



Testimony

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

For Release on Delivery
Expected at 10:00 a.m. ET
Tuesday, March 10, 2015

DRUG DISCOUNT PROGRAM

Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight

Statement of Debra A. Draper
Director, Health Care

GAO Highlights

Highlights of [GAO-15-455T](#), a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The 340B Drug Pricing Program requires drug manufacturers to sell outpatient drugs at discounted prices to eligible hospitals, clinics, and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid. HRSA, an agency within the Department of Health and Human Services, is responsible for administering and overseeing the 340B Program. In recent years, questions have been raised regarding HRSA's oversight of the program, particularly given growth in the program since its inception in 1992. According to HRSA officials, as of 2015, more than 11,000 covered entities were participating in the 340B Program—an increase of approximately 30 percent since 2008.

In September 2011, GAO identified inadequacies in HRSA's oversight of the 340B Program and made recommendations to improve program oversight and ensure appropriate use of the program. This testimony describes (1) inadequacies in 340B Program oversight that GAO previously identified, and (2) progress HRSA has made implementing GAO's recommendations to improve program oversight.

This testimony is based largely on GAO's September 2011 report. For this testimony, GAO also obtained information and documentation from HRSA officials about any significant program updates and steps they have taken to implement GAO's 2011 recommendations.

View [GAO-15-455T](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

March 24, 2015

DRUG DISCOUNT PROGRAM

Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight

What GAO Found

In its September 2011 report, GAO found that the Health Resources and Services Administration's (HRSA) oversight of the 340B Program was inadequate to provide reasonable assurance that program participants—covered entities and drug manufacturers—were in compliance with program requirements. Specifically, GAO found the program

- primarily relied on covered entities and manufacturers to police themselves and ensure their own compliance with 340B Program requirements, and engaged in few other activities to oversee the program and ensure its integrity. For example, although HRSA had the authority to conduct audits to determine whether program violations had occurred, at the time of GAO's report, the agency had not conducted any.
- lacked guidance on key requirements with the level of specificity necessary to provide clear direction, making self-policing difficult, and raising concerns that the guidance could be interpreted in ways that were inconsistent with its intent. In particular, GAO found HRSA's guidance lacked needed specificity on the definition of a patient eligible for drugs discounted under the program, criteria hospitals not publicly owned or operated needed to meet to qualify for the program, and nondiscrimination guidance manufacturers needed to follow to ensure drugs were distributed equitably to both covered entities and non-340B providers.
- had increasingly been used in settings, such as hospitals, where the risk of diverting 340B drugs to ineligible patients was greater, because these settings were more likely to serve such patients.

To address these oversight inadequacies and to ensure appropriate use of the program, GAO recommended HRSA (1) conduct selective audits of covered entities to deter potential diversion; (2) further specify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; (3) finalize new, more specific guidance on the definition of a patient eligible to receive discounted drugs; and (4) issue guidance to further specify the criteria that hospitals not publicly owned or operated must meet to be eligible for the 340B Program.

In fiscal year 2012, HRSA implemented two of GAO's four 2011 recommendations. Specifically, the agency implemented a systematic approach to conducting audits of covered entities and issued updated nondiscrimination guidance. With regard to the other two recommendations, HRSA planned to address the definition of a patient and hospital eligibility criteria in a comprehensive 340B Program regulation it submitted to the Office of Management and Budget in April 2014. However, HRSA withdrew this proposal following a May 2014 federal district court ruling addressing HRSA's statutory authority to issue a separate 340B regulation, which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA reported that after assessing this ruling, it plans to issue proposed guidelines later this year to address 340B Program areas where it does not have explicit rulemaking authority, including the definition of a patient and hospital eligibility.

Chairman Pitts, Ranking Member Green, and Members of the Subcommittee:

I am pleased to be here today as you examine the 340B Drug Pricing Program (340B Program), including issues concerning its oversight. The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),¹ requires drug manufacturers to sell outpatient drugs at discounted prices to eligible clinics, hospitals, and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid. According to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.² In recent years, questions have been raised regarding HRSA's oversight of the 340B Program, particularly given growth in the program over time. According to HRSA officials, as of 2015 more than 11,000 covered entities were participating in the 340B Program—an increase of approximately 30 percent since 2008. According to the most recent estimate available from HRSA, covered entities' spending on 340B drug purchases was estimated to be approximately \$7.5 billion in 2013.

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the costs of the drugs, according to HRSA. In addition, covered entities can generate 340B revenue. For example, they can purchase drugs at 340B prices for all eligible patients regardless of the patients' income or insurance status and generate revenue that may exceed the 340B price paid for the drugs, such as through a patient's insurance reimbursement. Because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are

¹42 U.S.C. § 256b.

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

strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from diverting 340B drugs—that is transferring 340B drugs to individuals who are not eligible patients of the entities.³ Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to non-340B health care providers (referred to as HRSA’s nondiscrimination guidance throughout this statement), such as by imposing minimum purchase requirements or other restrictive conditions.⁴

In a September 2011 report, we identified inadequacies in HRSA’s oversight of this program and recommended actions that should be taken to improve program oversight and ensure appropriate use of the program.⁵ My statement today will describe (1) inadequacies in 340B Program oversight that GAO previously identified and (2) progress HRSA has made implementing our recommendations to improve program oversight. This statement is based largely on GAO’s 2011 report. More detailed information on the related objectives, scope, and methodology can be found in that report.⁶ For this statement, we also obtained information and documentation from HRSA officials about any significant program updates, and steps they have taken to implement our 2011 recommendations.

We conducted our 2011 work from September 2010 to September 2011, and updated this work in February and March 2015. The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that

³42 U.S.C. § 256b(a)(5)(B).

⁴Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

⁵See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, [GAO-11-836](#) (Washington, D.C.: September 23, 2011).

⁶[GAO-11-836](#).

we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program was created following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to state Medicaid agencies.⁷ HRSA is responsible for administering and overseeing the 340B Program, which, according to federal internal control standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures should include internal controls that provide reasonable assurance that an agency has effective and efficient operations, and that program participants are in compliance with applicable laws and regulations.⁸

Program Participants

Eligibility for the 340B Program is defined in the PHSA.⁹ Entities generally become eligible by receiving certain federal grants or by being one of six hospital types. Eligible grantees include clinics that offer primary and preventive care services, such as Federally Qualified Health Centers, clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, and state operated AIDS Drug Assistance Programs, which serve as a “payer of last resort” to cover the cost of providing HIV-related medications to certain low-income individuals. Eligible hospitals include certain children’s hospitals, free standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and general acute care hospitals that

⁷The Medicaid Drug Rebate Program was established through the *Omnibus Budget Reconciliation Act of 1990* and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508 § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

⁸See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives.

⁹See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

serve a disproportionate number of low-income patients, referred to as disproportionate share hospitals (DSH).¹⁰ To become a covered entity and participate in the program, eligible entities must register with HRSA and be approved.

Hospital eligibility for the 340B Program has more requirements compared to the requirements for federal grantees. Specifically, hospitals must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify.¹¹ Additionally, they must be (1) owned or operated by a state or local government, (2) a public or private nonprofit corporation that is formally delegated governmental powers by a unit of state or local government,¹² or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare.

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

Program Structure, Operation, and Key Program Requirements

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a participating drug manufacturer may charge covered entities.¹³ Covered entities typically purchase and dispense 340B drugs through pharmacies. Historically, only covered entities that did not have an in-house pharmacy

¹⁰Medicare DSH hospitals receive an additional Medicare payment based on their DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

¹¹Critical access hospitals are exempt from this requirement.

¹²According to HRSA, a hospital is said to be “formally granted governmental powers” when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

¹³Manufacturers may sell a drug at a price that is lower than the ceiling price. As such, covered entities may negotiate prices below the ceiling price.

were allowed to contract with a single outside pharmacy to dispense drugs on their behalf. In 2010, however, HRSA issued guidance allowing all covered entities to contract with multiple outside pharmacies.¹⁴

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

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

¹⁵See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

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

Criteria for patient eligibility:^a

| | |
|----|---|
| 1. | The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual’s health care. |
| 2. | The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity. ^b |
| 3. | The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided. ^c |

Source: GAO analysis of HRSA guidance. | GAO-15-455T

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

^aThese criteria do not apply to AIDS Drug Assistance Programs (ADAP); rather an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

^bAn individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

^cDisproportionate share hospitals are exempt from this requirement.

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

GAO Previously Found Inadequacies in HRSA's Oversight of the 340B Program and Made Recommendations for Improvement

In our September 2011 report, we found that HRSA's oversight of the 340B Program was inadequate because it relied primarily on self-policing by program participants and because HRSA's guidance on key program requirements lacked the necessary level of specificity to provide clear direction for participants.¹⁶ We also found that changes in the settings where the 340B Program was used resulted in heightened concerns about HRSA's inadequate oversight. We made four recommendations to address these oversight inadequacies and to ensure appropriate use of the program.

Reliance on Self-Policing

In its oversight of the 340B Program, we found in 2011 that HRSA primarily relied on covered entities and manufacturers to police themselves and ensure their own compliance with program requirements. Upon enrollment into the program, HRSA required participants to self-certify that they would comply with applicable 340B Program requirements and any accompanying agency guidance. HRSA also expected participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrated compliance, and inform HRSA if violations occurred. For example, covered entities had to develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as by using inventory tracking systems that separately processed the purchase and logged the dispensation of 340B drugs. Similarly, manufacturers had to ensure that they properly calculated the 340B price of their drugs. HRSA officials told us that covered entities and manufacturers could also monitor each other's compliance with program requirements, but we found that, in practice, participants could face limitations to doing so.

Beyond relying on participants' self-policing, we found that HRSA engaged in few activities to oversee the 340B Program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, officials told us that they did not require a review of the procedures participants put in place to ensure program compliance. Further, although HRSA had the authority to conduct audits of program participants to determine whether program violations had

¹⁶[GAO-11-836](#).

occurred, at the time of our report, the agency had never conducted an audit.

Lack of Specificity in Program Guidance

We found that HRSA's guidance on key program requirements lacked the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance and raising concerns that the guidance could be interpreted in ways that were inconsistent with its intent. Specifically, we found that

- HRSA's guidance on the definition of an eligible patient lacked the necessary specificity to clearly define the various situations under which an individual was considered eligible for discounted drugs through the 340B Program. As a result, covered entities could interpret the definition either too broadly or too narrowly. At the time of our report, agency officials told us that they recognized the need to provide additional clarity around the definition of an eligible patient, in part because of concerns that some covered entities may have interpreted the definition too broadly to include non-eligible individuals, such as those seen by providers who were only loosely affiliated with a covered entity.
- HRSA had not issued guidance specifying the criteria under which hospitals that were not publicly owned or operated could qualify for the 340B Program.¹⁷ For example, one way hospitals can qualify for the program is by executing a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. We found that HRSA did not outline any criteria that must be included in such contracts, such as the amount of care a hospital must provide to these low-income individuals, and did not require the hospitals to submit their contracts for review by HRSA.¹⁸ As a result, hospitals with contracts that provided a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not have been what the agency intended.

¹⁷We use the term "hospitals that are not publicly owned or operated" to refer to public and private, nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B Program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B Program.

¹⁸HRSA officials we interviewed for the September 2011 report told us that contracts were selectively reviewed if further clarification was necessary.

-
- HRSA’s nondiscrimination guidance was not specific in the practices that manufacturers should follow to ensure that drugs were equitably distributed to covered entities and non-340B providers when distribution was restricted.¹⁹ Some stakeholders we interviewed for the report, such as covered entities, raised concerns about the way certain manufacturers interpreted and complied with the guidance in these cases.

Changes in Program Settings

In 2011, we also concluded that changes in the settings where the 340B Program was used may have heightened the concerns about the inadequate oversight we identified. In the years leading up to our report, the settings where the 340B Program was used had shifted to more contract pharmacies and hospitals than in the past. We concluded that increased use of the 340B Program by contract pharmacies and hospitals may have resulted in a greater risk of drug diversion to ineligible patients, in part because these facilities were more likely to serve patients that did not meet the definition of a patient of the program. According to HRSA officials, the number of covered entities using contract pharmacies had grown rapidly after it issued its guidance allowing all covered entities to use multiple contract pharmacies;²⁰ as of July 2011 there were more than 7,000 contract pharmacy arrangements in the program. In addition, based on our own analysis, we found that hospitals’ participation in the 340B Program had grown from 591 in 2005 to 1,673 in 2011.²¹ Further, although participation in the 340B Program also had increased among other covered entity types, we found that hospitals’ participation had grown faster than that of federal grantees. For example, in 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

¹⁹Restricted distribution may occur when there is a shortage in drug supply or when shortages are anticipated.

²⁰Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to dispense drugs on their behalf. In 2010, however, HRSA issued guidance allowing all covered entities to contract with multiple outside pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

²¹According to HRSA, as of January 2015, the number of contract pharmacy arrangements in the program had increased to 36,000 and the number of hospitals participating in the program had increased to 2,170.

Recommendations to Improve Program Oversight

To address these oversight inadequacies and to ensure appropriate use of the program, we recommended that the Secretary of HHS instruct the administrator of HRSA to take the following four actions: (1) conduct selective audits of covered entities to deter potential diversion; (2) further specify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; (3) finalize new, more specific guidance on the definition of an eligible patient; and, (4) issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.

HRSA Has Implemented Two of GAO's Four Recommendations and Reported Plans for Addressing the Other Two

In fiscal year (FY) 2012, HRSA implemented two of the four recommendations from our 2011 report. Specifically, in response to our recommendation that HRSA conduct selective audits of 340B covered entities to deter potential diversion (that is, diversion of 340B drugs to non-eligible patients), the agency implemented a systematic approach to conducting audits of covered entities that is outlined on its website.²² The FY 2012 audits included 45 covered entities that were randomly selected and 6 selections targeted based on information from stakeholders, for a total of 51 audits that encompassed more than 410 outpatient facilities and 860 contract pharmacy locations.²³ Since 2012, HRSA has conducted annual audits of covered entities with plans to continue these annual audits going forward. As a result of the audits already conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion. The agency has developed a process to address non-compliance through corrective action plans. The results of each year's audits are available on HRSA's website.

In response to our recommendation that HRSA further specify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of 340B discounted drugs, HRSA issued updated nondiscrimination guidance in May of 2012. This guidance outlined

²²See <http://www.hrsa.gov/opa/>.

²³Multiple outpatient facilities may be affiliated with a 340B covered entity, such as hospitals' off-site outpatient facilities. Similarly, a covered entity may have multiple contract pharmacy arrangements.

HRSA's policy for manufacturers who intend to restrict distribution of a drug and provided additional detail on the type of information manufacturers should include in their restricted distribution plans. Additionally, HRSA officials told us that they may require manufacturers to submit their restricted distribution plans for review if, after implementation, they receive complaints from covered entities that they are not able to access the drug at the 340B price.

HRSA had planned to address our remaining two recommendations in a comprehensive 340B program regulation. Specifically, we had recommended that HRSA (1) finalize new, more specific guidance on the definition of a patient and (2) issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program. HRSA had planned to address both of these issues in a comprehensive 340B Program regulation that it submitted to the Office of Management and Budget for review in April 2014. However, HRSA withdrew this proposed comprehensive regulation in November 2014 following a May 2014 federal district court ruling that addressed whether HRSA had statutory authority to issue a regulation concerning the ineligibility of certain drugs for 340B pricing.²⁴ After the district court ruled that HRSA lacked statutory rulemaking authority under the 340B statute except in three specified areas, HRSA officials reported that they had to assess the impact of the ruling on the proposed comprehensive regulation. The outcome of this assessment is that HRSA plans to issue guidelines to address 340B program areas where it does not have explicit rulemaking authority. HRSA officials said they expect to publish proposed guidelines later this year and that they will address

²⁴Specifically, the litigation involved HRSA's promulgation of a regulation in response to an amendment to the 340B statute made by the Patient Protection and Affordable Care Act, which eliminated 340B discount pricing for certain covered entities for drugs designated for the treatment of rare diseases or conditions under the Orphan Drug Act. See Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016 (July 23, 2013). The district court held that HHS lacked statutory rulemaking authority to promulgate the orphan drug rule. With respect to the 340B statute, the court found that Congress specifically authorized rulemaking in three places—none of which provided authority for HHS's orphan drug rule: (1) the imposition of civil monetary penalties, (2) the methodology for calculating the 340B ceiling price, and (3) the establishment of an administrative dispute resolution process. *Pharm. Research & Mfrs. of Am. v. United States HHS*, No. 13-1501, 2014 U.S. Dist. LEXIS 70894 (D.D.C. May 23, 2014).

areas such as the definition of a patient and hospital eligibility under the 340B program.

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

GAO Contacts and Staff Acknowledgments

For further information about this statement, please contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Key contributors to this statement were Gerardine Brennan, Assistant Director; Jennie Apter; Kelli Jones; Rachel Svoboda; and Jennifer Whitworth.

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#). Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#). Visit GAO on the web at www.gao.gov.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548

