

EXAMINING THE 340B DRUG PRICING PROGRAM

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS FIRST SESSION

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¹ Ms. Pedley did not offer an oral or written statement.

² The information has been retained in committee files and also is available at <http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=103082>.

EXAMINING THE 340B DRUG PRICING PROGRAM

TUESDAY, MARCH 24, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Upton (ex officio), Green, Butterfield, Castor, Sarbanes, Schrader, Kennedy, Pallone (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Noelle Clemente, Press Secretary; Michelle Rosenberg, GAO Detailee, Health; Chris Sarley, Policy Coordinator, Environment and the Economy; Adrianna Simonelli, Legislative Clerk; Heidi Stirrup, Policy Coordinator, Health; Josh Trent, Professional Staff Member, Health; Gregory Watson, Staff Assistant; Traci Vitek, Detailee, Health; Ziky Ababiya, Policy Analyst; Christine Brennan, Press Secretary; Jeff Carroll, Staff Director; Tiffany Guarascio, Deputy Staff Director and Chief Health Advisor; Meredith Jones, Director, Outreach and Member Services; Rick Kessler, Senior Advisor and Staff Director, Energy and the Environment; Rachel Pryor, Health Policy Advisor.

Mr. PITTS. The subcommittee will come to order.

The Chair will recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today we will hear from witnesses about the 340B Discount Drug Program. Section 340B of the Public Health Service Act requires drug manufacturers who wish to participate in Medicaid to provide discounted outpatient drugs to eligible healthcare organizations known as covered entities who serve uninsured, low-income populations.

This program designed to stretch scarce Federal dollars is critically important for indigent and low-income patients who may otherwise be unable to access needed drugs or afford treatment.

Eligible covered entities are defined in statute and include HRSA supported health centers and look-alikes, Ryan White Clinics, State AIDS Drug Assistance programs, Medicare and Medicaid dispropor-

tionate share hospitals, children's hospitals, and other safety-net providers.

The Health Resources and Services Administration, HRSA, the agency that administers the 340B Drug Discount Program, indicates that approximately 11,000 covered entities currently participate in the program, with more than 1 in 3 hospitals participating. Some 800 or more manufacturers also participate in the program.

Although the program was created in 1992, recent years have seen significant changes and expansions of the program. For example, from 2001 to 2011, the number of covered entities roughly doubled. Since HRSA issued guidance related to contract pharmacies in 2010, their use in the program has grown exponentially.

Today we will hear from three witnesses who are experts on the program. The witnesses from GAO and the Inspector General's Office have both helped author reports advising Congress on the program and continue to monitor HRSA's management of the program.

GAO and OIG have reported that unclear program guidelines and inconsistent oversight is partially responsible for some of the challenges the program currently faces in being accountable to taxpayers, patients, and stakeholders. Covered entities and manufacturers understandably cannot comply with rules that are unclear.

We benefit today from hearing directly from HRSA about the agency's day-to-day work to respond to the findings of those reports as they seek to more effectively oversee and efficiently operate the 340B Program.

HRSA has taken steps and made improvements in recent years, so we are glad they can be here today. Recent developments have hamstrung their ability to promulgate regulations to better manage the program, so we look forward to hearing from them.

One thing I hope we can all agree on is that to preserve the 340B Program and ensure that it is serving those who most need help, greater oversight and transparency is needed to increase the program's accountability. Today's hearing marks the first step in that direction.

I would like to welcome all of our witnesses today. We look forward to your testimony on this important subject.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

Today, we will hear from witnesses about the 340B Drug Discount Program. Section 340B of the Public Health Service Act (PHSA) requires drug manufacturers, who wish to participate in Medicaid, to provide discounted outpatient drugs to eligible health care organizations known as "covered entities" who serve uninsured, low-income populations.

This program, designed to stretch scarce Federal dollars, is critically important for indigent and low-income patients who may otherwise be unable to access needed drugs or afford treatment.

Eligible covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.

The Health Resources and Services Administration (HRSA), the agency that administers the 340B drug discount program, indicates that approximately 11,000 covered entities currently participate in the program, with more than one in three hospitals participating. Some 800 or more manufacturers also participate in the program.

Although the program was created in 1992, recent years have seen significant changes and expansions of the program.

For example, from 2001 to 2011, the number of covered entities roughly doubled. Since HRSA issued guidance related to contract pharmacies in 2010, their use in the program has grown exponentially.

Today we will hear from three witnesses who are experts on the program. The witnesses from GAO and the Inspector General's office have both helped author reports advising Congress on the program, and continue to monitor HRSA's management of the program.

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We benefit today from hearing directly from HRSA about the agency's day-to-day work to respond to the findings of those reports as they seek to more effectively oversee and efficiently operate the 340B program. HRSA has taken steps and made improvements in recent years, so we are glad they can be here today. Recent developments have hamstrung their ability to promulgate regulations to better manage the program, so we look forward to hearing from them.

One thing I hope we can all agree on, is that to preserve the 340B program and ensure that it is serving those who most need help, greater oversight and transparency is needed to increase the program's accountability. Today's hearing marks the first step in that direction.

I would like to welcome all of our witnesses today. We look forward to your testimony on this important subject.

Mr. PITTS. And at this point, I have a UC request today. There are 31 documents that I would like to submit for the record. There are letters, articles, policy statements, reports, testimony, and various white papers on the 340B program included submitted by a wide range of stakeholders we have shared. Without objection, so ordered.¹

Mr. PITTS. And I yield the rest of my time to Ms. Blackburn.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

And I concur with everything that you have had to say on this. We all appreciate the 340B Program. We do have questions and we do have concerns. And we know we are responsible for the oversight. We want to be diligent in that manner. I think the rapid growth in the program has raised concerns including the adequacy of oversight, so I appreciate the hearing.

Also questions on accountability and how that accountability may vary from grantees who receive 340B funds and hospitals who also receive those funds. Additional questions have been raised concerning the definition of a patient and how those 340B revenues are distributed.

And so I thank you all for being here.

And, Mr. Chairman, I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentlelady, and now recognizes the ranking member of the subcommittee, Mr. Green, for 5 minutes for an opening statement.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman.

And good morning and thank you all for being here today. And I want to thank our witnesses for coming here to testify.

¹The information has been retained in committee files and also is available at <http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=103082>.

The 340B Drug Pricing Program was created by Congress to help safety-net providers care for their most vulnerable patients and afford drugs that would otherwise be out of reach. Since its inception in 1992, stakeholders and policymakers have been discussing and debating the intended purpose and appropriate scope of the 340B Program.

I thank the chairman for having this hearing today to examine this critical program and the role that it plays in our healthcare system.

It was the hope of policymakers when designing 340B that lower drug prices would enable safety-net providers to stretch scarce Federal resources as far as possible to reach more patients and provide a more comprehensive service through these savings.

The law does not specify how these savings incurred under 340B discounts must be used by covered entities, a point that has been brought up by both opponents and proponents of the program, yet a GAO study in 2011 confirmed that at large, covered entities use these savings to provide more care to more patients including medications that would otherwise be unaffordable to those they serve.

For example, Houston Harris Health System which primarily serves the indigent population in Houston, Harris County, Texas saves approximately \$17 million a year through participating in the 340B Drug Program. Harris Health uses savings from the program on patient care services which includes the cost of treatment, administration, management of services and facilities, and improving access to quality healthcare for our community.

Harris Health System has, like other safety-net hospitals across the country, provide access to cost-effective, quality healthcare delivered to all the residents of Harris County regardless of their ability to pay.

There is always more patient need than we have the capacity to provide and the community's access to care depends upon the contribution of every possible source of funding such as the 340B Drug Program.

I cannot underscore enough how important the 340B Program continues to be for hospitals and other entities that provide care to under-served patients in every district across the country. It is a key part of the multi-prong approach to provide all individuals with access to quality care.

With that said, the program has grown significantly and oversight is appropriate to ensure that it is working properly. Since 1992, the 340B Program has expanded significantly both directly due to the categories of covered entities and indirectly due to the broader eligibility criteria for existing categories.

According to the GAO, the number of 340B covered entities has doubled in a little over 10 years to more than 16,500 sites. Similarly, the number of contract pharmacy agreements has expanded dramatically over the last decade, particularly since April of 2010 when 340B entities were allowed to contract multiple pharmacies.

The 2011 GAO study found that the Health Resources and Services Administration or HRSA oversight of 340B was, quote, "inadequate to provide reasonable assurance that covered entities and

drug manufacturers are in compliance with the program requirements,” unquote.

HRSA has taken great steps to implement recommendations made by the GAO in its 2011 study including conducting selected audits and clarifying 340B nondiscrimination policy. But additional administration action and potentially additional authorities may be needed for HRSA to conduct proper oversight of such a large and important program.

I understand HRSA has been working to establish a formal set of regulations to standardize the definition of an eligible patient, compliance requirements for contract pharmacy agreements, clarify hospital eligibility criteria, and eligibility of off-site facilities.

Steps such as updating HRSA guidance on the definition of a patient could address challenges that arise from different interpretations of the current guidance. This would further program integrity efforts and make certain that the 340B Program is achieving its intended outcomes and maintaining the long-term viability.

Congress should let HRSA release its guidance and analyze its impact before making changes to the 340B Program that would harm safety-net hospitals and our vulnerable patients. I know HRSA strives to achieve the best outcomes for those they serve. The agency does great work to fulfill its mission of improving access to healthcare services for people who are medically underserved.

As we examine the 340B Program and oversight efforts during today’s hearing, it is important to remember that for 23 years, 340B’s mission has been to lower drug costs for safety-net providers so they can buy more comprehensive services and reach more individuals.

The program enables providers to decide how to best serve their communities through obtaining and leveraging savings from manufacturers so more patients can receive more care in their communities.

I thank the agency for their continued efforts to implement and oversee 340B and GAO and OIG for their work and look forward to the hearing.

And, Mr. Chairman, I would also like to ask unanimous consent to place into testimony a statement submitted by Ascension on the 340B Program.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. The Chair now recognizes the chair of the full committee, Mr. Upton, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Good morning. Since its inception in 1992, the 340B Program has provided critically important pharmaceutical drugs at a discounted price to a range of entities providing healthcare to some of our Nation’s most needy and most vulnerable patients. These facilities include community health centers, Ryan White Clinic, State AIDS Drug Assistance programs, as well as a range of qualifying hospitals.

Through the years, the program has allowed covered entities to stretch scarce resources to better serve millions of patients in Michigan and across the country who are uninsured, under-insured, or dependent on programs like Medicaid and Medicare.

I have seen firsthand the great work that this program does in my district in southwest Michigan. From the Bronson Health System in Kalamazoo, to Lakeland in Berrien and Cass Counties, to Allegan General Hospital in the north, to numerous family health centers, the 340B Program has ensured that many of my underserved constituents have access to affordable, life-saving medicines that they otherwise would not be able to afford.

There is no doubt that the 340B Program has played an important role in helping reduce costs while also extending access.

I am pleased that this committee today will have the opportunity to learn more about some of these issues facing the 340B Program. This committee has not held a hearing on the program since 2005, but there have been some very important changes to the program in recent years.

The program was expanded, as we know, under the Affordable Care Act and more types of providers were allowed to participate as covered entities. Since HRSA guidance in 2010, there has been a rapid expansion of the use of contract pharmacies.

GAO and the Inspector General's Office have raised some concerning findings for sure about the mixed successes of current oversight of the program that need to be examined. And more recently, HRSA, the agency charged with overseeing the 340B Program, has found itself unable to successfully promulgate binding regulations, thus hampering its ability to effectively manage the program as we would like to see it.

As a strong supporter of the 340B Program, I believe that there has been and will continue to be an important role for this program to continue. However, some of the findings from the careful work conducted by the GAO and the IG's Office are of concern.

I appreciate GAO, OIG, and HRSA coming today to help the committee better understand the challenges before us. We look forward to learning what steps HRSA has taken to strengthen the program for all patients, the uninsured, seniors, Medicaid patients, and the insured patients which are served by covered entities.

It is in the interest of good Government to see program integrity strengthened, the program's operating parameters clarified, and the program's rules consistently enforced.

I believe that the biggest supporters of the program should be the biggest champions of ensuring that the 340B Program is well run in a manner that is transparent and accountable to all stakeholders.

And I yield back the balance of my time.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Since its creation in 1992, the 340B program has provided critically important pharmaceutical drugs at a discounted price to a range of entities providing health care to some of our Nation's most needy and vulnerable patients. These facilities include community health centers, Ryan White clinics, State AIDS Drug Assistance programs, as well as a range of qualifying hospitals.

Through the years, the program has allowed covered entities to stretch scarce resources to better serve millions of patients in Michigan and across the country who are uninsured, underinsured, or dependent on programs like Medicaid and Medicare.

I've seen the great work this program does in my district. From the Bronson Health System in the Kalamazoo area, to Lakeland in Berrien and Cass Counties, to Allegan General Hospital in the north, to the numerous Family Health Centers, the 340B program has ensured that many of my underserved constituents have access to affordable, lifesaving medicine. There's no doubt that the 340B program has played an important role in helping reduce costs while also extending access.

I am pleased that our committee today will have the opportunity to learn more about some of the issues facing the 340B program. This committee has not held a hearing on the program since 2005, but there have been important changes to the program in recent years.

- The program was expanded under the Affordable Care Act and more types of providers were allowed to participate as covered entities.

- Since HRSA guidance in 2010, there has been a rapid expansion of the use of contract pharmacies.

- GAO and the Inspector General's office have raised some concerning findings about the mixed successes of current oversight of the program.

- More recently, HRSA—the agency charged with overseeing the 340B program—has found itself unable to successfully promulgate binding regulations, thus hampering its ability to effectively manage the program.

As a strong supporter of the 340B program, I believe there has been, and will continue to be, an important role for the program. However, some of the findings from the careful work conducted by the GAO and Inspector General's Office are of concern. I appreciate GAO, OIG, and HRSA coming today to help the committee better understand the challenges HRSA and the program face.

We look forward to learning what steps HRSA is taking to strengthen the program for all the patients—the uninsured, seniors, Medicaid patients, and the insured patients—which are served by covered entities. It is in the interest of good Government to see program integrity strengthened, the program's operating parameters clarified, and the program's rules consistently enforced. I believe that the biggest supporters of the program should be the biggest champions of ensuring the 340B program is well-run in a manner that is transparent and accountable to all stakeholders.

I look forward to hearing from our witnesses.

Mr. PITTS. Anyone on the majority side seeking time? We still have 1 minute.

Mrs. ELLMERS, you are recognized.

Mrs. ELLMERS. Thank you, Mr. Chairman.

And thank you to our panel for being here.

And, Mr. Chairman, thank you so much for holding this hearing on 340B.

I just want to start off by saying that I realize HRSA received several million dollars in our last appropriations bill and appropriate steps you have taken to increase oversight in the program.

For the record, I would like to make it clear that I understand and appreciate the importance of the 340B Program and the critical role it plays for many patients in the U.S. To be clear, this is a program set up by the Federal Government, yet the Federal Government does not know where the money is going. That is a big concern.

For example, an analysis by IMS Institute for Healthcare Informatics calculated prices of 10 common chemotherapy treatments and found that hospitals charge 189 percent more on average or nearly triple what the same infusion would cost an independent doctor's office.

These are the questions that we have. My hope is that we are going to get transparency and we are going to understand how the program is being utilized. Covered entities participating in the

340B Program must be fully transparent and accountable for dispensing medicines and ensuring the program's integrity.

As the program has exploded in growth over the past 2 decades, Congress should have a clear understanding as to how that money is being spent to ensure that it is still serving its intended purpose.

Thank you very much. I yield back the remainder of my time.

Mr. PITTS. The Chair thanks the gentlelady, and now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

In 1992, a bipartisan Congress established the 340B Program to expand access to affordable healthcare by limiting the cost of outpatient drugs paid for certain safety-net providers. And since that time 22 years ago, the 340B Program has played a critical role in our healthcare system to ensure that low-income and vulnerable individuals have access to affordable healthcare.

In supporting our vital Nation's safety net from community health centers to safety-net hospitals, HIV clinics, and hemophilia treatment centers, the 340B Program has made the difference between patients getting access to life-saving healthcare services and drugs or going without.

And Congress' intention when this program was created was to help covered entities expand their capacity to serve their patients. Through savings from the drugs purchased at a discounted rate, 340B providers are able to stretch scarce resources to reach more eligible patients and provide more comprehensive health services.

It is without a doubt that the resources provided through the 340B Program have a direct impact on augmenting patient care throughout the country and will continue to play an integral role in the future by supporting the mission of safety-net providers to serve low-income, uninsured, and under-insured patients.

Of course, for this program to continue to function as Congress intended, proper oversight of 340B is of paramount importance. And I think we can all agree here today that the mission of this program is sound and a continued emphasis on program integrity will make the 340B Program stronger now and in coming years.

So I wanted to thank the chairman again for calling this long-overdue hearing. I don't know if anybody on my side, I don't think, wants any additional time, so I will just yield back the balance of my time, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

I would like to thank the chairman for calling this hearing on the 340B Program. And thank the witnesses for their testimony here today.

In 1992, a bipartisan Congress established the 340B Program to expand access to affordable health care by limiting the cost of outpatient drugs paid for certain safety net providers.

Since that time 22 years ago, the 340B Program has played a critical role in our health care system to ensure that low-income and vulnerable individuals have access to affordable health care. In supporting our vital Nation's safety net—from com-

munity health centers to safety net hospitals to HIV clinics and Hemophilia treatment centers—the 340B Program has made the difference between patients getting access to lifesaving health care services and drugs or going without.

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I thank the chairman again for calling this long-overdue hearing, and I yield back the balance of my time.

Mr. PITTS. All right. The Chair thanks the gentleman.

As always, written statements from all Members, opening statements, will be made part of the record.

We have 1 panel today and I will introduce them in the order that they will present testimony.

First, Ms. Diana Espinosa, Deputy Administrator at the Health Resources and Services Administration. She is accompanied by Commander Krista Pedley, the Director of the Office of Pharmacy Affairs at the Health Resources and Services Administration; Dr. Debbie Draper, Director of Health Care at the Government Accountability Office; and Ms. Ann Maxwell, the Assistant Inspector General for Evaluation and Inspections in the Office of the Inspector General at HHS.

Thank you all for coming. Your written testimony will be made a part of the record. You will each be given 5 minutes to summarize your testimony. And at this point, the Chair recognizes Ms. Espinosa for 5 minutes for her summary.

STATEMENTS OF DIANA ESPINOSA, DEPUTY ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY KRISTA M. PEDLEY, DIRECTOR, OFFICE OF PHARMACY AFFAIRS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DEBRA A. DRAPER, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE; ANN MAXWELL, ASSISTANT INSPECTOR GENERAL, OFFICE OF EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF DIANA ESPINOSA

Ms. ESPINOSA. Good morning, Chairman Pitts, Ranking Member Green, and Members of the subcommittee. I appreciate the opportunity to appear before you today to discuss the steps we have taken to strengthen the oversight of the 340B Drug Pricing Program and the challenges we face.

The Health Resources and Services Administration or HRSA is the primary Federal agency within the Department of Health and

Human Services charged with improving access to healthcare services for people who are medically under-served.

HRSA works to strengthen our primary care infrastructure, bolster the healthcare workforce, and achieve health equity. HRSA strives to achieve the best outcomes for those we serve and make the best use of taxpayer dollars. To that end, program integrity is essential to all HRSA programs including the 340B Program.

The program was authorized to stretch scarce Federal resources by substantially reducing the cost of covered outpatient drugs to participating eligible entities also known as covered entities.

In fiscal year 2013, covered entities saved an estimated \$3.8 billion on covered outpatient drugs. While the law does not specify how 340B Program savings must be used, covered entities have indicated that they use the savings to provide more care to more patients and provide medications to those who may not otherwise be able to afford them.

As part of our oversight of the 340B Program, HRSA verifies that both 340B covered entities and manufacturers are in compliance with program requirements. The Congress provided HRSA with an additional \$6 million in fiscal year 2014 which has allowed us to expand our oversight.

In 2012, HRSA began conducting selective audits and clarified the 340B nondiscrimination policy. As a result, GAO closed 2 recommendations related to those issues from its 2011 report. The remaining 2 recommendations direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient. HRSA plans to address them in a proposed guidance we will be issuing for public comment later this year.

The HHS Office of the Inspector General recommended that HRSA develop a pricing system and we expect this pricing system to be operational later this year.

HRSA uses a comprehensive approach to ensure compliance by covered entities. An entity must apply for participation in the program and recertify annually. Additionally, HRSA conducts risk-based and targeted on-site audits of covered entities.

Entities are required to develop and implement corrective action plans to respond to audit findings. Summaries of the findings are posted for the public on the HRSA Web site and this information is also used to help inform our technical assistance efforts.

HRSA also has mechanisms in place to ensure manufacturers comply with statute and offer the 340B ceiling price to covered entities. In addition, we are currently developing protocols for conducting additional audits of manufacturers.

Let me now turn to the forthcoming HRSA omnibus proposed guidance and speak to our rule-making authority. As many of you know, last year, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional clear, enforceable policy to advance our program oversight.

Before HRSA was scheduled to issue the omnibus proposed regulation, the U.S. District Court issued a ruling invalidating the 340B orphan drug regulation finding that HRSA lacked explicit statutory authority to issue it. In light of this ruling, HRSA withdrew the omnibus proposed regulation from Office of Management and Budget review.

There are 3 areas of the 340B statute with explicit regulatory authority, calculation of the 340B ceiling price, imposition of manufacturer civil monetary penalties, and implementation of a dispute resolution process.

We expect this year to issue notices of proposed rule making on all 3 of these areas. We lack explicit regulatory authority for the other provisions in 340B Program statute. Absent that authority, HRSA intends to release a proposed omnibus guidance for public comment later this year. We will then consider the public comment and finalize the guidance.

HRSA will continue to use the full extent of agency authorities in its efforts to ensure the integrity of the 340B Program. With support from the Congress, we have strengthened our management and operations to manage this program as effectively and efficiently as possible.

I appreciate the opportunity to testify today and look forward to your questions. Thank you.

[The prepared statement of Ms. Espinosa follows:]



STATEMENT OF

DIANA ESPINOSA

DEPUTY ADMINISTRATOR,
HEALTH RESOURCES AND SERVICES ADMINISTRATION

BEFORE THE
U.S. HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH

WASHINGTON, D.C.

MARCH 5, 2015

Good morning Chairman Pitts, Ranking Member Green and Members of the Subcommittee. I appreciate the opportunity to appear before you today to discuss the history and importance of the 340B Drug Pricing Program, the steps we have taken to strengthen oversight and management of the Program and the challenges we have faced in managing the program.

The Health Resources and Services Administration (HRSA) is the primary Federal agency within the Department of Health and Human Services (HHS) – and across the Federal Government – charged with improving access to health care services for people who are medically underserved because of their economic circumstances, geographic isolation, or serious chronic disease, among other factors. To address these issues, HRSA works through partnerships with states, community-based organizations, academic institutions and programs, health care providers, and others to strengthen our primary care infrastructure, bolster the health care workforce, and achieve health equity. This Subcommittee has a long history of leadership on and engagement in a number of HRSA programs and activities—including the Ryan White Care Act; Community Health Centers; the National Health Service Corps; Children’s Hospitals Graduate Medical Education, Maternal, Infant, and Early Childhood Home Visiting; Poison Control Centers; Newborn Screening; and the C.W. Bill Young Cell Transplantation Program—to name a few.

HRSA works continuously to achieve the best outcomes for those that we serve. To that end, program integrity is essential to all HRSA programs, including the 340B Program.

We also strive to improve program performance – not only to deliver the greatest possible impact for the populations we serve – but also to improve how we as an Agency administer Federal resources. This has been an expectation of HRSA under the tenure of the Administrator, Dr. Mary Wakefield, and is also an expectation of HHS Secretary Sylvia Mathews Burwell. As part of this focus, in 2010, HRSA formally launched its “Program Integrity Initiative.” Under this approach, we fully integrate program integrity into daily operations and ensure a culture of integrity throughout HRSA programs.

As we work within the Agency to identify and respond to opportunities for continuous improvement, we make every attempt to maximize what we learn from individual programs and apply these lessons learned more broadly.

The 340B Drug Pricing Program

The 340B Program was authorized by the Veterans Health Care Act of 1992. Congressional report language accompanying the bill¹ noted that the program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as “covered

¹ The H. Report for the 340B Program states the following intent: “[i]n giving these ‘covered entities’ access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

entities” in order to stretch scarce Federal resources. 340B covered entities are mostly nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs, and hospitals meeting criteria specified in law. Some examples of eligible entities include Federally-Qualified Health Centers (Community Health Centers), Ryan White grantees, hemophilia treatment centers, and critical access hospitals. These covered entities must apply to participate in the program and once eligibility is confirmed by HRSA the entity can then begin purchasing drugs at the statutorily defined price.

In Fiscal Year (FY) 2013, these covered entities saved an estimated \$3.8 billion on covered outpatient drugs. Covered entities can only administer or dispense drugs purchased under the 340B program to patients of the covered entity, and 340B drugs can only be administered or dispensed on an outpatient basis.

While the law does not specify how 340B Program savings must be used, covered entities have indicated that they use the savings to provide more care to more patients and provide medications to those who may not otherwise be able to afford them. A 2011 Government Accountability Office (GAO) study confirmed this self-reported data.² It found that entities participating in the 340B Program are able to expand the type and volume of care they provide to the most vulnerable patient populations as a result of access to these lower- cost medications.

340B Program Oversight and Administration

Overview

HRSA places the highest priority on the integrity of the 340B Program and has strengthened oversight of this program, particularly in the last four years.

As part of our oversight of the program, HRSA verifies that both 340B-covered entities and manufacturers are in compliance with 340B Program requirements. As a result of our enhanced focus on compliance issues, there has been more attention paid to compliance of program requirements by covered entities, which has resulted in increased self-disclosures and voluntary terminations initiated by the covered entities when requirements were not being met.

In order to augment these efforts, the Congress provided HRSA with an additional \$6 million in the Consolidated Appropriations Act for FY 2014. This funding has enabled HRSA to:

- Improve information technology (IT) systems to more effectively track entity and manufacturer compliance;
- Increase the number of audits performed on covered entities and manufacturers in order to ensure compliance; and

² *Drug Pricing: Manufacturer Discounts in the 340B Program Shows Benefits, but Federal Oversight Needs Improvements.*

- Hire additional auditors and staff to implement new IT investments for expanded program integrity efforts.

Response to Previous GAO Findings

We have also made progress with recommendations made by the GAO in its 2011 study. We have implemented two recommendations: conducting selective audits, which we have actively done since FY 2012, and clarifying 340B nondiscrimination policy. We issued a clarification on our nondiscrimination policy in 2012. The remaining two recommendations direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient. We plan to address these items in an upcoming omnibus proposed guidance, which will be posted for public comment.

In 2005 and 2006 reports, the HHS Office of the Inspector General (OIG) recommended that HRSA develop a pricing system to improve the oversight of the 340B Program and to allow entities access to secure pricing data to ensure that they are charged at or below the 340B ceiling price. We expect this pricing system to be operational by late FY 2015.

With respect to these recommendations, we have carefully reviewed the feedback received and where feasible and appropriate found effective ways to address issues that were within our statutory authority. We also continue to welcome feedback from our stakeholder community, Members of the Congress, GAO, and OIG to help strengthen our program operations.

Covered Entity Oversight

HRSA uses a comprehensive, multipronged approach to ensure compliance by covered entities. For example, an entity must apply for participation in the program and recertify annually. Additionally, HRSA conducts risk-based and targeted on-site audits of covered entities. A summary of final audit findings are posted for the public on HRSA's website. In addition to ensuring compliance from the covered entity being audited, the information collected informs the development of educational tools and resources designed to improve overall program integrity. These tools and resources are shared through webinars and in-person trainings and inform technical assistance provided through the Program's call center. In some instances, allegations and self-disclosure reports of non-compliance are reported to HRSA. In these cases, HRSA investigates the allegations of non-compliance and takes corrective action.

Manufacturer Oversight

HRSA also works to ensure manufacturers comply with the statute and offer the 340B ceiling price to covered entities. For example, the statute requires HRSA to verify the accuracy of 340B ceiling prices and make that ceiling price available to covered entities using a secure system. We

expect to operationalize the system to provide pricing information to covered entities by the end of 2015. Additionally, HRSA verifies that manufacturers participating in the Medicaid drug rebate program have signed a pharmaceutical pricing agreement, expects manufacturers to refund covered entities if they are overcharged, and reviews other allegations brought to our attention. HRSA also has statutory authority to audit manufacturers. We are currently developing protocols for conducting additional audits of manufacturers in FY 2015.

Omnibus Proposed Guidance

We were requested to address the process for the forthcoming HRSA omnibus proposed guidance and speak to our rulemaking authority. In 2014, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional clear, enforceable policy to advance our oversight of covered entities and manufacturers. In May 2014, before HRSA was scheduled to issue the omnibus proposed regulation, the U.S. District Court for the District of Columbia issued a ruling addressing a 340B regulation concerning orphan drugs (certain drugs used to treat rare conditions or diseases). The court invalidated the orphan drug regulation, making a finding not on the merits of the policy, but by finding that HHS lacked explicit statutory authority to issue it. In light of this ruling, HRSA withdrew the omnibus proposed regulation from the Office of Management and Budget review.

There are three areas of the 340B statute where HRSA has explicit regulatory authority: calculation of 340B ceiling prices, imposition of manufacturer civil monetary penalties, and implementation of a dispute resolution process. We expect to release this year a Notice of Proposed Rulemaking on manufacturer civil monetary penalties and calculation of the ceiling prices, as well as rule on dispute resolution. We lack explicit regulatory authority for other provisions in the 340B Program statute. HRSA intends to release proposed omnibus guidance for public notice and comment later this year, consider public comments, and finalize the guidance.

Conclusion

Mr. Chairman, we share the goal of ensuring strong oversight of the 340B Program. HRSA will use the full extent of agency authorities in its efforts to ensure the integrity of the 340B Program. As the program and associated responsibilities grow, with support from the Congress, we have strengthened our management and operations to manage this program as effectively and efficiently as possible. Opportunities for enhanced program integrity are outlined in the President's FY 2016 Budget. These proposals would allow HRSA to further implement comprehensive program integrity efforts, including program audits and entity recertification; invest in improvement of the 340B public database, which provides information on covered entities and participating manufacturers to external stakeholders; and increase compliance of manufacturers.

HRSA is fully committed to strengthening 340B program integrity efforts and ensuring that our management and oversight supports the program's continued success. As I've outlined today, with our multi-faceted strategy, we are employing many effective tools within our authority to maximize our oversight reach and manage compliance in the 340B Program.

I appreciate the opportunity to testify today.

Mr. PITTS. The Chair thanks the gentlelady.

Commander Pedley, do you have an opening statement?

Ms. PEDLEY. I do not.

Mr. PITTS. All right. Dr. Draper, you are recognized for 5 minutes.

STATEMENT OF DEBRA A. DRAPER

Ms. DRAPER. Chairman Pitts, Ranking Member Green, and Members of the subcommittee, I appreciate the opportunity to be here today to discuss the 340B Program including issues concerning its oversight.

Administered by HRSA, the 340B Program was initially created in 1992 with various legislative changes in the ensuing years. While participation is voluntary, there are strong incentives to do so.

For participating entities such as federally qualified health centers and certain hospitals, substantial cost savings, 20 to 50 percent of the cost of outpatient drugs, can be realized through the program. For drug manufacturers, participation is required to receive Medicaid reimbursement.

The 340B Program has seen significant growth in recent years. According to HRSA, for example, there were over 11,000 unique entities participating as of January 2015, a 30 percent increase since 2008. Additionally, spending on 340B drug purchases was estimated at \$7.5 billion for 2013, up from \$6 billion for 2011.

My comments today focus on inadequacies in 340B Program oversight that we identified in our September 2011 report as well as progress HRSA has made in implementing related recommendations.

We found that HRSA primarily relied on participating entities and manufacturers to self-police and ensure their own compliance with program requirements. Beyond that, HRSA engaged in few other oversight activities of the program.

At the time of our review, for example, the agency had never conducted audits of participating entities to ensure compliance with the program. We found that HRSA's guidance was often inadequate, increasing the risk for interpretation of requirements that might result in misuse of the program.

For example, HRSA's guidance was not specific in the practices drug manufacturers were to follow to ensure that drugs were equitably distributed to both participating and nonparticipating entities when distribution was restricted, such as when a drug was in short supply.

Additionally, HRSA's guidance on the definition of a patient did not clearly define when an individual was considered eligible for discounted drugs under the program.

Furthermore, HRSA had not issued guidance specifying the criteria for participation in the program for hospitals that were not publicly owned or operated.

To address these oversight inadequacies, we made a number of recommendations to ensure the appropriate use of the 340B Program. And in response, HRSA has taken actions to implement them.

We recommended that HRSA conduct audits of participating entities to better ensure compliance including ensuring that 340B drugs are not being diverted to ineligible patients. In response, HRSA began conducting audits of participating entities which they have done since 2012.

Through these audits, instances of noncompliance have been identified including violations related to drug diversion. The agency has developed a process to address noncompliance through corrective action plans. Among other things, participating entities may be required to repay manufacturers if they inappropriately receive discounts.

We recommended that HRSA provide more specific guidance on cases in which drug manufacturers restrict the distribution of drugs at 340B prices. In response, HRSA issued updated guidance in 2012 which outlined the agency's policy for manufacturers who intend to restrict the distribution of a drug.

Although HRSA took steps to address our other two recommendations, it has not yet implemented them. We recommended that HRSA provide more specific guidance on the definition of a patient eligible for drug discounts under the 340B Program. We also recommended that HRSA issue guidance to clarify the criteria that hospitals not publicly owned or operated must meet to be eligible for participation in the 340B Program.

HRSA planned to address both of these recommendations in a comprehensive regulation which had been developed and submitted to OMB in 2014. However, a Federal Court ruling narrowly defined HRSA's statutory rule-making authority for the 340B Program which prompted the agency to withdraw its comprehensive regulation.

HRSA officials told us that they expect to issue guidelines that will address these remaining recommendations this fiscal year.

Moving forward, it is essential that HRSA continue its oversight activities including monitoring and audits of 340B Program participants. Because of the complex nature of and significant growth in the program, it is also critical that program requirements are clearly and explicitly laid out in guidance or regulations. Otherwise, much is left to interpretation, increasing the risk of misuse of the 340B Program.

Mr. Chairman, this concludes my opening remarks. I am happy to answer any questions.

[The prepared statement of Ms. Draper follows:]



United States Government Accountability Office

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 24, 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.

United States Government Accountability Office

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).

⁶GAO-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

¹⁶GAO-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 & Mfg. 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.

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Mr. PITTS. The Chair thanks the gentlelady, and now recognizes Ms. Maxwell 5 minutes for opening statement.

STATEMENT OF ANN MAXWELL

Ms. MAXWELL. Good morning, Chairman Pitts, Ranking Member Green, and other distinguished Members of the subcommittee. I am pleased to join you today to discuss the integrity and the effectiveness of the 340B Drug Discount Program.

This program allows safety-net providers to purchase outpatient drugs at a discount from drug manufacturers. Specifically the law establishes a maximum ceiling price that drug manufacturers are allowed to charge these providers.

To ensure robust program integrity, the OIG has recommended numerous actions to improve this program. In response to OIG and GAO recommendations as well as congressional action informed by those recommendations, HRSA has strengthened its oversight, but there is more that could be done to strengthen program integrity.

OIG work shows some continuing challenges. These challenges affect 340B providers like community-access hospitals, community health centers, critical-access hospitals, and children's hospitals, as well as State Medicaid agencies and drug manufacturers.

OIG's work highlights two major areas of concern. One is lack of transparency in the program and the other is a lack of clarity in program guidance.

With respect to transparency, key stakeholders are in the dark. Neither providers nor State Medicaid agencies have all the information needed to ensure the integrity of 340B transactions.

OIG recommends three steps HRSA can take to increase transparency and ensure the program achieve its goals. The first two have to do with sharing ceiling prices. We recommend that HRSA shares ceiling prices with providers. This will allow providers to ensure they are not being overcharged by drug manufacturers.

We also recommend that HRSA shares ceiling prices with State Medicaid agencies. This will allow State Medicaid agencies to ensure they are not overcharged when they reimburse 340B providers for Medicaid patients. Making this happen would require a new authority from Congress.

Finally, we recommend greater claims transparency. HRSA should further improve tools intended to make 340B claims transparent to Medicaid. Medicaid agencies need this information to protect drug manufacturers from providing rebates on drugs that have already received an up-front discount through the 340B Program.

In addition to the lack of transparency, program guidance lacks clarity, failing to keep up with the evolving and complex marketplace. One key change that has taken place over the past 5 years is a growing reliance on retail pharmacies.

In retail pharmacy settings, we found that providers made different determinations on what prescriptions were eligible for the discount. Let me illustrate that with an example.

Let's imagine a doctor sees a patient at a community health center. Later that same doctor sees the same patient at her private practice. If that doctor prescribes a drug to that patient at her private practice, is that prescription eligible for the 340B discount?

One provider we talked to in our study said yes. Another provider in our study said no. And yet another provider said maybe. So who is right? We couldn't tell based on current guidance.

HRSA's guidance addresses patient eligibility, leaving room for interpretation as to which of a patient's prescriptions might, in fact, be eligible for the program.

Furthermore, guidance doesn't address how to handle uninsured patients at retail pharmacies. We found that because of the way retail pharmacies operate, uninsured patients may end up paying full price for their prescriptions.

We believe it is important that HRSA update program guidance to more clearly and specifically define patient eligibility as well as address other complexities introduced by the use of retail pharmacies. Without more clarity, it is hard to determine or enforce compliance.

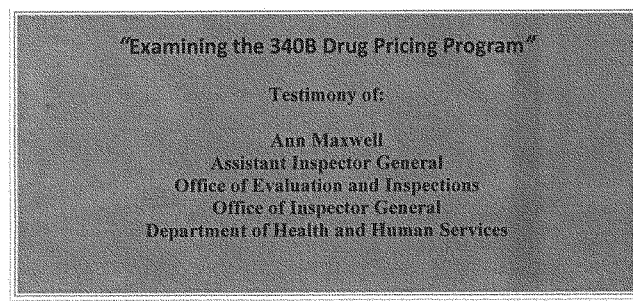
We appreciate and share your interest in the integrity and the effectiveness of the 340B Program. Towards that end, we have ongoing work in this area that we plan to issue later this year and can share with you at that time.

At this time, I am happy to be of assistance if you have any questions. Thank you.

[The prepared statement of Ms. Maxwell follows:]



**Testimony Before the United States House of Representatives
Committee on Energy and Commerce:
Subcommittee on Health**



March 24, 2015

10 a.m.

Location: Rayburn House Office Building, Room 2322

Testimony of:

Ann Maxwell

Assistant Inspector General for Evaluation and Inspections
Office of Inspector General, U.S. Department of Health and Human Services

Good morning Chairman Pitts, Ranking Member Green, and members of the Subcommittee. I am Ann Maxwell, Assistant Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you to discuss the integrity of the 340B Drug Pricing Program (340B program).

In 1992, Congress enacted section 340B of the Public Health Service Act (PHS Act), 42 U.S.C. 256b, to establish the 340B program, which is managed by the Health Resources and Services Administration (HRSA). The program was created to generate savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at discounted prices. These savings could then be used to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ HRSA estimated that the annual savings attributable to the 340B program in 2013 was \$3.8 billion.²

Pursuant to the PHS Act, drug manufacturers sign a Pharmaceutical Pricing Agreement stipulating that they will charge certain eligible health care providers (340B providers) at or below specified maximum prices, known as ceiling prices. The manufacturers calculate 340B ceiling prices each quarter by applying a statutorily-defined formula to confidential drug pricing data. 340B providers benefiting from these discounted prices include such safety-net providers as community health centers, critical access hospitals, and hospitals that serve a disproportionate number of low-income patients. As of February 28, 2015, 11,180 providers were participating in the 340B program.

For over a decade, OIG has performed evaluations and audits reviewing HRSA’s oversight of the 340B program and various other aspects of the 340B program to ensure that it was meeting its intended goals.³ Our initial work, released in the early 2000s, found numerous deficiencies in HRSA’s oversight of the program. These deficiencies included inaccurate information about which providers were eligible for the discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices. In the latter case, confidentiality protections prevented HRSA from sharing the ceiling prices with the 340B providers, leaving them in the dark as to whether they were

¹ H.R. Rept. No. 102-384 (Part 2), at 12 (1992) (Conf. Rept.).

² The U.S. Department of Health and Human Services. *HRSA FY2015 Budget Justification*.

³ OIG has issued five evaluations on the 340B program: (1) *Deficiencies in the 340B Drug Pricing Program’s Database*, OEI-05-02-00071, June 2004; (2) *Deficiencies in Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, October 2005; (3) *Review of 340B Prices*, OEI-05-02-00073, July 2006; (4) *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011; and (5) *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

being charged correctly by drug manufacturers. Furthermore, we also pointed out that HRSA lacked the necessary enforcement tools for dealing with compliance violations.

In response, HRSA has significantly strengthened its oversight of the 340B program. In addition, Congress took action to improve program integrity, including authorizing HRSA to share the discounted ceiling prices with 340B providers as well as empowering HRSA with new enforcement tools. HRSA's actions and the statutory changes to the 340B program addressed many of OIG's recommendations.

However, despite these improvements, the 340B program faces continuing challenges. In this testimony, OIG recommends further improving the 340B program by: (1) increasing transparency, and (2) clarifying program rules. These recommendations are explored in detail below.

OIG RECOMMENDS INCREASED TRANSPARENCY TO SUPPORT OVERSIGHT AND STRENGTHEN PROGRAM INTEGRITY

More transparency is needed in both 340B ceiling prices and Medicaid claims for 340B-purchased drugs. OIG's work on the 340B program has consistently found that a lack of transparency in both 340B ceiling prices and Medicaid claims for 340B-purchased drugs has negatively affected 340B providers, State Medicaid programs, and drug manufacturers.

The lack of transparency in prices prevents 340B providers and Medicaid from ensuring that they have paid the correct amount for 340B-purchased drugs.

Currently, neither 340B providers nor States Medicaid agencies have access to 340B ceiling prices. Because of confidentiality provisions in the Medicaid statute that protect manufacturer pricing data, HRSA previously could not share ceiling prices with 340B providers. Consistent with an OIG recommendation, Congress, as part of the Affordable Care Act (ACA), authorized HRSA to share ceiling prices with 340B providers; however, HRSA has not yet established a mechanism to do so. These same confidentiality provisions continue to prevent HRSA from sharing 340B ceiling prices with States.

Without access to ceiling prices, 340B providers cannot ensure that they are being charged the appropriate amount by drug manufacturers. OIG's work has shown that 340B providers have, in fact, been overcharged for 340B-purchased drugs in the past: we found that 14 percent of drug purchases under the 340B program in June 2005 exceeded applicable ceiling prices; as a result, 340B providers overpaid by a total of \$3.9 million during that month.⁴

Lack of access to 340B ceiling prices also prevents States Medicaid agencies from effectively enforcing their Medicaid payment policies for 340B-purchased drugs. States pay for 340B-purchased drugs when 340B providers dispense them to Medicaid patients. Many States have established Medicaid policies to pay for 340B-purchased drugs at 340B providers' actual acquisition cost; these policies ensure that Medicaid realizes savings from the discounted 340B prices. However, OIG found that without access to 340B ceiling prices, States are unable to implement automated, prepayment edits to enforce these policies. Instead, some States conduct labor-intensive and potentially costly audits and post-payment reviews in an attempt to ensure that they have paid 340B providers correctly for

⁴ OIG, *Review of 340B Prices* (OEI-05-02-00073), July 2006.

340B-purchased drugs.

**OIG recommends HRSA share 340B ceiling prices
with 340B providers and State Medicaid agencies**

Making 340B ceiling prices transparent to 340B providers and to State Medicaid agencies would enable them to ensure that they have paid the correct amounts for 340B-purchased drugs.

HRSA has made improvements in 340B ceiling price transparency, but more action is needed to implement outstanding OIG recommendations. The ACA directed HRSA to share ceiling prices with 340B providers via a secure Web site. HRSA initially indicated that it could not do so given limited funding, but announced that it would move forward with the project after receiving increased appropriations in 2014. The ACA also required HRSA to take additional steps, such as spot checks of sales records, to ensure that 340B providers are not overcharged for 340B-purchased drugs. The ACA did not, however, authorize HRSA to share 340B ceiling prices with *States*; additional legislative authority would be required to do so.

The lack of transparency regarding which Medicaid claims represent 340B-purchased drugs limits States' efforts to pay correctly and prevent duplicate discounts.

In addition to needing greater transparency concerning 340B ceiling prices, States need greater transparency as to which Medicaid claims represent 340B-purchased drugs to enforce their Medicaid payment policies. The increasing complexity of 340B program operations, including contract pharmacy arrangements, has made it more difficult for States to accurately identify these claims. This means that even if States can determine *how much* they should be paying 340B providers for 340B-purchased drugs, they still may not know *which claims* to reimburse at that rate.

Transparency as to which Medicaid claims represent 340B-purchased drugs is also a critical component of preventing duplicate discounts. Subjecting drug manufacturers to duplicate discounts on 340B-purchased drugs is prohibited by law. Duplicate discounts occur when drug manufacturers pay State Medicaid agencies rebates under the Medicaid drug rebate program on drugs they sold at the already-discounted 340B price.

When States invoice manufacturers for Medicaid drug rebates, they exclude claims representing 340B-purchased drugs from invoices to prevent duplicate discounts. States must therefore be able to accurately identify these claims to prevent duplicate discounts from occurring. HRSA maintains a tool, the Medicaid Exclusion File, to assist States in this process. However, OIG has found the use and value of this tool to be limited. Specifically, we found that in 2010 over half of States had developed alternatives to the Medicaid Exclusion File, and many cited inaccuracies in the Medicaid Exclusion File as a reason for

doing so.⁵

The ACA's extension of Medicaid rebates to drugs paid through Medicaid managed care organizations (MCOs) has further complicated the process of identifying Medicaid claims for 340B-purchased drugs to prevent duplicate discounts. The share of all Medicaid beneficiaries covered by Medicaid MCOs has increased significantly in recent years, from approximately 58 percent in 2002 to approximately 74 percent of beneficiaries in 2011.⁶ HRSA issued a policy release in December 2014 to clarify that the Medicaid Exclusion File is intended for use only with fee-for-service Medicaid, not Medicaid MCOs; however, HRSA has not developed or officially endorsed any alternative tools for use with Medicaid MCOs.⁷ Additionally, OIG's 2014 report on 340B contract pharmacy arrangements found that difficulties in identifying beneficiaries covered by Medicaid MCOs contribute to duplicate discount vulnerabilities.⁸ OIG has work underway that will assess States' current methods of preventing duplicate discounts for drugs paid through Medicaid MCOs.

OIG recommends HRSA improve tools and guidance to help States and drug manufacturers identify which Medicaid claims have received the 340B discount

Transparency as to which Medicaid claims represent 340B-purchased drugs would further enhance States' efforts to pay correctly and would help them protect manufacturers from duplicate discounts.

Although HRSA and CMS have made progress in this area, OIG encourages HRSA and CMS to continue working with 340B providers and State Medicaid agencies to improve claims transparency. In response to OIG's recommendation, HRSA started collecting new information as part of 340B providers' annual recertification to improve the accuracy of the Medicaid Exclusion File. Also in response to an OIG recommendation, CMS issued guidance to States on alternate ways to identify claims for 340B-purchased drugs. OIG's ongoing work on preventing duplicate discounts for drugs paid through Medicaid MCOs may result in additional recommendations to improve claims transparency.

OIG RECOMMENDS CLARIFYING 340B PROGRAM RULES TO SUPPORT OVERSIGHT AND STRENGTHEN PROGRAM INTEGRITY

Since 2010, 340B providers have increasingly used contract pharmacies to dispense 340B-purchased drugs on their behalf. Contract pharmacies are external pharmacies (often retail pharmacies) that partner with 340B providers to dispense 340B-purchased drugs to the providers' patients. In its 2014 report, OIG found that the percentage of all 340B providers that use contract pharmacies had risen from 10 percent to 22 percent since 2010. Moreover, the number of unique pharmacies serving as 340B contract pharmacies had grown by

⁵ OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs* (OEI-05-09-00321), June 2011.

⁶ Centers for Medicare & Medicaid Services (CMS), *Medicaid Managed Care Enrollment Report*, July 2011.

⁷ HRSA, *Clarification on Use of the Medicaid Exclusion File*, December 12, 2014.

⁸ OIG, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431), February 2014.

770 percent.⁹

OIG has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements. Their operations are often quite complex, and this complexity has important consequences—variation in eligibility determinations across different 340B providers and inconsistencies in whether uninsured patients benefit directly from the 340B program.

HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements.

340B providers are prohibited by law from dispensing 340B-purchased drugs to anyone who is not their patient. However, the law does not further define what constitutes a “patient.” HRSA’s official definition of patient eligibility comes from guidance issued before 340B providers were permitted to contract with networks of retail pharmacies. That guidance specifies that an individual is an eligible patient only if he or she has an established relationship with the 340B provider, he or she receives health care services from the 340B provider, and those services are consistent with the service or range of services for which Federal funding is being granted.¹⁰

Dispensing a 340B-purchased drug to an ineligible patient, which is prohibited by law, is referred to as “diversion.” Thus, appropriately determining patient eligibility for 340B-purchased drugs is critical to preventing diversion.

Although the law and HRSA guidance currently define 340B eligibility at the patient level, operationally, contract pharmacies determine eligibility at the prescription level. Retail contract pharmacies generally have no way to distinguish a 340B patient from any other customer filling a prescription at their stores. To address this reality, many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory. Only later, after dispensing a drug, do these contract pharmacies determine which prescriptions were given to 340B-eligible patients. They then order the appropriate quantity of drugs at 340B prices to replenish their inventory.

To identify which prescriptions were given to 340B-eligible patients, contract pharmacies often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, OIG found wide variation in these eligibility determinations. Different determinations of 340B eligibility appear to stem from the application by 340B providers and their contract pharmacies of the patient definition to a wide variety of prescription-level scenarios. Depending on the interpretation of HRSA’s patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.

HRSA’s current guidance on patient definition does not account for many of the 340B eligibility decisions that arise in contract pharmacy arrangements. The following example illustrates how contract pharmacy operations have led to different determinations of 340B

⁹ Ibid.

¹⁰ Disproportionate share hospitals are exempt from the requirement that services be consistent with the service or range of services for which Federal funding is being granted.

eligibility in the absence of a clearer patient definition:

Scenario: Nonexclusive physician

A physician practices part time at a 340B entity, but also has a private practice. The physician first sees an individual at the 340B entity. On a separate occasion, the physician sees the same individual at his private practice and writes a prescription for the individual. The individual fills the prescription at the 340B entity's contract pharmacy.

Whether contract pharmacies determine the prescription in this scenario to be 340B-eligible depends on how they match their dispensing data to information from the 340B provider. One 340B provider in OIG's report noted that it would automatically categorize the prescription in this scenario as 340B-eligible because it uses a list of all prescribers working at the 340B provider to identify 340B-eligible prescriptions. Because the physician in this scenario would be on the prescriber list, the prescription would be categorized as 340B-eligible, even though it was written at the physician's private practice (i.e., originated outside the 340B provider).

Another 340B provider in OIG's report noted that it would *not* categorize the prescription in this scenario as 340B-eligible because, although the 340B provider's contract pharmacy also uses a prescriber list to identify 340B-eligible prescriptions, it limits the prescriber list to only those prescribers who work exclusively for the 340B provider. Because the physician in this scenario would not be on the prescriber list (as he does not work exclusively for the 340B provider), the prescription would not be categorized as 340B-eligible.

Yet another 340B provider in OIG's report noted that it may or may not categorize the prescription in this scenario as 340B-eligible, on the basis of a manual review. Prescriptions from nonexclusive physicians go into a queue for 340B provider staff to review and categorize as 340B-eligible or not 340B-eligible.

Neither the 340B statute nor HRSA guidance addresses whether 340B providers must offer the discounted price to uninsured patients at their contract pharmacies.

Despite the 340B program's ultimate goal of increasing access and providing more comprehensive care, neither the 340B statute nor HRSA guidance speak to how 340B providers must use savings from the program—nor do they stipulate that the discounted 340B price must be passed on to uninsured patients. Given this discretion, some 340B providers have chosen to institute extra measures to ensure that uninsured patients benefit through lower drug costs when filling prescriptions at contract pharmacies. If they do not, uninsured patients can pay full price for drugs filled at contract pharmacies and thus not directly benefit from the 340B discount on their prescriptions. Guidance on how the program should apply to uninsured patients in these scenarios should be clarified to ensure that patients are treated consistently across 340B providers and that operations align with the program's intent.

Several 340B providers in OIG's 2014 report did not offer the 340B price to their uninsured patients at contract pharmacies. These 340B providers' contract pharmacy arrangements

would have required additional processes to identify uninsured patients as 340B eligible. Because, as previously noted, many contract pharmacies do not know which patients are from the 340B providers when they come to the pharmacy. Not knowing whether the patient is 340B eligible may not have a financial impact on insured patients, because their costs are often determined by standard copayments stipulated in their insurance plans. OIG did not assess the specific consequences for insured patients in its report. For uninsured patients, not knowing whether the patient is 340B eligible means that they may be charged the full price for their drugs. Contract pharmacies may later identify uninsured patients' prescriptions as 340B-eligible, but those patients will have already paid full price.

**OIG work suggests clarifications to the 340B program rules
are needed in these areas:**

- Clarifying HRSA guidance on patient definition as it applies to different prescription-level transactions. This could address challenges that arise from different interpretations of the current guidance, help to improve program integrity, and ensure that the program is achieving its intended outcomes.
- Further guidance on how 340B discounts should apply to uninsured patients at contract pharmacies.

HRSA has announced plans to issue wide-ranging 340B program guidance, in June 2015, that will address patient definition and other contract pharmacy issues.

Although OIG work has focused on the potential benefits of additional guidance in relation to contract pharmacy arrangements, such guidance would also benefit the 340B program more generally.

CONCLUSION

We appreciate the Subcommittee's interest in these important issues. Further, we are encouraged by HRSA's response to our recommendations and the progress it has made thus far in improving its oversight of the 340B program. We continue to urge HRSA to fully address OIG's recommendations related to improving transparency of 340B pricing information for 340B entities and State Medicaid agencies and improving transparency of 340B claims. It is also important that HRSA strengthen and clarify program rules regarding how the 340B discount should be applied. Without clear rules, HRSA oversight is compromised, interpretations of program rules vary, and vulnerabilities in 340B program integrity will persist.

OIG is committed to continued oversight of this program. Ongoing OIG work is assessing the prevention of duplicate discounts for drugs paid through Medicaid MCOs. Additional OIG work underway is examining the intersection of the 340B program and Medicare

Part B. We anticipate final reports on these issues in 2015, and we look forward to sharing those results with the Committee at that time. This concludes my testimony. I would be happy to answer your questions. Thank you.

Mr. PITTS. The Chair thanks the gentlelady.

And we will now begin questioning. I will recognize myself 5 minutes for that purpose.

First for the GAO. Dr. Draper, in your report, you noted that using the DSH adjustment percentage as part of the 340B eligibility criteria for hospitals has the effect of making eligibility for 340B expand as more people become insured due to broader Medicaid coverage.

Since your report was written, we have seen the uninsured rates decline at hospitals in States that have expanded Medicaid.

The question is, do you think it makes sense for hospitals in those States to gain full access to 340B just as their charity care burden is decreasing due to patients gaining Medicaid or do you think there might be another metric for 340B eligibility that could work better than the DSH metric to help ensure the program reaches the hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients?

Ms. DRAPER. Well, it is probably best if I first explain what DSH is. It is actually an inpatient indicator. The 340B Program is an outpatient program. DSH is actually the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income and the percentage of total inpatient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A.

So it really is an inpatient indicator and it is sometimes used as a proxy for uncompensated care or the amount of low-income clients a particular facility serves.

So the question is an interesting one. And part of the issue is that it is a difficult question to answer because much has changed in the healthcare landscape over the last several years since the 340B Program was created in 1992.

One of the big things, of course, is the healthcare reform that was recently enacted which provided coverage for more people than originally was the case when the program was initially established.

However, I think the bigger question is, what is the intent of the 340B Program. And there is a lot of uncertainty or lack of clarity around what is this program intended to do.

In our prior work when we issued our 2011 report, there were a lot of varying interpretations of what the 340B Program was. HRSA talks about the program. And the purpose of the program is to enable covered entities to stretch scarce Federal resources to reach more patients and provide more comprehensive services. And this was based on the committee report for the House Energy and Commerce that accompanied the—when this was first created in 1992.

Others believe that this is a program to assist low-income individuals in need of medications. And while it does that, there is no criteria in terms of patient eligibility, no criteria related to level of income. So it could benefit anyone, any level of income as long as they meet the other criteria for an eligible patient.

And I can just tell you when we conducted our work in 2011, we found a range of payer mixes in the hospitals that we interviewed. We asked them about their Medicaid and uninsured payer mix and it ranged anywhere from 15 percent to 85 percent.

So it is really all over the board, and I think it is just really being able to add more clarity. It is important to add more clarity and more specificity to what is the intent of the program, what is it intended to do.

Mr. PITTS. Thank you.

Ms. Espinosa, under the 340B Program, prisons and jails are not 340B covered entities eligible to purchase drugs under the 340B Drug Pricing Program. However, according to HRSA's prime vendors Web site, in some case, quote, "State law or other arrangements create programs where a covered entity provides healthcare services to incarcerated persons such that the incarcerated persons can be considered patients of the entity eligible for 340B drugs," end quote.

In these cases, to receive 340B drugs, incarcerated persons must meet the 340B patient definition. But given HRSA's own statements about the lack of a clear, enforceable standard definition of the patient, this rings a bit hollow.

What is HRSA doing to address this issue?

Ms. ESPINOSA. The definition of a patient is a key aspect of our oversight practice. And we plan to address that in the omnibus proposed guidance that we will be issuing later this year. We understand that clarifying the patient definition is essential to oversight and it is a priority for us. We will clarify it to the greatest extent that we can within our ability.

Mr. PITTS. How many covered entities provide healthcare services to incarcerated persons?

Ms. ESPINOSA. I don't think we have that specific data point with us, sir, but certainly we can provide it to you in follow-up.

Mr. PITTS. My time is expired. The Chair recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Ms. Espinosa, HRSA was given more funding for the past two budget cycles for program integrity activities in the 340B Program. Can you detail the actions that were taken with this funding?

Ms. ESPINOSA. Yes, sir. We use the funding to strengthen our oversight using various strategies. We have increased the number of audits that are performed and we have also used it to hire auditors. Those audits are conducted by auditors in one part of HRSA that work together with program staff. So we have that check and balance of different parts of our organization that can kind of discuss the issues and ensure that we are applying a uniform standard.

We have also strengthened and modernized the system, the 340B system that we use for keeping track of eligible entities and their compliance. Frankly, we had a lot of disparate systems and we have been working to connect them all to help facilitate our oversight and use different pieces of information to check against each other and also—

Mr. GREEN. Let me just—

Ms. ESPINOSA. Sure.

Mr. GREEN. Have you shown any savings and the audits have been useful to HRSA, additional audits?

Ms. ESPINOSA. The additional audits are always useful to us because they help us understand the areas where we can be helpful

and provide additional assistance to the covered entities to provide technical assistance on how to comply. So they are always helpful to us in that regard as well as identifying any potential issues that need to be corrected.

Mr. GREEN. Is it too early to quantify what those audits did and the savings or reallocation of funds?

Ms. ESPINOSA. We have not summed the information from the audits in that fashion.

I think, ask my colleague Commander Pedley if that is information that we have available that we could potentially—

Ms. PEDLEY. In terms of savings, where it comes into play is if we do find a covered entity, for example, has diversion or duplicate discounts, they are now required to repay manufacturers.

So there is money exchanged there. HRSA does not get involved in the amounts of money that are involved through that process, but we do ensure that they repay and have a corrective action plan in place moving forward.

Mr. GREEN. So there is no direct savings to the Federal Government to actually reimburse the manufacturers?

Ms. PEDLEY. Correct.

Mr. GREEN. OK. Well, my next question is, do you need additional Federal appropriations, that is where I was looking for, to carry forward with the remaining recommendations from GAO and OIG?

Ms. ESPINOSA. We are moving forward with the IG and GAO recommendations. As I mentioned, the pricing system will be operational later this year with the resources that we already have. And we are moving forward to clarify the guidance.

We have requested in the President's budget an increase to continue to expand our oversight to get greater coverage of both covered entities and manufacturers to ensure that they are meeting the program requirements.

Mr. GREEN. OK.

Ms. ESPINOSA. So we have requested additional funds, but we are moving forward on the IG and GAO recommendations with our current budget.

Mr. GREEN. OK. Both today and in the past, Congress has weighed in a lot about the program integrity and oversight of 340B.

I want to ask you directly today what were the specifics of the court decision last year that resulted in HRSA pulling back from the so-called mega regulations from the Office of Management and Budget, and I would like specifically what regulations HRSA can issue in light of the court decisions on 340B?

Ms. ESPINOSA. Uh-huh. So the court decision was not based on the merits of the orphan drug regulation but rather on the method that we—the court found that we did not have explicit rule-making authority for orphan drugs. And so as a result, we have, as I mentioned, pulled back the proposed regulation that we had in process and we are developing that through guidance.

The three areas where we do have explicit rule-making authority are civil monetary penalties for manufacturers, dispute resolution process, and—

Ms. PEDLEY. And the ceiling price.

Ms. ESPINOSA [continuing]. The ceiling price.

Mr. GREEN. OK. So I guess for practical purposes under current law, unless it is one of these three items mentioned, HRSA is prohibited from issuing regulations on the 340B Program?

Ms. ESPINOSA. Yes, sir. The court ruling was very clear that without explicit rule-making authority, HRSA cannot issue regulations.

Mr. GREEN. Mr. Chairman, I have some other questions that I would like to submit, but I would like that last one for us to consider. And I yield back my time.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Welcome. It is good to have you. And it is always good that we look at a program that was established a long time ago, especially when there is some interest in rural America. When you have small rural hospitals and federally qualified health clinics, it has been very, very helpful.

But we also know that that is not true in every case. And so it is important to, you know, follow the money and see the qualifications and the payment structures.

So I want to go to Dr. Draper. On covered entities who participate in the 340B Program through grants are required to follow strict reporting requirements about how the funds are used. However, DSH hospitals do not have a similar requirement. The OIG previously found a significant difference in how community health centers support needy patients through contract pharmacies compared to DSH hospitals.

Have any of your research, have you been able to do work to track revenue generated by 340B prescriptions and what 340B entities do with those dollars?

Ms. DRAPER. It is really likely to vary by facility because it is not a program requirement that facilities track how they use the revenue generated from the 340B Program. I will say that—

Mr. SHIMKUS. Let me, just to have a discussion, based upon the intent of the original law, I mean, wasn't there basically intent that the revenue be provided to be helpful to the low-income population?

Ms. DRAPER. For our past report, the report that we issued in 2011, we did interview entities including hospitals and other like community health centers and other grantees. And it was a small sample of entities, but they were all reporting using the revenues generated consistent with their missions.

So, for example, they use the revenues to provide more comprehensive services in terms of case management services or patient education. Some facilities reported using the revenue to expand services to other locations.

So they all reported using it consistent with their missions, which is required for grantees like community health centers and other types of grantees. It gets a little bit more difficult to track for hospitals just because of the complex nature of those organizational environments.

Mr. SHIMKUS. And that is a great statement. So there are differences based on the type of eligible entity in the reporting?

Ms. DRAPER. There are differences in just how they use the 340B Program, yes.

Mr. SHIMKUS. And the reporting. And so the follow-up debate is really, should be now, I think you alluded to, the complexity of hospitals may not be as easy to identify where the benefit goes to, but I think part of our internal debate is really?

Ms. DRAPER. Well, this might provide some help because the majority of growth in the 340B Program has really been in hospitals. As of January, there were just over 2,000 unique entities, which represented about 20 percent of the total unique entities. But if you add on their affiliated sites or outpatient clinics, it does represent about 51 percent of the total 340B sites.

HRSA report told us that about 78 percent of all current 340B drug purchases are made by DSH hospitals. So the majority of the spending is through the DSH hospitals.

Mr. SHIMKUS. And just following up on this line of questioning, don't you think just as we debate the program and the benefits, information provided by all users of the program regardless of the entity would be helpful in us making a determination of the credibility of the program and the value to the identified population?

Ms. DRAPER. I think that it is important for the program to ensure that the program is working as intended and benefitting the intended populations.

Mr. SHIMKUS. Ms. Maxwell, do you want to add anything to that?

Ms. MAXWELL. Yes. Our work points to a need for greater transparency not exactly the way that you are talking about, but I do believe we have concerns about program integrity that then compromise the ability of the program to achieve its goals. So more clarity around how the savings are used would allow us to understand the benefits of the program.

Mr. SHIMKUS. And, Ms. Espinosa, any comments on this?

Ms. ESPINOSA. Yes. I wanted to just offer a clarification. So the program requirements that have been discussed, for example, on the health centers, I mean, those are in the health center statute.

So the 340B Program overall does not impose any requirements on recipients regarding how they use the savings. It is in the case where they are paired together with other grant programs and so, for example, the health centers. In that program, there is a requirement that any savings or revenue generated in the program benefit the grant, so—

Mr. SHIMKUS. Yes. My time is expired, but I guess that is the point of a hearing to identify if you want to do a legislative fix to make sure there is greater transparency and give you the authority to do that.

Ms. ESPINOSA. Sure. I just wanted to clarify where the—

Mr. SHIMKUS. I know. That is what we are looking at.

So thank you, Mr. Chairman. Yield back.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

My questions are for Ms. Espinosa. Congressional history states that the 340B Drug Pricing Program was created to help designated healthcare providers stretch scarce resources to provide more comprehensive care to more patients. So, in other words, the program was established to support these designated providers.

You stated in your testimony that this is still the intent of the program. But for the record, can you provide a practical example of how the structure of the 340B Program has helped providers to get patients more comprehensive services?

Ms. ESPINOSA. Sure. The way the program works is that we could use a health center example, you know, a patient that is insured may get a prescription at a health center. That prescription is purchased by the health center at a 340B price, which has a discount.

And then the health center is able to charge that patient's insurer, a third-party insurer for the full price. So that margin, which, as has been discussed, is about 25 to 50 percent of the drug cost, that helps to support the cost of the health center running the pharmacy, even just having a pharmacy.

And in the cases with the health centers where there are additional savings beyond just operating their pharmacy, many have reported that they use them to enhance services. One example was on patient education—so educating patients on drug interactions, something that is very important for people who have multiple chronic conditions—and expanding hours of pharmacies. Those are the types of services that we hear the health centers and many of the other grantees report that they use the funding for.

Mr. PALLONE. OK. Thanks a lot.

It is my understanding that HRSA intends to issue a mega guidance which deals with many of the outstanding program integrity issues that are being raised today. And you touched on this somewhat in your testimony.

However, I wanted to ask you, can you describe in more detail the items that HRSA will tackle in the forthcoming guidance and how those items relate to the GAO and OIG recommendations that we have heard today?

Ms. ESPINOSA. Sure. As I mentioned, the patient definition will be addressed in the proposed omnibus guidance. That relates both directly to the GAO recommendation and also to some of the IG's findings as far as being able to track prescriptions.

There is also language on hospital eligibility that we would like to include in proposed guidance. And just to mention that these will all be put out for public comment because we do value the input from stakeholders and others.

A third area is contract pharmacies, guidelines on contract pharmacies. I think those are kind of the big key areas and then there are other aspects of policy that we would use the opportunity to clarify where we can.

Mr. PALLONE. Is the guidance on these outlier issues that GAO and OIG identified an adequate, long-term solution in your opinion?

Ms. ESPINOSA. Well, sir, we will continue to oversee this program using all the tools that we have available to us. Certainly we see the guidance as bolstering our efforts. I think that we will need to see, you know, if additional tools were available, we would certainly use those as well.

Mr. PALLONE. And then what about the difficulties, other difficulties with enforcing guidance in the absence of rule-making authority?

Ms. ESPINOSA. Generally rule making allows an agency to be more specific about its requirements and that is clearly something that has been identified by both the GAO and IG. So greater specificity, clarity on the requirements. It also has a stronger enforcement ability than guidance. So, yes, overall, rule making is a stronger enforcement tool than guidance.

Mr. PALLONE. Let me just get 1 more question. Well, the auditing practices HRSA has undertaken over the past couple of years have gone a long way towards improving program integrity. And I understand that audits are risk based and targeted.

But could you describe in a little detail how HRSA's risk-based methodology helps to best target which of those entities to audit?

Ms. ESPINOSA. So we have been in—the risk-based criteria take into account the level of complexity of the program. So understanding that covered entities that have more sites dispensing prescriptions are going to be more complex and will require greater oversight.

So our risk-based criteria take into account the number of sites that a covered entity has as well as the number of contract pharmacies. So those are two examples of things that might trigger us to select a covered entity for an audit.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman.

Do appreciate this hearing. I am learning a lot and that is why I like coming to these hearings. But let me ask some questions on some of the answers that have come up.

Ms. Espinosa, you indicated that you only had rule-making authority on civil penalties, dispute resolution, and ceiling price. Does that mean you don't have rule-making authority on what constitutes a 340B patient?

Ms. ESPINOSA. That is right. We do not have explicit rule-making authority on that.

Mr. GRIFFITH. And when did the court case that defined this come down?

Ms. ESPINOSA. It was over the summer.

Mr. GRIFFITH. So summer of 2014?

Ms. ESPINOSA. Yes.

Mr. GRIFFITH. All right. And you pulled back your omnibus guidance that you were working on at the time?

Ms. ESPINOSA. At the time, we were working on a regulation.

Mr. GRIFFITH. OK. All right. But how much difference is there particularly—and I am looking at defining the patient under 340B—how much difference would there be between your regulation and your guidance? It seems to me you just change a few words and you are ready to go on that portion of it. Wouldn't that be true?

Ms. ESPINOSA. Well, not according to our attorneys. But I think essentially it keys into the fact that there is different enforcement authority associated with each one. And because of that, we cannot be as perhaps clear or definitive in the requirements—

Mr. GRIFFITH. Well, I understand the court case—

Ms. ESPINOSA [continuing]. Depending on what the rule—

Mr. GRIFFITH [continuing]. Got in the way, but it still bothers me, and this is a criticism of the Federal Government as a whole, that the recommendations came out in 2011 and even with the guidance, if you hadn't had the court case or the rules, you probably were looking at late 2014 or early 2015. A student could get an undergraduate degree in that period of time and we are having a hard time defining what a patient is in that same period of time.

And I love lawyers. I am one. But sometimes you have just got to move forward with common sense and you might be held back by that. Also, sometimes you don't need to have an omnibus.

The definition of a patient seems to be a problem GAO pointed out. Why not get that one moved along and let some of the more complicated things stay behind for the harder work, get the simple things done quickly?

I do want to congratulate you, Dr. Draper, on a small point that is 1 of my pet peeves. Thank you for listing the Medical College of Virginia in your bio because so many people think that it is all VCU. And, of course, they are united, but there wouldn't be a U in VCU if it hadn't been for the Medical College of Virginia being added to the Richmond facility. So thank you for listing that and appreciate your hard work on this.

Ms. DRAPER. Thank you.

Mr. GRIFFITH. Are there other suggestions you think that would be simple things that they could work on and get them out more quickly that Ms. Espinosa ought to be focused on in the short run as opposed to some of the more difficult things?

Ms. DRAPER. Well, one of the things I mentioned in my testimony was that this is a very complex program. You have a lot of different types of entities and no one entity looks like another type of entity. So it is a very complex program. And the growth in the program in recent years has been really significant.

So I think those factors really make it clear that the program rules and regulations really need to be very clear and explicitly laid out either in guidance or in regulation. But on top of that, I can't stress enough the importance of continuing oversight and enhancing the oversight to ensure that program participants are using the program as intended.

Mr. GRIFFITH. And let me say this to Ms. Espinosa: Thank you so much for your comments, but we are here for a reason. And if the court said you didn't have authority, I would think that we would be willing to give you—now, we have the same problem. Everybody wants an omnibus bill. But I would think that we would give you authority to define what a 340B patient is if you all wanted to ask for it.

Ms. Maxwell, let's go to you. We have got the national trends in healthcare provider consolidations where a hospital goes out and buys up an outpatient clinic and then takes a clinic perhaps that is break even but once they qualify that clinic as a part of their hospital, they can get 340B money.

Can you tell me what problems you see with that because a Berkeley research group said that that led to about \$200 million in additional costs for the Federal Government? Your comments?

Ms. MAXWELL. That is an area that we have not looked at yet in the Office of Inspector General, so I don't really have a lot of data at my disposal to comment on that topic.

Mr. GRIFFITH. All right. Well, I appreciate it.

My time is just about up. Thank you all for being here and thank you so much for an interesting hearing.

I yield back.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the gentlelady from Florida, Ms. Castor, 5 minutes for her questions.

Ms. CASTOR. Well, thank you, Mr. Chairman, for calling this hearing.

I want to start by saying that 340B is a lifesaver for so many hard-working Americans. Whenever I visit children's hospitals or community health centers or safety-net hospitals back home in Florida, they emphasize to me how important 340B is to meeting their mission of taking care of families and to ensuring that the cost of pharmaceuticals doesn't put care out of reach for so many.

So I really appreciate the work that all of you are doing to ensure that 340B is functioning as intended, that the program has integrity, that money is being spent appropriately.

So thank you, HRSA, for following up on the important recommendations of GAO and the Office of Inspector General and because in 2011, GAO made recommendations. They said the discounts offered in the 340B Program provide substantial benefits, but HRSA has got to improve its oversight.

So in 2012, HRSA began doing both risk-based and targeted audits. Is it true, Ms. Espinosa, you did 51 audits in 2012?

Ms. ESPINOSA. Yes.

Ms. CASTOR. That is correct?

And then to my colleagues, thank you for working on a bipartisan basis to give HRSA the funds last year, an additional \$6 million to support program integrity efforts.

I understand that now in 2015, the agency is on track to do 200 audits; is that correct?

Ms. ESPINOSA. Two hundred and ninety-five.

Ms. CASTOR. Two hundred and ninety-five.

And, Dr. Draper, can you confirm that they have started doing the audits and they have been able to ratchet up year over year?

Ms. DRAPER. Yes. In 2012, they did 51. They went to 94 the next year and 99. And then they told us that it is actually 200, so 200 audits—

Ms. ESPINOSA. Yes. I am sorry. I misspoke.

Ms. DRAPER [continuing]. This fiscal year. So we are happy to see that. Prior to our work, no audit had been done of any participating entities, so we see that they are working to implement that recommendation.

Ms. CASTOR. Good.

Ms. Espinosa, when Congress created the 340B initiative in 1992, it intended that eligible providers use the 340B drugs for any patient of the entity regardless of insurance status.

For the program to have any meaningful value to providers and the patients they serve, 340B providers must be able to generate

savings by using 340B drugs for all eligible patients including those with insurance.

So as noted in the GAO report, these savings are then used to cover the cost of providing comprehensive healthcare services to more vulnerable patients or those who would struggle to afford high-priced pharmaceuticals.

My understanding is that the law does not nor was it ever intended to require that discounted drugs only be provided to uninsured patients or that program savings only be used to lower the cost of drugs or health services for uninsured patients.

Do you agree with that?

Ms. ESPINOSA. Yes, that is correct. The law does not specify how the savings are to be used, and it also does not specify the status of any of the patients that could potentially benefit from the program.

Ms. CASTOR. And that goes back to what I hear and I know other Members hear from all of the children's hospitals, safety-net hospitals, health centers, Ryan White Centers that the reason why 340B is so important to their overall mission.

I also wanted to ask a different question. Ms. Maxwell, we talk a great deal about compliance on the part of covered entities and HRSA's work to ensure proper program integrity.

However, I am curious about how we actually know that manufacturers are offering the 340B price for drugs fairly to all entities because there have been press reports in the past that manufacturers are overcharging for 340B drugs.

In OIG's review of these issues, have you found evidence of manufacturers overcharging for 340B products?

Ms. MAXWELL. Yes. Our work looking at the oversight of 340B spans back about a decade. In our early work in 2005, we did, in fact, find instances of manufacturers overcharging. At that time, it was 13 percent of interactions we found actually had been overcharged resulting in \$13.9 million for the month that we looked at which is why our recommendations continue to be to allow for greater transparency, to share those prices with the providers so they know they are not being overcharged.

We also have an outstanding recommendation to improve HRSA's oversight of how manufacturers calculate the 340B ceiling price as well as doing spot checks of transactions so they know that the correctly calculated prices are what, in fact, are being charged.

Ms. CASTOR. Thank you very much.

I yield back.

Mr. PITTS. The Chair thanks the gentlelady, and now recognize the gentleman from Missouri, Mr. Long, 5 minutes for questions.

Mr. LONG. Thank you, Mr. Chairman.

And thank you all for being here today.

Ms. Espinosa, let me start with you. There are 435 Members of Congress, and approximately half of the Members of Congress were not here 5 years ago.

HRSA has yet to share 340B ceiling prices with covered entities since it was provided that authority to do so 5 years ago when half the Members of Congress weren't here, were not in Congress.

Why has it taken so long for HRSA to do this and when does HRSA plan to begin sharing this information with these covered entities?

Ms. ESPINOSA. I think, as I mentioned, we are working on the pricing system which will be operational later this year. The issue of the gap in time between the authority and implementing it relates to funding. It was the funding that the Congress provided in 2014 that allowed us to move forward on this particular system.

The 340B Program historically, you know, originally did not receive an appropriation. Then it received an appropriation and HRSA provided additional funds through some of its program funding. But until the Congress provided that increase, we did not have the resources to implement.

Mr. LONG. OK. Does HRSA believe it would be useful to have similar authority to share 340B ceiling prices with State Medicaid agencies and if such authority is provided, how long would it take HRSA to begin sharing that information with the States?

Ms. ESPINOSA. That would require a legislative change. So we currently do not have authority to share that information.

Mr. LONG. OK. Sticking with you, Ms. Espinosa, with respect to the comprehensive guidance which is expected later this year, how does HRSA intend to ensure adoption of the policies by the covered entity?

Ms. ESPINOSA. We would continue to implement our current practices, which have multiple aspects to them. First, entities have to register before they can participate, so this guidance would provide more specificity as far as those requirements.

And then there is annual recertification, and that is kind of a regular process, regular time that we have to ensure compliance. Entities at that time also attest they are complying. And then finally, we have the audit process that we use to go in, as has been discussed, for the targeted and the risk-based audits.

Mr. LONG. What can we as Members of Congress do to help HRSA promote the integrity of the 340B Program?

Ms. ESPINOSA. I think Congress has already been quite supportive of HRSA's activities. As I mentioned, the additional resources that we got beginning in 2014 were a real boost to our program integrity efforts.

The President's budget for fiscal year 2016 also requests additional funding for 340B to continue to modernize our oversight practices as well as to enhance and expand them.

Mr. LONG. OK. Thank you.

And, Ms. Draper, somewhat recently a study published in Health Affairs suggests that generic dispensing rates are lower for 340B prescriptions than for all prescriptions overall, possibly leading to greater spending under Medicare Part D and Medicaid.

Is that an issue that GAO has looked into in any detail?

Ms. DRAPER. We have not looked at that, but I am aware of that study that was published in 2012. And there were a couple factors that the authors described as potentially leading to the lower dispensing rates for generics. One was related to not having generic equivalents for HIV/AIDS and antiviral, which is a population that is served by the 340B Program.

Another factor that they talked about was that the underlying comorbidities and complexities of the 340B patients may not compare to the patients at large, so they may require more—so generic drugs may not be appropriate. So those were the two factors that the authors discussed in that study.

Mr. LONG. OK. OK. I think everyone realizes how important this is to a lot of entities in our congressional districts. And this is a very important hearing. I thank you all for being here today and for your testimony.

With that, Mr. Chairman, I yield back.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the gentleman from North Carolina, Mr. Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Let me thank you, Mr. Chairman, for holding this important hearing on the 340B Program.

And I thank the witnesses for your testimony today.

As my colleague, Ms. Castor, said a few moments ago and Mr. Long from Missouri just reiterated it a moment ago, this is a big deal back at home. 340B is critical to the communities that I represent in eastern North Carolina and its importance cannot be overstated.

North Carolina's first district has one of the highest poverty rates in the country and prior to the Affordable Care Act, many of my constituents were uninsured or under-insured. Even now many remain uninsured because the Governor and the General Assembly have been unwilling to expand the Medicaid Program.

For many North Carolinians, the only way to access the care they need is through 340B. This bipartisan program helps bring providers together with pharma to ensure our most vulnerable populations do not go without necessary medicine.

The integrity of the program is very important. To that end, I ask that we proceed with caution to avoid disruption to the patient populations that heavily depend on hospitals for their healthcare needs.

I, too, would like to go to you, Ms. Espinosa. I would like to discuss the purpose of the 340B Program to highlight how important it is to communities like the one that I represent.

Can you describe the type of populations who benefit most, the very most, from the 340B Program?

Ms. ESPINOSA. Yes, sir. As has been discussed, many of the 340B entities are the ones that are essential to providing the safety net for individuals who have limited access to healthcare or are low income or have other chronic conditions that may limit their access to healthcare.

So as we have discussed, the Health Center Program is one example that serves anybody who walks through their doors, basically, regardless of insurance status or income. And so for those programs, the 340B savings allow them to continue operations and to continue to serve those individuals.

Mr. BUTTERFIELD. Well, it is obvious to me that the amount of covered entities participating in the 340B Program has actually exploded. It has grown exponentially.

What do you attribute that growth to?

Ms. ESPINOSA. Well, there are a couple of factors. One is, just in general, there has been kind of a decentralization of health care with care being provided in more sites. And then there is also that we, in the 340B Program, have beginning in 2012 changed the way that we were accounting for eligible entities. And so we started counting not only the organization but also all of its sites, and that was done to also bolster our oversight effort so that we knew all the sites that were using 340B.

So that is somewhat of a technical aspect, but it does make the numbers go up. But I should note since there have been several comments about the growth in 340B that over the last several years, the 340B sales have remained at about 2 percent of overall pharmaceutical sales. So while the number of entities has increased, the sales, the 340B as a proportion of the pharmaceutical sales has stayed about 2 percent.

Mr. BUTTERFIELD. OK. Your testimony indicates that the \$6 million in additional funding for HRSA has helped implement additional program oversight. Specifically, the additional funding helped increase HRSA's ability to improve compliance by hiring additional investigators and increasing your administration's capability to review participants.

Can you explain the relationship between the additional money and HRSA's ability to provide greater oversight?

Ms. ESPINOSA. Sure. I think I am going to ask Commander Pedley, who is accompanying me, just to describe some of the specific things that we have done with that additional funding.

Mr. BUTTERFIELD. Yes.

Ms. PEDLEY. Sure. There are a few aspects that we have been able to utilize with the additional funding. One is around IT systems, specifically the pricing system that we have been talking about. We are now able to operationalize that system to make ceiling prices available to the covered entities the end of this year.

We are also able to implement a system that we are able to internally track compliance across the board. Right now there are a lot of different manual systems that we can now combine and use the system as early warning signs to help trigger any issues that may be occurring.

And another major area again is around issuing the proposed guidance and the regulations that we spoke to in addition to being able to really double the number of audits in this fiscal year to 200 as we were able to hire more auditors in the field to conduct these audits to really pay more attention to the compliance efforts.

Mr. BUTTERFIELD. All right. Thank you very much, Mr. Chairman. I yield back.

Mr. PITTS. The Chair thanks the gentleman, and now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman.

And, again, thank you to the panel for being here today.

Ms. Espinosa, I am going to start with you on HRSA. Some private nonprofit hospitals enter the program through their DSH percentage, yet provide very modest amounts of charity care. In fact, 1 recent report found that the level of charity care provided by

DSH hospitals enrolled in the 340B Program is lower than the national average of all hospitals.

Does HRSA collect the information from hospitals about how they use the program's dollars and how they support the poor and indigent patients in a manner that reconciles the 340B Program's intent to serve this as a safety-net program?

Ms. ESPINOSA. The statute for the 340B Program does not impose any requirements on how savings are used by covered entities and as such, HRSA has not systematically collected that information since it doesn't tie to a statute.

Mrs. ELLMERS. Would HRSA support requirements for additional transparency for those DSH hospitals with the use of the 340B?

Ms. ESPINOSA. I think we would need to see those requirements. And I can't speak hypothetically, but certainly we would support greater clarity to hospital eligibility. And that is one of the items that we are including in our omnibus guidance that we will release later this year.

Mrs. ELLMERS. Thank you.

Ms. Draper, your 2011 report had a section that focused on covered entities reporting that they use the program and the revenue generated to support or expand access to services. However, some reports suggest that for two-thirds of the 340B hospitals, charity care as a percentage of patient cost is less than the national hospital average of 3.3 percent.

Other than self-reporting data, is there objective data on how hospitals are using the 340B Program or savings in the program, I guess I should say?

Ms. DRAPER. Yes. There is no program requirement for hospitals to report how they are using the savings. For some of the grantees, the community health centers, they have to use it in accordance with their grant program.

In our report in 2011, we did interview entities about how they were using savings and entities that we talked to were using it consistent with their particular missions, so—

Mrs. ELLMERS. With their particular mission statement?

Ms. DRAPER. Right. And they were using it for things like to add additional sites, provide patient education, help pay for patient's co-pays or help them get the drugs that they needed, so things like that.

Mrs. ELLMERS. Uh-huh. OK. I am just keeping an eye on time.

Ms. Maxwell, the agency has certified the results of 178 audits since fiscal year 2012. Out of the total of 295 audits conducted with more than 11,000 entities participating in the program, do you think that the current level of audits are appropriate or given the vulnerabilities that have been identified, should the agency be more for leaning in its audit work?

Ms. MAXWELL. I think the fact that HRSA now conducts audits of covered entities is a significant strengthening of their oversight. I am encouraged to see HRSA take that step and to hear they are going to be auditing manufacturers as well.

As to the correct number of audits, without more information about how HRSA actually targets those audits, I couldn't really say how many audits would be sufficient to provide coverage.

I would say 1 area in which our work speaks to that would be helpful for their audit program and could really strengthen their audit program is that they strengthen the clarity of the guidance.

Mrs. ELLMERS. The clarity of the guidance?

Ms. MAXWELL. What we found with respect to the contract pharmacy setting is the guidance was not clear enough to make determinations about whether or not entities were, in fact, in compliance or out of compliance.

Mrs. ELLMERS. Ms. Espinosa, I have one more question for you. There again, getting back to the issue of transparency and how the savings are used, isn't it true that under current guidelines some insured patients may receive lower cost drugs from a covered entity participating in the program while other uninsured patients may not receive that same discount from other covered entities in the program?

So I guess my question is, there just seems to be too much—it is too muddy as to how an uninsured patient might end up being charged the full cost of a drug. Can you just give us a little bit of information on that? There again, I get back to the fact that, for the DSH hospitals or the 340B hospitals that are getting a 20 to 50 percent discount for the commercial price, how can an uninsured patient be charged that full price being part of that program?

Ms. ESPINOSA. Because the statute does not include any requirements for how savings are used, we have not imposed any requirements or stipulated for covered entities. We don't have the statutory authority to do that. What they do now is based on their own business decisions and their own needs.

Mrs. ELLMERS. Uh-huh. Which, there again, in my 9 seconds, I will just say that—or, I am sorry. I take it back. I have gone over time. And, there again, if this is going to be a safety net for those who are the most vulnerable, we have got to ensure transparency on this issue.

Thank you again to the panel.

Mr. PITTS. The gentlelady yields back.

The Chair recognizes the gentlemen from Indiana, Dr. Bucshon, 5 minutes for questions.

Mr. BUCSHON. Thank you, Mr. Chairman.

This is to Ms. Draper and this has kind of partially been answered, but currently about one-third of all hospitals qualify for 340B. GAO's 2011 report noted that HRSA did not have specific eligibility criteria for nonpublic DSH hospitals. Instead noting that hospitals with contracts provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts which may not be what the agency intended.

After the report was issued, HRSA did release some eligibility criteria for nonpublic hospitals. However, these criteria potentially allow hospitals with very limited contracts for specific populations to qualify hospitals for 340B for all of their patients.

Do you think HRSA's guidance addresses your concerns?

Ms. DRAPER. First of all, it is now up to 40 percent of DSH hospitals that are eligible for 340B.

Mr. BUCSHON. There you go.

Ms. DRAPER. That is the most recent data. Basically the guidance that was issued was a restatement of what already existed, so

there was really nothing new related to when we had done our 2011 work.

Mr. BUCSHON. OK. So you can still—

Ms. DRAPER. It was 2013 they issued a policy that restated what their existing policy was from our read of that issuance.

Mr. BUCSHON. OK. So I am assuming you think additional steps are needed for the program's eligibility criteria for hospitals to be consistent with the program's mission to support entities that care for uninsured and vulnerable patients?

Ms. DRAPER. Yes. We believe the guidance needs to be clear as to who participates.

Mr. BUCSHON. OK. Ms. Espinosa, I understand that when 340B hospitals acquire physician practices, the drugs dispensed to those practices' patients often are converted to 340B.

When this happens, do the acquired practices take on any new statutory or regulatory obligations to provide access to their practices for indigent patients?

Ms. ESPINOSA. Our policy is that when an outpatient facility is reported as part of the cost report, then it is part of the same entity and can use 340B, as far as the first part of your question.

On the second, because there is no statutory requirement for how savings are used, there is no requirement that the savings be used for any particular types of patients.

Mr. BUCSHON. OK. And do you think hospitals should make a profit off the program? What I mean is, do you think that we should have a prescriptive way that people that participate need to show us with oversight how they are using the savings versus just including it as part of their larger budget for their entire facility? Does that make sense?

Ms. ESPINOSA. Well, sir, since we implement the statute and the specificity that is in the statute, right now the statute does not have those requirements. And so it is challenging for us to go beyond that. Our guidances can interpret statute, but to go and provide greater specificity is challenging without—

Mr. BUCSHON. Because my understanding is hearing through kind of the grapevine, so to speak, is that there are some facilities out there who are budgeting for profit from the 340B Program into their regular budget.

And so I think we have all pointed out that we probably need to address that because that is not the intent of the program. The intent of the program would be to use savings to help further the education or healthcare of the serviced population of people, not have it a line item in a budget as here is our profit from 340B next year and going into the general budget. Whether that is true or not, I don't know, but that is what I have heard.

So I just want to at the end with my remaining time state this is a critical program for many institutions in my district as well as across the country to serve the individuals that it serves. But clearly if we want to maintain a program that seems to be exploding in size and make sure that these patients continue to have access to this type of program, more aggressive oversight and probably congressional action may very well be needed to maintain that long-term program integrity.

Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the gentleman from New York, Mr. Collins, 5 minutes for questions.

Mr. COLLINS. Thank you, Mr. Chairman.

A lot of the questions I was going to ask have been asked. That is the problem of being last. But I think there is a lot of misunderstanding here when it comes to 340B, so maybe just as I am going last some clarification.

Who sets, and this would be for Ms. Espinosa, who sets the ceiling price? Is that a fixed price for a particular drug? Who sets that price?

Ms. ESPINOSA. I am going to ask Commander Pedley to describe the ceiling price.

Ms. PEDLEY. Sure. It is defined in the law for how it works. It is based on components that manufacturers report to CMS, average manufacturer price and unit rebate amount. They are subtracted from each other to get the ceiling price. So it is actually defined in the law.

Mr. COLLINS. So once a manufacturer has a ceiling price, is that price then the 1 price charged throughout the entire United States to every covered entity?

Ms. PEDLEY. Not necessarily. They can then go below that price to certain types of entities, but stay at the ceiling price for other entities. They just can't charge anyone above, but they don't need to charge everyone the same exact price.

Mr. COLLINS. What would be a reason why they would give someone a discount and someone else not below the ceiling price?

Ms. PEDLEY. It could depend on market, the type of entity that they serve, the volume of drugs that they purchase, for example.

Mr. COLLINS. That is interesting. So when we talk about transparency and the need to publish the ceiling price, have we found cases where they would charge more than the ceiling price?

Ms. PEDLEY. On occasion, we do get reports from covered entities that they believe they may have been overcharged. We investigate that and research it with the manufacturer. Those are often resolved between the manufacturer and the entity, usually an error in some type of pricing calculation, but we do follow-up and ensure that they do not overcharge. And if they do, they are required to refund the covered entity.

Mr. COLLINS. If they have a ceiling price, how often can they modify that, monthly, quarterly, yearly?

Ms. PEDLEY. It is changed quarterly.

Mr. COLLINS. It is? OK.

Ms. PEDLEY. Based on the pricing submitted to CMS.

Mr. COLLINS. And that is where transparency would at least be helpful, I think, to everyone. I think this is 1 of the common-sense things we could do.

Now, we have talked about clarifying a patient definition. So another point which I don't think is fully understood by a lot of our Members, myself included. If an entity, a DSH hospital is a covered entity and they are allowed to get 340B pricing, does it also link to a particular patient that meets the definition or is it for every patient in the hospital every time they use that particular drug, they get 340B pricing?

Ms. ESPINOSA. The 340B pricing would only be available to those patients that meet the criteria of our patient definition. So that would be outpatient services and other aspects of the definition that we currently have.

Mr. COLLINS. Which is what I thought, but I think through some of the questions today, on occasion, it sounded like every patient in the hospital got the discount pricing.

Ms. ESPINOSA. No.

Mr. COLLINS. And that is why it is important to define who is a covered patient.

Now, the ceiling price versus a Medicaid price for a particular drug, are they different? Are they the same? Is one higher? Is one lower?

Ms. PEDLEY. We have some information that usually the 340B price is slightly lower than the Medicaid price, but it depends on the type of drug it is. For example, if it is brand or generic, it can vary.

Mr. COLLINS. So tell me how does a 340B drug end up with a negative price because I have heard there are occasions it is a negative number and then they have the penny pricing that said, all right, we are not going to make the manufacturer give you the drug and give you cash on top of that. They should at least get a penny for that. So in the common-sense world, I guess could you help me understand?

Ms. ESPINOSA. Go ahead.

Ms. PEDLEY. So in the calculation, as I mentioned, the average manufacturer price minus the unit rebate amount, that can calculate out to a zero. Obviously we do not expect manufacturers to charge a zero ceiling price, so we have a policy in place that they charge a penny per unit when that is the case.

Mr. COLLINS. I am sure they appreciate the penny, but it was actually a negative number.

Ms. PEDLEY. It can actually, I believe. Since the Affordable Care Act has passed, because of how the calculation works, it can no longer be negative. It can just be a zero.

Mr. COLLINS. OK. So now, when does a drug become eligible for 340B pricing and in particular, I have only got 38 seconds, but the new Hep C drug that we have all talked about that is a cure for Hep C, it is extraordinarily expensive, but a single treatment regime cures that disease? Is that one on the 340B Program now?

Ms. PEDLEY. So the drugs that are covered, the manufacturer that participates in Medicaid signs an agreement with HRSA, then all of their covered outpatient drugs have to be priced at the 340B ceiling price.

And then on the entity level, as long as the drug is used on an outpatient basis and that patient meets the patient definition, the drug can be covered. So in this instance, if the drug is specifically used on an outpatient basis, the manufacturer has an agreement with HRSA, it would be 340B eligible.

Mr. COLLINS. All right. Well, thank you for that. It was very educational.

Mr. Chairman, thank you, and I yield back.

Mr. PITTS. The Chair thanks the gentleman, and now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you. I appreciate it, Mr. Chairman.

Administrator Espinosa, I appreciate the steps HRSA has taken to step up its compliance efforts for manufacturers and covered entities.

In the interest of having a level playing field and increasing accountability, do you think it would be prudent to subject manufacturers to similar compliance and auditing standards as covered entities have? Now, if they are covered and they are subjected to this compliance, that is fine, but I am asking that question. Do you feel that it should be a level playing field?

Ms. ESPINOSA. We have efforts in place for manufacturer compliance as well. For manufacturers, though, their requirements under the law are much narrower. Their requirements are just that they offer the ceiling price.

So the establishment of the pricing database will help to ensure that that is happening to a greater extent than our ability to ensure today. And then also we have authority to audit manufacturers and we are developing protocols to audit manufacturers as well.

Mr. BILIRAKIS. OK. Thank you.

Administrator Espinosa, one thing many of us like about the 340B Program is that it doesn't cost taxpayers dollars. Of course, we love the program because it helps out our constituents. So I am hopeful you can shed some light on the financial impact of the 340B Program.

In GAO's testimony, it was noted that according to the most recent estimate available from HRSA, covered entity spending on 340B drug purchases was estimated to be approximately \$7.5 billion in 2013, yet HRSA's fiscal year 2015 budget justification estimated that the annual savings attributable to the program in 2013 was \$3.8 billion.

If I am reading that right, it would be significant amount of savings, roughly 50 percent of the total covered entities' drug expenditure in the year.

Can you explain how HRSA calculated the savings attributable to the program?

Ms. ESPINOSA. I am going to defer to Commander Pedley to answer that question.

Ms. PEDLEY. So how we do that calculation is, on average, the 340B pricing is about 25 to 50 percent lower than what they would have otherwise paid. So we do base that number and their savings on the highest, which would be \$3.8 billion in savings.

Mr. BILIRAKIS. OK. Thank you.

Again for Administrator Espinosa, I understand that HRSA received about \$6 million in the Consolidated Appropriations Act of the fiscal year 2014 and you are using those funds for IT systems, new auditors, and staff.

Can you walk us through when you think the capacity developed with those funds will be fully operational and deployed?

Ms. ESPINOSA. We have various systems that we are rolling out. We have mentioned the system that we use, the 340B system that we use for compliance monitoring. Aspects of that system will be operational this year, but we are continuing to enhance its functionality.

We find that the system is also helpful in reducing the burden of reporting for covered entities and manufacturers. So it is something that helps us kind of tie together our oversight activities but also be more efficient in the way that they provide information to us.

We also, with those funds, are establishing the protocols for the manufacturer audits which we will begin this year and that will continue. And then we have the pricing system which will be operational this year with expanded functionality into next year.

So that investment has laid the groundwork for many aspects of our oversight activities, but we are going to continue to improve and enhance them as we implement them and identify other opportunities for increased oversight.

Mr. BILIRAKIS. OK. Thank you.

This is for the panel. I walked in a little late because I had another event that I had to go to, but name some of the entities that are eligible for the 340B Program. I heard the federally qualified community health centers, the DSH hospitals, what have you. Can you name some other nonprofit clinics, for example?

Ms. PEDLEY. So there is about 22 different types of entities, as you mentioned, federally qualified health centers, hemophilia treatment centers, federally qualified health centers, as I mentioned, HIV/AIDS clinics, Indian Health Service clinics, disproportionate share hospitals, critical access hospitals, rural referral centers, a lot of the rural hospitals.

Mr. BILIRAKIS. OK. Thank you very much.

I yield back, Mr. Chairman. Thank you.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the questions of the Members present. We will have follow-up questions that we will provide to you in writing. We ask that you please respond promptly.

I have a UC request from the ranking member.

Mr. GREEN. Mr. Chairman, I ask unanimous consent to place in the record a letter of support that Congresswoman Capps has from the National Association of Community Health Centers in support of the program and also from Congressman Matsui from the Ryan White Clinics for 340B access. And I ask unanimous consent to place it in the record.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. I remind Members they have 10 business days to submit questions for the record. That means Members should submit their questions by the close of business on Tuesday, April 7th.

Very interesting, informative hearing. It looks like Congress has some follow-up responsibilities. Thank you very much for your attendance today.

And without objection, the subcommittee is adjourned.

[Whereupon, at 11:37 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Testimony Before the
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
“Examining the 340B Drug Discount Program”

March 24, 2015
Statement Submitted By
Ascension

Ascension appreciates the opportunity to provide testimony that is relevant to the Subcommittee’s review of the functionality of the 340B Drug Discount Program, especially its desire to understand how the program is impacting patients, providers and other stakeholders.

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As the largest non-profit health system in the U.S. and the world’s largest Catholic health system, Ascension is committed to delivering person-centered care to all with special attention to those who are poor and vulnerable.

Last year, Ascension provided \$1.8 billion in care of persons living in poverty and other community benefit programs. More than 150,000 associates and 35,000 affiliated providers serve in 1,900 sites of care – including 131 hospitals and more than 30 senior care facilities – in 23 states and the District of Columbia.

At the time of the 340B Drug Discount Program’s creation, the stated intent was to permit safety net healthcare providers and other covered entities to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹

As a non-profit health system committed to serving all persons with special attention to those who are poor and vulnerable, a number of Ascension Health hospitals rely significantly on this program—as critical access hospitals, sole community hospitals, disproportionate share hospitals, and other covered entities—to serve their communities.

¹ H.R. Rep. No. 102-384(II), 12

Together, we can see, through the patients we serve every day that the 340B Drug Discount Program is delivering on the original Congressional intent.

In support, I offer the following examples:

- **The Seton Healthcare Family, Central Texas**, the leading provider of healthcare services in Central Texas, serving an 11-county population of 1.9 million, has participated in the 340 Program for more than 10 years.
 - Discounts provided by the 340B Program have allowed the organization to provide free drugs to patients (\$750,000 worth in one year alone), maintain six pharmacy-run clinics, which allow pharmacists to provide routine, follow-up care to patients, and support a Coumadin clinic, which would most likely close without funding from 340B.
- **St. Vincent Hospital, Indianapolis, Indiana**, part of St. Vincent Health, is an 873-bed facility that serves patients in Indianapolis and surrounding counties.
 - Without the 340B Program, the hospital's Joshua Max Simon Primary Care Center clinic would not be able to provide its patients the prescription medications they need at a cost they can afford.
 - The 340B discounts also support a diabetes educator, the hospital's *MedSync* prescription coordination system, which automates manual processes in the pharmacy to encourage improved health outcomes for patients with multiple, ongoing medical conditions, and education for pharmacists-in-training on providing the best care to the poor and vulnerable.
- **St. Mary's Warrick Hospital, Boonville, Indiana**, serves a three-county rural community where almost 18 percent of residents have incomes below the poverty line; 32 percent are participating in Medicaid or are uninsured.
 - In 2011, the hospital began using 340B drug pricing in its outpatient infusion clinic and the discounted drug prices amount to an annual program discounts of \$40,000. This clinic provides outpatient infusion medications when a condition is so severe that the patient cannot be treated effectively at home.
- **Via Christi Health, Wichita, Kansas**, the largest provider of healthcare services in Kansas and northeast Oklahoma, became eligible for the 340B Program on January 1, 2012, resulting in 340B discounts of \$1.2 million each year.
 - The 340B Program has helped Via Christi Health expand its programs and services for patients in need; in a single recent year, it provided more than \$145 million in charity care.
 - 340B Program savings have allowed Via Christi to provide free medications to patients who qualify based on income, support a medication assistance program (under which over-the-counter medications are sold at cost), and maintain a medication reconciliation

system that helps prevent adverse drug events and future complications for patients.

- **St. Joseph Health System, Tawas City, Michigan**, which provides primary, secondary and referral for tertiary care to more than 100,000 patients annually, began participating in the 340B Program in July 2012.
 - 340B discounts help support the St. Joseph infusion center, which treats infections that do not respond to oral antibiotics, cancer-related pain, dehydration, and other serious conditions, and a prescription assistance program, which helps financially needy patients obtain medications and supplies at free or reduced cost.
- **Ministry Healthcare, Northern and Central Wisconsin**, comprised of 15 hospitals with 1,600 licensed beds and 46 clinic locations providing more than a million outpatient visits annually, started the 340B Program in 2011 at several of its critical access hospitals.
 - The 340B Program helps Ministry Healthcare maintain numerous programs for poor, underserved, and vulnerable patients, including a Community Care Program at Our Lady of Victory Hospital, which connects low-income residents to social services and provides low-cost prescription drugs, the Affinity Care Program at St. Elizabeth's Hospital, which helps patients who are unable to pay for services and who are not eligible for other governmental assistance programs, and the Diabetes Care Program at Saint Joseph's Hospital, which helps low-income patients with diabetes purchase glucose meters and test strips, and insulin-related supplies.

Together these hospitals rely significantly on the 340B Drug Discount Program to help improve the health of low income patients. It has proven to be a successful and critical program that allows hospitals and other covered entities to help underserved patients with the high cost of prescription drugs.

To preserve this valuable service for those who need it most, Ascension supports good stewardship of the 340B program through compliance and integrity audits. We are grateful that Congress already has directed the Secretary of Health and Human Services to develop systems to improve manufacturer and covered entity compliance and program integrity activities, and adopt administrative procedures to resolve disputes. In addition, for the past few years, the Health Resources and Services Administration has been conducting program integrity audits of covered entities. We believe those quality control efforts will help ensure that the 340B Drug Discount Program continues to fulfill its Congressionally-intended purpose—for all the patients we serve who need it most.



March 24, 2015

Chairman Fred Upton
House Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Subcommittee Chairman Joe Pitts
House Energy and Commerce Committee
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
House Energy and Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Gene Green
House Energy and Commerce Committee
Subcommittee on Health
U. S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Subcommittee Chairman Pitts, Ranking Member Pallone, and Subcommittee Ranking Member Green:

The National Association of Community Health Centers (NACHC) appreciates the opportunity to provide a statement for the record for the House Energy and Commerce Subcommittee on Health's hearing on the 340B program.

Role of Community Health Centers

For 50 years, community health centers (otherwise known as Federally Qualified Health Centers or health centers) have provided access to quality and affordable primary and preventive health care services to millions of uninsured and medically underserved people nationwide, regardless of their ability to pay. Today there are over 1300 health center organizations, serving more than 23 million patients, including nearly seven million children and more than a quarter of a million veterans. All health centers provide a full range of primary and preventive care services, as well as services that enable patients to access health care appropriately (e.g., translation, health education, transportation). A growing number of health centers also provide dental, vision, behavioral health, pharmacy, and other important supplemental services.

Health centers receive federal funding under Section 330 of the Public Health Service Act. This grant funding comes with several important requirements, such as: being open to all regardless of one's ability to pay, providing services on a sliding fee scale, being located in a medically underserved area or serving a medically underserved population, and having a board made up of a patient majority in order to

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ensure that the health center is best meeting the needs of the community that it serves. Health centers pride themselves on these requirements, which make them unique in the health care delivery system.

No two health centers are alike, but they all share one common purpose: to provide primary health care services that are coordinated, culturally and linguistically competent, and community-directed to uninsured and medically underserved people. Nationally, health centers see a mix of patients, which break down as follows:

- 41% are Medicaid recipients
- 35% are uninsured
- 14% are privately insured
- 8% are Medicare recipients

Health centers and the 340B Program

Health centers are eligible covered entities for the 340B Drug Discount Program, either as federally qualified health centers or as health center lookalikes¹ (as defined in the Social Security Act). With this designation, health centers are not only able to provide their patients with access to high quality health care but also access to affordable prescription drugs. According to a recent NACHC survey, 96 percent of respondents deemed the 340B program “highly important,” especially for increasing access to prescription drugs for patients in need. In fact, many health centers report that before the 340B program, they were not able to provide pharmacy access to their patients.

Not only does the 340B program allow health centers to provide their patients better access to medication, but the savings achieved from purchasing prescription drugs at the reduced 340B prices are critical to health center operations, allowing them to use more of their limited resources to expand services for those in need of care. In fact, many health centers report that due to their slim operating margins, without the savings from the 340B program they would not be able to sustain operations. The investment of these dollars takes many forms, such as providing funds for a new exam room or provider, increasing access to services, extended evening or weekend hours, and improved technologies, among many others. According to the NACHC survey, 60 percent of health center respondents stated that they were able to use their savings to extend services beyond those related to the pharmacy, which is especially meaningful because improved comprehensive care can improve health outcomes and reduce total health care spending by reducing hospital and ER admissions.

The 340B program is critically important to health centers, not only because it allows them to provide access to affordable prescription drugs, but also allows them to stretch scarce federal resources to continue providing high quality primary and preventive care. NACHC believes this program provides health centers with a sound base from which to best serve the needs of some of our nation’s most vulnerable patients, and we urge you to take this into account when considering proposals related to 340B in this committee.

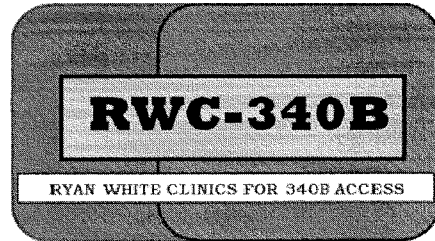
¹ An FQHC lookalike is a health center that meets all of the 330 grant requirements but does not receive federal funding.

We appreciate your time and attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel R. Hawkins, Jr.", with a stylized, cursive script.

Daniel R. Hawkins, Jr.
Senior Vice President
Public Policy and Research
National Association of Community Health Centers



**WRITTEN TESTIMONY OF
RYAN WHITE CLINICS**

**SUBMITTED FOR THE RECORD
TO THE
SUBCOMMITTEE ON HEALTH COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

**HEARING ON
“EXAMINING THE 340B DRUG PRICING PROGRAM”
MARCH 24, 2015**

RWC-340B Members

**AIDS Care Group (PA)
AIDS Healthcare Foundation (CA, DC, FL,
GA, IL, LA, MD, MS, NV, NY, OH, SC, TX, WA)
Cares Community Health (CA)
Evergreen Health Services of Western NY (NY)
Trillium Health (NY)
Whole Family Health Center (FL)**

RWC-340B allies

**ActionAIDS (PA)
AIDS Project New Haven (CT)
Apicha Community Health Center (NY)
Chase Brexton Health Care (MD)
Desert AIDS Project (CA)
Northern Nevada HOPES (NV)
Pittsburgh AIDS Task Force (PA)
Ryan White Medical Providers Coalition (Nationwide)
University of Alabama HIV Outpatient, Dental and Research Clinic (AL)
Waikiki Health (HI)
Western North Carolina AIDS Project (NC)**

Contact: Peggy Tighe, Ryan White Clinics representative,
at 202-872-6752 or peggy.tighe@ppsv.com

Thank you for the opportunity to submit testimony for the record for the subcommittee's hearing, "Examining the 340B Drug Pricing Program." The undersigned Ryan White clinics welcome the opportunity to comment on the 340B program and the importance of the program in providing healthcare to individuals living with HIV or AIDS.

Established as part of the Veterans Health Care Act of 1992, the 340B program allows certain classes of safety net providers, called "covered entities," to purchase covered outpatient prescription drugs from manufacturers at discounted prices. **The 340B program is not funded by taxpayers**; it is a discount that drug manufacturers agree to provide as a condition of Medicaid covering their drugs.

Each of our clinics provides primary care and many other services to persons living with HIV/AIDS through support from the Ryan White CARE Act. The CARE Act provides funding for services to uninsured and underinsured people living with HIV/AIDS. Ryan White providers are eligible to participate in the federal 340B drug discount program, which enables them to expand and support care.

The 340B program is a lifeline that allows safety net providers, including Ryan White-funded HIV/AIDS clinics, to obtain prescription drugs at substantial savings. With these savings, Ryan White clinics are able to fulfill the purpose of the 340B program, which is to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Through 340B, Ryan White Clinics offer a wider range of services and improve the quality of care delivered to persons living with HIV/AIDS.

In 2011, Ryan White clinics served approximately half of all Americans with HIV/AIDS, over fifty percent of whom were indigent and/or uninsured. Our patients face challenges that extend beyond drug affordability, and which must be addressed if we are to treat successfully their HIV, allowing them to be healthy, care for their families, and prevent new infections. The 340B program is an integral part of our ability to treat the disease and the patient, and successfully end the AIDS epidemic.

Experts recognize that, to be successful in the fight against HIV/AIDS, persons living with the disease need more than medical care. Ryan White clinics often serve as a gateway to a broader range of services. The 340B program allows them to stretch their resources to support the full continuum of care that their patients need, from diagnosis, to linkage to care, to medication adherence and viral suppression.

Ryan White funded HIV/AIDS clinics embody the success of and need for the 340B program. Effectively treating HIV/AIDS requires much more than simply seeing a doctor regularly. Comprehensive services to test routinely for HIV, to link HIV-positive individuals to care, to retain them in care, and to ensure that they are adherent to a medication regimen – services no commercial insurance plan, Medicaid or Medicare pays for – are required to maintain HIV suppression. When a person's HIV is suppressed, she is healthy, able to work, able to care for her family, and – perhaps most importantly – virtually noninfectious. The Centers for Disease Control and Prevention (CDC) recently issued a report that found that ninety percent of new HIV infections in the United States come from people living with HIV who are not in care for the disease. Proper HIV care not only results in healthy people, it reduces new infections.

Unfortunately, because most Americans with HIV/AIDS do not have access to these comprehensive testing, linkage, retention, and adherence services, ***fewer than 28% of Americans with HIV/AIDS have their virus suppressed***. But for people receiving medical care at Ryan White funded clinics, the story is remarkably better. The resources generated by participation in the 340B program in these clinics are used to fund these comprehensive services. As a result, for people with HIV/AIDS – regardless of insurance status – who receive medical care in Ryan White-funded clinics, HIV suppression is as high as 70% nationally and up to 85% for some of the clinics submitting this testimony. Patients with viral loads that are sufficiently suppressed do not transmit the disease to others. Just as it was designed to do, the 340B program is allowing safety net HIV/AIDS providers to serve more patients, provide more services, and generate better health outcomes.

Recently, an individual came to one of our clinics after being exposed to HIV. If an individual takes antiretrovirals shortly after exposure, they have a very good chance of not contracting HIV. Because the patient arrived late in the evening, the clinic could not verify the patient's insurance, but was able to provide antiretrovirals purchased with 340B discounts to the individual and prevent HIV infection, without concern about whether it would be later reimbursed. These sorts of preventative treatments, which are possible because of the 340B program, result in cost savings to the health care system.

For people with HIV/AIDS, the 340B program is not broken, and even small changes to the program could have adverse unintended consequences. Changes to the program that would limit patient access or eligibility would greatly harm their health, create gaps in care, and result in increased federal expenditures to address these gaps. Ryan White Clinics strongly oppose any legislative change that would limit the eligibility of a person receiving care in a Ryan White-funded clinic to participate in the program. Limiting program use to uninsured patients only would be especially disastrous – both for the HIV population and federal taxpayers.

We hope to work with the members of this subcommittee to provide information about the importance of the 340B program to Ryan White Clinics and the HIV/AIDS community. We pledge our assistance as policy-makers assess the 340B program.

Ryan White Clinics for 340B Access (RWC-340B) is a coalition of Ryan White grantees and sub-grantees that (1) provide primary care and related services to HIV/AIDS patients and (2) participate in the federal 340B drug discount program. Members of RWC-340B have organized to advocate for the interests of 340B Ryan White providers and to educate policy makers about the important role that the 340B program plays in improving care for HIV patients. Numerous other Ryan White clinics that are not RWC-340B members are joining with RWC-340B to submit this testimony. All of the clinics are identified in the cover sheet to this testimony.

Thank you for the opportunity to submit written testimony on this important issue.

For further information, contact Peggy Tighe, at 202-872-6752 or peggy.tighe@ppsv.com.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (2021) 225-2927
Minority (2021) 225-3941

April 20, 2015

Ms. Diana Espinosa, MPP
Deputy Administrator
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Room 14-71
Rockville, MD 20857

Dear Ms. Espinosa:

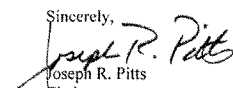
Thank you for appearing before the Subcommittee on Health on Tuesday, March 24, 2015, to testify at the hearing entitled "Examining the 340B Drug Discount Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, May 4, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green Ranking Member, Subcommittee on Health

Attachment

Diana Espinosa
Deputy Administrator,
Health Resources and Services Administration
House Energy and Commerce Committee
340B Hearing Questions for the Record
March 24, 2015

The Honorable Joseph R. Pitts

1. **The President's FY2016 Budget Request proposes a new user fee totaling \$7.5 million as a long term financing strategy to support the program's activities. The Budget envisions allowing HRSA to "collect a fee of 0.1 percent of each purchase of 340B drugs from entities participating in the Drug Pricing Programbased on sales data that shall be submitted by drug manufacturers." The goal of this proposal seems like it is to strengthen HRSA's capabilities and grow its capacity to oversee the program – a proposal I think many of my colleagues would support. How would such a fee financially impact an average covered entity? Can you provide detailed legislative specs for this proposal?**

Response: 340B-covered entities receive a significant benefit from participating in the 340B Program, and the proposed user fee allows HRSA to meet the demands of program oversight, the changing marketplace, and ensure the cost of administering the 340B Program is paid for as a small fraction of the received benefit. Without the user fee, the funding necessary to administer the program comes exclusively from appropriations.

The user fee would be 0.1 percent – one cent for every thousand dollars – of the total 340B drug purchases paid by participating covered entities. The vast majority of entities would be assessed a fee less than \$1,000.

The FY 2016 Budget includes appropriations language to authorize the Secretary to collect and spend user fees for the 340B Program, which states:

"Provided, That the Secretary may collect a fee of 0.1 percent of each purchase of 340B drugs from entities participating in the Drug Pricing Program pursuant to section 340B of the PHS Act to pay for the operating costs of such program: Provided further, That fees pursuant to the 340B Drug Pricing Program shall be collected by the Secretary based on sales data that shall be submitted by drug manufacturers and shall be credited to this account, to remain available until expended."

2. **In the 2007 Patient Definition Notice, HRSA outlined few specific requirements for an entity to qualify its provider-based departments for 340B pricing eligibility. Among them is the requirement that "loose affiliations" would be insufficient because it wouldn't support an appropriate level of clinical nexus between the covered entity and the patient's health care. Has HRSA considered other arrangements beyond "loose affiliations" that should be proscribed under its rules? Is HRSA concerned that the**

340B program is motivating these arrangements, which have consequences (e.g., site of care shift) on programs outside of 340B?

Response: HRSA plans to issue proposed omnibus guidance for public comment later this year. HRSA is unable to provide specific details of the proposed omnibus guidance until it is issued.

- 3. The DSH metric is calculated based on inpatient hospital stays by Medicaid and low-income Medicare beneficiaries. However, hospitals are continuing to see a downward trend in the number of inpatient admissions and are seeing more patients in the outpatient setting.¹ Do you think it makes sense for 340B eligibility to be based on an inpatient metric, when more and more hospital care is being received in the outpatient setting and the program is only applicable to outpatient drugs?**

Response: As you indicate, eligibility for the 340B Program for many hospitals is based in part on the DSH patient percentage calculation, and is statutory. We can provide technical assistance to any proposal you share with us relative to changes in the program authority.

- 4. It is my understanding that entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements but that eligible hospitals have no such requirement. Is that accurate? For each type of covered entity, please describe what requirements, if any, exist regarding their use of 340B revenue and the source of those requirements?**

Response: The 340B statute does not have requirements for covered entities regarding how revenue must be used. However, HRSA grantees that participate in the 340B Program (*i.e.*, community health centers, Ryan White HIV/AIDS Program grantees and hemophilia treatment centers), do have grant requirements whereby any program income generated must be used consistently with the purposes and conditions of the grantee's federal award. In the case of community health centers, Ryan White HIV/AIDS Programs, and the Hemophilia Treatment Center Program, that would include furthering the project's objectives by serving more patients and providing more comprehensive services.

- 5. Both GAO and OIG testimony alluded to the fact that participating 340B hospitals are not required to disclose how they reinvest any revenue generated from participation in the program—whether they lower costs for the uninsured, whether they provide additional charity care, or whether they offer any number of health programs to their**

¹ <http://www.modernhealthcare.com/article/20150127/NEWS/301279903/hospitals-saw-fewer-admissions-in-outpatients-in-2013>

community. Since the purpose of the 340B program is to stretch federal dollars further, it would seem to make sense to require covered entities to report on how they use the revenue from the program. Could HRSA require covered entities to report this information as a condition of program participation and wouldn't this be positive for the program? Why has the agency not done so?

Response: The 340B statute speaks only to covered entity eligibility and compliance requirements and does not specify how 340B savings must be used; therefore, HRSA does not collect this information.

6. Avalere data shows that more than two-thirds of 340B hospitals provided less charity care (calculated as a percent of patient costs) than the average of all hospitals - including for-profit hospitals.² Additionally, about a quarter of 340B hospitals provide charity care that represents less than 1% of their costs.³ Do you think these results show that the current hospital eligibility metrics are consistent with the program's original intent? Do you think it is fair that some hospitals that provide minimal charity care should be able to access 340B discounts with no obligation that they pass any of that savings on to patients or invest the savings in care for the uninsured and vulnerable?

Response: The 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating covered entities. The 340B Program statute requires drug manufacturers to provide covered outpatient drugs to eligible covered entities at significantly reduced prices. The 340B statute does not specify how the covered entities must use the savings or require that entities pass savings onto their patients (whether they are insured or uninsured).

7. A quick search of HRSA's Office of Pharmacy Affairs 340B database showed that the Cedars Sinai Plastic Reconstructive Center in Los Angeles, California is a 340B covered entity. According to a list based on CMS cost report data and analyzed by the American Hospital Directory, Cedars-Sinai is the third-highest grossing non-profit hospital in the U.S. Does it seem incompatible with the program's original intent that a plastic surgery center located in Hollywood is eligible for 340B discounted drugs?

Response: Based on the information submitted by the covered entity, HRSA has determined that the above-mentioned site is not eligible. The site has been terminated from the 340B Program.

² <http://340breform.org/userfiles/Final%20AIR%20340B%20Charity%20Care%20Paper.pdf>

³ <http://340breform.org/userfiles/Final%20AIR%20340B%20Charity%20Care%20Paper.pdf>

8. In 1996, HRSA issued guidance permitting 340B entities to operate a single contract pharmacy if they did not have an on-site pharmacy. In that guidance, HRSA stated that 340B entities use differing approaches to charging patients for 340B drugs, with some passing through all the savings and others setting a slightly higher price. The 1996 guidance⁴ went on to state, "The Department intends to examine the section 340B pricing activities of covered entities to determine the various approaches used and the rationale for these approaches. However, until it completes its examination of the issue, the Department notes that a modest section 340B markup... does not appear inconsistent with the drug pricing program," so long as savings are used for the purposes of the federal program providing an entity 340B eligibility.

- a. What were the specific findings of the Department's examination of the approaches used by 340B entities in setting prices for 340B drugs dispensed to patients?
- b. When has the examination completed and released? Since the 1996 guidance was in part premised on the examination, what actions were taken based upon the findings?
- c. What information does HRSA collect or otherwise have about the markups charged to patients for 340B drugs?
- d. Are the markups today the "modest" amount envisioned in the 1996 guidance? And how did HRSA take the examination's results into account when it issued the 2010 guidance that expanded the contract pharmacy program?

Response: A formal examination was not conducted. The Program does not prohibit a covered entity from billing the patient's insurer at a negotiated rate that is higher than the 340B price paid to obtain the drug. The 340B statute is silent on how entities use savings, so HRSA has not collected this information from covered entities. HRSA does not collect information about potential markups charged to patients.

9. Does HRSA believe it would be useful to have authority to share 340B ceiling prices with state Medicaid agencies and, if such authority is provided, how long would it take HRSA to begin sharing such information with the states?

⁴ 61 Fed Reg. 43549, 43551, Aug. 23, 1996.

Response: A 2011 HHS Office of the Inspector General (OIG) Report recommended that HRSA share 340B ceiling prices with states. Section 340B(d)(1)(B)(iii) of the Public Health Service Act specifically limits the disclosure of 340B ceiling prices to 340B covered entities; therefore, HRSA lacks statutory authority to provide the prices to the states.

- 10. We understand that even with the Medicaid Exclusion File, duplicate discounts continue to be an issue for the 340B program. Can you comment on the viability of private sector solutions to eliminate duplicate discounts and promote compliance with federal requirements? Are you aware of any existing private sector programs that help eliminate duplicate discounts (that is, preventing 340B drugs from also collecting a Medicaid rebate)?**

Response: HRSA is aware of at least one product that has been created in the marketplace. However, despite these private-sector products that aim to eliminate duplicate discounts, covered entities are still responsible for evaluating and overseeing compliance with the 340B statutory prohibition against duplicate discounts. Covered entities that, through audits, are found to be in violation of the duplicate-discount prohibition, are subject to repayment for noncompliance.

- 11. Has HRSA conducted any analysis on the financial impact the 340B program has on manufacturers or state Medicaid programs? If so, what have you found?**

Response: HRSA has not conducted this type of analysis.

- 12. Since the contract pharmacy program guidance was issued in 2010, OIG and GAO issued reports indicating that contract pharmacy arrangements create heightened risks for drug diversion. HRSA's expectation in its guidance is that 340B entities would use annual audits performed by independent, outside auditors. However, OIG's February 2014 report found that 23 of 30 340B entities it interviewed had not engaged an independent auditor. Certainly, the violation of HRSA's expectations must concern you, and I know you would welcome statutory clarity on contract pharmacies.**

- a. What action did HRSA take prior to the OIG report to address the lack of independent audits called for in your own guidance?**

Response: The responsibility for contract pharmacy compliance in the 340B Program rests with the covered entity – including oversight of their contract pharmacy arrangements. In 2010, HRSA issued final guidelines requiring that covered entities that choose to use contract pharmacies have mechanisms in place to prevent diversion and duplicate discounts in alignment with the statute. HRSA also requires that covered entities oversee compliance with their contract pharmacy arrangements. HRSA views independent audits as an important compliance tool but

it is only one approach that covered entities can utilize in their oversight of contract pharmacies. Other examples of compliance include the expectation that they “carve out” Medicaid in order to avoid duplicate discounts and the requirement that the covered entity and pharmacy maintain auditable records and policies and procedures to demonstrate compliance with all Program requirements. If HRSA determines that a covered entity is not providing oversight of the contract pharmacy arrangement, the contract pharmacy is terminated from the 340B Program.

- b. What action have you taken since the OIG report to see to it that independent audits are conducted? How many 340B entities in each eligibility category are now conducting independent audits?**

Response: HRSA continues to audit 340B covered entities and their contract pharmacy arrangements to ensure they are conducting oversight of the contract pharmacy arrangements. HRSA does not collect information as to how many covered entities conduct independent audits of their contract pharmacy arrangements. However, HRSA does ensure that if a covered entity is found not to be providing any oversight of its contract pharmacy arrangement, the contract pharmacy is terminated from the 340B Program.

- 13. Which types of covered entities are most likely to have large networks of contract pharmacies and what share of entities with large contract pharmacy networks are grantees versus hospitals?**

Response: The vast majority of covered entities do not contract with pharmacies. Currently, 27 percent of covered entities utilize contract pharmacy arrangements. Health centers represent the largest proportion of covered-entity sites (48 percent) that have arrangements with contract pharmacies. These arrangements enable health centers to expand the type and volume of care they provide to vulnerable patient populations. For those covered entities that offer reduced price medications to their low-income uninsured patients, contract pharmacies make medications more accessible by offering additional locations and extended hours.

- 14. HRSA stated in the 2010 Guidance on contract pharmacy that 340B entities are responsible for ensuring compliance of their contract pharmacy arrangements with all 340B Program requirements to prevent diversion and duplicate discounts. HRSA also states that 340B entities must maintain auditable records and are expected to conduct**

annual audits of contract pharmacies that are performed by an independent auditor.⁵ Yet the 2104 OIG report that found that 23 of 30 surveyed entities (76.7%) reported they did not use independent auditors for their contract pharmacy arrangements. Given the exponential growth of contract pharmacy arrangements over the years, how can HRSA be sure that contract pharmacies are taking appropriate steps to ensure compliance with the law?

Response: The responsibility for contract pharmacy compliance in the 340B Program rests with the covered entity – including oversight of their contract pharmacy arrangement. If a covered entity is found not to be providing any oversight of its contract pharmacy arrangement, the contract pharmacy is terminated from the 340B Program.

In 2010, HRSA issued final guidelines requiring that covered entities that choose to use contract pharmacies have mechanisms in place to prevent diversion and duplicate discounts in alignment with the statute. HRSA also requires covered entities to oversee compliance with their contract pharmacy arrangements. HRSA views independent audits as an important compliance tool but it is only one approach that covered entities can utilize in their oversight of contract pharmacies. The following program integrity measures are in place for HRSA to provide oversight of covered entities that utilize contract pharmacies:

- Through its audits of covered entities, HRSA samples 340B drugs at the contract pharmacy and reviews contract pharmacy compliance.
- Covered entities must attest to compliance at the contract pharmacy during the annual recertification process.
- HRSA's Bureau of Primary Health Care, which oversees the health center program representing the largest proportion of covered entities using contract pharmacies, has integrated program integrity questions into their regular site visits, including questions regarding contract pharmacies.
- HRSA has also developed educational tools and resources in order to inform all 340B stakeholders and improve overall program integrity. Some examples of the resources and tools include:
 - Webinars: Monthly HRSA webinars for all stakeholders to address patient eligibility, compliance with Medicaid requirements, prevention of duplicate discount, and how to prepare for an audit. In addition, high performing 340B covered entities are identified and share best practices with other participating sites via webinars and other forums.
 - Sample policies and procedures that can be adapted to a particular site.
 - Specific guidelines on the determination of patient eligibility for those individuals receiving 340B drugs.

⁵ <http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

- Call Center and 340B University (through the 340B Prime Vendor Program): Through 340B University courses, HRSA is able to address eligibility/database issues, diversion and patient eligibility, and prevention of duplicate discounts. A call center is also available to all stakeholders to answer questions regarding implementation of the 340B Program.

Manufacturers can also audit contract pharmacies through the participating covered entity once the audit is approved by HRSA.

15. **HRSA's 2010 guidance⁶ allowing an unlimited number of contract pharmacies was justified on the basis that "some patients currently face transportation barriers or other obstacles that limit their ability to fill prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements" which would "create wider patient access by having more inclusive arrangements in their communities." Yet the guidance did not include any standards that would assure that contract pharmacy arrangements would benefit patients in this way, or any data collection that would allow us to determine whether patients are getting better access in their communities. Most troubling, in 2014 the Office of the Inspector General issued a report⁷ showing that of 15 DSH hospitals interviewed, more than half reported not offering the 340B-discounted price to uninsured patients in even one of their contract pharmacy arrangements, meaning they pay the full, non-340B price. Please explain how the contract pharmacy program HRSA created in the 2010 guidance meets HRSA's stated goal of creating wider access for patients in their communities when patients do not get a discount.**

Response: The 340B statute is silent as to the drug-delivery systems covered entities may utilize. The 340B contract pharmacy guidelines did not create a new right to use contract pharmacy arrangements, but recognized that covered entities already contracted for pharmacy services. HRSA's contract-pharmacy guidelines are aimed at making certain that if entities are going to contract with these pharmacies, the arrangements are constructed in ways that comply with 340B requirements against diversion and duplicate discounts. For example, for HRSA grantees that participate in the 340B Program (*i.e.*, health centers, Ryan White HIV/AIDS Program grantees and hemophilia treatment centers among others), there are grant requirements whereby any program revenue generated must be used consistently with the purposes and conditions of the grantee's Federal award. In the case of health centers, Ryan White HIV/AIDS Programs and the Hemophilia Treatment Center Program, that would include furthering the project's objectives by serving more patients and providing more comprehensive services.

⁶ 75 Fed Reg. 1072, 1073, March 5, 2010.

⁷ OIG Memorandum Report: "Contract Pharmacy Arrangements in the 340B Program," Feb. 4, 2014, pg.14

Covered entities without an in-house pharmacy would be unable to participate in the program without the ability to contract with pharmacies. However, in the 340B Program, contract pharmacy arrangements are not common. Currently, only 27 percent of covered entities use contract pharmacy arrangements. Covered entities report that common examples of use of the savings generated include clinical pharmacy programs for medication adherence or medication management, and sliding fee discounts for other services. In addition, covered entities that use contract pharmacies benefit from the reduced costs incurred by not having to undertake the space, staffing, and capital costs that would be required to run an in-house pharmacy.

16. What specific indicators of success or failure has HRSA publicly identified for the contract pharmacy program? How does HRSA track and publicly report on whether the program's results are achieving the specific goals HRSA stated in its own guidance, and how does HRSA respond when the program is not working as HRSA envisioned?

Response: HRSA places the highest priority on the program integrity of the 340B Program, and will continue to explore all avenues for improving the oversight of the Program. HRSA's role is to ensure covered entities and manufacturers are in compliance with 340B Program requirements, and our program integrity efforts focus on specific compliance elements. The covered entity compliance requirements for contract pharmacies require the covered entity to have mechanisms in place to prevent diversion and duplicate discounts. Per the 340B statute and HRSA's 2010 guidelines, all covered entities are required to maintain auditable records and provide oversight of their contract pharmacy arrangements.

As a result of our enhanced focus on compliance issues, there has been more attention paid to compliance of program requirements by covered entities, which has resulted in increased self-disclosures and voluntary terminations of contract pharmacies initiated by the covered entities when requirements were not being met. Through its audits of covered entities, HRSA also reviews samples of 340B drugs at the contract pharmacy and reviews contract pharmacy compliance. Through FY 2014, HRSA has completed 244 audits of covered entities.

17. Given the concerns that have been raised about the integrity and accountability with some parts of the program, I'm interested in better understanding your audit notice and hearing process. Can you elaborate a bit on that, as well as what you can-and cannot-use to terminate a covered entity or manufacturer from the program? For example, I believe the statute only envisions repayment if there is a proven case of a duplicate discount or diversion?

Response: HRSA employs a systematic approach to program integrity that begins with initial certification upon entry into the program and continues with annual recertification for all entities to ensure compliance with program requirements. We conduct on-site audits using a risk-based selection method, and in instances where there are potential compliance

issues, HRSA conducts targeted audits. A covered entity receives a Final Report, and is granted, per statute, the opportunity for “notice and hearing,” by which they can submit one written disagreement to HRSA with supporting documentation. If a covered entity submits a disagreement, HRSA considers their additional points, which may result in adjusted findings. In instances of an adjusted finding, HRSA then issues a revised Final Report. Once an audit report is finalized, the findings and any associated corrective action will be summarized on the HRSA public website. If findings are included in the Final Report, the covered entity is required to submit a Corrective Action Plan to HRSA as well as a Public Letter informing manufacturers of the potential need for repayment.

Since 2012, HRSA has terminated over 870 covered entities for failure to recertify. HRSA terminates covered entities from the 340B Program when we find they are no longer eligible for the program. The reasons for termination include:

- a covered entity’s Disproportionate Share Hospital (DSH) percentage falls below the DSH adjustment percentage threshold;
- the covered entity loses their qualifying grant or designation;
- a hospital violates the Group Purchasing Organization prohibition;
- a covered entity fails to annually recertify; or
- if after a HRSA audit and after notice and hearing, a covered entity is found to have violated diversion or duplicate discount prohibitions, HRSA can terminate the covered entity if they fail to provide HRSA a Corrective Action Plan.

Section 340B(d)(2)(B)(v) of the Public Health Service Act authorizes the Secretary of HHS to impose sanctions on covered entities, who knowingly and intentionally violate the diversion prohibition. The statute allows removal from the Program if the diversion violation is systematic and egregious. We plan to address covered entity sanctions in future guidance.

With regards to manufacturers, in any instance of an overcharge, manufacturers are required to issue the covered entity a refund. The manufacturer may be subject to termination from the 340B Program for violations of statutory requirements.

18. What sanctions does HRSA impose or plan to impose for violations of statutory requirements or HRSA guidance discovered in audits, and what appeal process is open to covered entities? How, if at all, does the lack of regulatory authority affect HRSA’s ability to impose sanctions on covered entities or manufacturers?

Response: As discussed in an earlier question, after audit, notice and hearing, if a covered entity is found in violation of diversion or duplicate discounts, a covered entity must repay manufacturers. The notice and hearing process allows covered entities to submit one written disagreement to HRSA with supporting documentation after they receive HRSA’s Final audit report. If a covered entity submits a disagreement, HRSA considers their additional points, which may result in adjusted findings. HRSA then issues a revised Final

Report. Once an audit report is finalized by HRSA, the findings and any associated corrective action will be summarized on the HRSA public website. If findings were included in the Final Report, the entity is required to submit a Corrective Action Plan as well as a Public Letter informing manufacturers of the potential need for repayment.

In addition to repayment for violations of diversion and duplicate discounts, section 340B(d)(2)(B)(v) of the Public Health Service Act authorizes the Secretary of HHS to impose additional sanctions on covered entities who knowingly and intentionally violate the diversion prohibition. The statute allows removal from the Program if the diversion violation is systematic and egregious. We plan to address covered entity sanctions in future guidance. With regards to manufacturers, in any instance of an overcharge, manufacturers are required to issue the covered entity a refund.

- 19. MedPAC's recent public meeting raised the possibility of extending the 340B discount to seniors participating in Medicare. The idea is that the Medicare's drug reimbursement is ASP+6, while the 340B program, yields savings of 20 to 50 percent off of commercial prices. If Congress were to modify the 340B statute, seniors—and the Medicare Trust Fund—could potentially save money. What considerations – cautions or encouragements – would you offer on this policy proposal?**

Response: The 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities. While the statute does require manufacturers to provide covered outpatient drugs to eligible covered entities, it is silent on how the covered entity is to use those savings. We would be happy to work with the Congress to provide technical assistance on any specific proposals regarding the 340B Drug Pricing Program that are submitted for our review.

- 20. At the hearing, you indicated that despite growth in the number of covered entities, 340B sales have remained at about 2 percent of overall pharmaceutical sales. Please describe how HRSA calculated this figure, including the data sources used.**

Response: HRSA is able to track the majority of 340B pharmaceutical purchases through its 340B Prime Vendor and the pharmacy wholesaler relationships. The IMS Institute for Healthcare Informatics reports annually the total U.S. spending on pharmaceuticals. The total percentage of 340B spending in the market is determined using the following formula:

$$\frac{340B \text{ Spending on Pharmaceuticals}}{\text{Total U.S. Spending on Pharmaceuticals}} = 340B \text{ Percentage of Pharmaceutical Sales}$$

For example, in 2013, 340B purchases totaled \$7,123,638,209 and IMS reported U.S. spending on pharmaceuticals to be \$329,000,000,000. Using the formula stated above:

$$\frac{\$7,123,638,209}{\$329,000,000,000} = 2.17\% \text{ or } 2\% \text{ (rounded)}$$

- 21. Given that hospitals are making greater use of contract pharmacies compared with other covered entities, do you think the program is working as intended and is meeting its original goal?**

Response: Health centers, rather than hospitals, represent the largest proportion of covered-entity sites (48 percent) that have arrangements with contract pharmacies. These health centers benefit from contract pharmacies because those arrangements enable them to expand the type and volume of care they provide to vulnerable patient populations. For those covered entities that offer reduced price medications to their low-income uninsured patients, contract pharmacies make medications more accessible by offering additional locations and extended hours.

While HRSA lacks statutory authority to govern how covered entities use savings, many covered entities have reported to GAO [and others] using the savings generated by contract pharmacies to support numerous activities that enhance access for underserved populations. For example, HRSA grantees that participate in the 340B Program have grant requirements whereby any program revenue generated must be used consistently with the purposes and conditions of the grantee's Federal award. In the case of health centers, Ryan White HIV/AIDS Programs and the Hemophilia Treatment Center Program, that would include furthering the project's objectives by serving more patients and providing more comprehensive services. Other common examples include clinical pharmacy programs for medication adherence or medication management, and sliding fee discounts for other services. In addition, covered entities that use contract pharmacies benefit from reduced costs by not having to incur the substantial space, staffing, and capital costs that would be required to run an in-house pharmacy.

- 22. What, if any, changes does HRSA think need to be made to the contract pharmacy program?**

Response: HRSA plans to issue proposed omnibus guidance for notice and public comment. We are unable to provide specific details of the proposed omnibus guidance until it is issued.

- 23. Some have argued that the 340B program creates incentives for hospitals to acquire physician practices, especially those with high rates of use of specialty pharmaceuticals, in order to take advantage of the discount drug prices and high drug margin. At the same time, national trends in health care provider consolidations have raised concerns about increased costs to patients and the entire health care system. Is HRSA concerned that the incentives created by the 340B program could be having negative effects on patient's access to affordable health care?**

Response: Covered entities in the 340B Program represent a wide range of health care providers, from large hospitals to small rural providers. HRSA recognizes that business decisions are made every day by covered entities, which may or may not pertain to access to 340B prices. We are uncertain what, if any, of the growth in hospital acquisition of physician practices is driven by hospital access to 340B pricing.

Beyond ensuring that the facility meets the definition of a covered entity in statute, HRSA does not have statutory authority to get involved in covered entities' decisions around acquisitions. These entities have varying mechanisms available to ensure compliance with the 340B Program requirements, which may include, but are not limited to, IT infrastructure and staffing. These entities make business decisions accordingly, and HRSA holds them accountable for ensuring compliance with essential 340B program requirements.

24. HRSA posted a letter in early February 2014 regarding the ability of 340B AIDS Drug Assistance Programs (ADAPs) to seek 340B rebates from manufacturers where the ADAP does not purchase the 340B drug outright but rather purchases private insurance for the ADAP enrollee or otherwise pays the enrollee's insurance premium, deductible, or co-insurance or co-payment amount for the drug. The letter suggests manufacturers are not required to pay 340B rebates to ADAPs in such circumstances.

- a. Can you please confirm whether, as the letter suggests, that manufacturers currently are not obligated to pay such rebates, particularly where the ADAP's expenditures (in whatever form) do not exceed the 340B ceiling price?**

Response: HRSA's February 2014 letter indicated that this issue will be addressed in future policymaking and encouraged manufacturers to continue their current ADAP rebate operations in order to maintain stability in the ADAP program.

- b. If HRSA believes such rebates are or may be required, what processes has HRSA put in place to ensure any drugs subject to such 340B rebates are not also subject to a Medicaid rebate, in violation of the duplicate discount prohibition?**

Response: As required by statute, HRSA established a mechanism which is known as the HRSA Medicaid Exclusion File, to assist covered entities in preventing duplicate discounts. Covered entities are required to inform HRSA at the time they enroll in the 340B Program whether they plan to bill Medicaid for covered outpatient drugs dispensed to Medicaid beneficiaries. If an eligible entity plans to use 340B drugs in billing Medicaid, it must notify HRSA to prevent a duplicate discount, and HRSA lists them on the Medicaid Exclusion File. This file is used by states and manufacturers so they know which drugs cannot have a subsequent rebate under Medicaid.

- c. **When does HRSA expect to issue a rule (or other guidance) on this topic, as referenced in the letter?**

Response: HRSA plans to address the issue in the proposed omnibus guidance for notice and public comment.

25. **As you know, the 340B statute prohibits duplicate discounts, which are defined to occur when a drug sold at the 340B price is also the subject of a Medicaid rebate claim by a State Medicaid Program. Since the 340B Program was enacted, Congress also has enacted a mandatory coverage gap discount for Part D drugs. Where a 340B drug is dispensed to a Part D beneficiary, therefore, it is possible that it could be the subject to a 340B discount and a Part D coverage gap discount.**

- a. **Does HRSA have any mechanisms in place to ensure manufacturers are not subject to duplicate discounts under the Part D coverage gap program?**

Response: The 340B statute only addresses duplicate discounts as they pertain to the Medicaid program. Therefore, 340B violations of the duplicate discount prohibition are not triggered by other federal insurance programs.

- b. **If not, what does HRSA need in order to implement such a prohibition?**

Response: HRSA is unable to comment without seeing a specific proposal related to this issue.

- c. **To the extent HRSA believes ADAPs are entitled to 340B rebates as discussed above, and HRSA has no controls in place to prevent Medicaid duplicate discounts, isn't it possible that the status quo could expose manufacturers to "triple-dipping" due to 340B, Medicaid, and Part D mandatory discounting?**

Response: HRSA has a mechanism in place to prevent duplicate discounts – the Medicaid Exclusion file. That mechanism is specific to 340B and Medicaid and does not include other Federal programs, as the 340B statute is specific to Medicaid only.

26. **When PPACA expanded manufacturer Medicaid rebate liability to managed care utilization, the legislation also expanded the 340B duplicate discount prohibition to apply to managed care utilization. We are now 5 years post-enactment.**

- a. **What has HRSA done to implement the duplicate discount prohibition as it relates to Medicaid managed care utilization? If no actions have been taken, please explain why.**

Response: In December 2014, HRSA clarified that the current mechanism in place to prevent duplicate discounts, the Medicaid Exclusion File, was specific to Medicaid Fee-For-Service. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with CMS to develop policy in this regard. HRSA plans to issue proposed omnibus guidance for notice and comment. In the meantime, we are aware that some covered entities have already worked with managed care organizations (MCOs) and state partners to develop models for the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their states to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs.

The Honorable Tim Murphy

1. **Could you provide more detail on the upcoming guidance you mention in your testimony and how it impacts patient definition, eligible prescription, and future hospital eligibility?**

Response: HRSA is unable to speak to the specifics of the proposed omnibus guidance until it has been issued. We expect to issue the proposed omnibus guidance for notice and public comment later this year.

2. **Could you clarify how you view HRSA's authority to issue and enforce guidance versus rulemaking, in light of statutory limitations and recent court findings?**

Response: In 2014, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional clear, enforceable policy to advance our oversight of covered entities and manufacturers. In May 2014, while the omnibus proposed regulation was in development, the U.S. District Court for the District of Columbia issued a ruling addressing an earlier 340B regulation concerning orphan drugs (certain drugs used to treat rare conditions or diseases). The court invalidated the orphan drug regulation, finding that HRSA lacked explicit statutory authority to issue it. In light of this ruling, HRSA will issue proposed rules where the statute is specific about rulemaking and provide guidance to address critical policy matters raised by 340B Program stakeholders for which there is a lack of explicit regulatory authority. The guidance will enable covered entities and manufacturers to comply fully with statutory 340B Program requirements and will increase the Department's ability to ensure effective implementation, oversight, and monitoring of the 340B Program. HRSA will use the full extent of agency authorities in its efforts to ensure the integrity of the 340B Program.

3. **Is HRSA aware of any hospitals or hospital systems acquiring a 340B eligible clinic for the purpose of purchasing their outpatient drugs at the 340B discounted price through these clinics?**

Response: HRSA does not have information related to internal business decision-making practices of hospitals, including the decisions that involve acquisitions of other sites. Covered entities in the 340B Program represent a wide range of health care providers, from large hospitals to small rural providers. HRSA recognizes that business decisions are made every day by covered entities, which may or may not pertain to access to 340B prices.

- a. **Would you consider the use of the program in this manner to be consistent with the original intent of the program?**

Response: The 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities in order to stretch scarce Federal

resources. Per statutory authority, HRSA focuses on ensuring covered entities and manufacturers comply with program requirements. If, through the verification process, an entity meets all of the eligibility requirements, the entity is listed on our database and may begin purchasing drugs on the first day of the calendar quarter.

b. Would the use of the 340B program in this manner be identified in the audits conducted by HRSA?

Response: HRSA's audits of 340B covered entities are focused on areas of program compliance with the 340B statute and guidelines, including covered entity eligibility, diversion and duplicate discounts. Beyond ensuring that the facility meets these compliance standards, HRSA's audits do not examine covered-entity independent business strategies or decisions.

The Honorable Leonard Lance

1. **It has come to my attention that some 340B hospitals, often with the assistance of consultants, have been retrospectively "reclassifying" past, noncompliant 340B purchases as 340B compliant purchases. These "reclassified" purchases are then "banked" in an attempt to justify additional 340B purchases-and this is done without informing OPA or the manufacturer. 340B program guidance states that HRSA does not, and has not in the past, endorsed any type of retrospective "correction" or "reclassification" process by a covered entity. Nevertheless, my understanding is that the practice is continuing. What steps is the Agency taking to address this issue?**

Response: HRSA has not authorized the use of a credit/rebill, banking, or similar process to re-characterize previous transactions. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as a 340B purchase, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction. The covered entity retains responsibility for ensuring full compliance and integrity of their use of the 340B Program.

2. **Some 340B stakeholders are concerned about evidence suggesting that some hospitals have changed the admission status of their patients for purposes of increasing the amount of 340B discounts the hospital receives. There have been expressions of concern, for instance, that some hospitals have delayed or otherwise manipulated patients' inpatient admissions in order to secure the 340B spread on a drug as an "outpatient" drug.**

- a. **Are you aware of this practice?**

Response: Covered entities are required to have in place a consistent process for defining inpatient and outpatient for purposes of the 340B Program. HRSA audits this information while on site to ensure 340B drugs are not provided to inpatients. If drugs are provided to inpatients, HRSA considers this a finding and the covered entity must repay the manufacturer.

- b. **What is the government doing to monitor and identify instances where patients' care pathways are being altered in an effort to capture 340B discounts?**

Response: HRSA audits entities' compliance with 340B program requirements, including current 340B patient guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)). If HRSA finds a covered entity is not following patient-definition guidelines and has diverted 340B drugs, the covered entity is required to repay the manufacturer.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
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Majority (205-225-2927)
Minority (202-225-3041)

April 20, 2015

Dr. Debra A. Draper
Director
Health Care Team
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

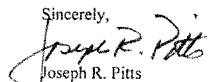
Dear Dr. Draper:

Thank you for appearing before the Subcommittee on Health on Tuesday, March 24, 2015, to testify at the hearing entitled "Examining the 340B Drug Discount Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, May 4, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green Ranking Member, Subcommittee on Health

Attachment



U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

April 30, 2015

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Dear Chairman Pitts,

This letter responds to your request that we address questions submitted for the record related to the March 24, 2015 hearing entitled *Examining the 340B Drug Pricing Program*. GAO's responses to these questions are enclosed.

If you have any questions about these responses or need additional information, please contact Debra A. Draper at draperd@gao.gov or call (202) 512-7114.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Debra A. Draper".

Debra A. Draper
Director, Health Care

Enclosure

Attachment—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. HRSA had been preparing a regulation to address the definition of a patient and hospital eligibility, but withdrew its proposal last year following a May 2014 federal district court ruling which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA has explained that the agency will be proposing *guidelines* later this year to address those issues. Are you aware of any other health care agency in recent history whose hands have been tied in this manner, by not being able to write rules governing the program they administer? In the interest of government accountability and program integrity, is this concerning to you?

The Health Resources and Services Administration (HRSA) had been preparing its regulations after GAO issued a report in 2011 which included recommendations that the agency finalize new, more specific guidance on the definition of a 340B patient, and issue guidance to further specify program eligibility criteria for certain hospitals. GAO recommendations generally provide flexibility to audited agencies in terms of implementation. Our recommendations did not require HRSA to issue such guidance through rulemaking.

In addition, GAO does not track instances where agencies have been found by a court to have exceeded their rulemaking authority. However, in ruling that HRSA's orphan drug rule exceeded the scope of its statutory rulemaking authority, the district court relied upon several cases that similarly held that Congress had not authorized agency rulemaking in specific areas. We bring to your attention three cases that the court discussed at length in its May 2014 opinion:

- In *Gonzales v Oregon*, 546 U.S. 243 (2006), the United States Supreme Court held that an interpretive rule issued by the U.S. Attorney General was not authorized by the *Controlled Substances Act*, in part, because the act did not grant the Attorney General broad authority to promulgate rules, but instead specified two areas where he had rulemaking power.
- In *Amalgamated Transit Union v Skinner*, 894 F.2d 1362 (D.C. Cir. 1990), the Court of Appeals for the D.C. Circuit vacated a Department of Transportation rule requiring mass transit grant recipients to implement an anti-drug safety program. The court found that the Urban Mass Transportation Act only authorized the agency "to investigate safety hazards . . . in a manner that requires case-by-case development of local solutions to those hazards," not to engage in rulemaking.
- In *Motion Picture Association of America v. FCC*, 309 F.3d 796 (D.C. Cir. 2002) the Court of Appeals for the D.C. Circuit vacated a proposed FCC rule that would have required the use of video description technology to enhance TV watching for hearing and visually impaired persons. The court found that the proposed video description regulation exceeded the scope of FCC's rulemaking under the *Telecommunications Act of 1996*. Whereas the Act required FCC to issue regulations for closed captioning technology, it only required FCC to prepare a report for Congress on the use of video description technology.

In responding to GAO's request for updated information with respect to the March 24, 2015 testimony, HRSA officials told us that the agency planned to issue guidelines in 340B program

areas for which it does not have explicit rulemaking authority. At the same time, these officials noted that having "clear legislative authority for 340B rulemaking authority would be most effective in facilitating HRSA's oversight and management of the 340B Program. Rulemaking authority would also allow HRSA to better ensure program integrity so that the program operates as effectively and efficiently as possible."

2. GAO cites the increase in hospital participation and the lack of clear guidance in a *patient* definition as the key reason for risks associated with drug diversion under the program. Did GAO track the scope or end of drug diversion occurring in the projects it examined—in other words, do we know if prescription drugs were improperly distributed for illicit purposes?

In our prior work, GAO did not track whether, or the extent to which, drug diversion was occurring under the 340B program. We identified situations where the risk of drug diversion may be higher than others, such as at contract pharmacies and hospitals.¹ For example, we reported that the risk of diversion was greater at hospitals because hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not receive 340B drugs (only outpatients are eligible). In addition, we reported that hospitals tend to have more complex contracting arrangements and organizational structures than other entity types, noting that in hospitals, 340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and other factors, diversion may be harder to detect in hospital settings. We recommended that the HRSA conduct audits of covered entities to deter potential diversion. In response to our recommendation, HRSA has conducted annual audits of covered entities and identified instances of violations related to drug diversion.

3. Around 20 percent of covered entities are private, non-profit hospitals that become eligible, in part, through their DSH percentage. However, these "DSH hospitals" account for over 80 percent of the discounts under the program. At the same time, recent reports question whether the use of the DSH percentage as eligibility criteria for these private, non-profit hospitals is appropriate in the first place. For example, MedPAC has noted "little evidence of a relationship between the DSH payments hospitals receive and the amount of uncompensated care they provide[.]" which raises doubts about the 340B program's reliance on DSH for eligibility purposes. Are there options that would establish a better charity care proxy for hospital entry into the program? What criteria that might better reflect a hospital's uncompensated care that would justify entry into the program?

Hospital eligibility criteria include minimum Medicare disproportionate share adjustment (DSH) percentages for most hospital types, as well as other requirements intended to ensure that they perform a government function to provide care to the medically underserved. The law does not specify why the DSH adjustment percentage is used as criteria. The DSH adjustment percentage identifies hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients. If this is being used as a proxy to identify hospitals that provide more uncompensated care than other hospitals, then the questions raised by MedPAC about

¹See 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).

the relationship between DSH payments and the amount of uncompensated care would raise questions about the appropriateness of DSH adjustment percentage for this proxy.

If Congress wishes to identify eligibility criteria that better ensure that certain hospitals participating in the program are those that provide more uncompensated care or more charity care than other hospitals, then it could consider using either the uncompensated care or charity care values that are reported in hospitals' Medicare cost reports as a basis for eligibility. However, questions have been raised about those measures as well. For example, the uncompensated care values include both charity care and bad debt. Some researchers contend that the bad debt measure could reflect the ability of a hospital to collect payments from patients and not whether or not those patients are able to afford the payments. The charity care measure is a more targeted measure; however, this is a relatively new measure included on the Medicare cost reports and questions have been raised about potential variation in how hospitals define and calculate charity care.

In addition, because the current eligibility criteria for hospitals also includes components related to ensuring that hospitals perform a government function to provide care to the medically underserved, Congress could consider the extent to which certain hospitals should qualify based solely on criteria related to the provision of these types of services. For example, in our 2011 report, we noted that there is no established definition of a safety net hospital. Some researchers have argued that this definition should include factors such as the disproportionate provision of critical services that are either too expensive or unprofitable for other hospitals to provide, such as trauma care.²

- 4. MedPAC's recent public meeting raised the possibility of extending the 340B discount to seniors participating in Medicare. The idea is that the Medicare's drug reimbursement is ASP+6, while the 340B program yields savings of 20 to 50 percent off of commercial prices. If Congress were to modify the 340B statute, seniors—and the Medicare Trust Fund—could potentially save money. What considerations—cautions or encouragements—would you offer Congress on this policy proposal?**

The pros and cons of reducing Medicare Part B payments for 340B entities depends upon Congress's goals for the 340B Program. Currently the program is structured so that participating entities financially benefit from the difference between the discounted price they pay to acquire 340B drugs and the amount that payers, including Medicare, reimburse the entities for these drugs. The 340B program generates revenue for participating entities and there is no requirement within the 340B program on how they use that revenue, or for participating entities to pass along to Medicare or its beneficiaries any of the savings associated with the 340B drugs. Whether such a requirement would be appropriate depends upon Congress's goals for the 340B program.

Reducing Medicare payments for 340B drugs or requiring that participating entities pass along some or all of the discounts to Medicare beneficiaries, would produce savings for the Medicare program and its beneficiaries, but it would also likely substantially reduce the revenues that

²See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," PM-1387-ASPE (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

entities generate from the 340B program. Specifically, in our 2011 report, we found that among the 340B entities that generated revenue through the program, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers. However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Reducing Medicare Part B payments for 340B drugs further limit entities' ability to generate revenues through the program.

Congress could also consider whether any reductions in Medicare Part B payment rates would apply to all types of 340B entities or to a subset of the entity types. For example, Congress might consider whether the benefit of using the program as a financing mechanism should only apply to certain types of entities. Entities generally become eligible for the program by being one of six hospital types or by receiving one of 10 federal grants. Hospitals eligible for the program include certain DSH hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. Federal grantees include clinics that offer primary and preventive care services, such as Federally Qualified Health Centers, family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Our interviews with a small nongeneralizable sample of 340B entities for our 2011 report found that some were more reliant on 340B revenue than others. For example, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations. Some other entities reported that 340B revenue represented a much smaller share of their operating budgets.

The Honorable Tim Murphy

1. The September 2011 GAO report (*Drug Pricing: Manufacturer Discount in the 340B Program Offers Benefits, But Federal Oversight Needs Improvement*) states, "Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report." (Page 10) Does this mean that a hospital or hospital system could acquire a 340B eligible clinic and purchase their outpatient drugs at the 340B discounted price through these clinics?
 - a. In the GAO's review of the 340B program, did you identify any examples of hospitals or hospital systems using the program in this manner?
 - b. Would you consider the use of the program in this manner consistent with the original intent of the program?

In order for a hospital to be eligible for the 340B Program, it must meet the 340B hospital eligibility criteria defined in statute. For example, some hospitals are eligible based on having a DSH adjustment percentage of 11.75 or greater and meeting other statutory criteria. Owning a clinic that is eligible for the 340B program does not make a hospital eligible for the 340B Program. A freestanding clinic that participates in the program based on its federal grantee status can be acquired by a non-340B hospital and continue to be eligible for and participate in

the 340B program. While patients of those clinics would be eligible for 340B discounted drugs, that eligibility does not transfer to all of the hospital's outpatients.

The section of our previous report that you cited in your question pertains to a different situation—that of a 340B hospital acquiring clinics that are not eligible for the 340B Program.³ Per HRSA's 1994 program guidelines and clarifying guidance issued in 2012, a 340B hospital can purchase outpatient clinics that can then be considered an integral part of that hospital. As an integral part of the hospital, a hospital outpatient clinic would be eligible for 340B drug discounts if it is a reimbursable facility and is included on the 340B hospital's Medicare cost report whether or not it is located in the main hospital building. When a clinic is acquired by a 340B hospital, 340B discounted drugs can be used for patients of that clinic. An example would be an oncology clinic that is acquired by a 340B hospital. Although a freestanding oncology clinic would not be eligible for the 340B program, if it is acquired by a 340B hospital, considered a reimbursable facility, and included on the hospital's Medicare cost report, 340B discounted drugs could be used for patients of that clinic.

³GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Washington, D.C.: September 23, 2011).

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
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Majority (207): 225-2927
Minority (202): 225-3041

April 20, 2015

Ms. Ann Maxwell
Assistant Inspector General for Evaluations and Inspections
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Maxwell:

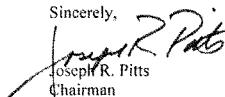
Thank you for appearing before the Subcommittee on Health on Tuesday, March 24, 2015, to testify at the hearing entitled "Examining the 340B Drug Discount Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, May 4, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green Ranking Member, Subcommittee on Health

Attachment

OIG Responses to Additional Questions from Chairman Pitts Regarding the 340B Program
May 4, 2015

1. HRSA had been preparing a regulation to address the definition of a patient and hospital eligibility, but withdrew its proposal last year following a May 2014 federal district court ruling which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA has explained that the agency will be proposing *guidelines* later this year to address those issues. However, as a practical matter, HRSA will be effectively just writing suggestions they have little ability to enforce. Are you aware of any other health care agency in recent history whose hands have been tied in this manner, by not being able to write rules governing the program they administer? In the interest of government accountability and program integrity, is this concerning to you?

OIG is not aware of other HHS agencies in the position of having to run a program on guidance alone. OIG concurs that enforceable rules are important for accountability and program integrity. In addition to having rules that are enforceable, the rules should be clear and specific so that all stakeholders understand how they will be interpreted and enforced. A 2014 OIG report entitled *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431) noted a lack of clarity and specificity in HRSA guidance with regard to contract pharmacies.

2. Your testimony noted more transparency is needed in the 340B program's ceiling prices and Medicaid Claims data for 340B-purchase drugs. What should Congress do to fix HRSA's transparency problems?

OIG work has shown that a lack of both price and claims transparency creates program integrity vulnerabilities in the 340B Program. Congress has already taken steps to address some of these vulnerabilities, but there are additional steps it can take to ensure stakeholders have the information they need to strengthen program integrity.

To improve price transparency, in the Patient Protection and Affordable Care Act (ACA), Congress required that HRSA share ceiling prices with covered entities. This will allow covered entities to verify that they are not being overcharged by manufacturers. HRSA has said it plans to implement a system to do so this year.

To further address vulnerabilities related to the lack of price transparency, Congress could give HRSA authority to share ceiling prices with States, per an outstanding recommendation from a 2011 OIG report entitled *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs* (OEI-05-09-00321). This would allow States to more accurately pay according to their Medicaid reimbursement policies.

To address the lack of 340B claims transparency, Congress could encourage CMS and HRSA to continue working with 340B providers and State Medicaid agencies to address vulnerabilities. Transparency as to which Medicaid claims represent 340B-purchased drugs is essential to States' efforts to pay correctly and would help them protect manufacturers from duplicate discounts.

Further action may be needed to ensure claims transparency for 340B-purchased drugs reimbursed by Medicaid Managed Care Organizations (MCOs). Ongoing OIG work is exploring tools that States use with Medicaid MCOs, which may result in recommendations to HRSA or CMS. OIG would be pleased to brief you on the results of that work when it is complete, as well as provide further technical assistance.

3. What are best practices for CMS, HRSA, and the states to prevent duplicate 340B discounts and Medicaid rebates?

OIG's 2011 report, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs* (OEI-05-09-00321), described the array of tools that States use to identify claims for 340B-purchased drugs when claiming Fee-For-Service (FFS) Medicaid rebates. In addition to HRSA's Medicaid Exclusion File, these tools include claim-line indicators and State-developed lists of covered entities. OIG did not evaluate these tools to determine which is most effective, but does note that any evaluation of these tools should consider, among other things, complications created by contract pharmacy operations, which are highlighted in OIG's 2014 report, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431).

Ongoing OIG work is assessing the tools States use to prevent duplicate discounts for drugs paid through Medicaid MCOs. OIG would be pleased to brief you on the results of that work when it is complete, as well as provide further technical assistance.

4. What is the volume of 340B prescriptions that are going through contract pharmacies?

OIG is not aware of any available data on the volume of 340B prescriptions going through contract pharmacies. However, OIG's analysis of HRSA's covered entity database shows that about 28 percent of covered entities used contract pharmacy arrangements in 2014.

5. The OIG report found that several contract pharmacy programs do not provide discounts on prescription medicines to uninsured individuals, the increased use of contract pharmacies may be resulting in a greater risk of dispensing 340B drugs where 340B drugs aren't permitted, and the sheer growth of the program heightens the concern that self-policing may be insufficient.

- a. Given these facts, do you think the agency's 2010 contract pharmacy sub-regulatory guidance should be reassessed or reevaluated to determine its appropriateness? What, if any, suggested changes do you have regarding the contract pharmacy program?

Yes, we think that program rules on contract pharmacies should be updated to address the evolution of the program. OIG suggests that any effort to update program rules governing contract pharmacies should address the following three

topics highlighted in OIG's 2014 report, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431).

First, OIG found a lack of clarity in HRSA's patient definition which can make it difficult to determine diversion in certain contract pharmacy scenarios. Updated contract pharmacy guidance should clarify how entities and their contract pharmacies should apply the patient definition in their contract pharmacy arrangements and also take into account the unique situations that contract pharmacies pose in determining eligibility so as to better prevent diversion.

Second, OIG highlighted a lack of clarity about whether covered entities need to extend the discounted 340B price to uninsured patients through their contract pharmacies. Guidance on how the program should apply to uninsured patients in these scenarios should be clarified to ensure that patients are treated consistently across 340B providers and that operations align with the program's intent.

Third, OIG found that entities were not exercising full oversight of their contract pharmacy arrangements. HRSA's 2010 guidance defined suggested practices for covered entity oversight of contract pharmacies but OIG work found that many covered entities did not conduct all of the oversight suggested in the guidance. Updated contract pharmacy guidance could reiterate or strengthen covered entity oversight requirements.

6. In 2010, HRSA issued guidance allowing entities to have an unlimited number of contract pharmacies. Even though the 340B statute does not mention the use of contract pharmacies, it has now become one of the biggest drivers for program growth, and as OIG's 2014 report noted, the use of contract pharmacies creates complications in preventing drug diversion and duplicate discounts. I wondered if the OIG has seen a correlation with increased incidence of duplicate discounts or diversion in contract pharmacies? If so, should certain parameters be in place (e.g., limits on the size or geographic reach of contract pharmacy networks) for contract pharmacies under the 340B programs to ensure program integrity?

OIG work has identified vulnerabilities related to contract pharmacies but we do not have information about increased incidence of duplicate discounts or diversion in contract pharmacy arrangements. Although OIG work has not evaluated this point or other parameters for contract pharmacies, including geographic reach, OIG's 2014 report, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431), found that few covered entities conducted all of the oversight recommended by HRSA in its 2010 contract pharmacy guidance. Greater covered entity oversight of contract pharmacy arrangements would help strengthen program integrity.

7. Do you believe that, with limited dollars and time, scarce resources for oversight should be targeted to the greatest vulnerabilities? If so, what covered entities provide the greatest risk to the integrity and accountability of the program? (Note: while I realize the contract pharmacy vulnerabilities, I'm specifically interested in the type of covered

entity.)

Yes, OIG agrees risk assessments and targeting limited resources for oversight are important. OIG work has not assessed which covered entity types pose the greatest risk to the 340B Program. Regarding vulnerabilities related to contract pharmacies, OIG's 2014 report assessed covered entities' oversight of contract pharmacies and identified general vulnerabilities in contract pharmacy arrangements, but did not to assess which types of covered entities had contract pharmacy arrangements that posed the greatest risk to the program. However, it is true that three types of providers – critical access hospitals, disproportionate share hospitals, and community health centers – most frequently use contract pharmacies.

8. Given HHS OIG's ongoing work, I wondered if the OIG has reviewed whether the growth in the 340B program has shifted the cost to other parts of the health care system. Has the OIG reviewed whether the 340B program has motivated hospitals to acquire practices and the impact of that behavior on the Medicare program because of the reimbursement differences between clinics and hospitals? Has the OIG considered whether the 340B program discourages use of cheaper generic drugs?

OIG work has focused primarily on program integrity issues and has not reviewed cost shifting, impacts on generic dispensing, or incentives for practice acquisition related to the 340B Program. The OIG work plan is flexible and evolving so we can consider these topics for potential future work. Ongoing OIG work is assessing the prevention of duplicate discounts for drugs paid through Medicaid MCOs. Additional OIG work underway is examining the intersection of the 340B Program and Medicare Part B. We anticipate final reports on these issues in 2015. OIG would be pleased to brief you on the results of that work, including any recommendations, when the reports are complete.

9. National trends in health care provider consolidations have raised concerns from health economists about increased costs to Medicare and the entire health care system. I've heard reports that hospitals are buying up community-based cancer clinics which do not at the time of purchase qualify for the 340B program. However, these clinics are later brought under the hospital umbrella. A June 2014 Berkeley Research Group study estimated that these dynamic led to almost \$200 million in additional costs over a three-year period to Medicare beneficiaries who faced greater costs being billed by a hospital. What policy remedies do you envision could reduce costs to seniors?

OIG work has not addressed this topic; as such we do not have any recommendations at this time.

10. MedPAC's recent public meeting raised the possibility of extending the 340B discount to seniors participating in Medicare. The idea is that Medicare's drug reimbursement is ASP+6, while the 340B program yields savings of 20 to 50 percent off of commercial prices. If Congress were to modify the 340B statute, seniors—and the Medicare Trust Fund—could potentially save money. What considerations—cautions or encouragements—would you offer on this policy proposal?

Additional OIG work underway is examining the intersection of the 340B Program and Medicare Part B and will include estimated savings for Medicare under a number of “shared savings” models and related policy considerations. We anticipate a final report on this topic in 2015 and would be pleased to brief you on the results of that work, including any recommendations, when it is complete.