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EXAMINING THE 340B DRUG PRICING PROGRAM

TUESDAY, MARCH 24, 2015
House of Representatives
Subcommittee on Health
Committee on Energy and Commerce
Washington, D.C.

The subcommittee met, pursuant to call, at 10:02 a.m., in Room 2322, Rayburn House Office Building, Hon. Joe Pitts, [chairman of the subcommittee] presiding.

Present: Representatives Pitts, Guthrie, Shimkus, Murphy, Blackburn, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Upton (Ex Officio), Green, Butterfield, Castor, Sarbanes, Schrader, Kennedy, Pallone.

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 & Economy; Adrianna Simonelli, Legislative Clerk; Heidi Stirrup, Health Policy Coordinator; Josh Trent, Professional Staff Member, Health; Greg Watson, Staff Assistant; Traci Vitek, Detailee; Ziky Ababiya, Policy Analyst; Christine Brennan, Press Secretary; Jeff Carroll, Staff Director; Tiffany Guarascio, Deputy Staff Director and Chief Health Advisor; Ashley Jones, Director, Outreach and Member Services; Rick Kessler; Senior Advisor and Staff Director, Energy and Environment; Rachel Pryor, Health Policy Advisor.

Mr. *Pitts.* The subcommittee will come to order.

The chair will recognize himself for an opening statement.

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, and State AIDS Drug Assistance programs, Medicare and 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 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 manager 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.

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.

[The information follows:]

**********COMMITTEE INSERT**********

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 gentle lady, and now recognizes the ranking member of the subcommittee, Mr. Green,

for 5 minutes for an opening statement.

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.

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 contact 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 under-served.

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 Ascensium on the 340B Program.

Mr. *Pitts.* Without objection, so ordered.

[The prepared statement of Ascenisum follows:]

**********COMMITTEE INSERT**********

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

The *Chairman.* 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 and 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 under-served 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.

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 gentle lady, and now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

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's 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.

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 five minutes for her summary.

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

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

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

[The prepared statement of Ms. Espinosa follows:]

**********INSERT**********

Mr. *Pitts.* The chair thanks the gentle lady.

Commander Pedley, do you have an opening statement?

Commander *Pedley.* I do not.

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

STATEMENT OF DEBBIE 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 update a 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 guidance 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:]

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Mr. *Pitts.* The chair thanks the gentle lady, and now recognizes Ms. Maxwell 5 minutes for opening statement.

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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 2 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 3 steps HRSA can take to increase transparency and ensure the program achieve its goals. The first 2 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:]

**********INSERT**********

Mr. *Pitts.* The chair thank the gentle lady.

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. So it 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, you know, 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 accompany 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, you know, 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 2 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 1 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, you know, ask my colleague, Commander Pedley if that is information that we have available that we could potentially--

Commander *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?

Commander *Pedley.* Correct.

Mr. *Green.* Okay. 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.* Okay.

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.* Okay. 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 relations 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 3 areas where we do have explicit rule-making authority are civil monetary penalties for manufacturers, dispute resolution process, and--

Commander *Pedley.* And the ceiling price.

Ms. *Espinosa.* --the ceiling price.

Mr. *Green.* Okay. So I guess for practical purposes under current law, unless it is 1 of these 3 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 mission.

So, for example, they use the revenues to provide more

comprehensive services in terms of, you know, case management services or patient education. You know, some facilities reported using the revenue to expand services to other locations.

So they all reported using it consistent with their mission which is required for grantees like, you know, 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, you know, 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 the hospitals, in hospitals. You know, 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 sites, 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 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.* Sure.

Mr. *Shimkus.* Maybe turn the mike on.

Ms. *Maxwell.* That will help.

Mr. *Shimkus.* It might.

Ms. *Maxwell.* Yeah. 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.* Yeah. 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 a patient that, for example, 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 been discussed, is about 25 to 50 percent of the drug, 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 is 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, 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.

Mr. *Pallone.* Okay. 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 kind of 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, you know, we would use the opportunity to clarify where we had.

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, you know, we see the guidance as bolstering our efforts. I think that, you know, 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, you know, greater specificity, you know, clarity on the requirements. It also has a stronger enforcement ability than guidance. So, yes, overall, you know, 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 taking 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.* Okay. 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, you know, 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.* --depending on what the rule--

Mr. *Green.* --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, you know, 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 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--

Mr. *Pitts.* Put your mike on.

Mr. *Griffith.* We are here for--

Mr. *Pitts.* Put your mike on.

Mr. *Griffith.* 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 gentle lady 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.* Yeah. I am sorry. I misspoke.

Ms. *Draper.* --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 is 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.* Yeah. 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 gentle lady, 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 is 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.* Okay. 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.* Okay. 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.* Okay. 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. And 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, you know, not compare to the patients at large, so they may require more--so generic brands of drugs may not be or generic drugs may not be appropriate. So those were the 2 factors that the authors discussed in that study.

Mr. *Long.* Okay. Okay. 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 it 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 been discussed, you know, many of the 340B entities are the ones that are essential to providing the safety net for, you know, 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, you know, the Health Center Program is 1 example that serves, you know, anybody who walks

through their doors basically, you know, 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. I mean, 1 is just in general, there has been kind of a decentralization of healthcare with, you know, care being provided in more sites. And then there is also that we, you know, in the 340B Program have, you know, 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.* Okay. 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.

Commander *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 is 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 gentle lady 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, you know, we would support greater clarity to hospital eligibility. And that is 1 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.* Yeah. There is no program requirement for hospitals to report how they are using the savings. And, you know, for some of the grantees, the community health centers, they have to use it in accordance with their grant program.

And 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. Okay. 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 1 more question for you. There again, getting back to the issue of transparency and how, you know, 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, you know, 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, you know, 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 need.

Mrs. *Ellmers.* Uh-huh. Which, you know, 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 gentle lady 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 hospitals, DSH hospitals 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.* Okay. 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.* Okay. 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.* Okay. 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, so 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.* Okay. 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, you know, 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, you know, 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.

Commander *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?

Commander *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?

Commander *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, you know, 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?

Commander *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?

Commander *Pedley.* It is changed quarterly.

Mr. *Collins.* It is? Okay.

Commander *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, you know, 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?

Commander *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.

Commander *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.

Commander *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.* Okay. 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?

Commander *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 needs 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 in the entities, the 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 we have, you know, the establishment of the pricing database will help to ensure that that is happening to a greater extent, you know, 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.* Okay. 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.

Commander *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 is 50 percent,

which would be $3.8 billion in savings.

Mr. *Bilirakis.* Okay. 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, you know, 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 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.* Okay. 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?

Commander *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.* Okay. 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 Congressman 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 follows:]

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

**********COMMITTEE INSERT**********

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.]