	Chain	• Flat fee of $8 for each brand prescription for patients using a drug discount card[b] • Flat fee of $24 for each brand prescription when patient has insurance coverage
Federally qualified health center	Chain	• Flat fee of $8 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $9 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Federally qualified health center	Independent	• Flat fee of $8 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $10 for each prescription when patient has insurance coverage • 14 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments
Federally qualified health center	Independent	• Flat fee of $6 for each brand and generic prescription for patients using a drug discount card[b] • Flat fee of $7 for each brand and generic prescription when patient has insurance coverage • 20 percent of the difference between the amount the patient's insurance company agrees to reimburse the pharmacy, including patient copayments, and the cost of the 340B drug
Other federal grantee	Alternate dispensing site[c]	• Flat fee of $0.06 per international unit of factor[d]
Other federal grantee	Chain	• Flat fee of $13 for each prescription when patient has insurance coverage • Up to 18 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Chain	• Flat fee of $0.09 per international unit of factor[d]
Other federal grantee	Chain	• Flat fee of $13.50 for each prescription when patient has insurance coverage • Up to 13 percent of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug • The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Chain	• Flat fee of $13 or $65 (for specialty drugs) for each prescription when patient has insurance coverage • 13 percent, or up to 13 percent (for specialty drugs), of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments • The covered entity does not pay any fees if the patient does not have insurance coverage
Other federal grantee	Independent	• Flat fee of $3 for each prescription
Other federal grantee	Independent	• Flat fee of $125 for each brand and generic human immunodeficiency virus drug • Flat fee of $1,750 for each brand Hepatitis C drug • Fee of $0 for each generic Hepatitis C drug • Flat fee of $75 for each brand and $0 for each generic drug not included above

Covered entity type	Contract pharmacy type	Description of fees covered entity pays contract pharmacy for dispensing 340B prescriptions
Other federal grantee	Not available[a]	• Flat fee of $10 for each prescription when patient does not have insurance coverage • Flat fee of either $10 when patient has insurance coverage or 12 percent of the of the amount the patient's insurance company agrees to reimburse the pharmacy for the drug, including patient copayments, whichever is greater

Source: GAO review of selected 340B contracts and DataQ data. | GAO-18-480

Note: Information on pharmacy type comes from the National Council for Prescription Drug Programs' DataQ, a database containing information reported by pharmacies that is used by health care payers and claims processors across the country to identify pharmacies.

[a]For these pharmacies information was not available in DataQ on pharmacy type.

[b]Some covered entities provide their patients with a drug discount card that the patient can present at the contract pharmacy. The pharmacy then uses the discount card to verify the patient as 340B eligible and determine the amount the patient will pay for the prescription.

[c]An alternate dispensing site is a pharmacy or dispensing site such as a physician's office or emergency department.

[d]Factor refers to blood clotting factor, which is the main treatment used for hemophilia—a bleeding disorder in which the blood does not clot normally. Patients with hemophilia are provided with infusions of blood clotting factor containing a protein to aid in clotting.

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

JUN 04 2018

Debra 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, "*Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*" (GAO-18-480).

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

Sincerely,

for

Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

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 Program and continually works to strengthen oversight of the Program, including ongoing improvement of its audit process. HHS appreciates GAO's examination of 340B covered entities use of contract pharmacies. During the course of the study, HRSA took the opportunity to make improvements to the program and has already implemented some of GAO's recommendations. While GAO's work will continue to inform our program integrity efforts, implementing some of the other recommendations in this report are not feasible at this time; they would require significant resources, currently not available under the Program's funding authorities. Successful implementation would require significant expansion of the Program's current information technology systems to account for new audit functions as well as strengthened enforcement authority and additional staff to oversee these efforts. In addition, HHS notes that some of the recommendations would impose additional audit requirements— and by extension, significant burden – on covered entities, especially smaller entities who are often resource constrained.

HHS also has significant concerns regarding many of the findings in the draft report. While discussion of the fees that covered entities pay their contract pharmacies and third party administrators (TPA) to dispense 340B drugs is within scope of the study's objectives, disclosing the actual fees, which are not widely available, could cause disruptions in the drug pricing market and lead to fluctuations in the fees that covered entities are charged. Further, it is important to note that HRSA has no legal authority to address the fees that a contract pharmacy or TPA may charge a covered entity for dispensing drugs to patients of the entity, as the fees are a private business matter between the parties involved. Covered entities utilize contract pharmacies and TPAs as an access point for patients to obtain 340B drugs. Without an explicit statement that HRSA lacks statutory authority to address these fees, the reader could be led to believe that fees are within the purview of the Program.

In addition, the GAO found in its analysis that the distance between a covered entity and its contract pharmacies was measured from the pharmacy to the closest site of the entity and that mail order pharmacies were excluded from distance calculations. GAO also explains that the maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut contracting with a specialty pharmacy in Hawaii. Important context missing from GAO's report is the rationale for why a specialty pharmacy may be needed in the first place – such as the case of restricted distribution by a manufacturer, which would be outside a covered entity's control. HRSA also notes that the hospital in Connecticut that contracted with a specialty pharmacy in Hawaii was registered for 17 days and the pharmacy contract was subsequently terminated by the covered entity on July 17, 2017.

GAO's analysis was also not fully reflective of HRSA's auditing efforts which was a central objective of the study. "Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), by Fiscal Year," lists the number of audits by fiscal year and the percent of covered entities audited. While the numbers are accurate,

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

it does not fully capture the significant number of sites included within each audit. HRSA notes the total number of audited sites below to provide the reader with the full scope of HRSA's oversight efforts.

- FY 12 – 51 audits, 410 outpatient/sub-grantee sites, 860 contract pharmacies
- FY 13 – 94 audits, 718 outpatient/sub-grantee sites, 1937 contract pharmacies
- FY 14 – 99 audits, 1476 outpatient/sub-grantee sites, 4028 contract pharmacies
- FY 15 – 200 audits, 2720 outpatient/sub-grantee sites, 4443 contract pharmacies
- FY 16 – 200 audits, 4011 outpatient/sub-grantee sites, 3531 contract pharmacies
- FY 17 – 200 audits, 2046 outpatient/sub-grantee sites, 4052 contract pharmacies

Finally, GAO makes several recommendations directing HRSA to issue guidance on specific policy matters. While HHS appreciates the recommendations to issue guidance, we would face challenges with issuing guidance on 340B policy matters in cases where our enforcement authority is quite limited. HHS notes that HRSA currently lacks explicit general regulatory authority in the 340B statute to issue regulations on most aspects of the 340B Program. Exceptions to this include the calculation of the ceiling price, manufacturer civil monetary penalties, and administrative dispute resolution. A regulation is a binding, enforceable document that would dictate specific 340B Program requirements and provide the clarity necessary for stakeholders to be fully compliant. HHS notes that the 2011 GAO report also included a recommendation related to hospital eligibility; however, HRSA remains unable to address the report's two recommendations without legislative changes, including the expansion of regulatory authority.

HHS notes that the FY 2019 President's Budget includes a proposal to amend the 340B statute to provide HRSA explicit general regulatory authority. If this proposal were enacted by Congress, HRSA could conduct rulemaking for all provisions in the 340B statute, affording it explicit, general regulatory authority, which would be most effective in facilitating HRSA's oversight over the 340B Program. In addition, explicit general regulatory authority would allow HRSA to provide greater clarity and specificity to Program requirements necessary for implementing GAO's 2011 recommendations and the recommendation in this report.

HRSA continues to support the development of program policy as a general matter and is working with the Administration to determine next steps on several aspects of Program policy.

Recommendation 1
The Administrator of the Health Resources and Services Administration (HRSA) should require covered entities to register contract pharmacies for each site of the entity for which a contract exists.

HHS Response
HHS non-concurs with GAO's recommendation.

- HRSA notes that its current process is already responsive to GAO's recommendation for covered entity types other than hospitals and health centers. Because HRSA recognizes

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

relationships of hospitals and health centers in a different manner (parent and child), and for administrative burden reasons, HRSA only requires that a contract pharmacy register with the parent covered entity, notwithstanding that child sites can still utilize that pharmacy. HRSA does require all covered entity sites and contract pharmacy sites to be listed on the written contract, and this information is audited by HRSA.

- For the FY 2019 audit cycle, HRSA will strengthen this risk-based audit strategy by including an assumption that all contract pharmacies registered with the parent entity would also be used by the child sites, prior to randomly selecting covered entities for audit. Adding this assumption to the methodology, rather than requiring registration for all contract pharmacy contracts, will preclude having to strain HRSA's IT system and, more importantly, it will avoid placing significant burden on covered entities that only list their contract pharmacy with the parent organization.
- GAO explains that because HRSA allows covered entities to utilize multiple contract pharmacy registration options, the likelihood of being selected for an audit is dependent on how an entity registers its pharmacies. HRSA does not believe that requiring entities to register each contract pharmacy in the database is the appropriate mechanism to address the GAO's specific concern. In assessing the scope and effectiveness of implementing this proposed recommendation, HRSA conducted an internal analysis in line with GAO's scenario where all contract pharmacies listed under the parent entity (for hospitals and health centers) are also listed under all of their child sites. HRSA concludes that its existing risk-based selection method is effective and efficient in selecting covered entities with the most contract pharmacy arrangements.

Recommendation 2

The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS, as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.

HHS Response

HHS concurs with GAO's recommendation.

- While HRSA recognizes the need for guidance, GAO's recommendation as currently stated does not account for the critical role that CMS would play in its successful implementation. Development of effective and comprehensive guidance would require that HRSA and CMS work closely together under the guidance of departmental leadership. In this regard, HRSA continues to hold calls with CMS and discuss concerns and strategize on effective ways to address the issue for both the Medicaid and 340B Program.

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.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

HHS Response
HHS concurs with GAO's recommendation.

- HRSA notes that this recommendation can only be accomplished after guidance has been issued as outlined in recommendation 2.
- While HRSA does not currently audit Medicaid managed care claims and has no policy on preventing duplicate discounts in this context, we encourage covered entities and manufacturers to work on strategies to ensure compliance with the duplicate discount prohibition. After reviewing our policy in this area, beginning April 1, 2018, HRSA now includes an area for improvement (AFI) in audits where Medicaid managed care claims are identified as potential risks. Further, HRSA has since updated its policy on April 1, 2018 to add that all entities with findings are required to provide information regarding their plan to implement any areas for improvement.

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.

HHS Response
HHS concurs with GAO's recommendation.

- The ability for HRSA to issue guidance is predicated on the challenges of issuing guidance versus regulations that are discussed above. HRSA supports the development of program policy and is working with the Administration to determine next steps.

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 on noncompliance.

HHS Response
HHS non-concurs with GAO's recommendation.

Now on p. 41.

- As indicated by the GAO in the draft report (page 35), beginning April 1, 2018, HRSA requires entities that are subject to target audits and re-audits 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 non-compliance.
- Covered entities must work in good faith with manufacturers to remedy any repayment owed after the entity determines the compliance. Covered entities and manufacturers have

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

access to the necessary data needed to resolve any repayment, which is a private matter between the two parties due to their established business relationship.

- HRSA notes that if this recommendation were implemented for all audits, it would create a significant burden for covered entities to comply with the additional documentation they would need to produce as part of the audit. In addition, the timeframe it would take HRSA to review GAO's recommended methodology for identifying the full scope of noncompliance and to close an audit would be significantly extended.
- HRSA has established an efficient audit process to ensure that if there is a compliance issue, particularly involving repayment to a manufacturer, covered entities are able to resolve the issue quickly and notify the manufacturer in order to work out repayments that may be owed in good faith. Additional requirements related to document submission will significantly delay the process and repayment to manufacturers due to program violations.

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' assessment of the full scope of noncompliance identified during an audit.

HHS Response

HHS non-concurs with GAO's recommendation.

- For all audits, HRSA requires covered entities to describe in detail their plan for corrective action. If during the course of review of the CAP concerns arise, HRSA would request additional documentation that would describe the steps taken to correct any noncompliance. As indicated by the GAO in the draft report (page 35), beginning April 1, 2018, HRSA took additional action to require evidence and documentation as outlined in the recommendation for entities that are subject to target audits and re-audits.
- Requiring all entities to providence evidence and documentation as outlined in the recommendation, would create a significant burden for covered entities to comply with the additional materials they would need to produce as part of the audit.
- In addition, the timeframe it would take HRSA to review GAO's recommended methodology for identifying the full scope of noncompliance and to close an audit would be extended. HRSA has established an efficient audit process to ensure that if there is a compliance issue, particularly involving repayment to a manufacturer, covered entities are able to resolve the issue quickly and notify the manufacturer in order to work out repayments that may be owed in good faith. Additional requirements related to document submission will delay the audit process significantly, thus delaying repayment to affected manufacturers due to program violations.

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.

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Now on p. 42.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: DRUG DISCOUNT PROGRAM: FEDERAL OVERSIGHT OF COMPLIANCE AT 340B CONTRACT PHARMACIES NEEDS IMPROVEMENT (GAO-18-480)

HHS Response
HHS concurs with GAO's recommendation.

- HRSA's ability to issue guidance is predicated on the challenges with issuing guidance versus regulations discussed above. HRSA supports the development of program policy and is working with the Administration to determine next steps.

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Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contact

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

Acknowledgments

In addition to the contact named above, Michelle Rosenberg (Assistant Director), N. Rotimi Adebonojo (Analyst in Charge), Jennie Apter, George Bogart, Amanda Cherrin, David Lichtenfeld and Dan Ries made key contributions to this report. Also contributing were Julianne Flowers and Vikki Porter.

United States Government Accountability Office

GAO

Report to Congressional Committees

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

GAO-11-836

September 2011

GAO Highlights

Accountability * Integrity * Reliability

Highlights of GAO-11-836, a report to congressional committees

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within in the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View GAO-11-836. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.

Contents

Abbreviations

ADAP	AIDS Drug Assistance Program
CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IVIG	intravenous immune globulin
PHSA	Public Health Service Act
PPACA	Patient Protection and Affordable Care Act
PSSC	Pharmacy Services Support Center
PVP	Prime Vendor Program

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 23, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Our nation's health care safety net provides services to low-income, uninsured, underinsured, and other individuals who experience barriers accessing care, regardless of their ability to pay. Certain types of providers within the safety net have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program.[1] The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),[2] requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.[3]

Covered entities include clinics and hospitals that provide general health care services, as well as those that serve patients with specific conditions or diseases, and are typically eligible for the program because they receive some type of federal support, such as a federal grant. According

[1]Outpatient drugs covered under the 340B program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, that can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. 42 U.S.C. §§ 256b(b)(2), 1396r-8(k)(2). When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

[2]42 U.S.C. § 256b.

[3]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. Medicaid programs vary from state to state.

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.[4] Covered entities' current spending on 340B drug purchases is estimated to be about $6 billion annually.

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 off the cost of drugs, according to HRSA. In addition, covered entities can generate 340B revenue.[5] For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the drugs.[6] As of July 2011, there were more than 16,500 covered entity sites

[4]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).

[5]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs.

[6]In 1996, HRSA issued a definition of a 340B patient that defines the situations under which covered entities can use drugs purchased at 340B prices for their patients. While income and insurance status do not dictate whether a patient is eligible under the program, certain patients, such as those who do not receive health care services consistent with the scope of a grant that made an entity eligible for the program or those whose only service from the covered entity is the dispensing of drugs, are prohibited from receiving drugs purchased at the 340B price. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

enrolled in the program—about double the number reported in 2001.[7] Because they must participate in the 340B program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from transferring 340B drugs to individuals who are not eligible patients of the entities.[8] Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued nondiscrimination guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to other, non-340B healthcare providers.[9] This includes not conditioning the sale of drugs to covered entities on restrictive conditions, such as requiring them to commit to minimum purchase amounts, which would discourage entities from participating in the program. However, stakeholders, including both covered entities and drug manufacturers, have raised questions about the extent to which 340B program requirements are followed and the extent to which HRSA ensures compliance. Further, because the 340B program has no requirements on how 340B revenue can be used,[10] stakeholders, such as drug manufacturers, have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program. Additionally, due to continued growth in the

[7]Data are the most recent available from HRSA's covered entity database and represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there are about 3,200 unique organizations currently participating in the program—the agency was unable to provide historical data on unique organizations for all entity types. Additionally, because a covered entity may enroll under any and all eligible grant types it receives, it is possible that certain unique organizations and eligible sites are reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[8]42 U.S.C. § 256b(a)(5)(B).

[9]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

[10]According to HRSA, while there are no 340B-specifc requirements, all covered entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements.

number of covered entities participating in the program, some stakeholders have raised questions about whether increased use of 340B discounts shifts a larger share of drug costs to others in the health care system.

The Patient Protection and Affordable Care Act (PPACA) amended the 340B program by expanding entity eligibility for the program to include additional types of hospitals.[11] PPACA also contained provisions to improve 340B program integrity, and included a provision explicitly prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, consistent with HRSA's nondiscrimination guidance.[12] The passage of PPACA has raised some questions for 340B stakeholders about the program. For example, although proponents of the explicit prohibition on manufacturers contend that it is necessary to prevent discrimination against covered entities, critics are concerned about how it could affect non-340B providers' access to drugs.[13] Additionally, PPACA extends health insurance coverage to more Americans, and some stakeholders, such as drug manufacturers, have questioned whether covered entities will need the discounts provided through the 340B program given this increased coverage.

PPACA directed us to address several questions related to the 340B program. In response to the mandate, we examined: (1) the extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program; (2) how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers; and (3) HRSA's oversight of the 340B program.

[11]Entities that became eligible for the 340B program through PPACA include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. 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.

[12]Pub. L. No, 111-148, § 7102(b).

[13]For this report, we consider providers as having access to a drug if they are able to obtain the amount necessary to meet the needs of their patients—for covered entities this includes being able to obtain the drug at the 340B price.

To examine the extent to which covered entities generate revenue through their participation in the 340B program, factors that affect their revenue generation, and how entities use the program, we conducted interviews with a judgmental sample of 29 covered entity organizations primarily selected to represent five covered entity types located in five states. We selected entity types based on factors, including high levels of participation in the 340B program and variation in organizational structure and the types of services provided. We selected states based on factors, including geographic variation and the percentage of uninsured in the state. Specifically, we interviewed 7 federally qualified health centers (FQHC),[14] 5 family planning clinics, 5 AIDS Drug Assistance Programs (ADAP), 5 hemophilia treatment centers, and 5 general acute care hospitals with a Medicare disproportionate share hospital (DSH) adjustment percentage of greater than 11.75 percent[15]—in this report we refer to these hospitals as DSH hospitals.[16] These entities were located in Illinois, Massachusetts, Tennessee, Texas, and Utah. We specifically selected Massachusetts to gain a better understanding of the potential effect of PPACA's health insurance reforms on the 340B program.[17] In addition to interviewing covered entities located in the five states, we conducted interviews with 2 additional DSH hospitals located in other states, because of questions raised in stakeholder interviews about how these hospitals were using the program. When possible, we collected

[14]FQHCs are urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations and have received a "Federally Qualified Health Center" designation from the Centers for Medicare & Medicaid Services (CMS).

[15]General acute care hospitals are eligible for the 340B program when they have a Medicare DSH adjustment percentage of greater than 11.75 percent and meet certain other requirements. Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. The Medicare DSH adjustment percentage is an additional Medicare payment to acute care hospitals paid under the inpatient prospective payment system—a Medicare reimbursement method based on a predetermined, fixed amount. A hospital's DSH adjustment percentage is generally based on its 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.

[16]While additional types of hospitals are eligible for the 340B program, we only interviewed DSH hospitals because the remaining hospital types had only recently started participating in the program.

[17]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

relevant documentation from covered entities. Although we selected covered entities to interview that represented a variety of entity types, not all covered entity types are represented. Further, our selection of covered entities was judgmental, and our sample is not generalizable. (See appendix I for more details on how we selected covered entities and appendix II for more information about the entity types eligible to participate in the 340B program.)

To examine how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers, we conducted interviews with 61 340B program stakeholders, including our judgmental sample of 29 covered entities, as well as 32 other program stakeholders representing a wide range of perspectives on the program.[18] Included were interviews with 6 drug manufacturers, selected based on factors such as having a large market share and producing drugs with reported challenges related to their distribution at 340B prices, and 6 organizations representing drug manufacturers and others involved in distributing drugs from manufacturers to providers. We also interviewed stakeholders representing providers, including 9 organizations representing covered entities, 2 organizations representing non-340B providers, and 5 organizations representing both covered entities and non-340B providers. Finally, we interviewed HRSA and the Centers for Medicare & Medicaid Services (CMS), as well as HRSA's 2 340B program contractors. (See appendix I for more details on interviewees and how we selected them.) Similar to our selection of covered entities, our selection of other program stakeholders was judgmental and, as such, responses are not generalizable. In addition, we reviewed relevant documentation from interviewees, and analyzed industry data as well as data from HRSA's covered entity database to determine the number of hospitals in the U.S. currently participating in the 340B program. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

To examine HRSA's oversight of the 340B program, we conducted interviews with the 61 program stakeholders discussed above and reviewed relevant documentation. We reviewed information from HRSA and other HHS agencies, including those that administer the grants that

[18]We conducted multiple interviews with certain organizations for a total of 65 interviews.

make entities eligible for the 340B program.[19] We also reviewed key laws, guidance, and relevant literature related to the program and to safety net providers. We analyzed data from HRSA's covered entity database to determine changes in 340B program participation among covered entity types since 2001. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

We conducted our performance audit from September 2010 through September 2011 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 was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives certain safety net providers discounts on outpatient drugs comparable to those made available to state Medicaid agencies.[20] HRSA, through its Office of Pharmacy Affairs, is responsible for administering and overseeing the 340B program,[21] which according to federal standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures include internal controls that provide reasonable assurance that an

[19]HHS agencies that administer the grants that make entities eligible for the 340B program include HRSA, Indian Health Services, Office of Population Affairs, and the Centers for Disease Control and Prevention. CMS calculates Medicare DSH adjustment percentages for hospitals.

[20]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).

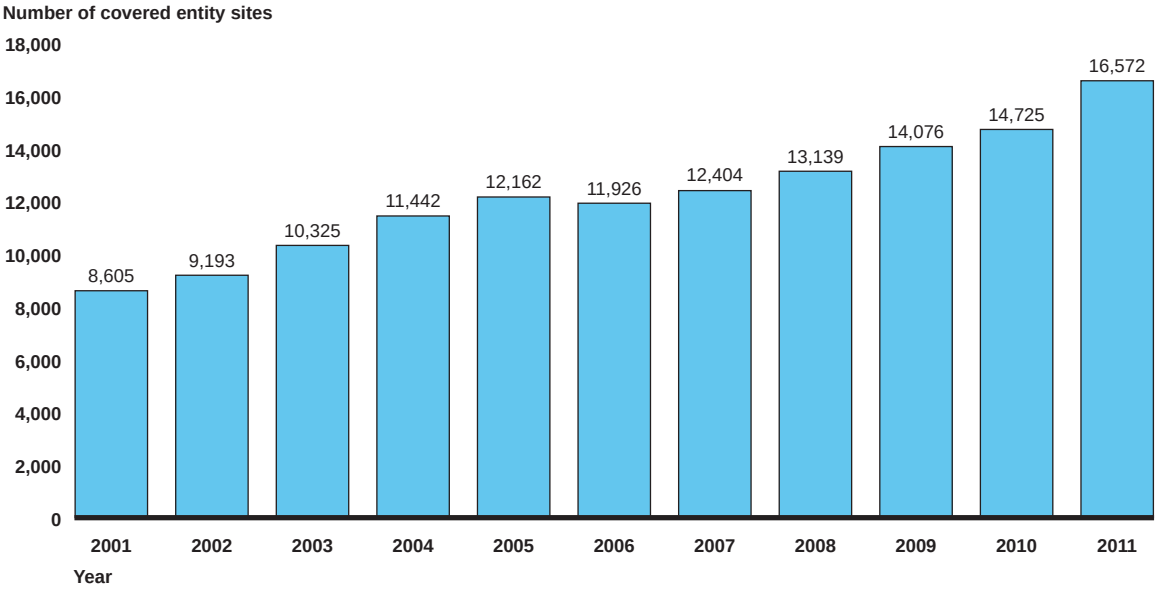
[21]The Pharmacy Services Support Center (PSSC) and the Prime Vendor Program (PVP) assist HRSA with the administration of the 340B program and are managed by contractors. The PSSC provides guidance and free technical assistance to covered entities and helps ensure that patients of covered entities receive comprehensive pharmacy services. The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price. Participation in the PVP is free and voluntary for covered entities.

agency has effective and efficient operations and that program participants are in compliance with applicable laws and regulations.[22]

Program Participants

Eligibility for the 340B program is defined in the PHSA. Entities generally become eligible by receiving one of 10 federal grants or by being one of six hospital types. (See appendix II for a complete list of covered entity types and their eligibility requirements.) To participate in the 340B program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include over 16,500 covered entity sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2001 to 2011



Source: GAO analysis of HRSA data.

[22]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Federal grantees are eligible for the 340B program by virtue of receiving certain federal grants administered by different agencies within HHS. Eligible grantees include clinics that offer primary and preventive care services, such as FQHCs,[23] family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Participating clinics may offer eligible services at one or multiple sites. They also include state-operated ADAPs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals.

Hospitals eligible for the 340B program include certain DSH hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. While DSH hospitals have been eligible for the program since its inception, children's hospitals became eligible in 2006, and the remaining hospital types became eligible through PPACA.[24]

Hospital eligibility for the 340B program has more elements than that of federal grantees, because unlike federal grantees, hospitals do not qualify for the program based on receipt of a federal grant. Rather, they 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; however, critical access hospitals are exempt from this requirement.[25] Additionally, all hospitals must be (1) owned or operated

[23]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[24]See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082. While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006) (amending 42 U.S.C. § 1396r-8(a)(5)(B)).

[25]To be eligible for the 340B program, rural referral centers and sole community hospitals must have a DSH adjustment percentage that is equal to or greater than 8 percent, and DSH, children's, and free-standing cancer hospitals must have a DSH adjustment percentage that is greater than 11.75 percent. Although children's and free-standing cancer hospitals do not receive payments under the Medicare inpatient prospective payment system, they must have a payer mix that would result in a DSH adjustment percentage of greater than 11.75 percent.

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,[26] 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. Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report.[27]

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B program and must participate if they want 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 and submit this agreement to HRSA.

Program Structure and Operation

Covered entities typically purchase and dispense 340B drugs through pharmacies and can structure their programs in different ways. Entities can have (1) an in-house pharmacy model, in which the pharmacy is housed within the covered entity, (2) a contract pharmacy model, in which the entity contracts with an outside pharmacy to dispense drugs on their behalf, or (3) both. Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to provide services. In March 2010, however, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.[28] Some covered entities use HRSA's Pharmacy Services Support Center (PSSC) or private companies that provide technical assistance, information

[26]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.

[27]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 180, 47884 (Sept. 19, 1994).

[28]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

technology, and other services to help develop, implement, and manage their 340B pharmacy program.

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 drug manufacturer may charge covered entities;[29] however, the provision establishing the 340B pricing formula indicates that manufacturers may sell a drug at a price that is lower than the ceiling price.[30] As such, covered entities may negotiate prices below the ceiling price. Manufacturers are responsible for calculating the 340B price on a quarterly basis. Occasionally the formula results in a negative price for a 340B drug.[31] In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

Key Program Requirements

Covered entities must follow certain program requirements as a condition of participating in the 340B program. For example, covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient. This definition was issued in 1996 and outlines three criteria which 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, from covered entities. (See table 1 for more information on HRSA's definition of a 340B patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

[29]In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers. 42 U.S.C. §§ 256b(b), 1396r-8(k).

[30]42 U.S.C.§ 256b(a)(10).

[31]When a drug's average manufacturer price increases more quickly than the rate of inflation, the government requires the manufacturer to pay an additional rebate amount. This may cause the drug's unit rebate amount to be greater than the drug's average manufacturer price, which would result in a negative 340B price.

Table 1: HRSA's Definition of a Patient Eligible for Discounted Drugs under the 340B Program

	Criteria for patient eligibility[a]
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.[b]
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 FQHC look-alike status has been provided.[c]

Source: GAO analysis of HRSA guidance.

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. 207, 55156 (Oct. 24, 1996).

[a]These criteria do not apply to ADAPs; rather, an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

[b]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.

[c]DSH hospitals are exempt from this requirement.

Covered entities also are prohibited from subjecting manufacturers to duplicate discounts whereby drugs prescribed to Medicaid patients are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. To avoid duplicate discounts, covered entities can either purchase drugs for Medicaid patients outside the 340B program, in which case the state Medicaid agency may claim the rebate, or they can use drugs purchased at 340B prices, in which case the agency may not claim the rebate. Covered entities that decide to use 340B drugs for Medicaid patients must notify HRSA so that it can coordinate with state Medicaid agencies for billing purposes. Further, certain covered entities—DSH hospitals, children's hospitals, and freestanding cancer hospitals—are prohibited from purchasing outpatient drugs through any group purchasing organization (GPO).[32] However, they may purchase drugs through the specified HRSA contractor, the Prime Vendor Program (PVP). Rural referral centers, sole community hospitals, and critical

[32]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

access hospitals participating in the 340B program are allowed to purchase outpatient drugs through any GPO.

Drug manufacturers also must follow certain 340B program requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price. In addition, 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 avenue 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 340B program.

340B Revenue Generated by Covered Entities Varied, but All Entities Reported That the Program Was Used to Support or Expand Access to Services

About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs—the costs of purchasing and dispensing a drug—and revenue generation depended on several factors. Regardless of the amount of 340B revenue generated or the savings realized through 340B discounts, covered entities generally reported using the 340B program to support or expand access to services.

About Half of Covered Entities Reported Generating 340B Revenue That Exceeded Drug-Related Costs, and Revenue Generated Depended on Several Factors

Thirteen of the 29 covered entities we interviewed reported that they generated revenue through the 340B program that exceeded drug-related costs.[33] Of the 16 remaining, 10 did not generate enough 340B revenue to cover all drug-related costs, and 6 covered entities were unable or did not report enough information for us to determine the extent to which they generated 340B revenue due, in part, to their inability to track 340B-specific financial information.

In general, 340B revenue—whether exceeding drug related costs or not—was generated through reimbursement received for drugs dispensed by 340B in-house or contract pharmacies, though several factors affected the extent to which the covered entities we interviewed generated revenue through the program:[34]

- **Third-party reimbursement rates**: Eighteen of the 29 covered entities we interviewed generated 340B revenue by receiving reimbursement from third-party payers and tracked revenue by payer source. Of the 18, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers.[35] However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers, including Medicare Part D plans, was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Of the 18 covered entities, most of those that used 340B drugs for Medicaid patients reported that state-determined Medicaid reimbursement rates for these drugs were generally lower, compared to private insurers and Medicare. For example, most reported that Medicaid reimbursement for a 340B drug was set at the price paid for the drug—the 340B price

[33]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs. When data provided by covered entities was used to determine revenue generation, the most recent year of reported data was used.

[34]Even though 6 covered entities were unable to report the amount of revenue they generated through the program, they were able to report what factors affected overall revenue generation.

[35]Medicare reimburses outpatient prescription drugs either through Medicare Part B or Part D. Part B covers drugs administered by physicians, such as chemotherapy drugs, and payment for those drugs is set by a fee schedule established quarterly by CMS. Part D sponsors are typically private insurers that contract with CMS to cover outpatient prescription drugs and negotiate reimbursement rates directly with health care providers.

or any lower price—plus a dispensing fee, the latter of which generally did not cover the costs of dispensing the drug.[36] This is typically referred to as reimbursement at actual acquisition cost, which reduces a covered entity's ability to generate revenue because the state, rather than the entity, benefits from any savings from purchasing drugs at the 340B price.[37] However, a few covered entities generated more 340B revenue through Medicaid than others because they had contractual agreements with their states to share 340B-related savings.[38] Covered entities in two of the five states included in our selection had such agreements. Finally, a majority of the 18 covered entities reported that revenue generated from uninsured patients was lower than that from all other payers.

- **ADAP status**: Factors that affected 340B revenue generation for the five ADAPs we interviewed were different than for other entity types, because unlike other covered entity types, ADAPs do not receive third-party reimbursement for drugs. Rather, ADAPs serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals who, for example, are uninsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs. ADAPs can choose to cover costs of drugs by either paying for the drugs directly or by assisting patients with the costs associated with health insurance, including payments for premiums and co-payments or deductibles. When ADAPs purchase drugs directly, they realize 340B savings on drugs—either at the point of purchase or after the fact through manufacturer rebates—but do not generate revenue through the program. When ADAPs assist with patients' health insurance by paying for co-payments or

[36]A dispensing fee is typically a set dollar amount per prescription that covers the overhead costs of dispensing a drug, such as pharmacy staff time.

[37]State Medicaid agencies may reimburse entities at actual acquisition cost, because when entities decide to use drugs purchased at 340B prices for Medicaid patients, the state can no longer claim Medicaid rebates for those drugs.

[38]These contractual agreements are commonly referred to as shared savings agreements. Shared savings agreements provide covered entities reimbursement above actual acquisition cost, for example, by paying a higher dispensing fee to covered entities than the fee paid to other providers. According to the HHS Office of Inspector General, states may be interested in shared savings agreements with covered entities because 340B prices can be considerably lower than states' standard Medicaid reimbursement rates and entering into such agreements could encourage entities to use 340B drugs for Medicaid patients while still saving money for states.

deductibles on a drug, they sometimes generate revenue by collecting the rebates representing the full 340B discount on a drug for which they may have only paid a portion of the price. Three of the five ADAPs we interviewed reported generating revenue this way.

- **Ability to leverage resources to access the lowest drug prices**: Some of the 29 covered entities we interviewed reported leveraging resources, such as through their larger parent organizations or the PVP, to access drugs at prices below the 340B ceiling price, potentially increasing the difference between the price paid for the drug and the reimbursement received. In addition, some covered entities said they had access to sophisticated information technology—for example by contracting with private companies—or had more staff to help ensure that they were obtaining the lowest priced drugs.

As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid,[39] which may affect the extent to which they generate 340B revenue. One covered entity located in Massachusetts reported that after the state implemented universal health care, while they received more revenue from reimbursement for low-income patients that gained private insurance, these patients often could not afford associated co-payments or deductibles, and the entity covered these costs.[40] In addition, according to one ADAP we interviewed, as more individuals gain private insurance, the ADAP may increasingly choose to pay for health insurance for patients rather than paying for patients' drugs directly. This may enable it to generate revenue through the 340B program if it can claim more rebates for drugs for the newly insured patients. According to some covered entities, the impact of serving more Medicaid patients may depend on the Medicaid reimbursement rate that entities receive. For example, patients that gain Medicaid coverage may begin to seek services from covered entities, and for those entities that lose money on Medicaid patients, this may decrease their ability to generate 340B revenue. Conversely, for covered entities that have contractual agreements to share 340B-related

[39]PPACA contains provisions to expand private health insurance and Medicaid coverage to more Americans. See, e.g., Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271.

[40]HRSA officials told us that this statement is consistent with their belief that low-income patients will continue to require assistance with health care costs after gaining insurance.

savings with their states, the increased Medicaid population may increase their ability to generate 340B revenue.

Covered Entities Reported Using the 340B Program to Support or Expand Access to Services

Regardless of the amount of revenue generated through the program, all of the 29 covered entities we interviewed reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program. For example, some covered entities reported that they used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services. Further, one covered entity reported that without 340B revenue or the savings on drugs through its participation in the program, it would be unable to offer all the services it provides—both pharmaceutical and clinical—and another reported that it would have to close its outpatient pharmacy without the program. In addition to maintaining services, some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs.

In addition, the 13 covered entities that generated 340B revenue that exceeded drug-related costs were able to use this revenue to serve more patients and to provide services that they might not have otherwise provided, including additional service locations, patient education programs, and case management, which is also consistent with the purpose of program. One covered entity, for example, reported that it used the revenue generated through the 340B program to provide additional service delivery sites in other parts of the state, which eliminated the need for some patients to travel more than 60 miles to receive services. A few covered entities reported using 340B revenue to support patient and family education programs, such as those where pharmacists provide education on drug interactions. Additionally, one covered entity reported using 340B program revenue to fund a case management program that did not generate any revenue on its own;[41] some services provided through this program included arranging

[41]Case management services facilitate access to appropriate health care, and are not typically reimbursed by payers.

transportation for patients to receive clinical services, coordinating necessary specialty care, and providing translation services.

Even though the uses of revenue generated through the 340B program were for similar purposes, some covered entities relied on the program more than others. For example, one FQHC reported that 340B revenue accounted for approximately 5 percent of its total budget, and was used to provide additional services within the organization. However, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations.[42]

Manufacturers' Distribution of Drugs at 340B Prices Generally Did Not Affect Providers' Access to Drugs Except in Two Situations

According to stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. For example, 36 of the 61 program stakeholders we interviewed did not report any effect on covered entities' or non-340B providers' access to drugs related to manufacturers' distribution of drugs at 340B prices. These stakeholders represented a wide range of perspectives on the 340B program, including those representing manufacturers, covered entities, and non-340B providers.

The remaining 25 program stakeholders—also representing a wide range of perspectives on the 340B program—reported that manufacturers' distribution of drugs at 340B prices affected providers' access to drugs primarily in two situations.[43] The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply

[42]The organizational structure of hemophilia treatment centers we interviewed varied, and those that operated stand-alone programs were more dependent on 340B revenue than those that were integrated into hospitals.

[43]While stakeholders consistently reported two situations in which manufacturers' distribution of drugs at 340B prices affected providers' access to these drugs, some, such as covered entities, reported other situations that had effects on access, but it was not clear that the other situations were related to manufacturers' distribution of drugs at 340B prices.

of which is inherently limited;[44] and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities. Both situations relate to the restricted distribution of drugs, which may occur during shortages or when shortages are anticipated.

Stakeholders reported that manufacturers' restricted distribution of IVIG at 340B prices resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices in order to meet their demand for the drug.[45] Manufacturers restrict the distribution of IVIG on an ongoing basis, because it is susceptible to shortages. Stakeholders, including five of the seven DSH hospitals we interviewed, reported that because of the restricted distribution of IVIG at 340B prices, 340B hospitals often must purchase some IVIG at higher, non-340B prices to meet their patients' needs. For example, DSH hospitals reported that when they were unable to access IVIG at 340B prices, additional IVIG was available for purchase at higher, non-340B prices directly from manufacturers, from specialty pharmacies,[46] or from GPOs.[47] Moreover, one DSH hospital reported that it had to purchase about one-third of the IVIG it needed at non-340B

[44]IVIG is primarily used to treat patients with immune deficiency diseases, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Factors inherent to the development and distribution of IVIG limit its supply making it susceptible to shortages, including that IVIG is made from human plasma, which is an inherently scarce resource, and that IVIG takes between seven and 12 months to manufacture. Additionally, only a few manufacturers develop and distribute these drugs in the United States.

[45]Hospitals are the primary purchaser of IVIG in the United States.

[46]Specialty pharmacies handle and distribute drugs that, among other things, have a high acquisition cost and require special handling practices.

[47]In general, 340B hospitals are prohibited from purchasing outpatient drugs through GPOs. While no DSH hospital we interviewed reported purchasing IVIG through GPOs, GPOs we interviewed told us that 340B hospitals have purchased IVIG through this avenue when they are unable to access it at the 340B price. During a December 2005 congressional hearing on the 340B program, an organization representing 340B hospitals argued that in situations when hospitals are unable to purchase IVIG at 340B prices, they are faced with either violating federal law by purchasing IVIG through GPOs, buying IVIG at cost-prohibitive retail prices, or denying their patients access to these drugs. See "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency," Hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, December 15, 2005. While 340B hospitals can receive the benefits of group purchasing through the PVP, the PVP does not have any contracts for IVIG.

prices—paying about $20,000 to $25,000 more per month than what it would have paid if it could have purchased it at 340B prices.

Although manufacturers' distribution of IVIG at 340B prices may not meet 340B hospitals' demand, some stakeholders, such as drug manufacturers, reported that changes in the amount of IVIG allocated for sale at 340B prices could negatively affect non-340B providers' access to these drugs. For example, one IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of the drug purchased by providers in 2004—allocating 95 percent of its projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B price.[48] This manufacturer stated that its distribution was fair, and that changing distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs. However, HRSA officials told us that the allocation of IVIG in this way is not sufficient or fair. Nearly a third of the nation's hospitals currently participate in the 340B program, and one large GPO we interviewed reported that 340B hospitals tended to be the bigger hospitals in the company's membership base.[49] Thus, if other manufacturers similarly restrict the distribution of IVIG at 340B prices, it is unlikely that covered entities' demands will be met at the 340B price.[50]

Stakeholders reported that manufacturers' distribution of drugs at 340B prices also affected providers' access to drugs when the 340B prices dropped significantly. In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs. In other cases

[48]This manufacturer reported that it based its allocation of IVIG on 2004 purchasing patterns, because this was the last period before demand exceeded supply for the product and an allocation system became necessary. While data on the number of hospitals participating in the 340B program in 2004 are not available, the number of 340B hospitals has grown from 591 in 2005 to 1,673 in 2011.

[49]While certain 340B hospitals are prohibited from purchasing outpatient drugs through GPOs, all 340B hospitals can purchase inpatient drugs through GPOs.

[50]The Department of Justice is examining the IVIG market in the United States, in part, due to concerns about the distribution of these drugs at 340B prices.

when the 340B prices dropped, manufacturers restricted the distribution of those drugs at 340B prices to ensure that all providers had equitable access. For example, one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA's penny pricing policy, it received an order from a covered entity that exceeded the manufacturer's current national supply by 50 percent. In response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns.

HRSA's Oversight of the 340B Program Is Inadequate

HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance. Changes in the settings where the program is used may heighten concerns about the inadequacy of HRSA's oversight, and HRSA's plans for improving oversight are uncertain.

HRSA's Oversight Is Inadequate to Ensure Participants' Compliance with 340B Program Requirements

HRSA's oversight of the 340B program is inadequate because it primarily relies on covered entities' and manufacturers' self-policing—that is, participants ensuring their own compliance with program requirements. Upon enrollment, HRSA requires both covered entities and manufacturers to certify that they will comply with applicable 340B program requirements and any accompanying agency guidance. As part of this certification, agency officials told us that they expect participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and inform HRSA if violations occur. For example, covered entities must develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as inventory tracking systems that separately purchase and dispense 340B drugs, and manufacturers must ensure that they properly calculate the 340B price of their drugs. In both cases, program participants must keep auditable records that can show that they have complied with program requirements and produce that documentation if requested by HRSA.

HRSA officials told us that covered entities and manufacturers can also monitor each other's compliance with program requirements, but in practice, participants may face limitations to doing so. For example, two covered entities we interviewed reported that it is difficult to determine whether they have been charged correctly for drugs because manufacturers' calculations of 340B prices are not transparent—namely,

there is no centralized list of 340B prices.[51] An organization representing covered entities also told us that its members had reported this difficulty. Similarly, three drug manufacturers we interviewed reported that, although they sometimes have suspected covered entities of diverting 340B drugs, it is difficult to prove diversion took place. An organization representing some manufacturers explained that, although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.

HRSA's guidance on key program requirements often lacks 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 may be interpreted in ways that are inconsistent with its intent.[52] For example, HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. However, one of these stakeholders representing covered entities also noted that, in order to ensure compliance, some entities may adhere to a narrow interpretation of the guidance and thus, limit the benefit of the program for their organization. The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly.

[51]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

[52]In May 2011, HRSA published its first proposed regulation on the 340B program, Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 76 Fed. Reg. 29, 183 (proposed May 20, 2011). Until this point the agency had provided program guidance through notices published in the Federal Register, which were typically finalized after a notice and comment period, as well as more informal guidance on its web site.

For example, HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However, HRSA does not define "other arrangements," and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.

In addition, HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program.[53] Rather, the agency bases eligibility for these hospitals on the application of broad statutory requirements that they are either formally delegated governmental powers by a unit of a state or local government or have a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. HRSA has stated that the determination of whether hospitals meet the first requirement is evaluated by the agency on a case-by-case basis. For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.[54] Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.

[53]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.

[54]HRSA officials told us that contracts are selectively reviewed if further clarification is necessary.

Moreover, HRSA's nondiscrimination guidance is not specific in the practices that manufacturers should follow to ensure that drugs are equitably distributed to covered entities and non-340B providers when distribution is restricted. Some stakeholders we interviewed, such as covered entities, have raised concerns about the way IVIG manufacturers have interpreted and complied with the guidance in these cases, because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. Additionally, given current guidance, one stakeholder reported that manufacturers can offer a certain amount of drugs at 340B prices, and while the distribution may not be equitable, still contend that they are complying with the guidance. Although PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, officials told us they do not have plans to provide any additional specificity to the nondiscrimination guidance.

Finally, in the case of HRSA's penny pricing policy, agency officials told us that it is well understood by 340B stakeholders and manufacturers we interviewed were generally aware of the policy. However, the agency has never formalized guidance in writing and there have been documented cases of manufacturers charging covered entities more than a penny for drugs when the policy should have been in effect.[55]

Beyond relying on participants' self-policing, HRSA engages in few activities to oversee the 340B program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, HRSA officials told us that the agency verifies eligibility for the 340B program at enrollment, but does not periodically recertify eligibility

[55]In a 2006 report, the HHS Office of Inspector General found that manufacturers did not always follow HRSA's penny pricing policy. Both in this report and in a 2005 report, the Office of Inspector General recommended that HRSA formalize its penny pricing policy in writing. See HHS Office of Inspector General, *Review of 340B Prices*, OEI-05-02 -00073 (Washington, D.C.: 2006); and HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

for all covered entity types.[56] As a result, there is the potential for ineligible entities to remain enrolled in the program. In addition, HRSA officials told us that they do not require a review of the procedures participants put in place to ensure compliance, and, although the agency has the authority to conduct audits of program participants to determine whether violations have occurred, it has never done so.[57] For example, officials said that they do not verify whether covered entities have systems in place to prevent diversion. Also, while HRSA encourages manufacturers to work with the agency to develop processes for restricting the distribution of drugs that are equitable to covered entities and non-340B providers, the agency only reviews manufacturers' plans to restrict access to drugs at 340B prices if a manufacturer contacts HRSA or concerns with a plan are brought to the agency's attention. Similarly, although HRSA calculates 340B prices separately from manufacturers, officials told us that, at this time, the agency does not use these calculations to verify the price that manufacturers charge covered entities, unless an entity reports a specific pricing concern.[58]

HRSA's oversight activities are further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur. If covered entities and manufacturers are not able to resolve conflicts on their own, HRSA has had an informal dispute resolution process in place since 1996 through which program participants can request that HRSA

[56]HRSA currently recertifies eligibility for sexually transmitted diseases, tuberculosis, and Ryan White grantees, consistent with requirements under the PHSA. In addition, HRSA verifies the grantee status of FQHCs as well as hospitals' DSH percentages on a quarterly basis. As resources allowed, HRSA has also periodically recertified 340B eligibility for other entity types. For example, HRSA recertified eligibility for family planning clinics in 2010. PPACA added a provision requiring HRSA to conduct annual recertification of eligibility for all covered entity types. HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[57]HRSA officials told us that while they do not conduct audits, if a potential violation of program requirements is brought to their attention, they will refer the matter to the HHS Office of Inspector General. Officials said that they have made two such referrals in the past year related to the diversion of 340B drugs.

[58]HRSA previously operated a voluntary pilot program with manufacturers to improve the integrity of 340B pricing calculations. Twelve manufacturers participated in the program, which was discontinued in March 2008 due to concerns regarding the confidentiality of drug pricing data and a lack of funding to run the program.

review evidence of a suspected violation and the agency then decides whether to initiate the process. However, despite reports by program participants about suspected violations they were unable to resolve on their own, HRSA officials told us that they have only initiated the dispute resolution process twice since its inception.[59] Additionally, HRSA has not issued regulations implementing monetary penalties for non-compliance established by PPACA, and HRSA has rarely utilized the sanctions that existed prior to PPACA. For example, participants found to be in violation of 340B program requirements face termination from the program. Yet according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturer has ever been terminated for this reason.[60] Covered entities also are expected to pay back manufacturers for discounts received while out of compliance, and manufacturers are expected to pay back covered entities for overcharges. However, HRSA has not enforced these expectations and officials were unable to tell us the extent to which repayments have occurred.

Because of HRSA's reliance on self-policing to oversee the 340B program as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk. As a result, covered entities may be inappropriately

[59]For example, a covered entity we interviewed said that it suspected certain drug manufacturers of implementing strategies to avoid offering drugs at correct 340B prices, but because of the lack of transparency in how 340B prices are calculated, could not determine this on its own. According to the entity, when it contacted HRSA about these strategies, agency officials said that they did not have the resources to help. However, HRSA officials told us that they were unaware of any instances where the agency has not helped a covered entity under these circumstances. Officials from one manufacturer reported that it provided HRSA with evidence that a covered entity had engaged in multiple instances of diversion, and after attempting to resolve the instances with the entity on its own, requested a hearing through the dispute resolution process in January of 2010. HRSA officials told us that the agency dismissed the manufacturer's request to initiate the process, because the covered entity disputed the manufacturer's claim that it had attempted to resolve the issue on its own, and that the agency is currently considering the manufacturer's appeal of this dismissal.

[60]In a 2005 report on the 340B program, the HHS Office of Inspector General noted that terminating a manufacturer from the 340B program also means that the manufacturer would be terminated from the Medicaid program, making it a difficult sanction to put into practice, given the effects on access to medications for Medicaid beneficiaries. See HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system. Additionally, manufacturers may be charging covered entities more than the 340B price for drugs, which would limit the benefit of the program for these entities.

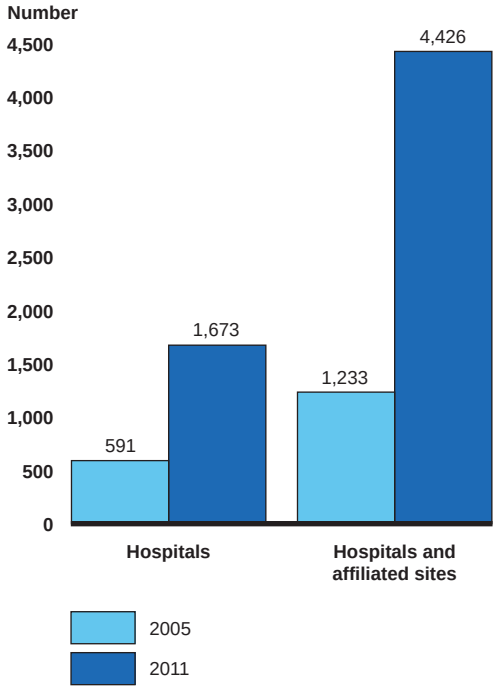
Changes in the Settings Where the 340B Program Is Used May Heighten Concerns about HRSA's Inadequate Oversight

Over time, the settings where the 340B program is used have shifted to more contract pharmacies and hospitals than in the past. According to HRSA officials, the number of covered entities using contract pharmacies has grown rapidly since its new multiple contract pharmacy guidance was issued in March 2010—as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.[61] Hospitals' participation in the 340B program has also grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005 (see fig. 2).[62] Further, although participation in the 340B program has increased among other covered entity types over time, hospitals' participation in the 340B program has grown faster than that of federal grantees. In 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

[61]HRSA was unable to provide the precise rate of growth of contract pharmacies within the 340B program due to data limitations. Specifically, HRSA currently only tracks contract pharmacy arrangements and is working to develop the ability to capture individual contract pharmacies. Data on the number of contract pharmacy arrangements are the most recent available from HRSA's covered entity database.

[62]One reason for hospital growth could be that more hospitals may have become eligible as a result of state-level Medicaid expansions in recent years. The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.

Figure 2: 340B Program Participation among Hospitals and Their Affiliated Sites, 2005 and 2011



Source: GAO analysis of HRSA data.

Note: 2005 was the earliest year data were reliable for hospitals without their affiliated sites.

Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients.[63]

[63]Some covered entities have in-house pharmacies that also serve as retail pharmacies for the broader community. However, among the covered entities we interviewed, we found that this was not often the case.

Also, for a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA's nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases.

The increasing number of hospitals participating in the 340B program has raised other concerns for some stakeholders we interviewed, such as drug manufacturers, including whether all of these hospitals are in need of a discount drug program. Nearly a third of all hospitals in the U.S. currently participate in the 340B program, and HRSA estimates that more may be eligible.[64] The number of hospitals eligible to participate may increase due to PPACA's Medicaid expansion, because the number of Medicaid patients served by a hospital affects its DSH adjustment percentage—one factor that determines hospital eligibility. Further, one organization we interviewed questioned whether the DSH adjustment percentage is the best measure to determine hospitals' eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.[65] The DSH hospitals we interviewed reported a wide range of payer mixes—with the percentage of Medicaid and uninsured patients ranging from about 15 percent of total patient volume for one hospital to about 85 percent for another. However, payer mix may not be the only factor to consider when identifying hospitals that provide care to the

[64]According to HRSA, over 400 additional DSH hospitals may be eligible for the 340B program based on their DSH adjustment percentage. This estimate does not include the additional hospital types made eligible for the program through PPACA.

[65]See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: 2007), pp.78-79.

medically underserved and are part of the health care safety net. There is no established definition of a safety net hospital, and some researchers have argued that it should include factors other than payer mix, for example the disproportionate provision of critical services, that are either too expensive or unprofitable for other hospitals to provide, such as emergency room or trauma care.[66]

HRSA's Plans to Improve Oversight of the 340B Program Are Uncertain and May Not Address All Areas of Concern

While PPACA's 340B program integrity provisions address many of the deficiencies in HRSA's current approach to oversight, the agency has taken few steps to implement these provisions. PPACA requires HRSA to increase oversight of both covered entities and manufacturers, and outlines specific steps for HRSA to take in accomplishing this goal. (See table 2 for the 340B program integrity provisions included in PPACA.) However, according to officials, the agency does not have adequate funding to implement the integrity provisions. Officials also noted that once funding is secured, it could take several years to develop the systems and regulatory structure necessary to implement them.

[66]See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," *PM-1387-ASPE* (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

Table 2: Key 340B Program Integrity Provisions Included in PPACA

Program participant	Requirements for HRSA	Required start date	Implementation status as of August 2011
Covered entities	Conduct annual recertification of eligibility for all covered entity types.	Not specified[a]	Developing implementation plan[b]
	Develop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount.	Not specified[a]	Not started
	Establish a standard identification system for all covered entities by which each covered entity site can be identified for the purposes of ordering, purchasing, and delivery of 340B drugs.	Not specified[a]	Not started
	Impose certain sanctions on covered entities that knowingly and intentionally divert 340B drugs, by one or more of the following: • requiring a covered entity to pay manufacturers interest on the discounts they received for those drugs; • if the violation was also systematic and egregious, terminating the covered entity from the program and prohibiting re-enrollment for a period of time; and • referral to federal authorities.	Not specified[a]	Not started
Manufacturers	Improve mechanisms to ensure manufacturers charge the correct 340B prices on drugs, including: • making a centralized list of HRSA-verified 340B prices available to covered entities, • conducting selective audits of manufacturers, and • establishing procedures by which manufacturers repay covered entities for overcharges.	Not specified[a]	Not started
	Impose civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the 340B price.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking
Both	Develop a formal dispute resolution process, including: • establishing procedures for covered entities to obtain information from manufacturers,[c] and • requiring manufactures to audit covered entities prior to submitting a request to initiate the dispute resolution process.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking

Source: GAO analysis of Pub. L. No. 111-148, § 7102, 124 Stat. 119, 823 and interviews with HRSA officials.

[a]PPACA provides that these activities are to be conducted from amounts appropriated under a new authorization of appropriations. As of August 2011, no such appropriations have occurred.

[b]HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[c]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

Independent of the provisions in PPACA, HRSA also has recently developed guidance to further specify the definition of a 340B patient. While the Office of Management and Budget completed its review of this definition in April 2011, as of August 2011, HRSA had not yet released it for stakeholder comment. In 2007, HRSA also proposed updating this guidance, but it was never finalized.[67]

Even if HRSA implements PPACA's provisions and updates its definition of a patient, these steps may not be sufficient to address all areas of concern. For example, PPACA specifically requires HRSA to conduct selective audits of manufacturers, but it did not establish the same requirement for audits of covered entities. As such, the effectiveness of HRSA's oversight of covered entities will, in part, be dependent on what additional steps the agency takes to ensure program integrity. Similarly, if in implementing PPACA's provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, HRSA does not add specificity to the existing nondiscrimination guidance, it may be inadequate to ensure that all providers are able to equitably access drugs, particularly when manufacturers restrict the distribution of drugs at 340B prices. Also, as part of its 2007 proposed guidance on the definition of a patient, HRSA requested stakeholder comment on the elements that should be required in private, nonprofit hospitals' contracts with state or local governments as well as the different situations in which hospitals that are not publicly owned or operated should be formally granted government powers. However, HRSA officials told us that they have not issued additional guidance on these issues, and that they are not addressed in the clarifying guidance on the definition of a patient currently awaiting agency approval.

Conclusions

The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on

[67]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance. With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place. For covered entities, this may be particularly true in settings where there is heightened concern about the opportunities for the diversion of 340B drugs.

PPACA outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis, which would help ensure entities that lose eligibility for the program do not remain enrolled. Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.

However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized. Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against

covered entities in the sale of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance. Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future.

Also, current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage. Even though the PHSA establishes additional eligibility requirements for hospitals that are not publicly owned or operated, these requirements are broad, and HRSA has not issued more specific guidance to implement them. We found that nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA. As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted. While HRSA officials reported that the agency does not have the resources to implement the PPACA provisions or otherwise increase oversight of the 340B program, limited resources could be prioritized to address areas of greatest risk to the program.

Recommendations for Executive Action

PPACA contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following four actions to strengthen oversight:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B 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; and

- 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.

Agency Comments and Our Evaluation

In commenting on a draft of this report, HHS stated that it agreed with our recommendations. HHS also had additional comments on several content areas of the report, and we made changes as appropriate to address these comments. (HHS' comments are reprinted in appendix III.) Finally, HHS provided technical comments, which we incorporated as appropriate.

HHS stated that HRSA would continue to work on 340B program integrity efforts and prioritize these efforts based on available funding. HHS also outlined steps that HRSA plans to take in response to each of our recommendations. While we appreciate HHS' commitment to improving oversight of the 340B program, we are concerned that the steps are not sufficient to ensure adequate oversight.

With regard to our first recommendation that HRSA conduct selective audits of covered entities to deter potential diversion, HHS stated that HRSA will continue working with manufacturers to identify and address potential diversion and implement a plan to better educate covered entities about diversion. However, HHS did not state that HRSA will conduct its own audits of covered entities and we reiterate the importance of the agency doing so as part of its ongoing oversight responsibilities.

With regard to our second recommendation that HRSA finalize new, more specific guidance on the definition of a 340B patient, HHS stated that HRSA will review the draft of proposed guidance to update the definition and revise this guidance in light of changes in PPACA. While we agree that it may be important for HRSA to consider the impact of PPACA on the definition, given that PPACA became law more than a year ago, and the potential for broad interpretations of current guidance, we encourage HRSA to complete its review in a timely fashion.

With regard to our third recommendation, that HRSA further specify its non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices, HHS stated that HRSA will: implement a plan to specify existing policy regarding 340B non-discrimination and drug distribution; provide clearer guidance to manufacturers for working with HRSA and develop specific allocation

plans where needed; and continue to work with the Department of Justice when fair, voluntary allocation plans are not developed. However, we are concerned that these steps do not require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices. Without taking this step, HRSA may not know when manufacturers are inequitably distributing drugs to covered entities and non-340B providers.

With regard to our fourth recommendation that HRSA 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, HHS stated that HRSA will implement a plan to better educate covered entities on existing criteria for hospital participation in the program and initiate a phased approach to recertifying eligibility for all participating covered entities. Here, we are concerned that these steps do not include further specification of eligibility criteria for hospitals that are not publicly owned or operated, because we determined that additional specification of statutory requirements was needed to ensure that the 340B program is appropriately targeted.

We are sending copies of this report to the Secretary of HHS and appropriate congressional committees. In addition, the report is available at no charge on the GAO web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Debra A. Draper
Director, Health Care

Appendix I: Selection of Interviews with Program Stakeholders

Type of stakeholder	Number of stakeholders interviewed	Interview details

Covered entities	29	27 were selected to take into account certain criteria:
		• Entity Type:
		  • We selected five types of covered entities and specifically interviewed: 7 federally qualified health centers (FQHC), 5 disproportionate share hospital (DSH) hospitals, 5 hemophilia treatment centers, 5 family planning clinics, and 5 AIDS Drug Assistance Programs (ADAP). (See appendix II for a list of all entities eligible to participate in the program.)
		  • We picked these types based on:
		  • variation in operational structure,
		  • variation in services and drugs provided,
		  • high levels of 340B participation,
		  • experience with the program, and
		  • potential difficulty accessing drugs at 340B prices.
		• Location:
		  • We selected entities in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah.
		  • States were selected based on variation in a number of factors, including: geography, percent of uninsured individuals, and Medicaid reimbursement policies.[a]
		  • We included Massachusetts to gain a better understanding of the potential effect of the Patient Protection and Affordable Care Act (PPACA) health insurance reforms on the 340B program.[b]
		• We used information provided by trade organizations representing covered entities to help select individual covered entities to interview.
		2 additional DSH hospitals were selected based on concerns raised in stakeholder interviews about how these entities were using the program.

Drug manufacturers	6	Selected based on market share and those that produce drugs with reported challenges related to their distribution at 340B prices.
Organizations representing drug manufacturers and others involved in drug distribution	6	Includes 4 manufacturer trade organizations, 1 distributor, and 1 pharmacy benefits manager.[c]

Type of stakeholder	Number of stakeholders interviewed	Interview details
Organizations representing providers	16	Includes organizations representing providers, including covered entities and non-340B providers: • 9 organizations that represent covered entities, including 6 trade organizations and 3 private companies that provide services and information technology to help covered entities establish and manage their 340B programs. • 2 organizations representing non-340B providers, including 1 trade organization and 1 non-340B provider. • 5 organizations that represent both covered entities and non-340B providers, including 3 trade organizations and 2 group purchasing organizations (GPO).[d]
Federal agencies and contractors	4	HRSA, the contractors that help administer the 340B program, and the Centers for Medicare & Medicaid Services.
Total	**61**	

Source: GAO.

[a]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

[b]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

[c]Distributors manage the sale of drugs to purchasers on behalf of manufacturers. Pharmacy benefit managers administer the prescription drug benefits of health insurance plans on behalf of plan sponsors.

[d]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

Appendix II: Select Information on Entities Eligible to Participate in the 340B Program

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Federal Grantees					
Federally-qualified health center (FQHC)[b,c]	Receives a section 330 grant under the Public Health Service Act (PHSA) (42 U.S.C. § 254b); meets the requirements to receive such a grant; or is an outpatient health program or facility operated by certain tribal or urban Indian organizations	Urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations.	1992[d]	4,826	Health Resources and Services Administration (HRSA)
Urban Indian organizations[e]	Receives funds under title V of the Indian Health Care Improvement Act (25 U.S.C. §§1651 et seq.)	Provide a variety of health programs to eligible individuals.	1992[d]	26	Indian Health Service
Family planning clinics (Title X)	Receives a grant or contract under Section 1001 PHSA (42 U.S.C. § 300)	Provide comprehensive family planning services.	1992[d]	3,868	Office of Population Affairs
Sexually transmitted diseases grantee	Receives funds under Section 318 of the PHSA (42 U.S.C. § 247c) and is certified by the Secretary of HHS	Provide screening and treatment for sexually transmitted diseases.	1992[d]	1,472	Centers for Disease Control and Prevention
Tuberculosis grantee	Receives funds under Section 317E of the PHSA (42 U.S.C. § 247b-6) and is certified by the Secretary of HHS	Provide treatment for tuberculosis.	1992[d]	1,221	Centers for Disease Control and Prevention
Native Hawaiian Health Centers	Receives funds under the Native Hawaiian Health Care Act of 1988 (42 U.S.C. §§ 11701 et seq.)	Provide comprehensive health promotion and disease prevention services to Native Hawaiians.	1992[d]	11	HRSA
State-operated Ryan White AIDS Drug Assistance Program (ADAP)	Receives financial assistance under title XXVI of the PHSA (42 U.S.C. §§ 300ff-11 et seq.)	Serve as a “payer of last resort” to cover the cost of providing HIV-related medications to low-income individuals who are uninsured or underinsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs.	1992[d]	90[f]	HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Other Ryan White grantees	Receives a grant under Part C of title XXVI of the PHSA or non-governmental grantees that receive any financial assistance under title XXVI of the PHSA if certified by the Secretary of HHS	Provide primary care and support services to individuals with HIV or AIDS.	1992[d]	520	HRSA
Hemophilia treatment centers	Receives a grant under section 501(a)(2) of the Social Security Act (42 U.S.C § 701(a)(2))	Provide medical care to individuals with hemophilia.	1992[d]	99	HRSA
Black lung clinics	Receives funds under Section 427(a) of the Black Lung Benefits Act (30 U.S.C. § 937(a))	Provide medical treatment to individuals disabled from pneumoconiosis (black lung) as a result of their employment at U.S. coal mines.	1992[d]	13	HRSA
Hospitals					
Disproportionate share hospitals (DSH)	DSH as defined under Section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)) with a DSH adjustment percentage greater than 11.75[g]	General acute care hospitals paid under the Medicare inpatient prospective payment system.	1992[d]	3,061	Centers for Medicare & Medicaid Services (CMS)
Children's hospitals	Children's hospital as described under Section 1886 (d)(1)(B)(iii) of the Social Security Act with a DSH adjustment percentage greater than 11.75[g]	Primarily provide services to individuals under 18 years of age.	2006[h]	147	CMS
Critical access hospitals	Critical access hospital as determined under Section 1820(c)(2) of the Social Security Act (42 U.S.C. § 1395i-4(c)(2)) (no DSH requirement)[g]	Located in rural areas, provide 24-hour emergency care services, and have no more than 25 inpatient beds.	2010[i]	941	CMS and HRSA
Sole Community Hospitals	Sole community hospital as defined under Section 1886(d)(5)(D)(iii) of the Social Security Act (42 U.S.C. § 1395ww(d)(5)(D)(iii))with a DSH adjustment percentage equal to or greater than 8[g]	Isolated from other hospitals by distance, weather, or travel conditions.	2010[i]	200	CMS and HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Rural Referral Centers	Rural referral center as defined under Section 1886(d)(5)(C)(i) of the Social Security Act (42 U.S.C. §1395ww(d)(5)(C)(i)) with a DSH adjustment percentage equal to or greater than 8[g]	Large rural hospitals that provide services for patients from a wide geographic area.	2010[i]	72	CMS and HRSA
Free-standing cancer hospitals	Free-standing cancer hospital as described under Section 1886 (d)(1)(B)(v) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B(v))with a DSH adjustment percentage greater than 11.75[g]	Not a unit of another hospital, has a primary purpose of treating or conducting research on cancer.	2010[i]	5	CMS
Total				**16,572**	

Source: GAO analysis of federal laws and regulations.

[a]Data are the most recent available from HRSA's covered entity database and represent both covered entities and their associated sites. Because a covered entity may enroll under any and all eligible grant types it receives, it is possible that a site is reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[b]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[c]This category includes: FQHC look-alikes; Consolidated Health Centers; Migrant Health Centers; Health Care for the Homeless; Healthy Schools/Healthy Communities; Health Centers for Residents of Public Housing; and Tribal Organizations created under the Indian Self Determination Act (Pub. L.. No. 93-638) and administered by the Indian Health Service.

[d]Eligible to participate in the 340B program from its inception. See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

[e]Section 1905(l)(2)(B) of the Social Security Act includes outpatient health programs or facilities operated by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services in the definition of FQHCs.

[f]According to HRSA, some states have both direct purchase and rebate programs, which are counted separately in the 340B covered entity database, which is the reason for the difference in the number of ADAPs in the database versus the number of states that have ADAP programs overall.

[g]Facility must also 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. Medicaid is the joint federal-state program that finances health care for certain low-income people, and Medicare is the federal health care program for the elderly and disabled. Children's hospitals and free-standing cancer hospitals do not receive payments under Medicare's inpatient prospective payment system; however, they must have a payer mix that would result in a DSH adjustment percentage greater than 11.75 percent. Facilities except critical access hospitals, Rural Referral Centers, and Sole Community Hospitals, must not obtain covered outpatient drugs through group purchasing.

[h]While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006).

[i]Became eligible to participate in the 340B program under PPACA. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302,124 Stat.1029, 1082.

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

Note: Page numbers in the draft report may differ from those in this report.

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 07 2011

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) draft report entitled: "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (GAO-11-836).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

The Department appreciates the opportunity to review and comment on this draft report. We offer the following general comments on several content areas of the report:

The extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program:

On Page 16, the report states that in Massachusetts where the state implemented universal health care, low-income patients gained private insurance, but "these patients often could not afford associated copayment or deductibles and the entity covered these costs". HRSA requests that the report reflect that this finding is consistent with the Health Resources and Services Administration's (HRSA) assessment that low-income patients will continue to require such assistance and the covered entities will provide valuable services to the safety net community.

On Page 18, the report states that "Even though the uses of revenue generated through the 340B Program were for similar purposes, some covered entities relied on 340B revenue more than others." The report goes on to state differences in revenue for FQHCs versus hemophilia centers. HRSA requests that the following explanation be incorporated into the report: Because each 340B entity type is unique in the types of services it provides and the patients it treats, the drug purchases of each entity type vary greatly (*i.e.*, generics versus brand or certain specialty drugs); therefore, their savings will also vary greatly.

Regarding how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers:

On Page 20, the report states that "One IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of drug purchased by providers in 2004--allocating 95 percent of the projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B Price" and "this manufacturer states that its distribution was fair and changing the distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs." HRSA requests that the report be edited to include:

> "HRSA does not believe that using the 2004 allocation of 95 percent to non-340B providers and 5 percent to 340B providers for a critical life saving drug is fair or sufficient. In 2005, there were 77 Hemophilia Treatment Centers and 591 Disproportionate Share Hospitals (DSH) purchasing IVIG through the 340B Program. This number has increased significantly to 99 Hemophilia Treatment Centers and

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

> 1,673 hospitals that now include children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, and rural referral centers. The allocation of IVIG drugs to 340B providers needs to be correlated to the increase in the 340B hospitals, as many of the same hospitals that purchased IVIG with no problems as non-340B providers in 2004 are now having tremendous difficulty in purchasing IVIG in 2011 as 340B providers. With 340B hospitals representing almost 33 percent of the hospitals of in the U.S. in 2011, 5 percent allocation for a life saving drug is not adequate."

On Page 21, the report states that some covered entities have stockpiled drugs when the price of a drug dropped. HRSA recommends that the report note that HRSA has worked with manufacturers in the past during an expected drop in price to develop an allocation process that is equitable across 340B and non-340B entities to prevent stockpiling. In addition, HRSA also encourages manufacturers to work with the agency to develop allocation processes to prevent issues with stockpiling.

HRSA's oversight of the 340B Program

On Page 24, the report states that HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. HRSA requests that the report reflect that while HRSA has not published formal guidance in this area, HRSA has both criteria and a process in place to ensure hospitals satisfy 340B requirements. These criteria are utilized during the enrollment process and include:

- The criteria for hospital eligibility to participate in the 340B Program is outlined in section 340B(a)(4)(L)(i) which states the hospital "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title." This information is on the HRSA Office of Pharmacy Affairs (OPA) website.
- Prior to enrolling a hospital into the Program, OPA verifies that the hospital meets the three statutory requirements for participation in the 340B program: 1) non-profit status is verified by IRS documentation; 2) DSH eligibility, if applicable, is verified by the Medicare-cost report and 3) private hospitals must have a contract with state or local governments to provide health care services to low income

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. Contracts are selectively reviewed if further clarification is necessary.

- OPA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract. HRSA strongly recommends and encourages the covered entity to seek legal counsel when preparing these contracts.

On page 24, the report states that some stakeholders expressed concern about the application of the requirements against non-discrimination. The conclusion of the report states that absent additional guidance, "access challenges covered entities have faced when manufacturers' have restricted distribution of certain drugs at 340B prices may continue." The language in the conclusion suggests that several challenges are known and identified; however, in its report the only access challenges identified involved IVIG. HRSA has been working with the Department of Justice (DOJ) to evaluate and improve access to IVIG for 340B entities. HRSA recommends that GAO provide additional detail regarding the access challenges found in order for HRSA to address these concerns and take appropriate action.

On Page 25, the report states that HRSA verifies eligibility for 340B at enrollment, but does not periodically recertify eligibility for all covered entity types. HRSA requests that the report reflect that HRSA has been meeting the statutory requirement; HRSA recertified and continues to recertify STD, TB, and HIV/AIDS programs annually as expressly required under section 340B (a)(7) of the Public Health Services Act (42 U.S.C. 256b). These were the only entities that required annual certification by the Secretary prior to the PPACA. In addition, HRSA monitors DSH percentages and FQHC grant status on a quarterly basis. Each quarter OPA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private hospitals are not participating. As a result of the PPACA, HRSA is required to annually recertify all 340B covered entities. OPA's FY2011 budget of $4.4M will allow for the planning of and initiation of a phased approach to recertification to begin in fall of 2011.

On Page 31, footnote (a) states that no appropriation has occurred for annual recertification. HRSA recommends that this statement be replaced with the following, "HRSA program FY2011 budget of $4.4M will allow for the planning and initiation of a phased approach to recertification to begin in fall 2011."

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

On Page 32, the report states that the PPACA specifically requires HRSA to conduct selective audits of manufacturers but it did not establish the same requirement for audits of covered entities. HRSA requests that the report clarify that the agency has had the authority to audit covered entities under section 340B(a)(5)(C) of the Public Health Service Act since the inception of the program.

GAO Recommendations

HRSA agrees with the recommendations and will continue to build on program integrity efforts and work to prioritize efforts based on funding. Implementation of a cost recovery fee as outlined in the FY 2012 President's budget would allow for the initiation of the implementation of all recommendations and program integrity provisions outlined in PPACA. The 340B Drug Pricing program integrity risk assessment is scheduled to begin in the fall of 2011.

GAO Recommendation #1: *Conduct selective audits of 340B covered entities to deter potential diversion.*

HRSA Actions:

- HRSA and the manufacturers have the authority to audit 340B covered entities. HRSA will continue to work with the manufacturers to identify potential diversion and work with manufacturers to develop audit plans where evidence suggests potential diversion may be occurring.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources, such as targeted webinars on diversion, peer to peer learning, FAQs, policy letters to covered entities, and more assistance to covered entities in assessing risk.

GAO Recommendation #2: *Finalize new, more specific guidance on the definition of a 340B patient.*

HRSA Actions:

- HRSA will review the draft of the proposed patient definition guidelines in view of PPACA changes and develop revised guidelines for publication.

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

Recommendation #3: *Further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.*

HRSA Actions:

- HRSA will develop and implement a comprehensive educational and communication plan which will specify the existing policy regarding 340B non-discrimination and drug distribution to include, webinars, and policy letters to manufacturers regarding non-discrimination guidance.
- HRSA will continue to work with manufacturers to provide clearer guidance for manufacturers on working with HRSA and develop specific allocation plans where needed.
- HRSA will continue to work with DOJ when fair, voluntary allocation plans are not developed.

Recommendation #4: 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.

HRSA Actions:

- HRSA will further publicize its existing criteria for hospital participation in the 340B program by placing the criteria and process on the program website and issuing policy letters to affected covered entities outlining these criteria.
- HRSA will initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011. This recertification process will enable HRSA to verify that hospitals continue to meet the statutory requirements for program participation.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources such as targeted webinars on the hospital criteria, peer to peer learning, FAQs, and letters to covered entities.

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Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Gerardine Brennan, Assistant Director; Jennie Apter; Kristin Ekelund; Kelli Jones; Dawn Nelson; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

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United States Government Accountability Office

Report to Congressional Requesters

June 2015

MEDICARE PART B DRUGS

Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals

GAO-15-442

June 2015

MEDICARE PART B DRUGS

Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals

GAO Highlights

Highlights of GAO-15-442, a report to congressional requesters

Why GAO Did This Study

Approximately 40 percent of all U.S. hospitals participate in the 340B Drug Pricing Program, and the majority of 340B discounted drugs are sold to hospitals. Medicare reimburses hospitals for Part B drugs under a statutory formula regardless of the prices hospitals paid for the drugs. Stakeholders have questioned the increase in hospital participation in the 340B program, and the implications for Medicare and its beneficiaries, especially regarding cancer care; and whether certain of the program's hospital eligibility criteria target hospitals appropriately.

GAO was asked to review hospitals' participation in the 340B and Medicare programs. This report (1) compares 340B hospitals with non-340B hospitals in terms of financial and other characteristics and (2) compares spending for Medicare Part B drugs at 340B hospitals, for all drugs and for oncology drugs, with spending at non-340B hospitals. To examine hospital participation using the most recent data available, GAO analyzed 2008 and 2012 data from HRSA and CMS to compare characteristics and Medicare Part B drug spending for 340B hospitals and non-340B hospitals.

What GAO Recommends

Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals.

View GAO-15-442. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

Certain providers, including hospitals that serve a disproportionate number of low-income patients, have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program, which is administered by the Health Resources and Services Administration (HRSA) within the Department of Health & Human Services (HHS). In 2012, these hospitals—referred to as 340B disproportionate share hospitals (DSH) because they are eligible for the program based on their serving a disproportionate share of low-income patients and other specified criteria—were generally larger and more likely to be teaching hospitals compared with non-340B hospitals. They also tended to provide more uncompensated and charity care than non-340B hospitals; however, there were notable numbers of 340B hospitals that provided low amounts of these types of care. For example, 12 percent of 340B DSH hospitals were among the hospitals that reported providing the lowest amounts of charity care across all hospitals in GAO's analysis. Overall financial margins for 340B DSH hospitals tended to be lower compared with non-340B hospitals, which could be attributable, in part, to the tendency for 340B DSH hospitals to provide more uncompensated and charity care.

GAO found that in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status. The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, uses a statutorily defined formula to pay hospitals for drugs at set rates regardless of hospitals' costs for acquiring the drugs. Therefore, there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. In addition, this raises potential concerns about the appropriateness of the health care provided to these beneficiaries. HRSA and CMS have limited ability to counter this incentive because the 340B statute does not restrict covered entities from using drugs purchased at the 340B discounted price for Medicare Part B beneficiaries and the Medicare statute does not limit CMS reimbursement for such drugs.

In commenting on a draft of this report HHS noted some concerns with GAO's conclusions and suggested that further analysis may be needed to examine patient outcomes and differences in health status. GAO believes its methods appropriately support its conclusions as further discussed in the report.

Contents

Figures

Abbreviations

CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
GME	graduate medical education
HHS	Department of Health & Human Services
HRSA	Health Resources and Services Administration
IME	indirect medical education
IPPS	inpatient prospective payment system
MDH	Medicare-dependent hospital
OPPS	outpatient prospective payment system
PPS	prospective payment system

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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June 5, 2015

Congressional Requesters

The 340B Drug Pricing Program requires drug manufacturers to sell most outpatient drugs at deeply discounted prices to certain providers and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid.[1] Entity eligibility for the program is defined in statute and includes certain hospitals that serve a disproportionate number of low-income patients.[2] Participating hospitals, referred to as 340B hospitals, benefit from lower outpatient drug prices and may also benefit from the revenue generated when they are reimbursed by Medicare and other payers at rates that exceed the discounted prices the hospitals pay for outpatient drugs.[3] The 340B statute does not specify how covered entities should use the savings or any resulting revenue associated with the discounts.[4]

Currently, approximately 40 percent of all U.S. hospitals participate in the program, and the majority of 340B discounted drugs are sold to hospitals.[5] Some members of Congress and certain stakeholders, such

[1]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

[2]Eligibility is also extended to clinics and other entities that participate in certain qualifying federal programs.

[3]Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. In general, Medicare Part A covers inpatient hospital services and Medicare Part B covers outpatient hospital services, as well as physician services and certain other services. Under Medicare Part B, Medicare reimburses all hospitals for outpatient drugs at set rates regardless of whether the drugs were obtained at a 340B discounted price. The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS).

[4]According to the Department of Health & Human Services (HHS), the intent of the 340B Program is to enable covered entities to stretch scarce Federal resources to reach more eligible patients and provide more comprehensive services.

[5]In 2011 we reported that nearly a third of all U.S. hospitals participated in the 340B Program. See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,* GAO-11-836 (Washington, D.C.: Sept. 23, 2011).

as drug manufacturers, have raised questions about the increasing number of hospitals that participate in the 340B Program. They question whether certain of the program's hospital eligibility criteria appropriately target hospitals for participation. They contend that participating hospitals do not necessarily use the program and program revenues to help vulnerable patients, such as low-income uninsured patients, and that the program gives hospitals incentives to maximize the revenue that they earn through it. In contrast, they contend that nonhospital entities that are eligible for the 340B Program on the basis of their participation in qualifying federal programs must operate within the rules of those programs, so there is some assurance that those entities will use the program, including any revenue generated through it, to help the vulnerable patients they serve. Other stakeholders, such as organizations representing 340B hospitals, emphasize that participating hospitals are safety net providers that serve more low-income, uninsured, and underinsured patients than other hospitals. Such stakeholders contend that the program is intended to allow hospitals to use the revenue they generate through the 340B Program to help them cover their operating costs and make up any financial losses, as well as to implement programs to benefit vulnerable patients.

Another issue raised by stakeholders, including groups representing independent oncology practices and oncology providers, is that hospitals' participation in the 340B Program might contribute to a recent trend in hospital acquisition of oncology practices.[6] Because independent outpatient oncology practices are not eligible for the 340B Program, they cannot obtain oncology drugs at the 340B discounted rate. Some stakeholders argue that 340B hospitals are acquiring independent oncology practices, in part, to expand their outpatient base for 340B oncology drugs and thus generate higher revenue for these drugs.[7] They assert that this trend has negative implications for payers and patients, including the Medicare program and its beneficiaries, because payments for services provided in hospital outpatient departments are generally

[6]According to the Community Oncology Alliance, since 2008, 313 clinical treatment sites have closed, and 544 practices have been acquired by or otherwise entered into formal partnership agreements with hospitals.

[7]American Society of Clinical Oncology, "Policy Statement on the 340B Drug Pricing Program by the American Society of Clinical Oncology," to be published in Journal of Oncology Practice, accessed May 7, 2014, http://jop.ascopubs.org/content/early/2014/04/15/JOP.2014.001432.extract.

higher than they are for services provided in free-standing community outpatient facilities. However, these stakeholders note that a variety of other factors could contribute to these acquisitions.

You asked us to examine hospitals' participation in the 340B Program and the potential implications for Medicare and its beneficiaries. In this report, we (1) compare 340B hospitals with non-340B hospitals in terms of financial and other characteristics and (2) examine how Medicare Part B drug spending at 340B hospitals, for all drugs and for oncology drugs, compares to spending at non-340B hospitals.

For both of our research objectives, we examined 2008 and 2012 data from the Health Resources and Services Administration's (HRSA) 340B Covered Entity Database to determine which hospitals participated in the 340B Program.[8] We focused our analysis on one of the six hospital types eligible for the program—disproportionate share hospitals (DSH)—because DSH hospitals account for the majority of drug purchases under the 340B Program.[9] To be eligible for the 340B Program, a DSH hospital must be a general acute care hospital that serves a disproportionate share of low-income patients—as generally indicated by a Medicare DSH adjustment percentage greater than 11.75—and that meets other

[8]We used 2012 data because it was the year in which all sources of data needed for our analysis were most complete. We chose 2008 data to capture any potential changes over time in hospitals' participation in the 340B Program.

[9]According to HRSA, as of January 2015, 978 340B DSH hospitals participated in the 340B Program and these hospitals accounted for 78 percent of total 340B drug purchases.

specified criteria.[10] We compared characteristics and payments for these hospitals with those for two groups: non-340B DSH hospitals (hospitals that received DSH payments but did not participate in the 340B Program) and all other non-340B hospitals.[11] We excluded from all analyses the following types of hospitals: (1) hospitals located outside the 50 states and Washington, D.C., (2) hospitals that were not acute care, (3) hospitals paid under a Medicare system other than the prospective payment system (PPS),[12] and (4) hospitals that participated in the 340B Program on the basis of one of the other five hospital eligibility categories.[13] We also excluded outliers and hospitals for which data were missing or inconsistent. We also spoke with stakeholders, including officials from three groups representing drug manufacturers, three groups representing 340B hospitals, and two groups representing independent oncology practices and providers, to obtain their views on these issues and the 340B Program generally.

[10]A hospital's DSH adjustment percentage is used to determine the additional payment a hospital can receive from Medicare if it serves a disproportionate number of low-income Medicare and Medicaid beneficiaries in its inpatient department. An alternative method for meeting the DSH requirement to participate in the 340B Program applies to hospitals that are located in an urban area, have 100 or more beds, and can demonstrate that more than 30 percent of their total net inpatient care revenues come from state and local government sources for indigent care (other than Medicare and Medicaid). These hospitals—known as "Pickle" hospitals—are referred to in this report as meeting DSH alternative criteria. In addition to meeting the DSH adjustment percentage requirement, or the DSH alternative criteria, 340B DSH hospitals must be (1) owned and 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 entitled to Medicare or eligible for Medicaid. These hospitals must also not obtain covered outpatient drugs through a group purchasing organization. See 42 U.S.C. § 256b(a)(4)(L).

[11]Over one-third of the hospitals in the non-340B DSH group had a DSH adjustment percentage greater than 11.75.

[12]Certain hospitals, including certain freestanding cancer hospitals, critical access hospitals, and hospitals located in Maryland that are paid under a cost containment waiver, are not paid under Medicare's PPS.

[13]Other types of hospitals that are eligible for the 340B program include children's hospitals, critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. In general, these hospitals must also meet certain DSH eligibility criteria. See 42 U.S.C. § 256b(a)(4)(M) – (O).

To compare financial and other characteristics of 340B hospitals with non-340B hospitals, we used 2012 Medicare hospital cost report data from the Centers for Medicare & Medicaid Services (CMS). We examined characteristics such as hospital size, teaching status (major teaching hospital, other teaching hospital, or nonteaching hospital),[14] ownership type (public, nonprofit, or for profit), location (urban or rural), DSH adjustment percentage (high or low),[15] and provision of charity care and uncompensated care (high or low).[16] We also examined whether hospitals with higher DSH adjustment percentages provided larger amounts of charity care and uncompensated care. We used the cost report data to examine hospitals' financial characteristics by calculating four types of hospital financial margins: (1) total facility margin, (2) total Medicare margin, (3) inpatient Medicare margin, and (4) outpatient Medicare margin.[17] In addition, we determined whether hospitals received the following Medicare payment adjustments and the size of each

[14]We defined major teaching hospitals as those that had a resident-to-bed ratio greater than 0.25.

[15]We considered hospitals to have a high DSH adjustment percentage if this percentage was greater than 11.75 percent. We considered hospitals to have a low DSH adjustment percentage if this percentage was less than or equal to 11.75 percent.

[16]Uncompensated care includes charity care and bad debt, including costs not reimbursed by public payers (such as Medicaid). Charity care generally represents services for which a hospital demonstrates that a patient is unable to pay, and is based on a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria. Bad debt generally represents services for which a hospital determines that a patient has the financial capacity to pay, but is unwilling to do so. We considered hospitals to have provided a high amount of charity care or uncompensated care if the amounts of charity care or uncompensated care that the hospital reported providing, as a proportion of total facility revenue, were within the top quartile across all hospitals in our analysis. We considered hospitals to have provided a low amount of charity care or uncompensated care if these amounts, as a proportion of total facility revenue, were within the bottom quartile across all hospitals in our analysis.

[17]Margins were calculated as revenue minus costs divided by revenue. The total facility margin included revenue and costs associated with all of a hospital's patients. The total Medicare margin included revenue and costs associated with a hospital's acute inpatient and outpatient Medicare patients (including revenue and costs associated with a hospital's graduate medical education activities). It did not include revenue and costs associated with Medicare patients served by the hospital's inpatient rehabilitation facility, inpatient psychiatric facility, skilled nursing facility, or home health agency. According to the Medicare Payment Advisory Commission, acute inpatient and outpatient services account for over 90 percent of hospitals' Medicare revenues. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 14, 2014), 65.

adjustment: (1) DSH adjustment, (2) indirect medical education (IME) adjustment, (3) direct graduate medical education (GME) payment, (4) outlier case adjustment, and (5) Medicare-dependent hospital (MDH) classification.[18] All of these adjustments apply to a hospital's inpatient payments. Only the GME and outlier case adjustments apply to a hospital's outpatient payments. There were 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals in our cost report analysis.[19]

To examine how Medicare Part B drug spending at 340B hospitals, for all drugs and for oncology drugs, compares with this spending at non-340B hospitals, we used CMS's 2008 and 2012 Medicare claims data combined with CMS's 2008 and 2012 Medicare hospital cost report data. For each year, we calculated per beneficiary Part B drug spending for separately payable outpatient drugs for each hospital that served at least one outpatient beneficiary during the year.[20] To examine oncology drug payments specifically, we identified separately payable Part B oncology drugs by Healthcare Common Procedure Coding System code. For each year we then calculated Part B oncology drug spending per Medicare oncology beneficiary for each hospital that received any of these payments.[21] For both the overall outpatient drug and the oncology drug spending analyses, we examined whether there were differences in

[18]The MDH classification applies to small rural providers for which Medicare patients make up a significant percentage of inpatient days or discharges. We included the DSH, IME, GME, and outlier case adjustments in our analysis because these adjustments are most commonly received by hospitals. We included the MDH classification because although a low number of hospitals receive this adjustment, the proportion of total Medicare revenue accounted for by the adjustment is relatively large. We excluded adjustments that were time limited (e.g., payment incentives for implementing electronic health records) or were directly related to eligibility for the 340B program (e.g., rural referral center) from our analysis of payment adjustments.

[19]Because hospitals can have varying fiscal year start and end dates, the time periods covered by the cost reports in our analysis vary. All cost reports in our analysis cover at least 10, but not more than 14, months.

[20]We based per beneficiary Part B drug spending on the number of unique outpatient Medicare beneficiaries served by each hospital in the respective year. We included only separately payable drugs because drugs paid as part of a bundled service under the PPS are not eligible for 340B discounts.

[21]We based per beneficiary Part B oncology drug spending on the number of unique outpatient Medicare beneficiaries served by each hospital who received payment for at least one oncology drug in the respective year. It is possible that some of these beneficiaries received an oncology drug to treat a condition other than cancer.

Part B drug spending between 340B DSH and non-340B hospitals that could not be explained by factors outside of the 340B Program, such as hospital teaching status or patient health status. To examine differences in patient health status, for each year we calculated an average risk adjustment score for each hospital, based on the risk scores of the hospital's outpatient population or outpatient population that received an oncology drug, specifically. We excluded payments for vaccines because they are not eligible for discounts under the 340B Program.[22]

To assess the reliability of the data we used in our analysis, we reviewed related documentation, interviewed officials from HRSA and CMS, and performed appropriate electronic data checks. This allowed us to determine that the data were sufficiently reliable for our purposes.

We conducted this performance audit from March 2014 to June 2015 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

340B Program

The 340B Program, which is administered and overseen by HRSA, within HHS, is named for the statutory provision authorizing it, which was added to the Public Health Service Act in 1992.[23] Eligibility for the program is statutorily defined and is limited to entities that participate in specified

[22]Our analysis was based on drugs identified by CMS as Part B drugs. According to HRSA, some Part B drugs may not be eligible for 340B discounts, such as certain skin substitutes; however, HRSA did not have a list of those drugs in 2008 and 2012.

[23]Pub. L. No. 102-585, 106 Stat. 4943, 4967 (adding § 340B to the Public Health Service Act) (codified as amended at 42 U.S.C. § 256b). Outpatient drugs covered under the 340B Program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, which can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

federal programs and hospital types that meet certain eligibility criteria.[24] A clinic or other site affiliated with a hospital, but not located in the main hospital building, is eligible to participate in the 340B program if it is an integral part of the hospital, which HRSA has defined as a reimbursable facility, included on the eligible hospital's most recently filed Medicare cost report.[25] Independent physician-based practices that do not participate in the qualifying federal programs are not eligible to participate in the 340B Program.

Covered entities may use 340B drugs for patients whether or not they are low-income, uninsured, or underinsured, and covered entities may receive payments from health insurers, such as Medicare, that are higher than the drug's discounted price, generating revenue through the program. A statutory pricing formula determines the 340B price of a drug. The amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid.[26]

Throughout calendar year 2012, there were 10,622 unique covered entities that participated in the 340B program—an increase of 20 percent since 2008.[27] Approximately half of the increase in unique covered

[24]Eligible entities include federally qualified health centers, urban Indian organizations, family planning clinics, sexually transmitted disease grantees, tuberculosis grantees, Native Hawaiian Health Centers, state-operated Ryan White AIDS Drug Assistance Programs, other Ryan White grantees, hemophilia treatment centers, and black lung clinics. Eligible hospitals include certain DSH hospitals, critical access hospitals, sole community hospitals, rural referral centers, freestanding cancer hospitals, and children's hospitals. Additionally, providers that meet all of the requirements for the federally qualified health centers program, but do not receive federal grants—referred to as federally qualified health center look-alikes—are eligible to participate in the 340B Program.

[25]See 59 Fed. Reg. 47884 (Sep. 19, 1994). Institutional providers that render services to Medicare beneficiaries are required to submit cost reports annually. Among other things, these reports contain self-reported information on facility characteristics, utilization data, and financial statement data.

[26]In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. The average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies.

[27]These counts do not include counts of affiliated sites and clinics. In order to improve the accuracy of the 340B database, HRSA changed the way that it required covered entities to register these sites beginning in 2012. As a result, we could not definitively measure the change in the number of affiliated sites and clinics over time.

entities was among entities that became eligible for the program based on expanded eligibility criteria enacted by the Patient Protection and Affordable Care Act in 2010.[28] The remaining increase was among entity types that were eligible for the program in both 2008 and 2012, including 340B DSH hospitals. In 1992, the House Energy and Commerce Committee estimated that approximately 90 DSH hospitals would have been eligible to participate in a 340B Program, had it been in effect at that time.[29] In 2012, 1,057 DSH hospitals participated in the program.

Medicare Payments to Hospitals

Medicare pays most hospitals through both the acute care inpatient prospective payment system (IPPS), which is covered by Medicare Part A, and the outpatient prospective payment system (OPPS), which is covered by Medicare Part B. Under these systems, Medicare pays providers a predetermined rate for a given service that is expected to cover the costs incurred by efficient providers. Within the OPPS, certain services, including most Part B drugs, are paid separately.

Payments under the IPPS are adjusted to account for the beneficiary's clinical condition and related treatment costs relative to the average Medicare case and payments under both the IPPS and the OPPS are adjusted for the market conditions in the hospital's location relative to national conditions. Hospitals may receive additional payments if they qualify for certain adjustments, such as:[30]

- **DSH adjustment**: The DSH adjustment generally provides supplemental payments for inpatient services to hospitals that treat a disproportionate number of low-income inpatients.[31] To qualify for this

[28]Entities that became eligible for the 340B Program through the Patient Protection and Affordable Care Act include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7107(a), 124 Stat. 821 (codified at 42 U.S.C. § 256b(a)(4)(M) –(O)). The expansion of Medicaid under the Patient Protection and Affordable Care Act could also result in more hospitals meeting the minimum 340B DSH eligibility criteria.

[29]See H.R. Rep. No. 102-384, Pt. 2 at 12 (1992) (discussing bill to amend the Social Security Act, containing language similar to what eventually became section 340B of the Public Health Service Act).

[30]Medicare also reimburses hospitals for 70 percent of bad debts resulting from beneficiaries' nonpayment of copayments and deductibles after a reasonable effort has been made to collect the unpaid amounts.

[31]See 42 U.S.C. § 1395ww(d)(5)(F).

adjustment, a hospital's disproportionate patient percentage—the share of low-income patients treated by the hospital—must generally equal or exceed a specific threshold level determined by a statutory formula.[32] The amount of the DSH payment adjustment varies by hospital location and size.

- **GME and IME adjustments**: Medicare reimburses teaching hospitals and academic medical centers for both the direct and indirect costs of their residency training programs. GME payments cover the direct costs of resident training, such as salaries and benefits, for both inpatient and outpatient services. The IME adjustment applies only to inpatient services, and reflects the higher patient care costs associated with resident education. The size of the IME adjustment depends on the hospital's teaching intensity, which is generally measured by a hospital's number of residents per bed.
- **Outlier case payment**: The outlier case payment protects hospitals from large financial losses due to unusually costly inpatient and outpatient cases. A hospital's costs for the case must exceed a certain threshold amount and additional payments are based on a percentage of the costs above this threshold.
- **MDH classification**: The MDH classification allows small rural hospitals for which Medicare patients make up a significant percentage of inpatient days or discharges to receive adjustments to their IPPS rates.[33] To qualify as an MDH, a hospital has to meet various criteria regarding location, size, and patient mix.

Medicare Spending for Part B Drugs

In 2012, the Medicare program and its beneficiaries spent a total of $6 billion for Part B drugs in the hospital outpatient setting. Part B drugs are typically administered by a physician or under a physician's close

[32]The disproportionate patient percentage is generally computed as the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income (the federal program that provides cash benefits to eligible low-income individuals who are aged, blind, or disabled) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A.

[33]Federal law refers to "Medicare-dependent small rural hospitals." See, e.g., 42 C.F.R. § 412.108 (2014). In this report, we refer to this category of rural providers as "Medicare-dependent hospitals" (MDH). Although the MDH program was originally enacted as a temporary program, it has been extended multiple times and is due to expire for discharges as of October 1, 2017.

supervision in physicians' offices or hospital outpatient departments. Under the OPPS, Medicare reimburses all hospitals for separately payable Part B drugs at rates determined by a statutorily defined formula regardless of the price the hospital pays for the drug. Medicare pays 80 percent of the payment rate for Part B drugs and the beneficiary is responsible for the remaining 20 percent. Typically, Part B drugs are provided with a physician service, which is also paid for by both Medicare and the patient. In general, spending for Part B drugs and other services has a financial impact on Medicare beneficiaries because monthly Part B premiums are set to cover 25 percent of total Part B expenditures.

340B DSH Hospitals Were Generally Larger and Had Lower Total Facility Margins, but Higher Medicare Margins Compared with Non-340B Hospitals

In 2012, 340B DSH hospitals were generally larger and more likely to be teaching hospitals—especially major teaching hospitals—compared with non-340B hospitals. Although 340B DSH hospitals tended to have lower total facility margins compared with non-340B hospitals, they tended to have higher total Medicare margins. Lower total facility margins among 340B DSH hospitals could be partly attributable to the tendency for these hospitals to provide more charity care and uncompensated care compared with non-340B hospitals, although there were notable exceptions. Higher total Medicare margins among 340B DSH hospitals could be partly attributable to the receipt of more Medicare payment adjustments by these hospitals.

340B DSH Hospitals Were Generally Larger and Many Provided More Charity Care and Uncompensated Care Compared with Non-340B Hospitals, with Notable Exceptions

Compared with non-340B hospitals—including both non-340B DSH hospitals and other non-340B hospitals—340B DSH hospitals in our analysis tended to be larger in terms of annual total facility revenue, annual Medicare revenue, and the number of inpatient beds in 2012.[34] The differences between 340B DSH hospitals and non-340B hospitals were most pronounced among major teaching hospitals, and among the 279 major teaching hospitals, 189 (or nearly 70 percent) were 340B DSH hospitals (see table 1). Further, the median DSH adjustment percentage among 340B DSH hospitals in our analysis was twice as high as the median DSH adjustment percentage among non-340B DSH hospitals—18 percent compared with 9 percent. Among major teaching hospitals,

[34]Unless otherwise noted, when we refer to "non-340B hospitals," we are referring to both non-340B DSH and other non-340B hospitals.

the median DSH adjustment percentage was over three times as high—28 percent compared with 8 percent.

Table 1: Median Value for Certain Characteristics of 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals, 2012

Characteristic	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
All hospitals	**N=925**	**N=1,461**	**N=567**
Total facility revenue (annual)	$221,798,171	$124,953,410	$86,558,543
Medicare revenue (annual)	$47,056,462	$27,095,156	$17,989,741
Number of inpatient beds	200	131	79
DSH adjustment percentage	18%	9%	N/A
Major teaching hospitals[a]	**N=189**	**N=73**	**N=17**
Total facility revenue (annual)	$678,101,836	$410,446,721	$324,935,756
Medicare revenue (annual)	$116,678,679	$96,614,102	$80,784,893
Number of inpatient beds	454	317	214
DSH adjustment percentage	28%	8%	N/A
Other teaching hospitals	**N=249**	**N=326**	**N=80**
Total facility revenue (annual)	$374,066,746	$261,520,835	$232,492,533
Medicare revenue (annual)	$76,816,940	$60,156,029	$56,697,908
Number of inpatient beds	311	241	203
DSH adjustment percentage	20%	9%	N/A
Nonteaching hospitals	**N=487**	**N=1,062**	**N=470**
Total facility revenue (annual)	$98,120,109	$90,166,366	$68,088,170
Medicare revenue (annual)	$20,721,543	$19,403,494	$13,698,803
Number of inpatient beds	109	102	64
DSH adjustment percentage	14%	9%	N/A

Legend: N/A = Not applicable.

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

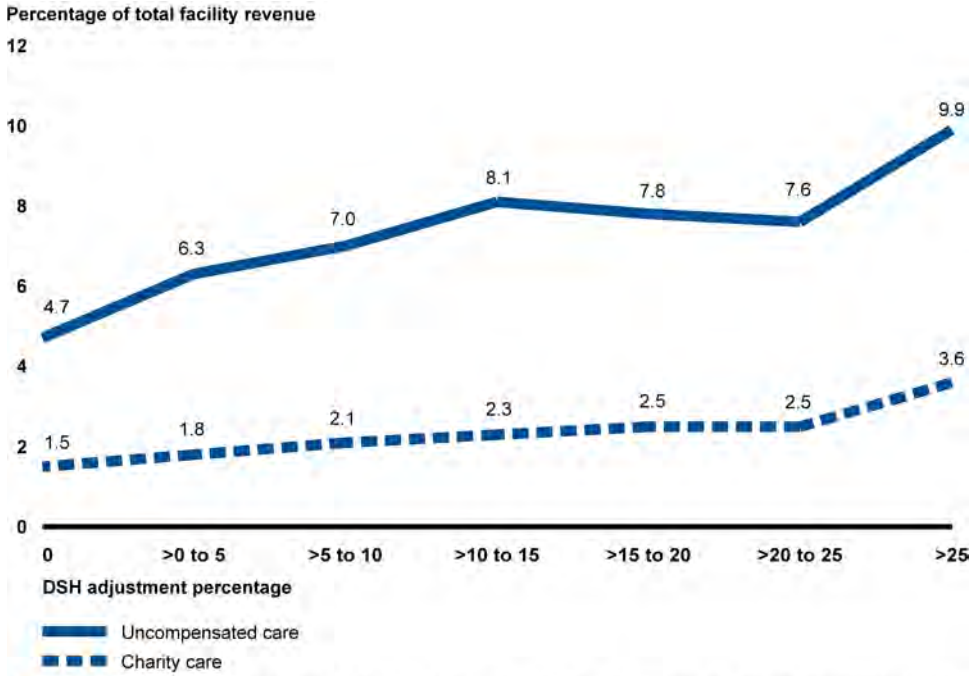
Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system.

[a]Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

Compared with non-340B hospitals, in 2012, 340B DSH hospitals generally provided more charity care and uncompensated care, as a proportion of total facility revenue—although there were notable exceptions. In addition, we found that higher DSH adjustment

percentages were often, but not always, associated with provision of greater amounts of charity care and uncompensated care by hospitals. Across all hospitals in our analysis, as hospitals' DSH adjustment percentages increased, the average amount of charity care and uncompensated care they provided, as a proportion of total facility revenue, generally increased. (See fig. 1.)

Figure 1: Average Amount of Uncompensated Care and Charity Care as a Percentage of Total Facility Revenue Provided by All Hospitals with Various Disproportionate Share Hospital (DSH) Adjustment Percentages, 2012



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Note: This figure is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; or participated in the 340B Program in an eligibility category other than the DSH hospital eligibility category. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care.

The median amount of uncompensated care provided by 340B DSH hospitals was 1.4 percentage points greater than the median amount provided by non-340B DSH hospitals, and 3.6 percentage points greater than the median amount provided by other non-340B hospitals. The median amount of charity care provided by 340B DSH hospitals was 0.8 percentage points greater than the median amount provided by non-

340B DSH hospitals, and 1.4 percentage points greater than the median amount provided by other non-340B hospitals. (See table 2.)

Table 2: Median Amount of Uncompensated Care and Charity Care Provided by 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals, as a Percentage of Total Facility Revenue, by Teaching Status, 2012

Characteristic	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
All hospitals	**N=925**	**N=1,461**	**N=567**
Uncompensated care	7.4	6.0	3.8
Charity care	2.1	1.3	0.7
Major teaching hospitals[a]	**N=189**	**N=73**	**N=17**
Uncompensated care	6.6	4.5	2.8
Charity care	2.5	1.1	1.4
Other teaching hospitals	**N=249**	**N=326**	**N=80**
Uncompensated care	6.4	5.2	3.9
Charity care	2.2	1.6	1.1
Nonteaching hospitals	**N=487**	**N=1,062**	**N=470**
Uncompensated care	7.9	6.4	3.8
Charity care	2.0	1.2	0.6

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care.

[a]Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

However, there were notable numbers of 340B DSH hospitals that provided low amounts of uncompensated care and charity care. For example, while we found that 340B DSH hospitals tended to provide a larger amount of charity and uncompensated care compared with non-340B hospitals, 12 percent of 340B DSH hospitals in our analysis were among the hospitals that provided the lowest amounts of charity care. We also found that 14 percent were among the hospitals that provided the lowest amounts of uncompensated care across all hospitals in our analysis. Additionally, among 340B DSH hospitals, the median amount of uncompensated care provided by major teaching hospitals was less than the median amount provided by all hospitals in the group, despite the fact that the major teaching hospitals in this group tended to have the highest DSH adjustment percentages. Additionally, nearly one quarter of 340B

DSH hospitals that were major teaching hospitals provided low amounts of uncompensated care. (See table 3.)

Table 3: Percentage of 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals That Provided High and Low Amounts of Uncompensated Care and Charity Care, by Teaching Status, 2012

Characteristic	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
All hospitals	**N=925**	**N=1,461**	**N=567**
High uncompensated care	37	23	11
Low uncompensated care	14	23	48
High charity care	36	22	14
Low charity care	12	26	43
Major teaching hospitals[a]	**N=189**	**N=73**	**N=17**
High uncompensated care	32	11	6
Low uncompensated care	23	37	63
High charity care	41	20	6
Low charity care	12	25	19
Other teaching hospitals	**N=249**	**N=326**	**N=80**
High uncompensated care	31	16	1
Low uncompensated care	18	28	43
High charity care	36	24	17
Low charity care	12	17	28
Nonteaching hospitals	**N=487**	**N=1,062**	**N=470**
High uncompensated care	41	26	12
Low uncompensated care	8	20	49
High charity care	34	22	13
Low charity care	12	29	46

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care. We considered hospitals to have provided a high amount of charity care or uncompensated care if the amounts of charity care or uncompensated care that the hospital reported providing, as a proportion of total facility revenue, were within the top quartile across all hospitals in our analysis. We considered hospitals to have provided a low amount of charity care or uncompensated care if these reported amounts, as a proportion of total facility revenue, were within the bottom quartile across all hospitals in our analysis.

[a]Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

340B DSH Hospitals Generally Had Lower Total Facility Margins than Non-340B Hospitals

Compared with non-340B hospitals, 340B DSH hospitals in our analysis generally had lower overall financial margins in 2012, as measured by their total facility margins. Specifically, the median annual total facility margin among 340B DSH hospitals (3.7) was 1.8 percentage points lower than the median annual total facility margin among non-340B DSH hospitals (5.5), and 3.3 percentage points lower than the median annual total facility margin among other non-340B hospitals (7.0). This finding was generally consistent when we looked at hospitals by characteristics such as teaching status (major teaching, other teaching, or nonteaching), ownership type (public, nonprofit, or for profit), and location (urban or rural). The lower total facility margins among 340B DSH hospitals could be attributable, in part, to the tendency for 340B DSH hospitals to provide a larger amount of charity care and uncompensated care, as a proportion of total facility revenue, compared with non-340B hospitals.

340B DSH Hospitals Generally Had Higher Medicare Margins and Received More Medicare Payment Adjustments Compared with Non-340B Hospitals

Compared with non-340B hospitals, 340B DSH hospitals in our analysis generally had substantially higher (i.e., less negative) total Medicare margins and inpatient Medicare margins in 2012 (see table 4). The median annual total Medicare margin that year among 340B DSH hospitals was -2.7, which was 4.6 and 13.3 percentage points higher than the median annual total Medicare margin among non-340B DSH hospitals and other non-340B hospitals, respectively.[35] Similarly, the median annual inpatient Medicare margin among 340B DSH hospitals was 0.2, which was 7.8 and 22.1 percentage points higher than the median annual inpatient Medicare margin among non-340B DSH and other non-340B hospitals, respectively.

[35]The total Medicare margin included revenue and costs associated with a hospital's acute inpatient and outpatient Medicare patients (including revenue and costs associated with a hospital's graduate medical education activities). It did not include revenue and costs associated with Medicare patients served by the hospital's inpatient rehabilitation facility, inpatient psychiatric facility, skilled nursing facility, or home health agency.

Table 4: Median Annual Medicare Margins for 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals, 2012

Margin type	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
Total Medicare[a]	(2.7)	(7.3)	(16.0)
Inpatient Medicare	0.2	(7.6)	(21.9)
Outpatient Medicare	(10.0)	(8.2)	(8.3)

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis included 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system. Margins were calculated for each hospital and the median margin represents the median among all hospitals within each group.

[a]The total Medicare margin included revenue and costs associated with a hospital's acute inpatient and outpatient Medicare patients (including revenue and costs associated with a hospital's graduate medical education activities). It did not include revenue and costs associated with Medicare patients served by the hospital's inpatient rehabilitation facility, inpatient psychiatric facility, skilled nursing facility, or home health agency.

The higher total Medicare margins and higher inpatient Medicare margins for 340B DSH hospitals may be attributable, in part, to the amount of Medicare payment adjustments they received. The 340B hospitals in our analysis were more likely to receive Medicare payment adjustments and receive higher payment adjustment amounts compared with non-340B hospitals, which resulted in increased Medicare revenue for these hospitals. For example, in 2012, 340B DSH hospitals were more likely than non-340B DSH hospitals to receive three of the five payment adjustments we examined—IME, GME, and outlier case (see table 5).[36]

[36]Due to the way that we categorized hospitals for our analysis, all 340B DSH hospitals and all non-340B DSH hospitals received DSH payments and none of the other non-340B hospitals received DSH payments.

Table 5: Percentage of 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals That Received Certain Medicare Payment Adjustments, 2012

Payment adjustment	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
Indirect medical education[a]	47	27	17
Direct graduate medical education[b]	51	30	20
Disproportionate share adjustment[c]	100	100	N/A
Outlier case[d]	98	96	96
Medicare-dependent hospital[e]	1	5	3

Legend: N/A = Not applicable.

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis included 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system.

[a]Supplemental payments to cover the indirect costs of hospitals' medical education activities.

[b]Supplemental payments to cover the direct costs of hospitals' medical education activities.

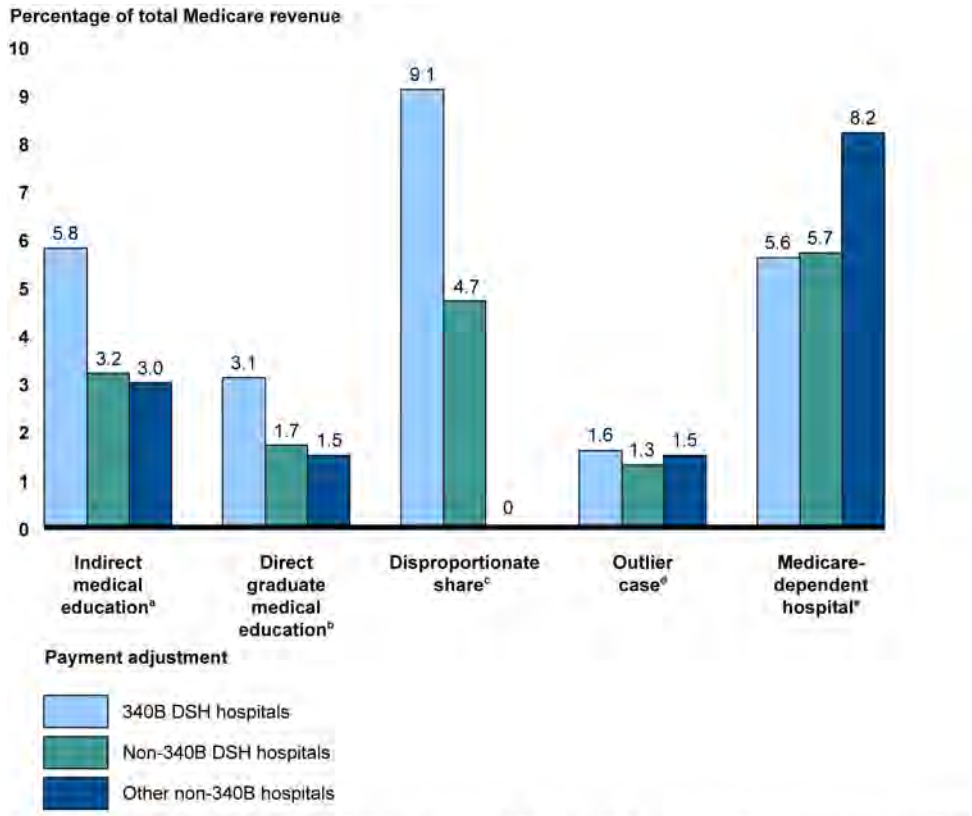
[c]Supplemental payments for hospitals that treat a disproportionate number of low-income Medicare and Medicaid patients.

[d]Supplemental payments for unusually expensive cases.

[e]Supplemental payments for small rural hospitals for which Medicare patients make up a significant percentage of inpatient discharges.

Additionally, in 2012, 340B DSH hospitals received higher payment amounts, as a proportion of total Medicare revenue, for four of the five payment adjustments we examined—IME, GME, DSH, and outlier case adjustments—compared with non-340B hospitals (see fig. 2).

Figure 2: Average Annual Medicare Payment Adjustment as a Percentage of Total Medicare Revenue for 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals That Received Certain Adjustments, 2012



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This figure is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis included 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system.

[a]Supplemental payments to cover the indirect costs of hospitals' medical education activities.

[b]Supplemental payments to cover the direct costs of hospitals' medical education activities.

[c]Supplemental payments for hospitals that treat a disproportionate number of low-income Medicare and Medicaid patients.

[d]Supplemental payments for unusually expensive cases.

[e]Supplemental payments for small rural hospitals for which Medicare patients make up a significant percentage of inpatient discharges.

Despite their participation in the 340B Program, 340B DSH hospitals in our analysis generally had lower outpatient Medicare margins compared with non-340B hospitals. In 2012, the median annual outpatient Medicare margin among 340B DSH hospitals was 1.8 and 1.7 percentage points lower than that of non-340B DSH hospitals and other non-340B hospitals, respectively. Lower outpatient Medicare margins among 340B DSH hospitals were likely due to a variety of factors. One potential factor is that there are fewer Medicare payment adjustments for outpatient services. Among the five payment adjustments we examined, only two—GME and outlier case—apply to outpatient payments.

Per Beneficiary Part B Drug Spending Was Substantially Higher at 340B DSH Hospitals, Which May Reflect Financial Incentives to Prescribe Outpatient Drugs

In both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than non-340B hospitals. This indicates that, on average, Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals. The differences we found did not appear to be explained by the hospital or patient population characteristics we examined. Because Medicare pays hospitals at set rates for Part B drugs regardless of their costs for acquiring them, there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or prescribe more expensive drugs to Medicare beneficiaries. The substantially higher spending at 340B DSH hospitals may reflect a response to this incentive.

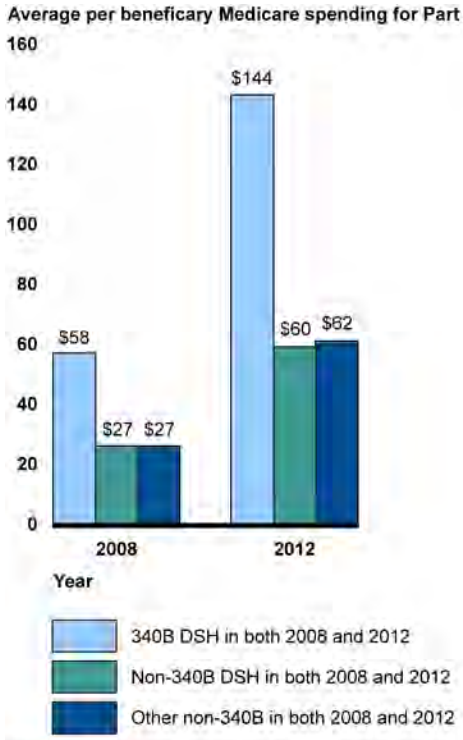
Per Beneficiary Part B Drug Spending Was Substantially Higher at 340B DSH Hospitals Compared with Non-340B Hospitals

Among the hospitals in our analysis that provided outpatient services and whose 340B status did not change between 2008 and 2012, on average, per beneficiary Medicare Part B drug spending was substantially higher at 340B DSH hospitals compared with non-340B hospitals in both 2008 and 2012. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to $60 and $62 at non-340B DSH and other non-340B hospitals, respectively.[37] (See fig. 3.) Because Medicare reimbursement rates for Part B drugs at all of the hospitals in our analysis were based on the same fee schedule, this indicates that, on

[37]For each year, we calculated per beneficiary Part B drug spending for separately payable outpatient drugs for each hospital that served at least one outpatient beneficiary during the year. We based per beneficiary Part B drug spending on the number of unique outpatient Medicare beneficiaries served by each hospital in the respective year.

average, Medicare beneficiaries at 340B DSH hospitals were prescribed more drugs or prescribed more expensive drugs, or both, than beneficiaries at the other hospitals in our analysis.

Figure 3: Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012 among Hospitals That Did Not Change 340B Status

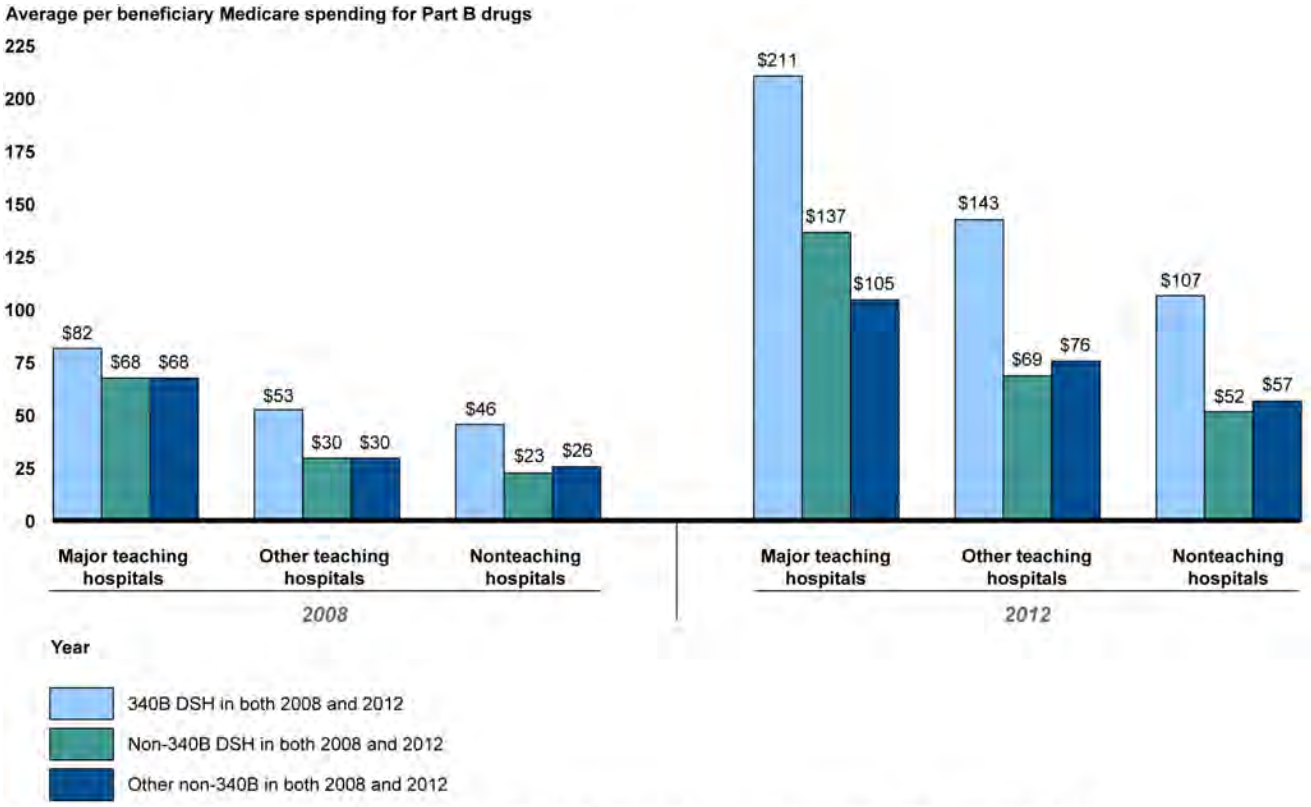


Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Note: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. The analysis included 645 340B DSH hospitals, 1,183 non-340B DSH hospitals, and 435 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they had either a Medicare disproportionate share hospital (DSH) adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient beneficiary. Per beneficiary spending is based on the number of unique outpatient beneficiaries served by each hospital in each year. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households.

The spending differences between 340B DSH hospitals and non-340B hospitals remained even after we accounted for teaching status, ownership type, or location (i.e., urban or rural). For example, among both teaching and nonteaching hospitals, average per beneficiary Part B drug spending was much higher at 340B DSH hospitals than at non-340B hospitals. (See fig. 4.)

Figure 4: Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012 among Hospitals That Did Not Change 340B Status, by Teaching Status



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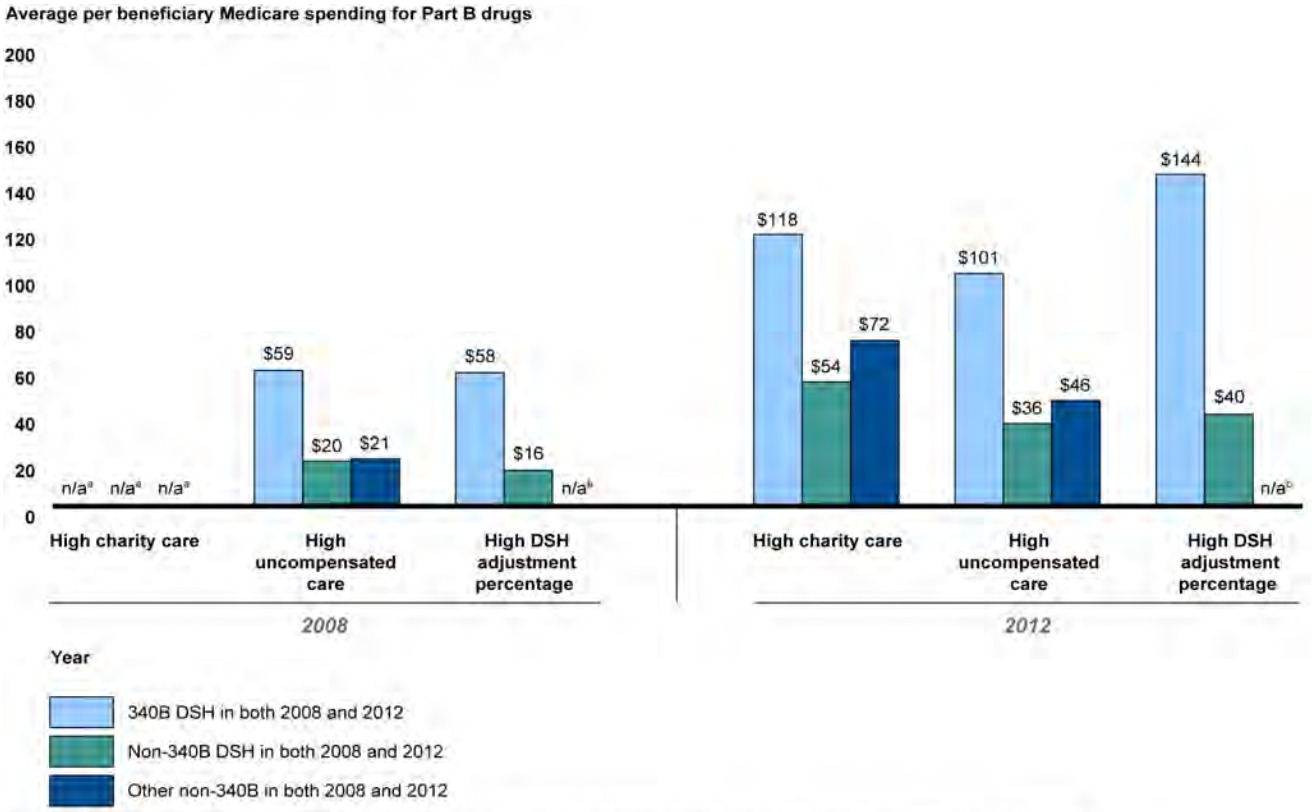
Further, these differences were not explained by the factors we examined that might disproportionately affect hospitals that treat higher proportions of low-income patients. For example, among hospitals with high levels of charity care or high levels of uncompensated care, and among hospitals with a high DSH adjustment percentage—all indicators that these hospitals treat a higher proportion of low-income patients—Part B drug spending was much higher among 340B DSH hospitals in both 2008 and 2012. (See fig. 5.)

Figure 5: Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012 among High Charity Care, Uncompensated Care, and Disproportionate Share Hospital (DSH) Adjustment Percentage Hospitals That Did Not Change 340B Status



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. The analysis included 645 340B DSH hospitals, 1,183 non-340B DSH hospitals, and 435 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they had either a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient beneficiary. Per beneficiary spending is based on the number of unique outpatient beneficiaries served by each hospital in each year. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care. We considered hospitals to have provided a high amount of charity care or uncompensated care if the amounts of charity care or uncompensated care that the hospital reported providing, as a proportion of total facility revenue, were within the top quartile across all hospitals in our analysis. We considered hospitals to have provided a low amount of charity care or uncompensated care if these reported amounts, as a proportion of total facility revenue, were within the bottom quartile across all hospitals in our analysis. We considered hospitals to have a high DSH adjustment percentage if this percentage was 11.75 or higher. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households.

[a]Charity care was not reported in 2008 hospital cost reports; therefore, we could not analyze 2008 spending using this characteristic.

[b]No hospitals in this category had a high DSH adjustment percentage in 2008 or 2012.

Additionally, the differences we found were likely not explained by the health status of the outpatients served. Specifically, in 2008 and 2012, the health status of outpatient beneficiaries was generally similar at 340B and non-340B hospitals. For example, in 2012 the average risk score—a measure of relative health status—of these outpatient beneficiaries at 340B DSH hospitals was 1.50, while it was 1.45 at non-340B DSH hospitals and 1.36 at other non-340B hospitals.[38] Risk scores are based on overall health care spending and are not limited to drug spending. However, the difference between the risk scores of beneficiaries treated at 340B DSH hospitals and non-340B hospitals relative to these hospitals' Part B drug spending suggests that the substantially higher spending at 340B DSH hospitals may not be explained by differences in patient health status.

The relatively higher Part B drug spending at 340B DSH hospitals potentially could, in part, reflect a tendency for some beneficiaries to receive all of their Part B drugs in a hospital outpatient department instead of a physician's office. To the extent this occurs, some of the higher spending at 340B DSH hospitals may not be associated with increases in overall Medicare spending for Part B drugs. However, we found that, in 2012, among patients who received Part B drugs in hospital outpatient departments, the percentage of patients who only received drugs in that setting—meaning that they did not receive any Part B drugs at a physician's office—was only slightly higher at 340B DSH hospitals (59 percent) compared to non-340B DSH hospitals (54 percent), and other non-340B hospitals (54 percent). Moreover, when we limited our analysis to patients who only received Part B drugs in a hospital outpatient department, the substantially higher spending at 340B DSH hospitals persisted. Specifically, in 2012, average per beneficiary Part B drug spending for these patients was $2,743 in 340B DSH hospitals,

[38]A risk score is based on a beneficiary's characteristics, such as age and gender, and major medical conditions generally obtained from diagnoses on claims. A higher risk score indicates that a hospital cares for a sicker beneficiary population. A risk score of 1.0 represents the predicted health care costs of the average Medicare beneficiary. In 2008, the average risk score of outpatient beneficiaries was 1.45 at 340B DSH hospitals, 1.40 at non-340B DSH hospitals, and 1.33 at other non-340B hospitals.

compared to $1,295 in non-340B DSH hospitals and $1,634 in other non-340B hospitals.

The Average Number of Oncology Patients Served Increased for All Hospital Groups from 2008 to 2012, but Increased the Most at 340B DSH Hospitals

Among the hospitals in our analysis that provided outpatient oncology services and whose 340B status did not change between 2008 and 2012, all three groups of hospitals served more oncology patients in 2012 compared to 2008. (See table 6).

Table 6: Average Number of Medicare Outpatient Oncology Beneficiaries and Average Per Beneficiary Medicare Part B Oncology Drug Spending in 2008 and 2012 among Hospitals That Did Not Change 340B Status

	340B Status					
	340B DSH in both 2008 and 2012 (N=645)		Non-340B DSH in both 2008 and 2012 (N=1,183)		Other non-340B in both 2008 and 2012 (N=435)	
	2008	2012	2008	2012	2008	2012
Percentage of hospitals treating oncology beneficiaries	84	89	65	66	59	61
Total number of outpatient oncology beneficiaries	44,853	68,576	24,795	33,886	10,172	13,398
Average number of outpatient oncology beneficiaries	83	120	32	43	40	51
Average per outpatient oncology beneficiary Part B spending for oncology drugs ($)	4,779	7,801	3,632	5,432	3,539	5,904

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Note: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they had either a Medicare disproportionate share hospital (DSH) adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient oncology beneficiary. Per outpatient oncology beneficiary spending is based on the number of unique outpatient oncology beneficiaries served by each hospital in each year. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households.

For both years, average per beneficiary Medicare Part B oncology drug spending was highest at 340B DSH hospitals. Higher average per beneficiary spending at 340B DSH hospitals compared to non-340B hospitals persisted regardless of teaching status or patient health status.[39] For example, in 2008 and 2012, the health status of outpatient oncology beneficiaries that received a Part B drug was similar at 340B and non-340B hospitals. In 2012, the average risk score of these outpatient oncology beneficiaries at 340B DSH hospitals was 2.29, while it was 2.11 at non-340B DSH hospitals and 2.14 at other non-340B hospitals.[40] Risk scores are based on overall health care spending and are not limited to oncology drug spending specifically. Nevertheless, the difference between the risk scores of beneficiaries treated at 340B and non-340B hospitals relative to these hospitals' Part B oncology drug spending suggests that the substantially higher Part B spending at 340B DSH hospitals may not be explained by differences in patient health status. Because Medicare reimbursement rates for Part B oncology drugs at all of the hospitals in our analysis were based on the same fee schedule, this indicates that, on average, Medicare beneficiaries at 340B DSH hospitals were prescribed more oncology drugs, or prescribed more expensive oncology drugs, than beneficiaries at the other hospitals in our analysis.

The average number of oncology patients served increased among all three of our hospital groups between 2008 and 2012, but 340B DSH hospitals saw the greatest increase in such patients served (83 to 120, or 45 percent). The increase across all three hospital groups in the number of oncology patients served may reflect recent trends in oncology treatment, such as where patients are treated, and could be due to multiple factors, including factors outside of the 340B program. For example, stakeholders that we spoke with noted that there is a larger trend toward integration in the health care industry. However, 340B DSH hospitals were much more likely to treat oncology patients compared with non-340B hospitals. In addition, there was a 5 percentage point increase from 2008 to 2012 in the percentage of 340B DSH hospitals that treated

[39]Additionally, median Medicare spending per oncology beneficiary at 340B DSH hospitals was higher than average spending per oncology beneficiary in 2008 and 2012, indicating that Part B per beneficiary oncology spending at 340B DSH hospitals tended to be at the higher end of the spending distribution.

[40]In 2008, the average risk score of outpatient oncology beneficiaries was 2.083 at 340B DSH hospitals, 1.960 at non-340B DSH hospitals, and 1.939 at other non-340B hospitals.

oncology patients, while the increases for non-340B DSH and other non-340B hospitals were 1 and 2 percentage points, respectively.

Differences in Per Beneficiary Part B Drug Spending at 340B and Non-340B Hospitals May Reflect Responses to Incentives in the 340B and Medicare Programs

Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs, and the 340B statute does not restrict covered entities from using drugs purchased at the 340B discounted price for Medicare Part B beneficiaries. Consequently, there is a financial incentive at these hospitals to prescribe more drugs and more expensive drugs to Medicare beneficiaries in order to maximize the revenue generated by the difference between the cost of the drug and Medicare's reimbursement. The substantially higher per beneficiary Medicare spending for Part B drugs at 340B DSH hospitals, which did not appear to be explained by hospital characteristics or patient health status, may reflect responses to this incentive. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs, and higher Part B premiums that reflect the increases in Medicare spending for those drugs. Moreover, there are potential concerns about the appropriateness of the health care provided to Medicare beneficiaries if it is overly influenced by financial incentives to prescribe outpatient drugs.

Conclusions

Certain providers, including hospitals that serve a disproportionate number of low-income patients, have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program. Currently, approximately 40 percent of all U.S. hospitals participate in the program, including approximately 1,000 DSH hospitals. Because DSH hospitals account for nearly 80 percent of all 340B drug purchases, it is important to understand the characteristics of the population that is served by these hospitals in order to evaluate the impact of the 340B program on hospitals and their patients. We found that 340B DSH hospitals generally provided more charity care and uncompensated care compared with non-340B hospitals. However, there were notable exceptions to this pattern. Specially, 12 percent of the 340B DSH hospitals reported providing relatively small amounts of charity care and 14 percent reported providing relatively small amounts of uncompensated care.

The financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns. Our work suggests that 340B DSH hospitals may be responding to this incentive to maximize Medicare revenues. On average, per beneficiary Medicare spending on Part B drugs in 2008 and 2012 was substantially higher at 340B DSH hospitals compared with non-340B hospitals—yet we did not find that these differences could be readily explained by hospital characteristics or patients' health status. While hospitals may be financially benefitting—which is not inconsistent with the legislative design of the 340B Program—this poses potentially serious consequences to the Medicare program and its beneficiaries. Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has direct financial effects on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B drugs. Furthermore, this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries. Absent a change in financial incentives, potentially inappropriate spending on drugs may continue. While limiting hospitals' Medicare Part B reimbursement for 340B discounted drugs or eliminating the 340B discount for drugs provided by hospitals to Medicare Part B beneficiaries could diminish the incentive to prescribe more drugs or more expensive drugs than necessary at 340B hospitals, CMS and HRSA are unable to take such actions because they do not have the statutory authority to do so.

Matter for Congressional Consideration

To help ensure the financial sustainability of the Medicare program, protect beneficiaries from unwarranted financial burden, and address potential concerns about the appropriateness of the health care provided to Part B beneficiaries, Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals.

Agency and Third Party Comments and Our Evaluation

We provided a draft of this report for review to HHS and received written comments that are printed in appendix I. Because of the focus on 340B hospitals in this report, we also provided 340B Health (formerly Safety Net Hospitals for Pharmaceutical Access) an opportunity to review a draft of this report and we have summarized the comments we received below. HHS and 340B Health also provided technical comments, which we incorporated, as appropriate. Following is our summary of and response to comments from HHS and 340B Health.

HHS Comments

In its comments, HHS stated that our examination of Medicare Part B outpatient drug spending is a useful initial analysis of differences in spending between 340B DSH hospitals and non-340B hospitals. HHS also noted concerns related to some of our conclusions; however, we believe our methods and findings were robust and appropriately support our conclusions, as discussed below.

First, HHS noted that although we examined differences in per beneficiary spending by hospital type, we did not examine differences in patient outcomes or quality. HHS acknowledged that higher spending for Part B drugs at 340B hospitals could represent unnecessary or excess spending for these drugs. However, HHS stated that it is also possible that a higher volume of physician-administered drugs could lead to better clinical outcomes. While we did not attempt to evaluate health outcomes as part of our analysis, we have no evidence to suggest that non-340B hospitals had an incentive to provide a lower volume of Part B drugs than required to achieve positive clinical outcomes. In particular, we believe that because Medicare reimbursed all hospitals in our analysis—including non-340B hospitals—based on the drug's average sales price plus a fixed percentage above the drug's average sales price, non-340B hospitals would have no incentive to underprescribe Part B drugs.

Second, HHS questioned our interpretation of the differences between the average risk scores among the three hospital groups (1.50 for 340B DSH hospitals vs. 1.45 and 1.36 for non-340B DSH and other non-340B hospitals, respectively). HHS believes that the differences in risk scores could represent a meaningful difference in the health status of beneficiaries. We acknowledge that the differences in risk scores could represent a difference in the health status of the beneficiaries served by each hospital group. However, we believe that the relative difference between the risk scores and the per beneficiary Part B drug spending at 340B DSH and non-340B hospitals indicates that the substantially higher spending at 340B DSH hospitals may not be explained by differences in patient health status. For example, based on the risk scores, overall health care spending for beneficiaries who received Part B drugs at 340B DSH hospitals in 2012 would have been expected to be, on average, 3.4 percent higher than overall health spending that year for beneficiaries who received Part B drugs at non-340B DSH hospitals. In contrast, spending for Part B drugs at 340B DSH hospitals was substantially higher—140 percent higher—than spending at non-340B DSH hospitals. While the spending expectation from the risk scores applies to overall health care spending, not just Part B drug spending, the relative

percentage differences suggest that the higher spending at 340B DSH hospitals may not be explained by differences in patient health status.

340B Health Comments

340B Health noted several concerns related to the methodologies we used for our analysis. However, we believe that our methods were sound, as described below.

340B Health expressed concerns about the methodology we used to examine the amount of charity care and uncompensated care provided by hospitals. In particular, 340B Health stated that the data from worksheet S-10 in the Medicare hospital cost reports that we used for this analysis are too unreliable to serve as the basis for policy conclusions because the data are not used by CMS to determine Medicare payments. However, before we conducted our analysis, we confirmed with CMS that the agency did not have any concerns about our use of the data in the S-10 worksheet for our analysis. In addition, we performed our own data reliability assessment and concluded that the cost report data were sufficiently reliable for our study. The Medicare cost report is collected annually from all institutional providers that render services to Medicare beneficiaries. Among other things, these reports contain self-reported information on facility characteristics, utilization data, and financial statement data. We used these data to describe various characteristics of hospitals, including hospitals' self-reported levels of charity care and uncompensated care.

340B Health also questioned whether our methods controlled for certain reasons it might be appropriate for Medicare Part B spending to be significantly higher at 340B hospitals. For example, they noted that 340B hospitals are larger, more likely to be teaching hospitals, and more likely to treat cancer patients or otherwise higher-risk patients. Our analyses controlled for each of these characteristics. To control for the size of each hospital, we calculated Part B drug spending at the per beneficiary level. To control for the effect of teaching hospital status, we examined Part B drug spending by teaching hospital level (major teaching, other teaching, and nonteaching) and we found substantially higher Part B drug spending at 340B DSH hospitals regardless of teaching status. To control for the possibility that 340B DSH hospitals were more likely to treat cancer patients, we conducted a separate analysis of Part B spending for oncology drugs at 340B DSH and non-340B hospitals and found similar results in spending.

Although controlling for teaching status and conducting separate analyses of oncology drug spending may have in part controlled for the treatment of higher risk patients, we also conducted analyses to determine whether patient health status at 340B DSH hospitals may explain the substantially higher Part B drug spending at these hospitals. 340B Health expressed concerns about the methodology we used in this analysis, noting that the patient risk scores we used were not intended to predict Part B drug spending—which was a limitation we noted in our report. However, the risk scores we used are an indication of the expected overall health care spending for the beneficiaries served by the hospitals in our analysis, and we found small differences in expected overall health care spending across the hospital groups. As we noted above, we believe that the relative difference between the risk scores and the per beneficiary Part B drug spending at 340B DSH and non-340B hospitals indicates that the substantially higher spending at 340B DSH hospitals may not be explained by differences in patient health status. Additionally, in expressing concerns about the risk score measures, 340B Health referred to a Medicare Payment Advisory Commission report that questioned the usefulness of these measures for assessing expected spending for individual beneficiaries.[41] However, the same report also stated that, on average, the risk scores are accurate predictors of patient health status, and for our report, we calculated an average risk score for each hospital group.

340B Health also questioned whether our exclusion of a group of hospitals—smaller, mostly nonteaching DSH hospitals that were in the 340B Program in 2012, but not in 2008—from our spending analysis might have skewed our findings. Our discussion in the report focused on our analysis of hospitals that participated in the 340B program in both 2008 and 2012 to ensure a like-to-like comparison. However, although we did not include a discussion of it in the report, we did separately examine Part B drug spending at DSH hospitals that participated in the 340B Program in 2012 but not in 2008. For example, we found that, in 2008, Part B drug spending at these hospitals was similar to spending at other non-340B DSH hospitals. However, in 2012, after the hospitals joined the 340B Program, Part B drug spending at these hospitals was 53 percent higher than spending at non-340B DSH hospitals (and among the

[41]Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (Washington, D.C.: June 13, 2014), 25.

nonteaching hospitals, spending at 340B DSH hospitals was 73 percent higher than non-340B DSH hospitals). Furthermore, although spending was higher at these 340B DSH hospitals in 2012, the average risk score of patients treated at these hospitals (1.41) was slightly lower than the average risk score of patients treated at non-340B DSH hospitals (1.45). These findings indicate that, like those we included in our report, these newer participants in the 340B program may have been responding to the financial incentives in the program.

Finally, 340B Health expressed concern that we did not attempt to review patient outcomes or otherwise evaluate the quality of care provided to beneficiaries at 340B DSH hospitals compared with non-340B hospitals and cited research that found that increased use of outpatient drugs can reduce spending on health services.[42] However, the research 340B Health cited was not focused on Part B drugs—which are generally drugs administered by a physician in a clinical setting—but rather on the effects of insurance coverage for prescription drugs on medical costs, so is not directly relevant to our analysis. In addition, as we noted above, while we did not attempt to evaluate health outcomes as part of our analysis, we have no evidence to suggest that non-340B hospitals had an incentive to provide a lower volume of Part B drugs than required to achieve positive clinical outcomes due to the structure of Medicare's payment for Part B drugs.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health & Human Services and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

[42]J. Christian-Herman, M. Emons, and D. George, "Effects of Generic-only Drug Coverage in a Medicare HMO," *Health Affairs* web exclusive, accessed May 21, 2015, http://content.healthaffairs.org/content/early/2004/09/29/hlthaff.w4.455.full.pdf+html.

If you or your staffs have any questions regarding this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.

James Cosgrove
Director, Health Care

List of Requesters

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate

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

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Michael B. Enzi
United States Senate

Appendix I: Comments from the Department of Health & Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

MAY 1 2 2015

James C. Cosgrove
Director, Healthcare
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"MEDICARE PART B DRUGS: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals"* (GAO-15-442).

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

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT: MEDICARE PART B DRUGS: ACTION NEEDED TO REDUCE FINANCIAL INCENTIVE TO PRESCRIBE 340B DRUGS AT PARTICIPATING HOSPITALS (GAO-15-442)

The U.S. Department of Health and Human Services (HHS) has reviewed the draft for report GAO-15-442, and appreciates the opportunity to review and comment.

The intent of the 340B Drug Pricing Program (340B Program) should be clearly highlighted within the GAO report. Based on Congressional report language,[1] the program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as "covered entities" in order to stretch scarce federal resources. HHS's authority regarding the 340B Program is limited by statute and focuses on ensuring covered entities and manufacturers comply with program requirements.

GAO's examination of Medicare Part B outpatient drug spending is a useful initial analysis of differences in spending between 340B disproportionate share hospitals (DSH) and non-340B hospitals. However, we are concerned that the report characterizing spending on Part B in 340B DSH hospitals as "excess," "potentially inappropriate," and "more…than necessary to treat Medicare Part B beneficiaries" is not supported by the study methodology. GAO's study, which only examined average differences in per-beneficiary spending by hospital type, did not examine any patient differences in terms of outcomes or quality. While we acknowledge that one possible interpretation for higher spending in 340B hospitals is (as asserted by GAO) that the higher spending may be unnecessary or excess, it is also possible that higher volume of physician-administered drugs can lead to better clinical outcomes. To identify whether patients did or did not receive the necessary level of care would require further analysis that accounts for patient-level characteristics and examines outcomes and quality of care.

GAO's study looked at average risk scores of patients at 340B DSH and non-340B hospitals to examine if differences in spending may be related to differences in the health status of beneficiaries. The study found that "the health status of outpatient beneficiaries was generally similar at 340B and non-340B hospitals…the average risk score…of these outpatient beneficiaries at 340B DSH hospitals was 1.50, while it was 1.45 at non-340B DSH hospitals and 1.36 at other non-340B hospitals." Based on this analysis GAO's study states that "the differences we found were likely not explained by the health status of the outpatients served." HHS has concerns that this claim is not supported by the analysis for two reasons. First, the average risk scores were higher at 340B DSH hospitals (1.50 vs. 1.45 and 1.36). HHS believes that this could represent a meaningful difference in health status of beneficiaries. Second, based on the initial findings of differences in average risk scores, further analysis of the differences in spending by risk score seems warranted (e.g., stratifying drug spending by risk score at 340B and non-340B hospitals). Without additional examination of differences in risk scores of patients at 340B and non-340B hospitals, thus differences in spending were not explained by differences in patient health status.

[1] The H. Report for the 340B Program states the following intent: "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

James Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Staff Acknowledgments

In addition to the contact named above, individuals making key contributions to this report include Gerardine Brennan, Assistant Director; George Bogart; Lori Fritz; Daniel Lee; Elizabeth T. Morrison; Aubrey Naffis; and Daniel Ries.