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May 11, 2023

The Honorable Cathy McMorris Rodgers  
Chair  
Committee on Energy and Commerce  
House of Representatives

**340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19**

**Accessible Version**

Dear Madam Chair:

The 340B Drug Pricing Program (340B Program) requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities (including certain types of hospitals) for the manufacturers' drugs to be covered by Medicaid.<sup>1</sup> According to the Health Resources and Services Administration (HRSA), the agency that administers the 340B Program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.<sup>2</sup>

In addition to realizing savings through 340B price discounts, covered entities can generate revenue when purchasing 340B drugs for eligible patients whose insurance 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. More than 2,600 hospitals were participating in the 340B Program as of January 2023.

To be eligible for the program, hospitals must meet various criteria, which may include treating a disproportionate number of low-income Medicare and Medicaid patients, as measured by the hospital's disproportionate share hospital (DSH) adjustment percentage.<sup>3</sup> Enacted in March

<sup>1</sup>42 U.S.C. § 256b. Medicaid is a joint federal-state program that finances health care for certain low-income and medically needy populations.

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

<sup>3</sup>A hospital's DSH adjustment percentage is generally based on its DSH patient percentage, which is determined by a calculation of the sum of two other percentages: (1) the low-income Medicare patient percentage, calculated as the ratio of Medicare Supplemental Security Income inpatient days to total Medicare inpatient days; and (2) the Medicaid patient percentage, calculated as the ratio of Medicaid, non-Medicare inpatient days to total inpatient days.

Medicare is the federal program that provides coverage of health care services for individuals age 65 and older, certain individuals with disabilities, and individuals with end-stage renal disease.

2022, the Consolidated Appropriations Act, 2022, allowed hospitals that were covered entities participating in the 340B Program on January 26, 2020, to request from HRSA a temporary exception to the 340B Program’s DSH percentage eligibility requirement and continue participating in the program if they were unable to meet the requirement because of factors related to the COVID-19 public health emergency.<sup>4</sup> For example, a hospital could request an exception if, as a result of the pandemic, it treated fewer Medicaid patients and more non-Medicaid COVID-19 patients, thereby causing its DSH percentage to fall below the required threshold. The exception applied to DSH percentages from hospital cost-reporting periods that began during fiscal year 2020 (or a subsequent fiscal year) and that ended no later than December 31, 2022, which would allow some hospitals to request the exception in 2023.<sup>5</sup>

In light of this temporary exception, you asked us to review the exception process and provide information on hospitals that received the exception. This report answers a series of questions related to hospitals that requested a 340B DSH percentage eligibility exception from HRSA as of May 31, 2022, and that were subsequently approved. (We refer to these approved hospitals as “excepted hospitals” in this report.) These questions are generally related to the following five areas:

1. HRSA’s administration of the 340B DSH percentage eligibility exception process;
2. characteristics of excepted hospitals;
3. amount of 340B drug purchases and discounts that excepted hospitals indicated they had in 2020 and 2021;
4. extent to which excepted hospitals indicated providing discounts on 340B drugs to low-income, uninsured patients; and
5. results of HRSA’s previous audits and other oversight activities to assess 340B Program compliance by excepted hospitals.

To answer these questions, we reviewed documents from HRSA and excepted hospitals about the exception process and about the results of HRSA’s previous oversight of these hospitals. For example, we reviewed HRSA standard operating procedures, materials provided by hospitals requesting an exception, and HRSA audit reports. We evaluated HRSA’s steps to administer the exception process against relevant federal laws related to the 340B Program and that process. We also interviewed agency officials about the exception process and HRSA’s oversight activities conducted since fiscal year 2012, the year HRSA began conducting audits of covered entities.

In addition, we examined data from HRSA’s 340B Office of Pharmacy Affairs Information System (referred to in this report as the “340B database”) as of November 2022—the most

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<sup>4</sup>Pub. L. No. 117-103, div. P, tit. I, subtit. C, § 121, 136 Stat. 49, 792. The statute refers to the COVID-19 public health emergency, which, for the purposes of this report, we refer to as the “pandemic.”

<sup>5</sup>Hospitals that render services to Medicare beneficiaries are required to submit cost reports to the Centers for Medicare & Medicaid Services annually (generally, within 5 months of the end of their cost-reporting periods). Among other things, these reports contain information on facility characteristics, utilization data (including DSH percentages), and financial statement data.

recent data available at the time of our analyses.<sup>6</sup> We also reviewed the excepted hospitals' Medicare cost reports from fiscal years 2017 through 2020—the most recent 4 years for which complete data were available at the time of our review.<sup>7</sup> Cost report data reviewed included geographic and other information, such as hospital location and size, as well as the hospitals' reported DSH percentages before and during the pandemic. To assess the reliability of the data we used in our analyses, we reviewed related documentation, interviewed officials from HRSA and the Centers for Medicare & Medicaid Services, and performed appropriate electronic data checks. We determined that the data were sufficiently reliable for the purposes of our reporting objectives. Finally, we administered a questionnaire to excepted hospitals requesting information about their 340B drug purchases in 2020 and 2021 and any discounts they provided on 340B drugs to low-income, uninsured patients.

We conducted this performance audit from June 2022 to May 2023 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

### Hospital Eligibility for the 340B Program

Entities eligible to participate in the 340B Program include six types of hospitals that generally perform a government function to provide care to low-income, medically underserved individuals.<sup>8</sup> Eligibility criteria for most types of hospitals include meeting specified minimum DSH percentages (see table 1). In addition, to be eligible to participate in the 340B Program, hospitals must be: (1) owned or operated by a unit of state or local government; (2) private, nonprofit hospitals that have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare—which we refer to as “nongovernmental hospitals”; or (3) nonprofit corporations that have been formally granted state or local governmental powers. Proprietary, for-profit hospitals are not eligible to participate in the program.

**Table 1: Types of Hospitals Eligible to Participate in the 340B Program**

Hospital type	Description	Disproportionate share hospital adjustment percentage requirement <sup>a</sup>
Children's hospitals	Hospitals with inpatients predominantly age 18 or younger	>11.75%
Critical access hospitals <sup>b</sup>	Small, rural hospitals with no more than 25 inpatient beds	N/A

<sup>6</sup>The 340B database contains information on hospitals, including each hospital's 340B identification number, hospital type, and participation history, such as start and termination dates.

<sup>7</sup>Our analyses were based on the most recent cost report data available as of September 2022.

<sup>8</sup>Other entities eligible to participate in the program include federal grantees that receive one of 10 types of federal grants, as specified in statute. See 42 U.S.C. § 256b(a)(4)(A)-(K). All such grant programs are administered by agencies within the Department of Health and Human Services.

Hospital type	Description	Disproportionate share hospital adjustment percentage requirement <sup>a</sup>
Disproportionate share hospitals	General acute care hospitals that serve a disproportionate number of low-income Medicare and Medicaid inpatients	>11.75%
Freestanding cancer hospitals	Independent, nonprofit hospitals that treat patients with cancer	>11.75%
Rural referral centers <sup>c</sup>	High-volume acute care rural hospitals that treat a large number of complicated cases	≥8%
Sole community hospitals <sup>d</sup>	Geographically isolated hospitals	≥8%

Source: Federal law and information from the Health Resources and Services Administration. | GAO-23-106095

<sup>a</sup>Among other criteria, to be eligible for the 340B Program, certain hospitals must treat a disproportionate number of low-income Medicare and Medicaid patients, as measured by each hospital's disproportionate share hospital adjustment percentage.

<sup>b</sup>Critical access hospitals are certified by the Centers for Medicare & Medicaid Services in accordance with 42 U.S.C. § 1395i-4(e).

<sup>c</sup>Rural referral centers are classified by the Centers for Medicare & Medicaid Services in accordance with 42 U.S.C. § 1395ww(d)(5)(C)(i).

<sup>d</sup>Sole community hospitals are classified by the Centers for Medicare & Medicaid Services in accordance with 42 U.S.C. § 1395ww(d)(5)(D)(iii). A hospital may generally qualify for this status if it is determined that because of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals, it is the sole source of inpatient hospital services reasonably available in a geographic area.

### 340B Program Registration and Participation

To register for the 340B Program, covered entities (including hospitals) must first submit an application through the online 340B database. They must provide specific information about themselves, including their affiliated pharmacies, and may be asked to provide other supporting documentation during registration. For example, certain hospitals must certify that they meet the applicable statutory DSH percentage requirement for participating in the program.

Once approved by HRSA and listed in the 340B database, covered entities can begin purchasing drugs from manufacturers at 340B discounted prices. These entities may provide 340B drugs to patients through one or more dispensing methods. For example, they may dispense these drugs through pharmacies—either through (1) in-house pharmacies they own; (2) contract pharmacy arrangements, in which covered entities contract with and pay outside retail pharmacies (contract pharmacies) to dispense drugs on their behalf; or both.

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. These contract pharmacies must be listed as active in HRSA's 340B database before they dispense 340B drugs. Covered entities may register an unlimited number of contract pharmacy arrangements with HRSA.<sup>9</sup>

### 340B Program Requirements

Covered entities (including hospitals) must maintain compliance with 340B Program statutory requirements in three areas to continue participating in the program. HRSA is responsible for overseeing the 340B Program, including compliance with these requirements, and historically has issued interpretive guidance and statements of policy to assist with compliance.

<sup>9</sup>See Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

**Eligibility.** As previously discussed, certain hospitals must meet specified DSH percentages, along with other eligibility requirements. Certain types of hospitals are also prohibited from procuring outpatient drugs through a group purchasing organization.<sup>10</sup> In addition, all covered entities must ensure that they have contracts in place for all contract pharmacy locations and maintain auditable records. They must also ensure that contact and eligibility-related information for themselves and their contract pharmacies is accurate and kept up to date in the 340B database.

**Diversion of 340B Program drugs to ineligible patients.** Covered entities cannot divert any drugs purchased at the 340B price to individuals not eligible to receive them. The 340B statute does not define an eligible patient. In the absence of a statutory definition, HRSA guidance states that diversion occurs when 340B drugs are given to individuals who are not patients of the covered entity.<sup>11</sup>

**Duplicate discounts.** Covered entities cannot subject drug manufacturers to duplicate discounts, which may occur when drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.<sup>12</sup>

#### HRSA's 340B Program Integrity and Oversight Measures

To oversee covered entities' (including hospitals') continued compliance with 340B Program requirements, HRSA has implemented several program integrity and oversight measures. These include audits, a self-disclosure process to identify noncompliance, quarterly DSH percentage integrity checks, nongovernmental hospital contract reviews, and contract pharmacy integrity checks.

**Audits.** HRSA began implementing a systematic approach for auditing covered entities in fiscal year 2012 and began its current practice of auditing 200 covered entities per year in fiscal year 2015. HRSA issues findings of noncompliance with 340B Program requirements based on information gathered through its audit process. Audited entities must then address any findings through corrective action plans. In addition to issuing findings, through the audits, HRSA officials may recommend areas for improvement based on failures to follow best practices that may

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<sup>10</sup>Hospitals buy drugs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations, which pool the purchasing power of multiple providers to bargain for lower prices from manufacturers. Disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals participating in the 340B Program may not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. See 42 U.S.C. § 256b(a)(4)(L)(iii) (incorporated by reference into 42 U.S.C. § 256b(a)(4)(M)).

<sup>11</sup>HRSA generally defines patients of a covered entity as individuals whose health care records are maintained by the covered entity, for whom the covered entity maintains responsibility for care, or who are receiving services that are consistent with the type of services for which the covered entity qualified for 340B eligibility. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996).

<sup>12</sup>42 U.S.C. § 256b(a)(5)(A). The Medicaid Drug Rebate Program, established under the Omnibus Budget Reconciliation Act of 1990, requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8). To determine whether duplicate discounts have 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.

For more information on duplicate discounts, see GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, [GAO-20-212](#) (Washington, D.C.: Jan. 21, 2020).

reflect applicable guidance but not statutory requirements. Audited entities are not required to submit corrective action plans to address areas for improvement.

**Self-disclosure to identify noncompliance.** Following the implementation of HRSA's audit process, officials said that the agency began a self-disclosure initiative to allow covered entities to report and correct self-identified instances of noncompliance with 340B Program requirements. Covered entities are required to prepare and submit corrective action plans related to any self-disclosed noncompliance.

**Quarterly DSH percentage checks.** In fiscal year 2015, HRSA began conducting quarterly checks of the Medicare cost reports of all hospitals for which 340B Program eligibility is dependent on maintaining a statutorily defined DSH percentage threshold. According to HRSA, officials review the hospital's cost report for the most recent fiscal year available at the time of the quarterly checks.

**Nongovernmental hospital contract reviews during registration.** In 2017, HRSA began conducting contract integrity checks for a random sample of 20 percent of nongovernmental hospitals during registration. In January 2020, this was expanded to include all nongovernmental hospitals registering for the program. As part of these reviews, HRSA officials verify that the contract document provided by the hospital is signed by both hospital and government officials, is in effect, and does not expire before program participation would begin. In July 2020, following a GAO review, HRSA officials implemented an additional analysis of the contracts collected during registration to determine whether they provided for the provision of health care services to low-income individuals not eligible for Medicare or Medicaid as required for 340B Program eligibility.<sup>13</sup>

**Quarterly program integrity checks of contract pharmacy arrangements.** Beginning in fiscal year 2017, HRSA began conducting quarterly checks of a random sample of 5 percent of new contract pharmacy arrangements to verify various elements of each contract.

In administering and overseeing the 340B Program, HRSA has also been responsible for developing and implementing the process through which hospitals could request an exception to the 340B DSH percentage eligibility requirement as authorized in the Consolidated Appropriations Act, 2022.

### **HRSA's Administration of the 340B DSH Percentage Eligibility Exception Process**

#### What steps did HRSA take to develop and implement the 340B DSH percentage eligibility exception process?

HRSA took a variety of steps to develop and implement the 340B DSH percentage eligibility exception process. According to HRSA officials, within 3 days of the Consolidated Appropriations Act, 2022, becoming law in March 2022, the agency

- developed and implemented an attestation form for hospitals to use to request exceptions;
- developed a standard operating procedure to guide its review and approval process;

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<sup>13</sup>See GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, [GAO-20-108](#) (Washington, D.C.: Dec. 11, 2019).

- shared information about the provision with stakeholder associations, including the American Hospital Association, the National Rural Health Association, America's Essential Hospitals, and 340B Health;
- identified hospitals that were potentially eligible for the exception and notified them about the process for submitting a request; and
- posted a notice on its website to make other potentially-eligible hospitals aware of the process for requesting an exception.

The attestation form HRSA developed for hospitals requesting an exception required each requesting hospital to provide information about itself, such as its 340B identification number, applicable cost-reporting period, applicable DSH percentage, and the name of the hospital executive responsible for its 340B Program (known as the authorizing official). In addition, the form included a justification section for each requesting hospital to describe how the pandemic affected its ability to meet its applicable required DSH percentage for 340B participation, including any actions the hospital may have taken in response to the pandemic.

HRSA's standard operating procedure for the exception process instructed agency officials to review hospital attestation forms to determine if the hospital's

- DSH percentage was below the eligible threshold for the hospital type;
- cost-reporting period in question began no earlier than October 1, 2019 and ended no later than December 31, 2022;
- form was signed by the hospital's authorizing official;
- form was submitted prior to statutory deadlines;<sup>14</sup> and
- justification provided information on actions taken by or other impact on the hospital in response to, or as a result of, the COVID-19 pandemic that may have affected the hospital's ability to meet the 340B DSH percentage.

In addition, according to the standard operating procedure, officials were to review information from HRSA's 340B database to verify that the hospital was a covered entity as of January 26, 2020—the day before the beginning of the COVID-19 public health emergency.<sup>15</sup>

#### What were the results of HRSA's review of 340B hospitals' requests for an exception?

Our review of HRSA documentation found that of the 61 hospitals that requested an exception as of May 31, 2022, HRSA approved 53 hospitals for the exception and denied eight.<sup>16</sup> All of the denials were for technical reasons based on statutory requirements, and none were related to

<sup>14</sup>Hospitals terminated from the 340B Program prior to March 15, 2022—the day the Consolidated Appropriations Act, 2022, was enacted—due to their DSH percentage were required to submit their attestation forms within 30 days (by April 14, 2022). Other hospitals were required to submit their forms within 30 days of filing a Medicare cost report with a DSH percentage that made the hospitals ineligible.

<sup>15</sup>On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency for the United States, retroactive to January 27, 2020.

<sup>16</sup>As of January 31, 2023, 94 hospitals requested an exception. Of those, 82 hospitals were approved (including 13 hospitals that received a second exception), and 12 were denied. All of the denials were for technical reasons based on statutory requirements; none were related to the COVID-19 justification section of the hospitals' attestation forms.

the COVID-19 justification section of the hospitals' attestation forms. Specifically, five hospitals were denied exceptions because they were not covered entities on January 26, 2020, which was a statutory requirement for receiving the exception; two because they requested an exception after the statutory deadline; and one because its DSH percentage was above the eligibility threshold and thus did not require the exception for participation in the 340B Program.

Of the 53 excepted hospitals, 33 received an exception to participate as disproportionate share hospitals, 14 as sole community hospitals, and six as rural referral centers.<sup>17</sup> According to HRSA, nine of the 53 excepted hospitals requested, as part of the exception process, to change their hospital type from either a sole community hospital or rural referral center to a disproportionate share hospital.<sup>18</sup> According to our analysis of data from HRSA and hospital cost reports, all nine had previously participated in the 340B Program as disproportionate share hospitals but had changed hospital type earlier in the pandemic. The hospitals generally could no longer meet the DSH percentage requirement for disproportionate share hospitals, but had met the lower DSH percentage requirements for sole community hospitals or rural referral centers.

HRSA officials told us that to change hospital type, hospitals were required to submit a "hospital entity type change" request, in addition to submitting their exception requests. HRSA officials reviewed all hospital entity type change requests to ensure that each requesting hospital met all 340B eligibility requirements for the requested hospital type (aside from the DSH percentage). HRSA only permitted hospitals to change to a hospital type they had used in previous participation in the 340B Program.

Hospitals may have chosen to change hospital type for a number of reasons. For example, drug manufacturers are not required to provide certain drugs—known as orphan drugs—at the 340B discounted price to sole community hospitals and rural referral centers, among other covered entities. In contrast, drug manufacturers are required to provide these drugs at the 340B discounted price to those participating in the 340B Program as disproportionate share hospitals.<sup>19</sup>

As part of its review of hospitals' requests for exceptions, HRSA identified program compliance issues with two hospitals. Specifically, HRSA determined that prior to the exception, two hospitals had continued participating in the program after filing cost reports with DSH percentages below the 340B eligibility threshold for their hospital types (in July 2021 and January 2022, respectively). HRSA officials told us that these hospitals requested and received the exception, but were required to work with manufacturers to repay any 340B discounts received during their period of ineligibility.

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<sup>17</sup>None of the 53 excepted hospitals were cancer hospitals or children's hospitals.

<sup>18</sup>Officials explained that hospitals may choose to participate in the 340B Program as types other than their Medicare-designated types. For example, a Medicare-designated sole community hospital may choose to participate in the 340B Program as a disproportionate share hospital as long as the hospital meets the 340B eligibility requirements for that hospital type.

<sup>19</sup>42 U.S.C. § 256b(e). Orphan drugs are drugs designated by the Secretary of the Department of Health and Human Services as treating a rare disease or condition.



What information did the excepted hospitals provide in their attestation forms to explain the impact of the COVID-19 pandemic on their ability to meet their required DSH percentage thresholds?

Excepted hospitals' explanations regarding the impact that the pandemic had on their ability to meet the DSH percentage requirement for participating in the 340B Program varied. Based on our review of the hospital attestation forms, the DSH percentages of excepted hospitals ranged from 0.2 to 9.0 percentage points below their required DSH percentage thresholds for the hospital types for which they later applied and were approved for exceptions. In their attestation forms, some hospitals noted that their overall lower DSH percentages could have been affected by changes in the key components used to calculate those percentages.<sup>20</sup>

- One hospital reported that its Medicare Supplemental Security Income patient days had decreased during the pandemic and 23 hospitals reported that they had more overall Medicare inpatient days. Either of these changes could have resulted in a decrease in the hospitals' low-income Medicare patient percentages.
- Twenty-nine hospitals reported that they had fewer Medicaid inpatient days, and 29 hospitals reported that they had more overall inpatient days. Either of these changes could have resulted in a decrease in the hospitals' Medicaid patient percentages.<sup>21</sup>

Some hospitals also noted other impacts that the pandemic had on their operations that may have affected their DSH percentages. For example, 36 hospitals reported staffing shortages, bed capacity issues, or deferred, delayed, or forgone care because of the pandemic. In some cases, hospitals reported that their states issued moratoriums of certain elective procedures and surgeries to allow hospitals to focus limited resources and staff on treating the high volumes of COVID-19 patients. According to these hospitals, the moratoriums to delay these elective procedures disproportionately affected their ability to care for Medicaid patients, which may have led to a decrease in their Medicaid patient percentages and in turn, their DSH percentages. (For more examples of the pandemic's effect on DSH percentages, see text box.)

**The COVID-19 Pandemic's Effects on 340B Disproportionate Share Hospital (DSH) Adjustment Percentages, as Noted by Excepted Hospitals**

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<sup>20</sup>As noted earlier, a hospital's DSH percentage is generally based on its DSH patient percentage, which is determined by a calculation of the sum of two other percentages: (1) the low-income Medicare patient percentage, calculated as the ratio of Medicare Supplemental Security Income inpatient days to total Medicare inpatient days; and (2) the Medicaid patient percentage, calculated as the ratio of Medicaid, non-Medicare inpatient days to total inpatient days.

Supplemental Security Income is a federal assistance program administered by the Social Security Administration that provides cash benefits to certain individuals who are elderly, blind, or have a disability. It acts as a safety net for individuals who have limited resources and little or no income.

<sup>21</sup>Hospitals could have experienced and reported more than one of these changes.

Excepted hospitals also reported similar trends in response to our questionnaire. For example, 18 hospitals reported changes that would have resulted in a decrease in their low-income Medicare patient percentage, and 24 hospitals reported changes that would have resulted in a decrease in their Medicaid patient percentage. These changes may have contributed to a lower overall DSH percentage.

The following are examples of the reported effects that the pandemic had on excepted hospitals' DSH percentages. (Excepted hospitals are those that requested exceptions to the 340B DSH percentage eligibility requirement as of May 31, 2022, and that were subsequently approved.)

"As COVID-19 cases surged... Medicare lengths of stay sharply increased while Medicaid days simultaneously declined. These outcomes are a result of longer COVID-related patient stays, especially among older Medicare beneficiaries, and fewer non-COVID visits. This is partly due to [state-] mandated limitations on the provision of non-urgent services."

"[The public health emergency] has impacted additional operational areas of the hospital including the emergency department.... The emergency department typically furnishes services to a large number of Medicaid patients, so the diversion resulting from COVID patients filling the emergency department and hospital has contributed to the overall decrease in Medicaid inpatient days at the hospital. During the public health emergency, [the hospital] cancelled elective overnight surgeries... due to a high number of COVID patient admissions. This resulted in the loss of... patient admissions, some of which would have been Medicaid admission[s]. Lack of elective overnight surgeries contributed to an increase in average length of stay at the hospital as well as an overall decrease in Medicaid inpatient days."

"[Among others,] the following items impacted the total number of Medicaid inpatient days or total patient days, [and] therefore affected [the hospital's] DSH percentage:

- **Capacity**—Total system capacity in fiscal year 2021 was reduced due to increased testing requirements for patients, increased employee absences due to COVID testing and quarantines, isolation requirements, reduced efficiency caused by increased PPE [personal protective equipment] usage, and a focus on patients with COVID-19. Due to lack of capacity, many patients that would have traditionally been admitted into the hospital were treated in an outpatient setting by their primary care provider or home health. This change in treatment patterns dramatically decreased the number of younger patients with Medicaid that were admitted to the hospital.
- **Patient days**—Many patients hospitalized with COVID-19 were critically ill resulting in prolonged lengths of stay. This, along with difficulty in transferring patients to skilled nursing and other facilities due [to] COVID-19 outbreaks and lack of staffing at the facilities, resulted in greater total patient days.
- **Reduction in pediatric admissions**—Community-wide use of masking, social distancing, and school and daycare closures reduced the incidence of Influenza and Respiratory Syncytial Virus infections and subsequent hospitalizations, which disproportionately impacted the Medicaid population."

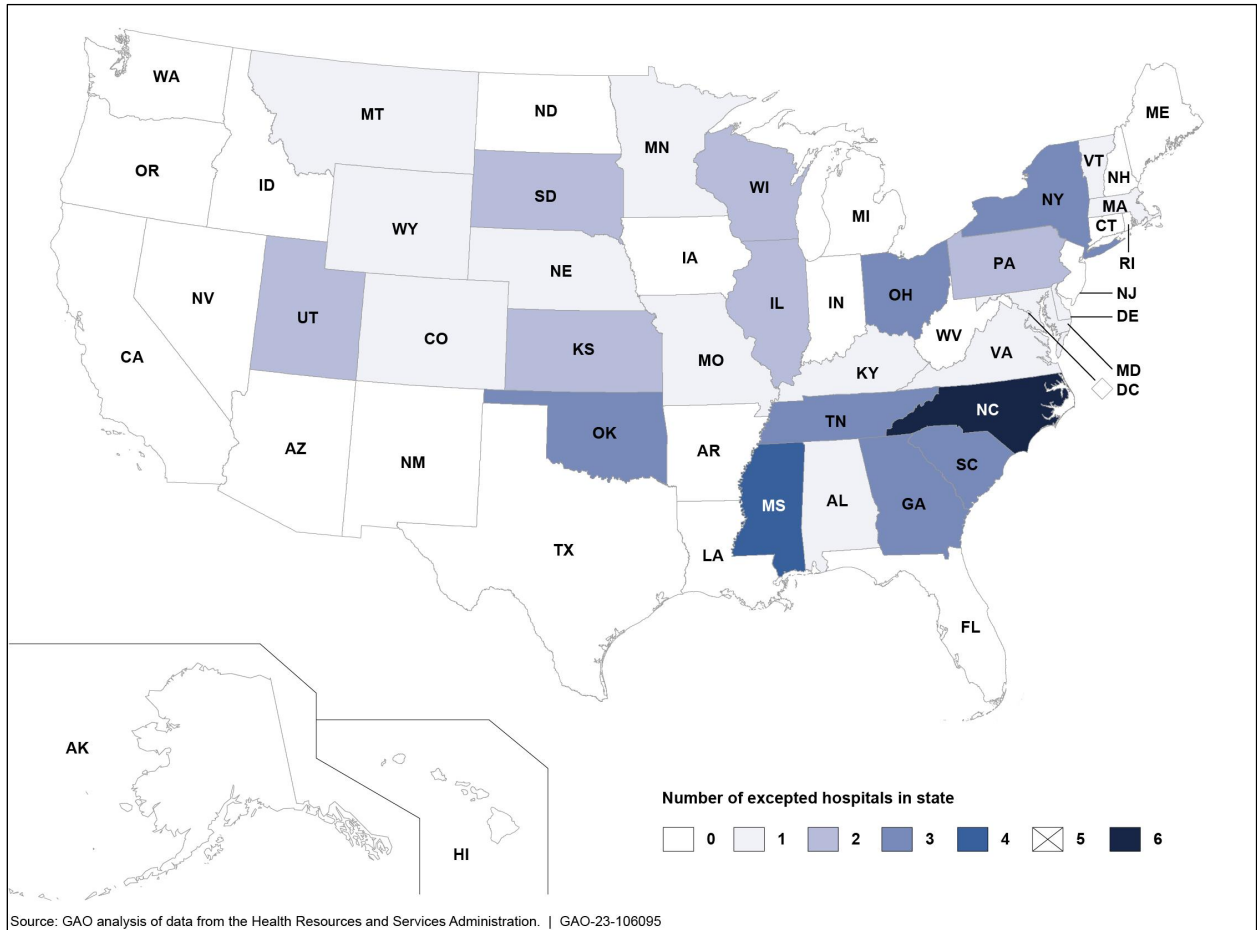
Source: GAO's review of excepted hospitals' attestation forms. | GAO-23-106095

## Characteristics of Excepted Hospitals

### What are the geographic and other non-financial characteristics of the excepted hospitals?

Our review of HRSA data found that the 53 excepted hospitals were geographically dispersed among 27 states. While most of the 27 states had three or fewer excepted hospitals, two states had more. North Carolina had the highest number of excepted hospitals (six), followed by Mississippi (four) (see fig. 1).

**Figure 1: Number of Excepted Hospitals, by State**



**Accessible Data for Figure 1: Number of Excepted Hospitals, by State**

<b>State</b>	<b>Number of excepted hospitals</b>
AL	1
CO	1
DE	1
GA	3
IL	2
KS	2
KY	1
MA	1
MD	1
MN	1
MO	1
MS	4
MT	1
NC	6
NE	1
NY	3
OH	3
OK	3
PA	2
SC	3
SD	2
TN	3
UT	2
VA	1
VT	1
WI	2
WY	1

Note: This analysis is of the 53 hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.”

According to data from HRSA and hospital cost reports, the excepted hospitals varied in terms of: hospital type and classification, whether they were located in urban or rural areas, and size as measured by the number of beds (see table 2). For example, 11 of the hospitals were government owned or operated, while the remaining 42 were nongovernmental hospitals or hospitals granted governmental powers. Most (35) of the hospitals were in rural areas, and most (31) had 100 or fewer beds.

**Table 2: Characteristics of Excepted Hospitals**

Category	Characteristic	Number of hospitals (N=53)
340B hospital type <sup>a</sup>	Disproportionate share hospital	33
340B hospital type <sup>a</sup>	Sole community hospital	14
340B hospital type <sup>a</sup>	Rural referral center	6
340B hospital classification <sup>a</sup>	Government owned or operated	11
340B hospital classification <sup>a</sup>	Nongovernmental hospitals	40
340B hospital classification <sup>a</sup>	Granted governmental powers	2
Location <sup>b</sup>	Rural	35
Location <sup>b</sup>	Urban	18
Number of beds <sup>b</sup>	<50	16
Number of beds <sup>b</sup>	51–100	15
Number of beds <sup>b</sup>	101–300	17
Number of beds <sup>b</sup>	301–400	4
Number of beds <sup>b</sup>	>400	1

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services and Health Resources and Services Administration (HRSA). | GAO-23-106095

Notes: This analysis is of the 53 hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.”

There are three classifications for 340B hospitals: (1) hospitals owned or operated by a unit of state or local government; (2) private, nonprofit hospitals that have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare—referred to as “nongovernmental hospitals”; or (3) nonprofit corporations that have been formally granted state or local governmental powers.

<sup>a</sup>Data on hospital types and classifications are from HRSA as of July 2022. The hospital type reflects the type for which the hospital was approved for the exception.

<sup>b</sup>Data on location and number of beds are as of fiscal year 2020, as reported in the hospitals’ Medicare cost reports.

### What are the financial characteristics of the excepted hospitals?

The financial characteristics of the 53 excepted hospitals varied, according to our analysis of their cost reports, and included the following specific characteristics:

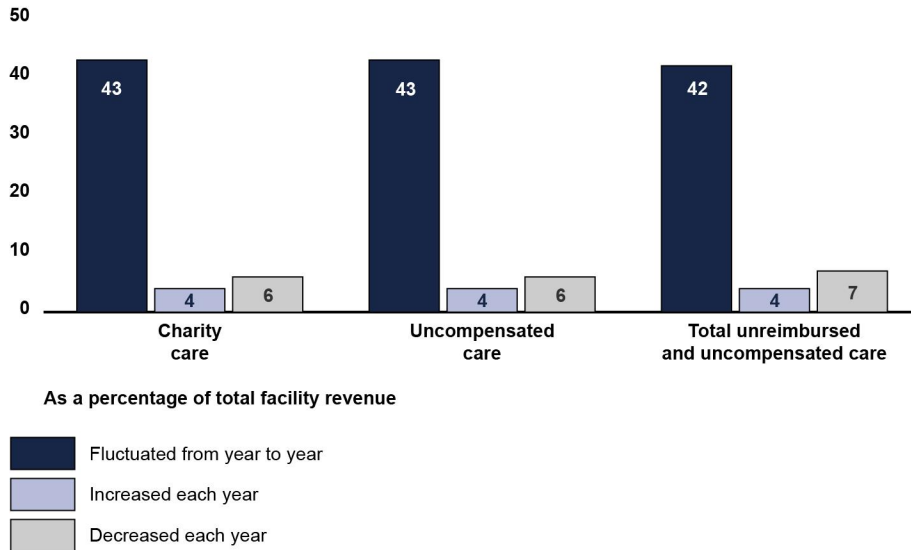
- Most (33) hospitals consistently operated with a positive total facility margin in each year from fiscal years 2017 through 2020 (meaning that their revenues exceeded their costs).<sup>22</sup> Of the remaining hospitals, four operated with a negative total facility margin each year (meaning that their costs exceeded their revenues), and 16 fluctuated between positive and negative margins.
- Most hospitals saw year-to-year fluctuations—both increases and decreases—in the amounts of charity care, uncompensated care, and total unreimbursed and

<sup>22</sup>Total facility margin was calculated as total revenue minus total costs divided by total revenue.

uncompensated care they provided as a percentage of total facility revenue.<sup>23</sup> However, for a few hospitals, the amounts either consistently increased each year or decreased each year, without fluctuations (see fig. 2). For example, for 42 of the 53 excepted hospitals, the amounts of total unreimbursed and uncompensated care as a percentage of total facility revenue fluctuated from year to year. For the remaining 11 hospitals, the amounts either increased each year (four hospitals) or decreased each year (seven hospitals).

**Figure 2: Trends in Amounts of Charity, Uncompensated, and Total Unreimbursed and Uncompensated Care Provided by Excepted Hospitals, as a Percentage of Each Hospital’s Total Facility Revenue, Fiscal Years 2017–2020**

Number of excepted hospitals



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services and Health Resources and Services Administration. | GAO-23-106095

**Accessible Data for Figure 2: Trends in Amounts of Charity, Uncompensated, and Total Unreimbursed and Uncompensated Care Provided by Excepted Hospitals, as a Percentage of Each Hospital’s Total Facility Revenue, Fiscal Years 2017–2020**

	Fluctuated from year to year	Increased each year	Decreased each year
<b>Charity care</b>	43	4	6
<b>Uncompensated care</b>	43	4	6
<b>Total unreimbursed and uncompensated care</b>	42	4	7

Notes: This analysis is of the 53 hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.” 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. Uncompensated

<sup>23</sup>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. Uncompensated care includes charity care and bad debt, which generally represents services for which a hospital determines that a patient has the financial capacity to pay, but is unwilling to do so. Total unreimbursed and uncompensated care includes charity care, bad debt, and costs not reimbursed by public payers.

care includes charity care and bad debt, which generally represents services for which a hospital determines that a patient has the financial capacity to pay, but is unwilling to do so. Total unreimbursed and uncompensated care includes charity care, bad debt, and costs not reimbursed by public payers.

- Across the 4 years we reviewed, only one of the 53 excepted hospitals (a sole community hospital) had increases each year in the amounts of charity care, uncompensated care, and total unreimbursed and uncompensated care the hospital provided, as a percentage of total facility revenue. In contrast, two hospitals (both disproportionate share hospitals) had decreases each year in all three types of care over the same time period.

#### What were the DSH percentages of the excepted hospitals in recent years?

Our review of cost report data from fiscal years 2017 through 2020 found that the DSH percentages—which, among other things, is a measure of the proportion of low-income Medicare and Medicaid patients treated by a hospital—for most excepted hospitals fluctuated in these years. Specifically, 39 of 52 excepted hospitals saw year-to-year fluctuations—both increases and decreases—in their DSH percentages.<sup>24</sup> The DSH percentage consistently decreased each year for 10 of the remaining hospitals and did not change for three hospitals.

During the 2 years prior to the pandemic, most, but not all, of the 53 excepted hospitals met or exceeded the required DSH percentage thresholds for the hospital types for which they later applied and were approved for the exceptions.<sup>25</sup>

- Forty-one hospitals had DSH percentages that met or exceeded the required thresholds in both years. The DSH percentages for 10 of these 41 hospitals were within 0.5 percentage points of the required thresholds in both years.
- In contrast, 12 hospitals had DSH percentages that were below the required thresholds in either one or both years.<sup>26</sup> Nine of the 12 had DSH percentages that were below the required thresholds in one of the 2 years and three had DSH percentages that were below the required thresholds in both years.

According to HRSA officials and our review of agency documentation, of the 12 hospitals with DSH percentages below the required thresholds in one or both years before the pandemic, two hospitals either did not participate in the 340B Program during the time for which their DSH percentages were below the required thresholds, or were participating as other hospital types and met the DSH percentage requirement for those types. In addition, one hospital was terminated from the 340B Program after submitting a cost report in which its DSH percentage was below the required threshold.

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<sup>24</sup>One hospital was excluded from this analysis because its cost report did not include a value for the DSH percentage for fiscal year 2017; it did not participate in the 340B Program during that year.

<sup>25</sup>The cost reports in this analysis all predated the pandemic, meaning that the end of the hospital's cost-reporting period was prior to and did not include January 27, 2020—the first day of the COVID-19 public health emergency. These cost reports may have included files from the Centers for Medicare & Medicaid Services' 2017, 2018, or 2019 fiscal years, depending on the hospital's cost-reporting period.

<sup>26</sup>Nine of the 12 hospitals were disproportionate share hospitals and three were sole community hospitals at the time of our review.

The other nine hospitals submitted cost reports that, according to HRSA officials, included DSH percentages that met or exceeded the required thresholds at the time HRSA conducted its quarterly DSH percentage check. As a result, HRSA determined that these hospitals were eligible for 340B participation at that time. HRSA officials said that the data in these hospitals' cost reports subsequently changed (for example, because of settlement), and the lower DSH percentages included in our analysis were the result of these changes.<sup>27</sup> According to officials, the lower DSH percentages were not identified during a subsequent quarterly DSH percentage check because the hospitals had filed cost reports for more recent years. As noted earlier, HRSA officials review the hospital's cost report for the most recent fiscal year available at the time of the quarterly checks, as that is what HRSA uses to determine a hospital's current 340B eligibility.

### Excepted Hospitals' 340B Drug Purchases

#### How much did excepted hospitals indicate they paid to purchase drugs through the 340B Program in 2020 and 2021, and what were their estimated 340B drug discounts?

The amount excepted hospitals reported paying for 340B drugs in 2020 and 2021 varied considerably (see table 3). For example, the 39 excepted hospitals that provided complete payment data for 2021 reported paying between about \$42,000 and \$70.9 million for 340B drugs in that year.<sup>28</sup> The median amount paid for 340B drugs was about \$6.9 million.

**Table 3: Amount Excepted Hospitals Reported Paying to Purchase Drugs through the 340B Program, 2020 and 2021**

	2020 (n=31)	2021 (n=39)
Minimum	\$99,842	\$42,000
Median	\$7,881,205	\$6,880,000
Maximum	\$74,625,003	\$70,899,182

Source: GAO analysis of questionnaire responses from excepted hospitals. | GAO-23-106095

Notes: This analysis was based on data reported by 48 of the 53 hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.” The analysis for each year (2020 and 2021) includes responses from excepted hospitals that provided dollar amounts for both (1) what they paid to purchase drugs through the 340B Program, and (2) what they would have paid to purchase the same drugs if they were not participating in the 340B Program in that year. In some cases, hospitals explained that they were unable to provide these requested dollar amounts because, for example, the drug purchase data available to them only covered part of the year, or they did not have access to historical drug pricing data.

The data for each year may include data for the calendar or fiscal year, depending on how excepted hospitals collected and reported data for the purposes of our questionnaire.

Excepted hospitals may have experienced lapses in enrollment in the 340B Program during 2021, which may have affected their 340B drug purchases.

<sup>27</sup>Our analyses were based on the most recent cost report data available as of September 2022.

Data in cost reports may change after their original submission in several circumstances. For example, data may change because of a settlement, which is a reconciliation between the Centers for Medicare & Medicaid Services and hospitals regarding hospitals' payments during the relevant cost-reporting periods. It may take up to a year or more for a cost report to be settled and finalized.

<sup>28</sup>To be included in the analysis for each year (2020 and 2021), excepted hospitals had to provide complete payment data for the entire year, meaning that they had to provide total dollar amounts for both (1) what they paid to purchase drugs through the 340B Program, and (2) what they would have paid to purchase the same drugs if they were not participating in the 340B Program for the year. In some cases, hospitals explained that they were unable to provide these requested dollar amounts because, for example, the drug purchase data available to them only covered part of the year, or they did not have access to historical drug pricing data.



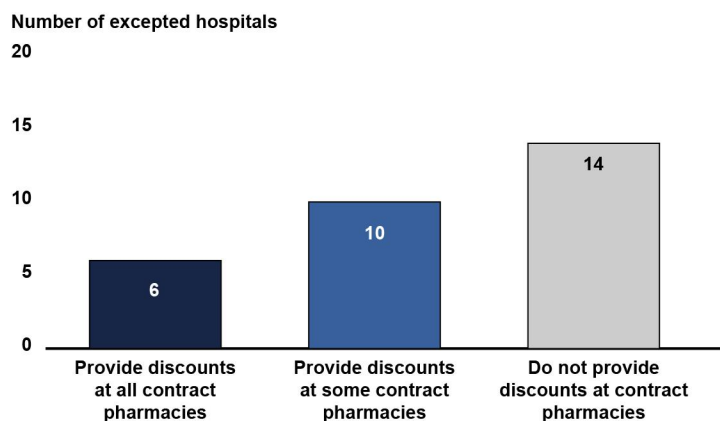
Based on excepted hospitals' estimates of what they would have paid to purchase drugs if not participating in the 340B Program in these years, the median discount percentage that the hospitals received on the 340B drugs they purchased was 42.4 percent in 2020 and 43.5 percent in 2021.<sup>29</sup>

### Discounts on 340B Drugs Provided by Excepted Hospitals to Patients

#### How many excepted hospitals reported providing low-income, uninsured patients with discounts on 340B drugs at contract pharmacies?

Of the 48 excepted hospitals that responded to our questionnaire, 30 reported having one or more active contract pharmacies that dispensed 340B drugs at the time they responded to the questionnaire.<sup>30</sup> Of the 30 hospitals, 16 reported providing discounts to low-income, uninsured patients at some or all of those pharmacies (see fig. 3).

**Figure 3: Number of Excepted Hospitals That Reported Providing Low-Income, Uninsured Patients with Discounts on 340B Drugs at Contract Pharmacies, 2022**



Source: GAO analysis of questionnaire responses from excepted hospitals. | GAO-23-106095

<sup>29</sup>We determined the discount percentage that an excepted hospital received on 340B drugs it purchased in each year by: (1) subtracting the amount a hospital reported paying to purchase drugs through the 340B Program in that year from what it estimated it would have paid that year if not participating in the program, and (2) dividing by what it estimated it would have paid. This percentage only includes drug costs and does not account for any costs a hospital may have incurred as a result of participating in the 340B Program, such as software or other costs to ensure compliance with program requirements.

<sup>30</sup>For the purposes of this study, we defined a contract pharmacy as a pharmacy not owned by the covered entity, but under contract with and listed on the covered entity's 340B database record. Some of the excepted hospitals that had pharmacies listed in the 340B database reported in our questionnaire that they did not have active contract pharmacies that dispensed 340B drugs at the time of the questionnaire. We previously reported that a covered entity that contracts with a pharmacy may not actually use the pharmacy to dispense 340B drugs. See GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (Washington, D.C.: June 21, 2018).

**Accessible Data for Figure 3: Number of Excepted Hospitals That Reported Providing Low-Income, Uninsured Patients with Discounts on 340B Drugs at Contract Pharmacies, 2022**

Category	Number of excepted hospitals
Provide discounts at all contract pharmacies	6
Provide discounts at some contract pharmacies	10
Do not provide discounts at contract pharmacies	14

Note: This analysis was based on data reported by hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.” Of the 53 excepted hospitals, 48 responded to our questionnaire. Of the 48 that responded, 30 reported having contract pharmacies that dispensed 340B drugs at the time they completed the questionnaire in September through November 2022.

Of the 16 excepted hospitals that reported providing low-income, uninsured patients with discounts at some or all of their contract pharmacies, the majority (10 hospitals) reported that the price patients pay for these drugs varies based on the specific pharmacy or on patient circumstances, such as patient need or their ability to pay. See table 4 for more information on the prices that hospitals reported their patients pay for 340B drugs at contract pharmacies.

**Table 4: Prices Low-Income, Uninsured Patients Pay for 340B Drugs, as Reported by 16 Excepted Hospitals with Contract Pharmacy Discounts, 2022**

Price	Number of excepted hospitals
Free/at no cost to the patient	0
More than \$0 but less than the 340B price (i.e., the price the hospital paid for the drug)	1
The 340B price	0
More than the 340B price but less than the wholesale price or what the pharmacy would charge a self-paying patient	2
<b>Other price:</b>	
	<b>Number of excepted hospital</b>
Price varies based on pharmacy or patient circumstances	10
Other specific amount (e.g., copayment)	3

Source: GAO analysis of questionnaire responses from excepted hospitals. | GAO-23-106095

Notes: This analysis was based on data reported by hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.” Of the 53 excepted hospitals, 48 responded to our questionnaire. This analysis includes the 16 hospitals that reported providing patients with discounts on 340B drugs at some or all of their contract pharmacies at the time they completed the questionnaire in September through November 2022.

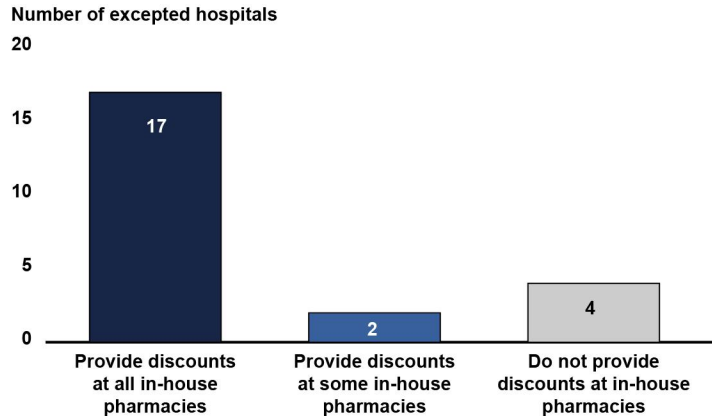
The wholesale price is the price that a wholesaler charges a pharmacy for a drug.

How many excepted hospitals reported providing low-income, uninsured patients with discounts on 340B drugs at in-house pharmacies?

Of the 48 excepted hospitals that responded to our questionnaire, 23 reported having one or more in-house pharmacies that dispensed 340B drugs for patients’ home use at the time they

responded to the questionnaire.<sup>31</sup> Of the 23 hospitals, 19 reported providing discounts to low-income, uninsured patients at some or all of these pharmacies (see fig. 4).

**Figure 4: Number of Excepted Hospitals That Reported Providing Low-Income, Uninsured Patients with Discounts on 340B Drugs at In-House Pharmacies, 2022**



Source: GAO analysis of questionnaire responses from excepted hospitals. | GAO-23-106095

**Accessible Data for Figure 4: Number of Excepted Hospitals That Reported Providing Low-Income, Uninsured Patients with Discounts on 340B Drugs at In-House Pharmacies, 2022**

<u>Category</u>	<u>Number of excepted hospitals</u>
Provide discounts at all in-house pharmacies	17
Provide discounts at some in-house pharmacies	2
Do not provide discounts at in-house pharmacies	4

Note: This analysis was based on data reported by hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.” Of the 53 excepted hospitals, 48 responded to our questionnaire. Of the 48 that responded, 23 reported having in-house pharmacies that dispensed 340B drugs for patients’ home use at the time they completed the questionnaire in September through November 2022.

Of the 19 excepted hospitals that reported providing low-income, uninsured patients with discounts at some or all of their in-house pharmacies, five reported that low-income, uninsured patients pay nothing for 340B drugs, and others reported that their patients pay various amounts (see table 5).

**Table 5: Prices Low-Income, Uninsured Patients Pay for 340B Drugs, as Reported by 19 Excepted Hospitals with In-House Pharmacy Discounts, 2022**

<u>Price</u>	<u>Number of excepted hospitals</u>
Free/at no cost to the patient	5

<sup>31</sup>For the purposes of this study, we defined an in-house pharmacy as a pharmacy owned by, and a legal part of, the 340B covered entity that dispenses drugs for patients’ home use. It does not include a contract pharmacy that is listed on the covered entity’s HRSA 340B database record, even if that contract pharmacy is located in the covered entity’s facility.

Price	Number of excepted hospitals
More than \$0 but less than the 340B price (i.e., the price the hospital paid for the drug)	0
The 340B price	1
More than the 340B price but less than the wholesale price or what the pharmacy would charge a self-paying patient	2
<b>Other price</b>	
Price varies based on pharmacy or patient circumstances	9
Other specific amount (e.g., copayment)	2

Source: GAO analysis of questionnaire responses from excepted hospitals. | GAO-23-106095

Notes: This analysis was based on data reported by hospitals that requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and that were subsequently approved—referred to as “excepted hospitals.” Of the 53 excepted hospitals, 48 responded to our questionnaire. This analysis includes the 19 hospitals that reported providing patients with discounts on 340B drugs at some or all of their in-house pharmacies at the time they completed the questionnaire in September through November 2022.

The wholesale price is the price that a wholesaler charges a pharmacy for a drug.

What other benefits did excepted hospitals report providing to their patients as a result of participating in the 340B Program?

Apart from providing low-income, uninsured patients with discounts on 340B drugs, 46 of the 48 excepted hospitals that responded to our questionnaire described other benefits to patients and communities from the hospitals’ participation in the 340B Program. For example, some excepted hospitals reported that the 340B Program allowed them to expand or offer additional health services and provide services to underserved populations, such as

- expanding chemotherapy infusion clinics, without which patients would have to travel long distances—often to another state—to receive care;
- adding primary care providers in their service area or retaining specialists to provide care in rural areas;
- conducting outreach to underserved communities, such as providing annual influenza vaccinations, COVID-19 testing and vaccination events, and health and wellness education; and
- providing mobile charity care to community members who are unhoused or living in rural areas.

In addition, some hospitals reported using 340B savings to offset costs or financial losses, thus indirectly benefiting their patients and communities by keeping the hospitals operational. For example, one excepted hospital noted that savings from the 340B Program helped it to absorb shortfalls from Medicaid reimbursements and other programs for low-income patients. Another hospital said its 340B savings feed into its overall operating budget, which helps keep its hospital afloat. A different hospital reported that the 340B Program allows it to keep clinics open that may otherwise be too costly to maintain.

## Results of HRSA’s Previous Audits and Other Oversight Activities of Excepted Hospitals

### How many excepted hospitals did HRSA audit since fiscal year 2012, and what issues did HRSA identify?

According to HRSA, as of July 2022, the agency had audited 25 of the 53 excepted hospitals. Our review of HRSA documentation found that the agency issued a total of 19 findings related to noncompliance for 14 of these hospitals as a result of these audits. Five of the hospitals had more than one finding of noncompliance. The most common finding among the excepted hospitals that were audited related to the potential for duplicate discounts (see table 6). The remaining 11 hospitals had no audit findings.

**Table 6: Findings from 340B Program Audits of Excepted Hospitals, as of July 2022**

<b>Audit findings related to noncompliance of 340B Program requirements</b>	<b>Number of findings</b>
<b>Duplicate discounts:</b> Inaccurate information on the Medicaid Exclusion File <sup>a</sup>	7
<b>Duplicate discounts:</b> Billing contrary to information on the Medicaid Exclusion File <sup>a</sup>	2
<b>Diversion of 340B Program drugs to ineligible patients</b> (e.g., individuals prescribed drugs at an ineligible site, individuals who did not meet patient definition set in the Health Resources and Services Administration (HRSA) guidance)	5
<b>Eligibility</b> (e.g., incorrect record in HRSA’s 340B Office of Pharmacy Affairs Information System)	5
<b>Total findings</b>	<b>19</b>

Source: GAO analysis of information received from the Health Resources and Services Administration. | GAO-23-106095

Note: Fifty-three hospitals requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and were subsequently approved—referred to as “excepted hospitals.” This analysis is based on the 25 excepted hospitals that were audited by HRSA from fiscal year 2012 (when the agency began conducting audits) through July 2022.

<sup>a</sup>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. HRSA has issued guidance for the prevention of duplicate discounts, which included establishing and clarifying the use of the Medicaid Exclusion File as a mechanism to assist in the identification of 340B drugs provided to certain Medicaid beneficiaries.

Our review of HRSA documentation found that the 14 hospitals for which HRSA had audit findings all submitted corrective action plans to address these findings, as required by HRSA. However, as we previously reported, HRSA does not require all covered entities (including all hospitals) to provide evidence of successful implementation of the corrective actions prior to closing audits and instead relies on the entities to self-attest that the audit findings have been addressed.<sup>32</sup>

Of the 25 hospitals that were audited, HRSA also issued a total of 39 areas for improvement for 22 of the hospitals. Areas for improvement are based on a covered entity’s failure to follow best

<sup>32</sup>See [GAO-18-480](#). While HRSA does not require all audited covered entities to provide evidence that their corrective action plans have been implemented, HRSA does expect that corrective action plans will be implemented within 6 months of being approved by the agency. Covered entities unable to meet this expectation may be subject to termination from the 340B Program. In GAO-18-480, we also found that while HRSA requires covered entities that have noncompliance issues identified during audits to assess the full extent of noncompliance, the agency does not require all entities to explain their methodology for doing so. Thus, HRSA does not know if covered entities have effectively identified the full extent of noncompliance. We made seven recommendations to HRSA to address these and other issues. As of March 2023, those recommendations remain open (see enclosure I).

practices that may reflect applicable guidance, but not statutory requirements and do not require corrective action plans. These areas for improvement for the 22 hospitals included the following:

- Twenty-eight related to hospitals developing, updating, or implementing their 340B Program policies and procedures. For example, five of these areas for improvement involved reviewing and updating hospitals' 340B Program policies and procedures related to procuring drugs and preventing duplicate discounts. There were also five areas for improvement related to engaging with an independent organization to perform annual audits of hospitals' contract pharmacies.
- Eleven related to hospitals maintaining accurate and complete documentation of their compliance with 340B requirements. For example, eight of these areas for improvement involved accurately identifying all contract pharmacy locations by name and address within the contracts.<sup>33</sup>

In addition to HRSA's oversight, drug manufacturers may conduct audits in certain circumstances. (See text box below.)

**Drug Manufacturers' Oversight of 340B Hospitals**

With approval from the Health Resources and Services Administration (HRSA), a drug manufacturer is permitted to conduct audits of covered entities (including hospitals) if it has documentation that indicates reasonable cause of a violation (e.g., transferring or otherwise reselling 340B discounted covered drugs to ineligible recipients). According to HRSA, no drug manufacturers have requested to audit any of the 53 hospitals in our review since the beginning of the 340B Program in 1992.

Source: GAO analysis of information received from HRSA and 61 Fed. Reg. 65,406 (Dec. 12, 1996). | GAO-23-106095

How many excepted hospitals have self-disclosed noncompliance to HRSA since 2012, and what issues did they report?

According to HRSA, as of July 2022, 10 of the 53 excepted hospitals have self-disclosed 11 noncompliance events, as part of HRSA's self-disclosure initiative. Our review of HRSA documentation found that most of the self-disclosed noncompliance related to the diversion of 340B drugs to ineligible patients (see table 7).

**Table 7: Self-Disclosures of Noncompliance Issues by Excepted Hospitals, as of July 2022**

Type of self-disclosed noncompliance issue	Number of self-disclosures
<b>Duplicate discounts</b> (e.g., failure to follow state Medicaid requirements)	1
<b>Diversion of 340B Program drugs to ineligible patients</b> (e.g. individuals prescribed drugs at an ineligible site, individuals who did not meet patient definition set in HRSA guidance)	7
<b>Eligibility</b> (e.g., obtaining covered outpatient drugs through a group purchasing organization) <sup>a</sup>	3
<b>Total self-disclosed noncompliance issues</b>	<b>11</b>

Source: GAO analysis of information received from the Health Resources and Services Administration (HRSA). | GAO-23-106095

Note: Fifty-three hospitals requested an exception to the 340B disproportionate share hospital adjustment percentage eligibility requirement as of May 31, 2022, and were subsequently approved—referred to as “excepted hospitals.” This analysis is based on

<sup>33</sup>According to HRSA guidance, covered entities are required to have written contracts in place with each pharmacy through which they intend to dispense 340B drugs.

the 10 excepted hospitals that self-disclosed noncompliance issues to HRSA from 2012 (when the agency began its self-disclosures of noncompliance initiative) through July 2022.

<sup>3</sup>Hospitals buy drugs at prices negotiated directly with manufacturers or at prices negotiated by buying intermediaries, known as group purchasing organizations, which pool the purchasing power of multiple providers to bargain for lower prices from manufacturers. Disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals participating in the 340B Program may not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. See 42 U.S.C. § 256b(a)(4)(L)(iii) (incorporated by reference into 42 U.S.C. § 256b(a)(4)(M)).

### How many excepted hospitals were subject to other HRSA oversight efforts?

According to HRSA officials, three of the 53 excepted hospitals were flagged for having a DSH percentage below the statutory eligibility threshold for their hospital type from fiscal year 2015 through July 2022 as part of HRSA's quarterly DSH percentage checks of all 340B participating hospitals. One of these hospitals was flagged prior to the pandemic, and another during the pandemic. HRSA officials told us that both hospitals submitted amended Medicare cost reports showing they met or exceeded the DSH percentages and were allowed to remain active in the 340B Program.

HRSA flagged the third hospital during the pandemic and contacted the hospital in February 2022. The hospital later submitted a request for an exception that HRSA subsequently reviewed and approved. HRSA officials told us that the hospital was required to work with manufacturers to repay any 340B discounts received during their period of ineligibility, namely the period of time between when the hospital filed its cost report and when the exception was granted.

According to HRSA, as of July 2022, no issues had been identified in its additional oversight activities of the excepted hospitals in recent years. These oversight activities included

- nongovernmental hospital contract reviews for six of the excepted hospitals during registration;<sup>34</sup> and
- contract pharmacy integrity checks for four of the excepted hospitals.<sup>35</sup>

### **Agency Comments**

We provided a draft of this report to the Department of Health and Human Services for review. The Department provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [RosenbergM@gao.gov](mailto:RosenbergM@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report included

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<sup>34</sup>HRSA began conducting reviews of nongovernmental hospital contracts in 2017. We previously reported on HRSA's oversight of nongovernmental hospitals in the 340B Program and made six recommendations to HRSA related to ensuring that participating nongovernmental hospitals meet eligibility requirements. As of March 2023, four of these recommendations had not been implemented (see enclosure I and [GAO-20-108](#)).

<sup>35</sup>HRSA began conducting contract pharmacy integrity checks in fiscal year 2017. We previously reported on the use of contract pharmacies in the 340B Program and made recommendations related to HRSA's oversight of contract pharmacies' compliance with 340B Program requirements. As of March 2023, these recommendations had not been implemented (see enclosure I and [GAO-18-480](#)).

Gerardine Brennan (Assistant Director), Melissa Trinh-Duong Ostergard (Analyst-in-Charge), Jennie F. Apter, Mallory Kennedy, Cynthia Khan, Daniel Lee, Ethiene Salgado-Rodriguez, Jeffrey Tamburello, Emily Wilson Schwark, and Jacob Wu.

Sincerely yours,

A handwritten signature in black ink that reads "Michelle B. Rosenberg". The signature is written in a cursive, flowing style.

Michelle B. Rosenberg  
Director, Health Care

Enclosure(s) – 1



## Enclosure I: Status of GAO Recommendations Related to the Health Resources and Services Administration’s (HRSA) Oversight of the 340B Program

GAO has made 20 prior recommendations related to HRSA’s oversight of the 340B Program. Five of these recommendations have been fully implemented, and 15 have not. Table 8 describes the 15 recommendations that have yet to be implemented and any actions HRSA has taken to implement them as of March 2023.

**Table 8: Status of 15 GAO Recommendations Related to the Health Resources and Services Administration’s (HRSA) Oversight of the 340B Program That Had Not Been Fully Implemented, as of March 2023**

Recommendations from: <i>Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (GAO-11-836)</i> Published: Sept. 23, 2011	Agency concurrence with recommendation (Y/N)	Progress toward implementation
<p>Recommendation 2: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B Program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of Health and Human Services (HHS) should instruct the administrator of HRSA to finalize new, more specific guidance on the definition of a 340B patient.</p>	Y	<p>Subsequent to the issuance of GAO-11-836, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. In March 2023, HRSA stated that, since fiscal year 2017, the agency has requested that Congress provide the agency regulatory authority for all aspects of the 340B Program. In its fiscal year 2024 budget request, HRSA again requested additional regulatory authority. HRSA officials told us that they believe having this authority would ensure the agency’s ability to implement this recommendation.</p>
<p>Recommendation 4: The Patient Protection and Affordable Care Act contained several important program integrity provisions for the 340B Program, and additional steps can also ensure appropriate use of the program. Therefore, the Secretary of HHS should instruct the administrator of HRSA to issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.</p>	Y	<p>Subsequent to the issuance of GAO-11-836, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. In March 2023, HRSA stated that, since fiscal year 2017, the agency has requested that Congress provide the agency regulatory authority for all aspects of the 340B Program. In its fiscal year 2024 budget request, HRSA again requested additional regulatory authority. HRSA officials told us that they believe having this authority would ensure the agency’s ability to implement this recommendation.</p>

<b>Recommendations from:</b> <i>Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (GAO-18-480)</i> Published: June 21, 2018	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
Recommendation 1: The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists.	N	<p>In March 2023, HRSA reiterated that it did not agree with this recommendation and noted that as long as the contract with a pharmacy says it includes all of the covered entities' sites, HRSA does not require the entity to register the pharmacy for each individual site.</p> <p>If HRSA audits a covered entity, its draft audit protocols call for the auditor to verify if the pharmacy contract specifies it includes all entity sites, and, if it does not, the auditor is to verify whether the pharmacy is registered for each entity site that is included in the contract. However, since HRSA only audits 200 covered entities per year, such procedures do not provide HRSA with complete data on entities' contract pharmacy arrangements.</p> <p>Complete data on contract pharmacy arrangements are also important for manufacturers to help ensure that 340B discounted drugs are only provided to pharmacies on behalf of a covered entity site with a valid 340B contract with that site. Thus, we continue to believe that HRSA needs more complete information on contract pharmacy arrangements to best target its oversight of covered entities with the most complex 340B programs.</p>
Recommendation 2: The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with the Centers for Medicare & Medicaid Services as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs. <sup>a</sup>	Y	<p>Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability.</p> <p>In March 2023, HRSA stated that, since fiscal year 2017, the agency has requested that Congress provide the agency regulatory authority for all aspects of the 340B Program. In its fiscal year 2024 budget request, HRSA again requested additional regulatory authority. HRSA officials told us that they believe having this authority would ensure the agency's ability to implement this recommendation.</p>

<b>Recommendations from:</b> <i>Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (GAO-18-480)</i> Published: June 21, 2018	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
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. <sup>a</sup>	Y	<p>Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability.</p> <p>In March 2023, HRSA stated that, since fiscal year 2017, the agency has requested that Congress provide the agency regulatory authority for all aspects of the 340B Program. In its fiscal year 2024 budget request, HRSA again requested additional regulatory authority. HRSA officials told us that they believe having this authority would ensure the agency's ability to implement this recommendation.</p>
Recommendation 4: The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit.	Y	<p>Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability.</p> <p>In March 2023, HRSA stated that, since fiscal year 2017, the agency has requested that Congress provide the agency regulatory authority for all aspects of the 340B Program. In its fiscal year 2024 budget request, HRSA again requested additional regulatory authority. HRSA officials told us that they believe having this authority would ensure the agency's ability to implement this recommendation.</p>

<b>Recommendations from:</b> <i>Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (GAO-18-480)</i> Published: June 21, 2018	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
<p>Recommendation 5: The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance.</p>	<p>N</p>	<p>In March 2023, HRSA reiterated that it did not agree with this recommendation. As noted in our published report, HRSA requires covered entities with audit findings to determine the full scope of noncompliance, and requires certain entities—those subject to targeted audits (which includes reaudits)—to provide to HRSA their methodology for such assessments.<sup>b</sup> However, targeted audits represent a small portion of the audits HRSA conducts.</p> <p>To implement this recommendation, HRSA should require all audited covered entities—not just those subject to targeted audits—to provide a written description of methodologies for HRSA review. HRSA stated that such requirements would create a significant burden for covered entities. However, these entities are already required to formulate and implement these methodologies; therefore, providing HRSA with documentation of the methodologies should not impose a significant burden for covered entities. Without this information, HRSA does not have reasonable assurance that the majority of covered entities have adequately identified all instances of noncompliance.</p>
<p>Recommendation 6: The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit.</p>	<p>N</p>	<p>In March 2023, HRSA reiterated that it did not agree with this recommendation. As noted in our published report, HRSA requires certain covered entities—those subject to targeted audits (which includes reaudits)—to provide evidence that their corrective action plans have been successfully implemented.<sup>b</sup> However, targeted audits represent a small portion of the audits HRSA conducts.</p> <p>To implement this recommendation, HRSA should require all audited covered entities—not just those subject to targeted audits—to provide evidence that their corrective action plans have been successfully implemented. HRSA stated that such requirements would create a significant burden for covered entities. However, these entities are already required to develop and implement these plans; therefore, providing HRSA with evidence of successful implementation should not impose a significant burden for covered entities. Without such evidence, HRSA does not have reasonable assurance that the majority of covered entities audited have corrected the issues identified in the audit, and are not continuing practices that could lead to noncompliance.</p>

<b>Recommendations from:</b> <i>Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (GAO-18-480)</i> Published: June 21, 2018	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
Recommendation 7: The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.	Y	Subsequent to the issuance of GAO-18-480, HHS indicated that it believed that guidance did not provide HRSA appropriate enforcement capability. In March 2023, HRSA stated that, since fiscal year 2017, the agency has requested that Congress provide the agency regulatory authority for all aspects of the 340B Program. In its fiscal year 2024 budget request, HRSA again requested additional regulatory authority. HRSA officials told us that they believe having this authority would ensure the agency's ability to implement this recommendation.

<b>Recommendations from:</b> <i>340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements (GAO-20-108)</i> Published: Dec. 11, 2019	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
<p>Recommendation 1: The Administrator of HRSA should ensure that the information it uses to verify nonprofit status for all nongovernmental hospitals that participate in the 340B Program is reliable—for example, by requiring and reviewing the submission of official documentation hospitals must already maintain or by ensuring the reliability of the data the agency uses.</p>	<p>Y</p>	<p>In March 2023, HHS reiterated that HRSA believes that the information it uses to determine nonprofit status is reliable because hospital administrators attest to its accuracy, and requested that the recommendation be closed as implemented. However, as noted in our published report, neither HRSA nor the agency that collects the data has evaluated the reliability of the data for verifying nonprofit status. In addition, although HRSA requires newly registering nongovernmental hospitals to submit documentation of their nonprofit status, such as Internal Revenue Service forms, this does not affect the nongovernmental hospitals that are already participating in the 340B Program, for which it continues to rely on Medicare cost report data. Without ensuring it is using reliable information, HRSA cannot effectively determine if nongovernmental hospitals participating in the 340B Program meet the statutory eligibility requirements.</p>
<p>Recommendation 2: The Administrator of HRSA should implement a process to verify that every nongovernmental hospital that participates in the 340B Program has a contract with a state or local government as required by statute.</p>	<p>N</p>	<p>As of March 2023, HRSA stated that it requires nongovernmental hospitals to certify the existence of such contracts and reviews contracts from certain nongovernmental hospitals—those that are newly registering, changing classification during recertification, or undergoing program audits. To implement this recommendation, HRSA should verify the existence of such contracts for all nongovernmental hospitals. As noted in our published report, HRSA stated that such requirements would create a burden for both the agency and covered entities. While we understand that verifying the existence of such contracts for all participating nongovernmental hospitals would require additional effort on HRSA’s part, we maintain that relying on hospitals’ attestations is not sufficient to ensure hospitals’ eligibility. In addition, nongovernmental hospitals are already required to maintain copies of their state or local government contracts; therefore, HRSA’s verification of such contracts should not impose a significant burden for covered entities. Without this information, HRSA does not have reasonable assurance that nongovernmental hospitals have the statutorily required contracts to participate in the 340B Program.</p>

<b>Recommendations from:</b> <i>340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements</i> (GAO-20-108) Published: Dec. 11, 2019	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
<p>Recommendation 4: The Administrator of HRSA should provide more specific guidance for 340B Program auditors on how to determine if nongovernmental hospitals' contracts with state and local governments require the provision of health care services to low-income individuals not eligible for Medicaid or Medicare.</p>	<p>Y</p>	<p>In March 2023, HHS reiterated that HRSA updated its audit guidance and procedures to more clearly specify that contracts must contain requirements for the provision of health care services to low-income individuals, and requested that GAO close this recommendation as implemented. Specifically, in October 2019, prior to the issuance of our report and its associated recommendation, HRSA added language to its audit guidance directing auditors who had questions concerning nongovernmental hospitals' contracts to contact HRSA. However, to implement this recommendation, HRSA should update its audit guidance to include information on how auditors are to determine whether contracts include any kind of requirement to provide services to low-income individuals not eligible for Medicaid or Medicare. For example, the guidance could provide examples of population and service descriptions that would likely meet, or not meet, the statutory requirement. Without more specific guidance for auditors' review of contracts, HRSA lacks reasonable assurance that the audits are appropriately identifying deficiencies in nongovernmental hospitals' contracts with state or local governments.</p>
<p>Recommendation 6: The Administrator of HRSA should require nongovernmental hospitals participating in the 340B Program to demonstrate that they have contracts with state or local governments in effect prior to the beginning of their audits' periods of review and should apply consistent and appropriate consequences for hospitals that are unable to do so.</p>	<p>Y</p>	<p>As of March 2023, this recommendation has been partially implemented as HRSA updated its draft audit procedures to specify that auditors should ensure that the contract effective dates cover the entire audit period. In addition, HRSA stated that it collects, reviews, and confirms that contracts are active for certain nongovernmental hospitals—those that are newly registering or changing classification during recertification. However, to fully implement this recommendation, HRSA also must show that it has ceased accepting retroactive contract documentation, and it has applied consistent and appropriate consequences when auditors find that nongovernmental hospitals did not have contracts in effect prior to the beginning of their audit periods. Allowing hospitals that are unable to demonstrate that they have contracts in place that cover their audits' periods of review to continue to participate without consequences undermines the effectiveness of HRSA's audit process, and it increases the risk that ineligible hospitals will receive discounts under the program.</p>





<b>Recommendations from:</b> <i>340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement (GAO-20-212)</i> Published: Jan. 21, 2020 <sup>c</sup>	<b>Agency concurrence with recommendation (Y/N)</b>	<b>Progress toward implementation</b>
Recommendation 2: The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs into its audit process, working with Centers for Medicare & Medicaid Services as needed to obtain states' policies and procedures.	N	In March 2023, HRSA reiterated that it did not agree with this recommendation. HRSA stated that through its audit process, if the agency finds that a hospital is not compliant with the state's Medicaid billing requirements and thus creating the potential for a duplicate discount, it issues an area for improvement (as opposed to an audit finding). However, as we previously reported, covered entities are not required to address areas for improvement. In addition, as noted in our report, HRSA does not require its auditors to review state Medicaid programs' actual policies, but instead relies on covered entities' descriptions of these policies if available, which are not always accurate. Without considering states' actual policies and procedures and ensuring that covered entities are following them, HRSA's audits cannot effectively identify compliance. Our recommendation suggests that HRSA work with the Centers for Medicare & Medicaid Services to obtain states' policies and procedures.
Recommendation 3: The Administrator of HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care.	N	As of March 2023, HRSA reiterated that it did not agree with this recommendation. When duplicate discounts are identified in Medicaid fee-for-service, HRSA requires covered entities to work with manufacturers to remedy them. HRSA has stated that covered entities' obligations for preventing duplicate discounts are the same for Medicaid fee-for-service and managed care. Thus, as noted in our published report, we believe the steps for addressing identified duplicate discounts in managed care should be similar. As a result, to implement this recommendation, HRSA should require—not just encourage—covered entities to work with manufacturers to remedy any duplicate discounts related to managed care as they do for those related to fee-for-service.

Source: GAO analysis of information received from HRSA. | GAO-23-106095

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

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

<sup>c</sup>GAO-20-212 also included one recommendation (Recommendation 1) to the Centers for Medicare & Medicaid Services.

## Related GAO Products

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

*340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement.* [GAO-20-212](#). Washington, D.C.: January 21, 2020.

*340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements.* [GAO-20-108](#). Washington, D.C.: December 11, 2019.

*Drug Discount Program: Improvements Needed in Federal Oversight of Compliance at 340B Contract Pharmacies.* [GAO-18-646T](#). Washington, D.C.: July 11, 2018.

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

*Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program.* [GAO-18-521R](#). Washington, D.C.: June 18, 2018.

*Drug Discount Program: Status of Agency Efforts to Improve 340B Program Oversight.* [GAO-18-556T](#). Washington, D.C.: May 15, 2018.

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

*Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.* [GAO-15-442](#). Washington, D.C.: June 5, 2015.

*Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight.* [GAO-15-455T](#). Washington, D.C.: March 24, 2015.

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