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EXAMINING HRSA'S OVERSIGHT OF THE 340B DRUG PRICING PROGRAM

TUESDAY, JULY 18, 2017

House of Representatives

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:15 a.m., in Room 2322 Rayburn House Office Building, Hon. Tim Murphy [Chairman of the Subcommittee] presiding.

Present: Representatives Murphy, Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Clarke, Ruiz, Peters, and Pallone (ex officio).

Staff present: Ali Fulling, Legislative Clerk, Oversight and Investigations; Brighton Haslett, Counsel, Oversight and Investigations; Brittany Havens, Professional Staff, Oversight and Investigations; Katie McKeogh, Press Assistant; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Sam Spector, Policy Coordinator, Oversight and Investigations; Josh Trent, Deputy Chief Health Counsel, Health; Natalie Turner, Counsel, Oversight and Investigations; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Rachel Pryor, Minority Senior Health Policy Advisor; and C. J. Young, Minority Press Secretary.

Mr. Murphy. Good morning.

Today's Subcommittee of Oversight and Investigation is holding a hearing entitled, "Examining HRSA's Oversight of the 340B Drug Pricing Program."

The 340B program was created by Congress in 1992 and mandates that drug manufacturers provide outpatient drugs to eligible entities at reduced prices in order for the manufacturers to remain eligible for reimbursement through entitlement programs such as Medicaid and Medicare.

Now, the 340B program covers entities, which are like hospitals and other nonprofit health care organizations, that have certain federal designations or receive funding from specific federal programs.

They are eligible for the 340B program by receiving certain federal grants administered by different agencies within HHS.

Hospitals eligible for the 340B program include certain disproportionate share hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals.

The Health Resources and Services Administration, or HRSA, an agency in the U.S. Department of Health and Human Services

is tasked with accepting applications and overseeing the covered hospitals and clinics.

HRSA faces several challenges in conducting oversight of the 340B program, one of which is the lack of reporting requirements in the 340B statute. Participating hospitals save between 25 to 50 percent of the average wholesale price for covered outpatient drugs.

They serve -- saved $6 billion on drug expenditures in fiscal year 2016, according to the HHS Office of Inspector General estimates.

Hospitals are not required to report their annual savings through participation in the program or how they use the money saved.

For many of these covered entities, those savings are vital to the entities' survival, particularly those that serve a large percentage of indigent patients and operate at a loss each year.

Other entities reinvest those savings in patient care, expanding access to patient care by opening centers in rural and underserved areas or passing along the savings to patients by providing discounted drugs.

However, as with so many federal programs, there are instances of errors and misuse. Specialists, oncologists in

particular, have told stories to us of their grave concerns about the way some entities use the 340B program.

For example, one store involves a doctor who referred many uninsured young breast cancer patients to a 340B hospital to receive cancer treatments but watched as 16 of those patients were placed on a wait list for care, simply waiting for treatment while their cancer progressed from entirely treatable to potentially life threatening.

According to this doctor, the wait list was not due to an overall capacity issue. Instead, it was because the hospital simply chose to set a cap on the number of uninsured patients they would treat.

I hope that instances like this are outliers -- the exception to the rule. The integrity of the 340B program must be protected. HRSA must be able to conduct oversight in a way that allows it to uncover fraud and noncompliance.

Indeed, HRSA audits from fiscal year 2012 to fiscal year 2016 demonstrate that noncomplying entities violate program requirements through duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting.

Unfortunately, while HRSA has made improvements to their

oversight efforts in recent years, the agency simply may not have the resources to adequately safeguard the program.

The program has experienced dramatic growth in recent years, due in part to program expansions in the patient protections in the Affordable Care Act.

At a hearing before the Health Subcommittee in 2015 we learned that from 2001 to 2011 the number of covered entities participating in the program roughly doubled.

The most recent data shows that from 2011 to 2017 the number of entities has nearly quadrupled.

HRSA indicates that as of October 2016, 12,148 covered entities were participating in the 340B program. Despite that growth, HRSA maintains only 22 staff to oversee the 340B program and conducts roughly 200 audits per year.

While HRSA has increased the number of audits conducted annually, which the committee applauds HRSA for, that number is still dwarfed by the vast number of participating entities and manufacturers.

Now, listen to this. At the current level of annual audits conducted, HRSA is auditing a mere 1.6 percent covered entities. That's 1.6 percent. That is all.

Further, because HRSA's audits consist of only a sample of

drugs within each entity, these audits cover just a fraction of a fraction of the program.

Despite that, HRSA's audits have uncovered between 63 and 82 percent of audited entities to be noncompliant with program requirements since 2012. Needless to say, that is a concern.

What would more intensive oversight including additional audits further reveal? What is the outcome if the hospital is found to be in noncompliance with diversion, duplication, or incorrect data?

Well, nothing. No one has ever lost a 340B eligibility because of these problems. I thank HRSA for their cooperation for using audit documents before this hearing in response to the committee's request last month.

We are in the process of reviewing these documents to gain a better understanding of the audit process and may have more follow-up questions at a later date.

Now, I am a big supporter of the 340B program. I will continue to defend them. But I don't buy the argument that some have presented to me that says show me someone who got caught, because chances are 94 percent that no one is even going to look at you, and so you won't be audited, and 100 percent chance that nothing is going to happen afterwards. That is why we are here,

to find out is there a concern or not a concern.

And we welcome all the witnesses today too and look forward to hearing HRSA's oversight efforts, the challenges HRSA faces and how this committee can best enable HRSA to overcome these challenges.

I now yield five minutes to Ms. DeGette.

Ms. DeGette. Thank you so much, Mr. Chairman.

Mr. Chairman, Congress created the 340B drug discount program 25 years ago to help safety net providers leverage their scarce resources to serve more people, especially people in low-income and vulnerable areas.

Thanks to this program, providers across the country have been able to purchase discounted pharmaceuticals and expand and improve their services.

I think we can stipulate that 340B is critical to provide critical medical services to low-income people. But we also can stipulate that we need to make sure that our oversight remains robust.

340B drug discounts allow eligible hospitals and other designated providers including community health centers, state and local health departments and family clinics to make the most of their limited resources.

But as the Government Accountability Office and the HHS Office of Inspector General have found, there is a need for more oversight of this important program to ensure that it achieves its critical mission.

GAO and OIG have conducted several reviews of the 340B program and have repeatedly underscored that it needs more effective oversight.

Of course, to conduct that oversight, HRSA must have the tools it needs to implement better controls over the program. These tools may require additional authority from Congress, which I would like explore today, and also, given the size of the agency, if you want more robust oversight you are going to have to give more funding.

I also want to point out, Mr. Chairman, that I am troubled by the rule that the Centers for Medicare and Medicaid proposed last week which would dramatically reduce reimbursements to Medicare Part B drugs for 340B hospitals.

The Trump administration claimed that this proposed rule was an important step to lower the cost of drugs to the American people. Unfortunately, that statement seems more fantasy than reality.

The proposed rule will do nothing to achieve the goal of

making prescription drugs more affordable to the general population. Reducing the repayment rate that 340B hospitals receive for Medicare Part B drugs does nothing to get to the root of high drug prices, and frankly, it tries to solve one problem by creating many others.

Rather than rolling up its sleeve and attempting to address the actual cost of high drug prices, the administration's proposed rule instead threatens to undermine the important safety net mission of 340B hospitals.

Many 340B hospitals are what are called disproportionate share safety net hospitals -- the DSH hospitals. This means they often serve low-income and rural communities and take on patients other parts of the health care system either cannot or will not impact.

In my district in Denver, Colorado, we have a number of these DSH hospitals including St. Joseph Hospital, which is a part of SCL Health, and SCL Health operates six other 340B hospitals and provides essential often uncompensated care which 340B drug discounts have helped to fund.

Now, the reduced payment rate pulls the rug out from under providers like St. Jo's and puts the patients they serve at risk of losing access to care.

As you know, Mr. Chairman, many of my colleagues and I have asked this subcommittee to open an investigation into why drug prices are so high and how we can address this problem.

I think we need an investigation -- a robust investigation and a series of hearings that explore in-depth the reasons for exorbitant costs of drugs and why the prices continue to rise.

Unfortunately, I don't think this hearing nor the rule proposed by CMS last week addresses the broad problem of high drug prices. I know that all of us are dedicated to ensuring that the 340B program achieves its critical mission of helping providers serve the indigent. I want to make sure, like you do, that sound controls are in place to prevent abuse.

And, Mr. Chairman, while I am glad to work with you to address some of the problems of the 340B program, the concerns associated with it are fundamentally separate from the high cost of drugs in the U.S. and I believe the issue should be treated differently.

Put simply, the committee should hold hearings, we should take meaningful action on the high cost of drugs and the rising costs.

In the meantime, I look forward to hearing from the witnesses today about what we can to do strengthen our safety net and to improve HRSA's oversight of the 340B program.

With that, I yield back. Thanks.

Mr. Murphy. The gentlelady yields back.

I now recognize the chairman of the full committee, Mr. Walden.

Mr. Walden. Thank you, Mr. Chairman, for this hearing. The committee is already ramped up its top to bottom oversight of many aspects of the cost drivers in our health care system and we have more work to do.

The subcommittee's hearing on 340B drug pricing program and the oversight role of the Health Resources and Services Administration, or HRSA, is part of this broader review and we appreciate our witnesses here today.

Since its creation by Congress in 1992, the 340B drug pricing program has provided lifesaving medicines at reduced prices to certain safety net health care providers.

Indeed, this program has helped these providers, known as covered entities, stretch scarce federal dollars as far as possible to better serve uninsured and under insured patients across the country.

HRSA estimated that in 2015 covered entities saved about $6 billion on 340B drugs through their participation in the program. For a variety of reasons, participation by hospitals

in the 340B program has grown substantially in recent years and the number of unique hospital organizations participating in the program has nearly quadrupled from 2011 to 2016, increasing from 3,200 participating hospitals in 2011 to 12,148 as of October of 2016.

Now with this growth concerns have been raised about HRSA's ability to adequately oversee this program, as the witnesses from HHS Inspector General's office and GAO will discuss in detail today.

HRSA's oversight of the program has improved in recent years though enhanced authority and resources -- through enhanced authority and resources but program vulnerabilities still exist. So today we will examine a number of important programmatic issues.

First, we want to learn how HRSA's oversight efforts can best meet the challenges of 340B growth. While HRSA has made improvements to its oversight efforts in recent years, HRSA's audit activities remain at or below 200 annual audits of covered entities since 2012, despite the rapid growth of the program.

That is one reason we are here today. That is to answer the question, how can HRSA improve its audits to better detect problems or somehow raise the annual number of audits.

Next, we will focus on the problems already discovered and how HRSA can address them. HRSA's annual audits reveal a high level of noncompliance with program requirements by covered entities including the potential for duplicate discounts and diversion of 340B drugs to ineligible patients.

We will also want to find out how HRSA can be more transparent. Lack of transparency hinders HRSA's oversight capabilities, and while the purpose of the program is to stretch scarce resources as far as possible, reaching more eligible patients, and providing more comprehensive services, neither 340B nor HRSA guidance explains how 340B providers must use savings from the program. That is an issue that has come to our attention.

Finally, we need to discuss how HRSA's lack of regulatory authority limits the agency's ability -- their ability to adequately oversee the program.

So the committee has been reviewing HRSA's oversight of the 340B program for pricing for two years and we plan to continue this work after this hearing.

And as we move forward it is important not to overreact and create unnecessary red tape for providers who are truly using the program to benefit patients.

And I have heard from hospitals in my district like those

in Bend and even down on the south coast outside of my district just how important this program is to patients.

While we do not want to overburden these safety net providers, we also need robust oversight over a program that has expanded this dramatically.

Just last month, the committee sent a letter the HRSA to gain more insight into the audits conducted in the 340B program and we want to extend our appreciation to HRSA for their timely production of information responsive to our requests.

Thank you for doing that and we look forward to hearing about the steps that HRSA's taking to strengthen the program.

I also want to thank the Office of Inspector General at the U.S. Department of Health and Human Services and the GAO for your good work as well.

With that, I yield the balance of my time to the chairman of the Subcommittee on Health, Dr. Burgess.

Mr. Burgess. Thank you, Mr. Chairman, and thank you, Mr. Chairman, for holding this hearing today.

As Chairman Walden pointed out, this program has saved billions of dollars for patients, ensuring that those in need could receive care and that the hospitals that provide that care can continue to support their communities.

But the program has challenges and audits by HRSA have found high levels of noncompliance among 340B-covered entities, raising questions as to who is currently overseeing the program and who should provide that oversight, going forward.

So I also want to thank our witnesses for being here today and discussing this very important program with us. There is -- this is a multifaceted problem.

The way forward isn't entirely clear but that is what this hearing is to -- is to sort out. So I am grateful we are having the hearing today and look forward for an opportunity to examine the 340B landscape, going forward.

And I yield back.

Mr. Murphy. Gentleman yields.

I now recognize the ranking member of the full committee, Mr. Pallone, for an opening statement for five minutes.

Mr. Pallone. Thank you, Mr. Chairman.

Twenty-five years ago, Congress passed bipartisan legislation establishing the 340B program. Since its inception, the 340B program has played a critical role in ensuring that low-income and vulnerable individuals have access to affordable health care.

The 340B program provides discounts on outpatient drugs that

have allowed safety net providers to be able to expand access to essential health care services for vulnerable patients.

This program has been vital for safety net providers like community health centers, inner city and rural hospitals, HIV clinics, and hemophilia treatment centers.

And the 340B program has made the difference between patients getting the lifesaving health care services and drugs they need or going without.

The Congress created this program with the intention of helping covered entities expand their capacity to serve their patients.

By purchasing drugs at a discounted rate, 340B providers are able to stretch scarce resources to provide more comprehensive health services.

Resources provided through the 340B program directly augment patient care throughout the country. It continues to support the mission of safety net providers that serve low-income, uninsured, and under insured patients.

And the 340 program is a critically important health care program and the Health Resources and Service Administration, or HRSA, should have the authority it needs to strengthen the integrity of the program.

GAO and OIG have identified weaknesses in the oversight of the program which can have negative consequences for both the participating providers and drug manufacturers.

HRSA should appropriately improve program integrity while protecting the mission of the 340B program and be given the necessary resources to oversee the program.

Last Congress, this committee worked on a bipartisan basis to try to address the concerns from stakeholders on all sides of this issue in a balanced and measured fashion.

Our goal was to strengthen and support the mission of 340B to provide health services to those most in need. Unfortunately, we were not successful. But I continue to believe and I think we can all agree here today that the mission of this program is sound and the continued emphasis on program integrity will make the 340B program stronger now and in the coming years.

I want to be clear, however, that while I was always happy to have a conversation about strengthening the 340B program, it would be disingenuous for anyone on this committee to say that this hearing today is in any way a hearing on rising drug prices.

The 340B program is not the problem or the solution to rising drug prices and that is why I am so concerned about the Trump

administration's recently proposed rule containing a provision that would slash reimbursements on Medicare Part B drugs to 340B hospitals under the guise that doing so would somehow address the rising cost of prescription drugs.

When Health and Human Services Secretary Price announced the proposed rule change, he claimed that this rule will somehow make drugs more affordable.

And I want to be clear -- this rule would have zero impact on the actual price of prescription drugs and would decimate the support that 340B hospitals rely on to serve needy patients.

This proposal is nothing more than a deep cut to many of the hospitals that serve as the bedrock of our safety net, and committee Democrats have repeatedly asked that this committee begin to have a real conversation about drug prices and this is not it.

And again, I urge the chairman to hold the hearing on drug pricing so we can hear from all the stakeholders involved and so we can begin to develop real solutions that will begin to drive down the cost of prescription drugs.

Until then, I remain dedicated to finding ways to strengthen the 340B program and ensure that it continues to fulfil its essential mission.

And I am grateful to our witnesses for being here today to talk about some of the challenges the program faces as well as its successes and the important role it continues to play.

And I yield back. Oh, you would like -- I yield the time remaining to the gentlewoman from Florida, Ms. Castor.

Ms. Castor. Great. Thank you, Mr. Pallone.

I just wanted to say that at a time when high and escalating drug prices are a top concern for all Americans, the 340B drug discount program is a real winner.

It is a very modest government initiative that has huge benefits and helps our disproportionate share hospitals and many community health centers and other clinics all across the country provide affordable prescriptions to folks that need it that may not have insurance, that are really struggling to get by and then that helps those hospitals and those clinics stretch the dollar and keep the burden off the taxpayer.

Doesn't mean that it is immune from oversight and that is important for our hearing today but 340B is a real godsend for so many families and health providers across the country.

Thank you, and I yield back.

Mr. Murphy. Gentlewoman yields back.

So now I ask unanimous that the members' written opening

statements be introduced into the record, and without objection the documents will be entered into the record.

[The information follows:]

**********COMMITTEE INSERT 1**********

Mr. Murphy. I would now like to introduce our panel of federal witnesses for today's hearing.

First, we have Captain Krista Pedley, director of the Office of Pharmacy Affairs at the Health Resources and Services Administration. I just want to say you also got your pharmacy degree from the University of Pittsburgh. Fine school. Fine school.

Next is Ms. Erin Bliss, who serves as assistant inspector general in the Office of Inspector General within the Department of Health and Human Service. I think more of a Notre Dame person there, right?

And Ms. Debra Draper, but you have a doctorate degree so I am going to call you doctor today. Yes, she is the director of health care for the Government Accountability Office.

Thank you all for being here today and providing testimony. We look forward to a productive discussion of HRSA's oversight of 340B drug pricing program.

You are all aware that this committee is holding an investigative hearing and when doing so has the practice of taking testimony under oath. Do any of you have any objections to testifying under oath?

Seeing no objections, the chair then advises you that under

the rules of the House and rules of the committee you are all entitled to be advised by counsel.

Do any of you desire to be advised by counsel during testimony today?

Okay. Seeing no things on that then we will proceed with swearing you in. Please rise, raise your right hand. I'll swear you in.

[Witnesses were sworn.]

Seeing all answered in the affirmative, you are now under oath and subject to the penalties set for in Title 18 Section 1001 United State Code.

We ask you all to give a five-minute summary of your written statement. Please try and stick with the five minutes. I will tap the gavel when you are close to that.

Captain Pedley, you are recognized first. Five minutes.

STATEMENTS OF CAPT KRISTA M. PEDLEY, PHARMD, MS, DIRECTOR, OFFICE OF PHARMACY AFFAIRS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ERIN BLISS, ASSISTANT INSPECTOR GENERAL, OFFICE OF EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DEBRA DRAPER, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF CAPT KRISTA M. PEDLEY, PHARMD, MS

Ms. Pedley. Good morning, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee.

I appreciate the opportunity to appear before you today to discuss the 340B program. HRSA shares the subcommittee's commitment to ensuring program integrity and today I will discuss steps we have taken to implement key provisions and strengthen oversight including some of the current challenges in managing the program.

The 340B program was authorized in 1992 to stretch scarce federal resources by reducing the cost of covered outpatient drugs to 340B-eligible entities.

Approximately 12,300 entities and 26,000 associated sites participate in addition to over 600 manufacturers. We appreciate

the work of the Office of Inspector General and the Government Accountability Office to provide recommendations on strengthening safeguards which inform our activities across all HRSA programs. Within our statutory authority HRSA has worked to address the majority of GAO and OIG recommendations through systematic efforts to improve the program.

Two recommendations remain open from GAO's 2011 study which direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient.

The OIG's 2005 and 2006 reports include open recommendations that HRSA develop a pricing system to improve oversight and allow entities to secure pricing data.

Since 1992, HRSA has administratively established many requirements of the program for a series of guidance documents published in the Federal Register, typically after public comment.

In 2014, HRSA planned to issue a proposed omnibus regulation. However, that same year the U.S. District Court for the District of Columbia invalidated a 2013 final rule on a provision related to orphan drugs.

HRSA then withdrew the proposed omnibus regulation from the Office of Management and Budget review. HRSA has prioritized

rulemaking in areas in which the D.C. circuit has clearly recognized our regulatory authority.

The agency finalized a rule in January 2017 on a calculation of ceiling prices and the imposition of civil monetary penalties for manufacturers which will become effective October 1, 2017.

HRSA also proposed a rule in August 2016 on the dispute resolution process. All other program policy areas were addressed in an August 2015 proposed omnibus guidance and we are working on next steps to address these policy issues.

The president's fiscal year '18 proposed budget commits to developing a legislative proposal to improve 340B program integrity and ensure that the benefits derived from participation are used to benefit patients, especially the low-income and uninsured.

Specific legislative authority to conduct rule making for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight and management of the program.

Specifically, regulatory authority would also allow HRSA to provide greater clarity and specificity of program requirements.

HRSA works to verify that both 340B entities and

manufacturers are in compliance. Regarding covered entity program efforts, we conduct initial certification, annual decertification and program audits.

We have completed over 800 covered entity audits since 2012, which encompass nearly 11,000 offsite facilities and 18,000contract pharmacy locations. HRSA also reaudits a select number of entities with findings that resulted in repayment to manufacturers. HRSA posts on our website a summary of audit findings. The findings have varied from minor database corrections to findings of diversion.

Through findings and audits, HRSA develops educational tools and resources for all 340B stakeholders in order to improve program integrity.

The statute specifies the types of entities eligible to participate but does not specify how a covered entity may provide or dispense such drugs to its patients.

HHS has issued guidance recognizing entity use of contract pharmacies to dispense 340B drugs. The majority, or 73 percent, of entities do not contract with pharmacies.

HRSA guidance outlines compliance requirements for entities that utilize these contract pharmacy, which HRSA reviews as part of our audits.

If a covered entity is not providing oversight of its contract pharmacy, the pharmacy arrangement is terminated from the program.

HRSA is also actively engaged in manufacture oversight and has the authority to conduct audits of manufacturers. HRSA has conducted seven audits of manufacturers in addition to developing regulations and guidance specific to manufacturer compliance.

In accordance with the statute, HRSA is required to collect information from manufacturers to verify the accuracy of 340B ceiling prices and then make those ceiling prices available to the covered entities.

HRSA appreciates the work of the OIG and GAO to help strengthen the program. We look forward to continuing our partnership with them as well as with Congress to strengthen program integrity and enforce program requirements as well as increase transparency on how entities use the program to benefit low-income and uninsured patients.

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

[The prepared statement of Capt Krista M. Pedley follows:]

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**********INSERT 2**********

Mr. Murphy. Thank you.

Ms. Bliss, you are recognized for five minutes.

STATEMENT OF ERIN BLISS

Ms. Bliss. Good morning, Chairman Murphy, Ranking Member DeGette, and other distinguished members of the subcommittee.

I am pleased to join you today to discuss ways to protect the integrity of the 340B drug discount program.

OIG has found that HRSA has strengthened its oversight of the 340B program over the years. However, more needs to be done.

Some longstanding and fundamental challenges persist and they impede effective program oversight and operations. OIG recommends two key improvements to 340B program integrity and oversight.

One, increase transparency to allow for payment accuracy, and two, clarify rules to ensure that the program operates as intended. I will explain both of these.

With respect to transparency, OIG recommends that HRSA shares ceiling prices with 340B providers and states. For providers, this will allow them to ensure that they are not overcharged by drug manufacturers.

Currently 340B providers cannot verify that they actually receive the required discount. Congress has given HRSA authority to do so and HRSA is working on it.

Sharing ceiling prices with states will allow them to ensure that Medicaid is not overpaying for 340B drugs. Making this happen may require new authority from Congress. States also need transparency as to which Medicaid claims represent 340B drugs.

Even when states can determine how much they should be paying for these drugs, they still may not know which claims to reimburse at that price.

This transparency is also essential for states to correctly claim Medicaid rebates from drug manufacturers. Without it, states put manufacturers at risk for paying more really than they should by inappropriately including 340B drugs.

At the same time, states risk forgoing rebates to which they are entitled by inappropriately excluding non-340B drugs. OIG recommends that HRSA work with the Centers for Medicare and Medicaid Services to help states accurately identify 340B claims.

The second key improvement is to clarify 340B program rules. For one, HRSA's guidance addresses patient eligibility but leaves room for interpretation as to which of a patient's prescription might be eligible in a retail pharmacy setting.

In these retail settings we found that providers in fact are making different determinations about which prescriptions are eligible for the 340B price.

Let me illustrate with an example. Let us imagine a doctor sees a patient at a 340B community health center. Later, that same doctor sees the same patient at her private practice.

If the doctor prescribes a drug to that patient at the private practice, is that prescription eligible for the 340B price? One provider in our study said yes and another said no, and another said it depends.

So who is right? We couldn't tell, based on the current guidance, and so we recommend that HRSA more clearly define this.

Furthermore, guidance does not address how to handle uninsured patients. In our review of retail pharmacies, we found that uninsured 340B patients sometimes received discounted prices but sometimes they paid full price for 340B drugs.

In other words, uninsured patients are not always receiving the benefit of the 340B discount on their prescriptions.

We recommend that HRSA address whether providers must offer discounted prices to uninsured patients.

In closing, lack of transparency and clarity make it harder to ensure integrity and harder to determine how well the program is working. If HRSA needs new authorities to make these key improvements, we encourage Congress to consider statutory changes

as appropriate to support increased transparency and better clarity.

OIG appreciates and shares your interest in improving program integrity and effectiveness for the 340B program. I will look forward to answering your questions. Thank you.

[The prepared statement of Erin Bliss follows:]

**********INSERT 3**********

Mr. Murphy. Thank you, Ms. Bliss.

Dr. Draper, you are recognized for five minutes.

STATEMENT OF DEBRA A. DRAPER

Ms. Draper. Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for the opportunity to be here today to discuss the 340B program including issues concerning its oversight.

The 340B program was created by statute in 1992 and is administered by HRSA. According to HRSA, the intent of the program is to enable participating entities, also known as covered entities, to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.

Participation is voluntary but there are strong incentives to do so. For covered entities such as certain hospitals and federally-qualified health centers, substantial cost savings or revenue on outpatient drugs can be obtained through participation in the program.

For drug manufacturers, participation is required to receive Medicaid reimbursement. Since the 340B program first became operational in 1993, it has experienced exponential growth in the number of covered entities.

In 1993, the program had approximately 400 covered entities and by 2017 there were more than 12,000 representing approximately

38,000 covered sites.

The 340B program has also seen exponential growth in the number of contract pharmacies particularly since 2010. Prior to March 2010, only one contract pharmacy as allowed for covered entities without an in-house pharmacy.

In March 2010, HRSA lifted that restriction and as a result, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 19,000 in 2017, encompassing more than 46,000 arrangements.

In 2011, we reported that HRSA's oversight of the 340B program was inadequate to provide reasonable assurance that participants were in compliance with program requirements.

As a result of the identified weaknesses, we made four recommendations. One recommendation was for HRSA to conduct audits of covered entities to ensure compliance with program requirements.

This recommendation was a result of our findings that HRSA primarily relied on participants to self-police and ensure their own compliance.

In fiscal year 2012, HRSA initiated audits of covered entities and now conducts 200 audits per year. While we are pleased that HRSA is conducting these audits, 200 per year may

be insufficient, given the continued escalation and the number of covered entities.

A second recommendation was for HRSA to clarify the guidance for cases in which the distribution of drugs is restricted including required reviews of manufacture plans to ensure that drugs are equitably distributed to all entities regardless of 340B, program participation.

This recommendation was the result of our finding that in cases such as when the drug is inherently limited, manufacturers may have restricted distribution but the manner in which they did so was not always clear.

HRSA issued updated guidance in fiscal year 2012, which addressed their recommendation. The remaining two recommendations were for HRSA to issue more specific program guidance on the definition of a patient eligible to receive discounted drugs through the program and the criteria that hospitals must meet to be eligible to participate.

These recommendations were the result of our findings that the lack of specificity in the guidance could be interpreted in ways that were inconsistent with the programs intent.

This was particularly troubling given that the 340B program has been increasingly used in settings such as hospitals where

the risk of diverting 340B drugs to ineligible patients is greater because these settings are more likely to serve such patients.

HRSA has attempted but not succeeded in addressing these two open recommendations. In 2014, it developed a comprehensive 340B program regulation but a court ruling found that HRSA's rulemaking authority for the program was limited to specified areas.

In 2015, it issued proposed guidance but withdrew plans to finalize it earlier this year following the administration's directive for agencies to withdraw pending regulations and guidance.

In summary, HRSA has undertaken efforts to improve oversight of the 340B program. However, there are a number of critical issues that remain unresolved including whether the intent of the program, which was established nearly 25 years ago, is still relevant today, given the vastly changed healthcare landscape and 340B program environment.

Continued lack of specificity and program guidance, most notably the definition of a patient and hospital eligibility criteria.

Until these issues are resolved there will continue to be concerns about the integrity of the 340B program and HRSA's

ability to provide effective oversight.

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

[The prepared statement of Debra A. Draper follows:]

**********INSERT 4**********

Mr. Murphy. Thank you, Doctor.

I now recognize myself for five minutes for questions.

Captain Pedley, let me just start off with this. There is a lack of clarity in how the intent of the program is, which you outlined in your testimony in your documents there.

The absence of reporting requirements and specific mandates on how savings must be spent -- can you elaborate a little bit more on what that impact is?

Ms. Pedley. So the statute is silent regarding how covered entities have to use their savings. Therefore, HRSA doesn't have authority to require what these entities are doing with their savings.

Mr. Murphy. So is that savings -- does it go into the general fund or the hospital or clinic or do they -- like, a separate account so even if you were to audit that separate account you could see where that money goes? Or is there no way to do that?

Ms. Pedley. I don't have insight into how a hospital may manage those funds.

Mr. Murphy. Okay. So we wouldn't -- you wouldn't know. But you don't audit that anyway. So --

Ms. Pedley. Correct.

Mr. Murphy. But their -- these entities are generally

supposed to serve specific vulnerable populations. But people who may go into a hospital or entity that has a 340B program there is not a means test by which says you can't go to this program based upon your income. They could come in regardless of income, correct?

Ms. Pedley. Correct. The statute is silent as well as to whether a patient is insured or uninsured. They just have to meet our patient eligibility guidance.

Mr. Murphy. And the patient eligibility guidance, I understand, is that records have to be kept there and the doctor treating them has to work there?

Ms. Pedley. Yes. There have to be records and HRSA audits those records.

Mr. Murphy. Okay. So do community health centers use a sliding scale to discount policy to determine a patient's ability to pay?

Ms. Pedley. I know under their separate grant requirements they do have different things in place. I am not familiar with those.

Mr. Murphy. Okay.

Ms. Pedley. But that is under their grant requirements, not under the 340B statute.

Mr. Murphy. My assumption is they would and that would be one way of passing on savings. Do hospitals use a sliding scale to discount policy to determine a patient's ability to pay?

Ms. Pedley. I don't have insight into that either as they are not required under the 340B statute to pass on the savings.

Mr. Murphy. But hospitals and other covered entities can acquire the drugs at a 25 to 50 percent discount, right?

Ms. Pedley. Correct.

Mr. Murphy. And then charge the patients full price for the same drug?

Ms. Pedley. So the amount that they charge the patient after they receive that discount, again, is a decision made at the hospital. The price that they charge is outside of the 340B statute.

Mr. Murphy. So if someone who is very, very low income, struggling, could come in and purchase it under the intent of the program.

But at that same clinic or hospital that was brought up before about oncology, someone could be in there -- for all we know could be a multi-billionaire and also they would be eligible to -- the drug would be eligible.

The hospital could buy at a discount and sell it to the person

at the full price?

Ms. Pedley. So the statute is silent again on the -- who is -- how the savings are used and whether the patient is insured or uninsured. If the patient is insured, then the entity would bill the insurer at the higher rate and then obtain that revenue to stretch their scarce federal resources.

Mr. Murphy. And so what happens, however, is that because they are not required to collect this data, you don't what's really happening. If you audit, you don't know, for example, how many people may come in there, what their eligibility level is by their -- excuse me, what their income level is because that is not a required thing for the eligible patient, correct?

Ms. Pedley. That's correct. HRSA does not audit that information as it is outside of our authority.

Mr. Murphy. And the money that comes through these savings you have no idea where that money goes because that information is not collected and it is -- correct?

Ms. Pedley. There is no requirements in the statute so we do not --

Mr. Murphy. Do they voluntarily say, here's how we spent the money? Does anybody do that?

Ms. Pedley. The do not voluntarily submit that information

to HRSA.

Mr. Murphy. And since the accounts may not be separate as far as you know, even if they put the money in the general fund that -- we couldn't even trace that, how that is done?

Ms. Pedley. That -- HRSA would not have access to that information. Again, I reiterate for the grantees, however, they are required under their grant requirements to report 340B program savings as income and put that back into the -- to their grant.

Mr. Murphy. Okay. But is there any data which would show the level of charity care they are providing? Anything that they are required to show you?

Ms. Pedley. They do not share anything with HRSA. They may report charity care information on their cost reports that is submitted to CMS.

Mr. Murphy. Do they -- and we don't know if that charity care money came from the 340B or came from something else?

Ms. Pedley. We -- yes, HRSA would not know that.

Mr. Murphy. So as I understand it so far with the vague guidelines of eligibility for patients, the intent of the program, of course, to help the indigent population -- good.

The idea that other people who may not fit that definition may still have the hospital or clinic purchasing at a discount

and can use that money in any way, shape, or form and you have no way of finding out and they are not required to keep data and the books aren't kept in such a way that anybody could trace it if they wanted to?

Ms. Pedley. Yes. The statute, again, does not in any way mention what covered entities --

Mr. Murphy. Okay.

Ms. Pedley. -- do with that savings or that they have to report it to HRSA.

Mr. Murphy. And operate under the assumption they are all doing good works but we don't know, and since 60 to 80 percent have some problems, we will see.

Ms. DeGette, five minutes.

Ms. DeGette. Thank you, Mr. Chairman.

I thought your line of questioning was quite interesting and I would like to follow up on it a little bit.

The chairman was asking appropriately, I think, what do hospitals do with the money. I don't think we have anybody here who would be able to answer that question, right?

Okay. So none of the three of you can answer that question. I would assume there is probably somebody who can answer that question and maybe we should have a follow-up hearing and have

some people from the hospitals come and talk about what they do with that money.

Dr. Draper, I do know that one of the GAO findings was that -- well, first of all, is the GAO aware of a practice with hospitals where they get the discounts under 340B and then they give -- they pass those discounts along to billionaires and things like that? Do you -- have you found any evidence of that?

Ms. Draper. We have not looked at that specifically.

And getting back to your earlier question --

Ms. DeGette. Yeah.

Ms. Draper. -- we did -- in our 2011 work we did interview a small number of covered entities to ask them what they did with the revenues and most said they don't -- they are not required to report that.

Ms. DeGette. Right.

Ms. Draper. So what they told us was that they use the moneys to expand services to patients and to provide more comprehensive services.

Ms. DeGette. So the limited evidence you got seemed to indicate they were using that for the original intended purpose?

Ms. Draper. Yes. It was very limited information and --

Ms. DeGette. I think -- number one, Mr. Chairman, I think

we should -- we should try to get some hospitals in here to talk to us, but number two, I think your inference is correct.

We probably do need to get more controls and that is why I said in my opening statement that we may need to have more -- we need to have more legislative reporting and more transparency because you can't have a program where nobody knows what's going on.

But let us get back -- let us get back for a minute to the original purpose of the 340B program. Captain Pedley, the -- what the 340B program was intended to do was to help providers stretch scarce resources and give services to people who are uninsured or lack insurance altogether. Is that right?

Ms. Pedley. Yes. From report language, the intent of the program was for these covered entities to be able to purchase the drugs at a discount in order to stretch their resources and provide more care to patients.

Ms. DeGette. Right. So if people didn't have this source of revenue, hospitals, assuming they are using the revenue for the originally intended purpose, they might have to cut back on services that they would provide to these underserved populations. Is that correct?

Ms. Pedley. So if the program were not --

Ms. DeGette. A yes or no will work.

Ms. Pedley. Yes.

Ms. DeGette. Thanks.

Now, so, Dr. Draper, I understand that in the GAO audits you found some weaknesses in HRSA's ability to oversee the program and also you found that the agency needs to issue guidance that defines a 340B patient and clarify the standard for hospital eligibility. Are those in general your concerns?

Ms. Draper. Well, to give you an example, the definition of a patient is very ambiguous. It is that the patient has an established relationship with the entity and the entity maintains the medical records and that the entity -- the provider of services for that entity is either employed or under contract arrangement or some other type of arrangement.

So we had concerns about the language about like some other type of arrangement --

Ms. DeGette. Right.

Ms. Draper. -- what specifically does that mean, and I think it has been interpreted very broadly.

Ms. DeGette. So let me ask you, do you think the agency has authority under the current statutory language to tighten those definitions up or do you think that we need to do something

with the statute?

Ms. Draper. Well, since 1992 the agency has issued program guidance to try to clarify the rules of the program. So we are not -- we are a little confused about why. I think there is some concern that they need some regulatory authority versus having guidance and --

Ms. DeGette. Okay. So we might have to -- we might have to go and look at the statute.

Ms. Draper. Perhaps.

Ms. DeGette. Yeah. Okay.

And Ms. Bliss, I just wanted to ask you quickly what tools or authorities do you believe HRSA needs in order to efficiently administer the 340B program?

Ms. Bliss. Thank you.

We believe that increasing transparency and clarity around the program rules is very important, and while I can't offer a legal opinion on HRSA's authority, our understanding is they may need additional authority from Congress to do this.

Ms. DeGette. Great. Thank you.

Thanks, Mr. Chairman. I yield back.

Mr. Murphy. Thanks. Can I follow up on that quickly?

I am just curious -- with regard to those definitions of

entities, are any of you receiving letters, pressures from other organizations, hospital associations, pharma, et cetera, on recommendations for these changes?

Ms. Draper. We have not.

Mr. Murphy. You have not? Ms. Bliss.

Ms. Bliss. No, not at all.

Mr. Murphy. Captain Pedley.

Ms. Pedley. So when we proposed in August 2015 our omnibus guidance, patient definition was a part of that and we did receive over 1,200 comments related to the entire guidance but within those specifically to the patient definition.

Mr. Murphy. Okay. I mean, just with regard to there might be some on this committee who would like to see some of those.

Ms. Pedley. Yes. I agree.

Mr. Murphy. We will sharpen our question to you. Thank you very much.

Chairman Walden.

Mr. Walden. Thank you, Mr. Chairman. Thanks for having this oversight hearing.

And I just want to follow up on a couple of things. Do we or do we not know or audit how the savings are spent? That seems to be one of the issues.

We all believe that everybody is a good actor and the money is going to the people most in need, as well as savings.

But I also am not clear that HRSA actually -- that there is a clear definition of how the money should be spent or that we track the money.

Is that correct?

Ms. Pedley. So the statute is silent as to how savings are used. Therefore, HRSA does not audit or have access to that information.

Mr. Walden. So we really don't have a trail of bread crumbs as to -- you know how much it saved, right? Or do you?

Ms. Pedley. The discount on the drug?

Mr. Walden. Right.

Ms. Pedley. So they're -- it is on average between 25 to 50 percent but it depends on the specific drug.

Mr. Walden. Do we know if those savings get passed specifically back to people who need reduction in prices on the drugs?

Ms. Pedley. The statute is silent in that area. So HRSA does not have that information.

Mr. Walden. Okay. So we don't know that.

And of those savings, could the 340B hospitals take that

money and use it for good things but not necessarily back to the same person that is buying the drugs?

Ms. Pedley. So that -- because the statute is silent --

Mr. Walden. Silent.

Ms. Pedley. -- we don't have access to that.

Mr. Walden. Okay. All right.

And these are issues I think both you have raised, right, from GAO and from IG that there is just lack of clarity here?

Ms. Draper. Yes. We don't know how the savings are used. The entities are not required to keep that information or to track it.

We are currently doing some work on looking at contract pharmacies and we are going to be looking at things like discounts to -- that are being provided to patients. So --

Mr. Walden. Okay.

Ms. Draper. But there -- as far as the savings, there are really no requirements and most of the entities in our 2011 work that we talked to were not able to provide that information.

Mr. Walden. So could a 340B get the savings from the drug manufacturer and not pass those on to the individual that actually charged the individual through their pharmacies, like, the retail price for that drug?

Ms. Draper. I think that is very possible. There is just no way to know --

Mr. Walden. We don't know.

Ms. Draper. -- without the transparency around that.

Mr. Walden. All right.

Yesterday, HRSA's website listed a total of 41,132 registered sites. That is an increase of 3,636 registered sites since the budget justification was released.

So from HRSA's perspective, do you -- do you know how many of these 3,636 sites are new unique covered entities and how many are these so-called child sites?

Ms. Pedley. I would have to go back and look at the specifics of the data as to how many are new -- the main facility or a child site, as you mentioned.

Mr. Walden. Yes. So we don't know for -- well, you just don't know off the top of your head?

Ms. Pedley. Correct.

Mr. Walden. Okay. All right.

Ms. Pedley. But we have that information.

Mr. Walden. And overall you are seeing a faster growth rate for the new covered entities or new child sites? Which are you seeing the fastest growth rate for?

Ms. Pedley. I would have to go back again and compare the growth rate of the new entities versus child sites.

Mr. Walden. Okay.

Ms. Pedley. We do have that.

Mr. Walden. And how many manufacturers are participating in the 340B program?

Ms. Pedley. Over 600.

Mr. Walden. Okay. And how has that number changed in the last few years?

Ms. Pedley. It stays about the same. So the manufacturers that participate in the program are based on the manufacturers that participate in the Medicaid program.

They are required to participate in 340B if they are in Medicaid. Again, so we monitor when manufacturers enter into the Medicaid program to ensure that they also sign an agreement with HRSA to participate in the 340B program.

Mr. Walden. And I don't know if this is a fair question to ask you, Captain, but it is my understanding that HRSA was given an additional $6 million in funding beginning in FY 2014 and I guess the question is how much does HRSA now receive in funding to oversee the program and is that enough?

Ms. Pedley. So we did receive an additional $6 million in

fiscal year '15 for program integrity efforts and information technology as well.

We continue to remain at the $10.2 million in total and that is in our proposed budget as well for fiscal year '18 in order to maintain our level of oversight in the program.

Mr. Walden. And you have got what -- how many staff involved?

Ms. Pedley. We currently have 16 FTEs.

Mr. Walden. And is that -- I mean, do they have other responsibilities other than just overseeing 340B?

Ms. Pedley. So they specifically work on the 340B program anywhere from our information technology systems to registering entities in the program to specifically the audit function.

Mr. Walden. So they are focused on 340B exclusively?

Ms. Pedley. Yes.

Mr. Walden. Okay. All right.

This has been most helpful. Obviously, there are some statutory issues here and some clarity issues on who is a patient and transparency and who gets the benefit from the program designed to help patients in one way or another.

So, Mr. Chairman, thank you for holding this hearing. I appreciate the input of our talented witnesses.

Mr. Murphy. Thank you.

I now recognize the gentleman from New Jersey, Mr. Pallone, for five minutes.

Mr. Pallone. Thank you, Mr. Chairman.

The 340B program is a critical component of the safety net that serves the most vulnerable among us and 340B drug discounts help safety net providers make the most of the limited resources they receive.

As a result, they are able to reach more eligible patients and provide those patients with more comprehensive health services, and I believe in both protecting 340B and improving the integrity of the program to ensure it remains strong for the future.

My questions are, Captain Pedley, could you describe how this program helps safety net hospitals and other covered providers give care to needy populations?

In other words, the 340B -- well, would you -- if you could answer that question.

Ms. Pedley. So the intent of the program was for these entities defined in statute to be able to purchase the drugs at a discount so they can stretch those scarce federal resources.

Once they are eligible for the program and listed on our

database and we validate to ensure they are eligible for the statute they are then able to purchase these drugs at a discount, typically 25 to 50 percent lower than what they would have otherwise paid.

Mr. Pallone. And so the discounts help ensure that all individuals including the under insured and the uninsured have access to care. Is that a correct statement on my part?

Ms. Pedley. Yes, based on the intent of the program.

Mr. Pallone. All right.

Now, Captain, can you please describe how the 340B drug discounts generate savings for providers while expanding services for patients?

Ms. Pedley. So the savings in the program are generated on the up front discounts that they receive on the drug.

In addition, if the patient is insured they bill the insurer at the higher rate in order to create revenue to provide then the care to those that do not have insurance there or the ability to pay.

Mr. Pallone. Okay, and I know some members have already expressed concerns that there is not sufficient transparency with respect to how some 340B hospitals use their money.

What actions is HRSA taking, if any, to improve transparency

in the program?

Ms. Pedley. The statute is silent on the savings but in the fiscal year '18 president's budget we did propose to intend to work with Congress on a legislative proposal to ensure the benefit of the program does benefit the low-income uninsured populations.

Mr. Pallone. Okay.

I wanted to ask Dr. Draper what are the most important actions out of GAO's recommendations to improve program integrity in 340B and how should Congress prioritize?

Ms. Draper. Well, I think one of the key pieces is really clarifying the intent of the program. The intent was set up 25 years ago and, you know, there is a -- I think there is a misperception that it does.

It doesn't explicitly talk about uninsured or under insured patients being treated by the -- by the -- to receive benefits through the program. That is implied, depending on -- you know, depending on the types of covered entities. So that is one issue.

The other issue is really clarifying the definition of a patient. That would go a long way as well as hospital criteria -- the criteria to participate.

So those are the weaknesses that we currently see remaining

that would really help improve the integrity of the program.

Mr. Pallone. Okay. So from what I am hearing, the 340B program does play a valuable role in our efforts to provide a robust safety net for vulnerable patients and while more can be done to improve transparency those efforts should be tailored towards helping the program serve more needy patients.

So I want to thank you all for being here this morning and, you know, the comments I think they are very helpful.

I yield back.

Mr. Murphy. Gentleman yields now.

I now recognize Mr. Barton or five minutes.

Mr. Barton. Thank you, Mr. Chairman.

This is a difficult hearing. We have got a program that I think both political parties strongly support. I have got a number of federally qualified health facilities and DSH hospitals in my district that use 340B and it is an integral part of the care they provide to the low-income population.

But, you know, it is a program that has just grown exponentially and, quite frankly, I think HRSA has done a pretty amazing job, given how many people you have -- 24 people at one time.

That is about this subcommittee. You did 200 audits.

That's 10 per month per person. I couldn't do 10 audits a month if I were a CPA. And yet, nobody really knows what's going on in the program because it is just -- it is so big.

I don't even understand what we are talking about when you talk about the money. So I am going to ask a very elementary question and see if you can explain it to me.

If the regular price for a drug from a manufacturer is $10 -- I am making it as easy as I can -- and the average discount for 340B is 50 percent, that means that the entity that is participating in the 340B program is charged $5.

Is that right? The hospital -- the hospital pharmacy, their cost is $5. Now, if they prescribe that to an outpatient -- an outpatient, what does Medicaid pay for that prescription?

Do they pay $5? Do they pay $10? Do they pay $7.50? In other words, what, if any, is the markup? Can anybody answer that?

Ms. Pedley. So, first, with the ceiling price, the price that an entity pays is actually set in statute. The calculation is set based on --

Mr. Barton. I don't need to know that. I am using my example. Ten dollars is what the retail price would be -- the normal price if it wasn't a 340B drug and you said the discount

is 25 to 50. So I made it 50.

So the price is $5. What I want to know is the patient who gets that drug, whoever is paying for it -- the patient or Medicaid -- what do they pay? Do they pay $5? Do they pay $10? Do they pay $15? Do they pay something in between?

Ms. Pedley. So if the patient has insurance they would pay their standard co-pay. If they are uninsured --

Mr. Barton. If they -- they are covered by Medicaid.

Ms. Bliss. So Medicaid has a rule -- CMS has a rule for state Medicaid programs that they would reimburse at that $5 plus a dispensing fee.

Mr. Barton. Plus a dispensing fee. But there is no profit?

Ms. Bliss. Not in the Medicaid context.

Mr. Barton. Okay. So, technically, whatever the discount is that is passed through?

Ms. Bliss. Yes, to the Medicaid --

Mr. Barton. But you have no way to prove that it really is passed through?

Ms. Bliss. State Medicaid agencies don't currently have access to those ceiling prices.

Mr. Barton. So nobody knows?

Ms. Bliss. There is no check and balance.

Mr. Barton. It is voluntary compliance. I guarantee you people are abusing that. I guarantee it.

But let us forget that. Let us forget that. So we really have no controls on the -- on that end. If the dispensing pharmacy -- they get the discount but let us say they charge Medicaid the regular rate, $10.

So they have got a profit of $5. Is that illegal under current law? Are they required to pass it through or can they keep it and in the best case use it to defray the cost of another patient?

Ms. Draper. If it is not required it is how they pass or whether they pass on discounts.

Unless it is part of their federal grants for, like, a federally qualified health center their grant may require them to pass on discounts but not for all facilities.

Mr. Barton. So they could -- they could -- even though they are getting a lower rate they could charge the higher rate and use that within their facility for some other purpose?

Ms. Draper. That is correct. It is not clear how --

Mr. Barton. It is not illegal.

Ms. Draper. -- that is being used.

Mr. Barton. I am just trying to educate the subcommittee

how screwed up this program is.

My last question -- my time has expired -- if we created a whistle blower option so that anybody in the country could turn somebody in if they think there is abuse and if there is abuse they got to keep some of the savings that was discovered would that help police the program?

Ms. Draper. Well, I think you would have to make sure that the rules are clear as to what -- you know, it goes back to patient eligibility, hospital eligibility criteria.

So those are -- I think some of that ambiguity is --

Mr. Barton. I am not even going down that trail.

Ms. Draper. Yes, but I think this --

Mr. Barton. I am assuming everybody in the program is allowed to be in the program.

Ms. Draper. Right. But I think those rules are not clear. So people have interpreted it very differently. So until the rule is clear --

Mr. Barton. It is a mess.

Ms. Draper. -- it is really difficult to do that, I think.

Mr. Barton. This is a great opportunity for this subcommittee. On a bipartisan basis, we all support the 340B program. But it has grown topsy-turvy. We really need to put

the best minds of this subcommittee on a bipartisan basis and see if we can come up with some solutions.

With that, I yield back.

Mr. Murphy. I will work on that. That is good.

Ms. Castor, you are recognized for five minutes.

Ms. Castor. Thank you, Mr. Chairman, and thank you to all of you for helping us keep the 340B program strong and true to its original purpose.

The providers in my local community that are covered entities that participate are the ones that are providing inordinate amounts of charity care.

They -- most of them never recoup the reimbursements that they need. For example, the St. Joseph's Children's Hospital Chronic Complex Clinic for medically fragile children -- that is part of the BayCare Health System -- behavioral health and substance abuse services at BayCare Behavioral Health and St. Joseph's Care Clinic that stretches the federal Ryan White funding to support a continuum of care to maintain a high retention rate of HIV patients.

Tampa General Hospital is our safety net hospital. They provide multi-million dollars in charity care though that is never recouped. So 340B has been a godsend to their mission in our

community.

Captain Pedley, HRSA has already audited a third of hospitals in the 340B program but only a small fraction of the drug manufacturers.

Program integrity is appropriate for all stakeholders. Can you please indicate your intention with regard to undertaking audits and ensuring compliance for the drug manufacturers?

Ms. Pedley. So we audit manufacturers every year. We have conducted seven audits thus far. We plan to conduct an additional five this year. As with --

Ms. Castor. What percentage is that?

Ms. Pedley. So there are 600 manufacturers -- whatever that comes out to be.

Ms. Castor. What have the audits found so far?

Ms. Pedley. Thus far, we do post the audits on our website and we have not had any findings whereby the manufacturers are not in compliance with the statute.

The manufacturers only have -- they have a more narrow focus than the 340B-covered and that is to provide the drug at or below the ceiling price and that is what we audit.

But that is only one tool we use for manufacture compliance. We also ensure that once they are in the Medicaid program that

they appropriately sign an agreement with HRSA to provide the drugs at or below the ceiling price.

We also issue regulation and guidance in the program related to manufacturer compliance. We also review all allegations that we receive if a covered entity is not receiving a price at or below the ceiling price and we investigate each of those situations.

Ms. Castor. And I think a lot of folks don't know that nearly one-third of the total of 340B discounts is due to a penalty that is enforced against drug manufacturers for raising the price of drugs higher than the rate of inflation or voluntarily providing a discount lower than the 340B price and that manufacturers could avoid the penalty by not increasing their drug prices at such high rates. How does that work?

Ms. Pedley. So the 340B ceiling price, again, it is in statute and it is informed by components reported under the Medicaid drug rebate program and that is the average manufacturer price and the unit rebate amount and we receive those components from CMS to calculate the price.

However, if the drug company does raise the price of their drugs higher than the rate of inflation there is a penalty that kicks in and that causes the 340B ceiling price to equal a zero.

HRSA has policy in place and a final regulation that is effective October 1 that when that ceiling price equals a zero that the manufacturer charge a penny.

Ms. Castor. So that is a very important incentive and, again, helps keep the burden off the taxpayers that I think needs to be maintained as we move forward.

Captain Pedley, all the witnesses here -- and you can hear the comments from the committee -- said HRSA needs regulatory authority to properly administer 340B and I strongly favor appropriate HRSA oversight to ensure the highest level of program integrity.

But HRSA's proposed Mega-Guidance last year would have dramatically limited the use of 340B well beyond congressional intent and harm many hospitals and their ability to provide charity care and the whole continuum of care.

For example, it would have prohibited discharge prescriptions needed to prevent unnecessary readmissions, eliminated 340B in infusion centers for patients with no other options for cancer care, and created a complex and unworkable definition of who is a patient.

If the Congress provides HRSA with such regulatory

authority, how can we be assured that harmful proposals such as these wouldn't go beyond the congressional intent?

Ms. Pedley. So HRSA's proposal in 2015 and the omnibus guidance we did address patient definition, and based on some of the things that we were seeing in our program integrity efforts such as audits informed our decisions around how to define certain elements in that guidance.

We did receive over 1,200 comments that we took into consideration very seriously in drafting a final guidance that was sent to OMB in the fall but was then withdrawn. So we do take the stakeholders' comments very seriously.

Ms. Castor. To be continued. Thank you very much.

Mr. Murphy. Dr. Burgess is not here so it will be Mrs. Brooks.

Mrs. Brooks, you are recognized for five minutes.

Mrs. Brooks. Thank you, Mr. Chairman.

Captain Pedley, I would like to talk a bit about what it means for diversion to occur in the 340B program and how common is it for you to find evidence of diversion in your audits.

Ms. Pedley. So the statute states that 340B drugs can only go to an eligible patient but the statute does not further define what a patient is in the program.

So we have historically defined in guidance what it means to be a patient.

We have guidance currently in place from 1996. We did attempt in 2015 in the proposed guidance to further clarify the definition of a patient and we do audit that information when we audit.

I don't have the specific numbers on findings for diversion and we can make sure to get those to you. But that is one of the areas that we specifically look at when we audit covered entities.

Mrs. Brooks. Could you provide, though, some examples of diversion that you have found in audits?

Ms. Pedley. So an example may be that a covered entity sees a patient. That patient is also seen at an outside provider at their private practice, and if that patient comes back to the hospital, for example, to see that patient.

There may not have been sensitive enough systems in place to know where the drug was prescribed from because the private practice doctor, unless it was a referral arrangement, would not have been eligible for the program. So that is an example of an ineligible patient.

Mrs. Brooks. And so would that be -- so that would be a

finding against that hospital or provider?

Ms. Pedley. Correct.

Mrs. Brooks. And then what happens? What happens next when you do have a finding like that?

Ms. Pedley. So when there is a finding of diversion, the statute does require that the covered entity offer repayment to the manufacturer.

They are also required to submit a corrective action plan to HRSA which we review and approve and then monitor the covered entity to ensure that that corrective action plan is appropriately implemented.

They do, again, have to offer the manufacturer repayment for any drugs that were diverted.

Mrs. Brooks. And how long is the duration of a corrective action plan, typically?

Ms. Pedley. It varies on the covered entity type and the -- how severe the issue was -- for example, whether it was one issue of diversion or many issues of diversion. So it does depend on that.

But we do follow the entity -- follow up with them and monitor them throughout the process.

Mrs. Brooks. Do you have any recollection of what is

probably one of the more egregious without -- one of the more egregious issues involving a corrective action plan -- findings in audits?

Ms. Pedley. So in terms of corrective action plans, we do assess. Many times it may be that they have to make corrections to their software systems that track eligible patients and they will have to adjust those accordingly. That is a common error that we will see.

Mrs. Brooks. And so what steps would you say that HRSA takes to minimize the amount of diversion that occurs in a 340B drug pricing program?

Ms. Pedley. So I would say first and foremost we provide education to the covered entities regarding the definition of a patient, best practices in this space, and how to ensure against diversion.

We also -- the covered entities have to annually recertify and attest to compliance with program requirements and then again through our audits we do ensure that there is no diversion.

If there is diversion or any audit whereby there is repayment, we do consider those entities for reaudit so that we can go back and check to make sure the corrective action plan has been appropriately implemented and that not continuing.

Mrs. Brooks. Have you ever terminated an entity?

Ms. Pedley. We have terminated one covered entity for not submitting a corrective action plan. We were able to terminate them through that mechanism.

We have terminated contract pharmacies through the program where a covered entity was not providing oversight and there were a few cases where we terminated a child or offsite clinic of a hospital because they were not eligible for the program.

But that is just through the audit process. We also terminate through our recertification process and some other quarterly integrity checks that we do to ensure compliance.

Mrs. Brooks. And Ms. Bliss, can you please let us know what recommendations does OIG have to help reduce diversion? What recommendations have you made?

Ms. Bliss. We have helped that -- we have recommended that the patient definition be clarified so that it is more clear which patients and which prescriptions in particular are eligible for the 340B discounted price.

We have also examined how covered entities work with their contract pharmacies and raise concerns that the covered entities themselves need to conduct additional oversight and independent audits of their contracted pharmacies to help ensure there is

not diversion.

Mrs. Brooks. Thank you. My time is up. I yield back.

Mr. Murphy. Okay. Mr. Tonko, you are recognized for five minutes.

Mr. Tonko. Thank you, Mr. Chair.

As we have heard today, the 340B program is a critical component of the safety net that serves our nation's most vulnerable patients.

Congress created 340B drug discounts to enable these safety net providers to stretch scarce resources and provide comprehensive services to vulnerable patients.

However, HHS's recent proposed rule calls for drastic cuts in Medicare payments to 340B hospitals. I am deeply concerned that these proposed cuts would greatly limit 340B hospitals' ability to provide vital services.

So Captain Pedley, can you elaborate on the types of services that 340B hospitals provide to vulnerable patients?

Ms. Pedley. So under the 340B program, they are able to purchase the drugs at a discount and, again, provide those drugs to their patients. But beyond that, that would be outside of HRSA's authority regarding the other types of services that they provide.

Mr. Tonko. Mm-hmm. If the -- if the CMS rule is successful and results in certain safety net hospitals having less revenue, what impact might that have on their ability to provide services for low-income populations?

Ms. Pedley. It is a CMS rule and because it is going through the rulemaking process I am unable to comment because it is out for public comment.

Mr. Tonko. Anyone on the panel able to suggest what that impact would be?

Ms. Draper. No.

Ms. Bliss. Not in a measured way. The CMS rule is proposing to reduce Medicare Part B reimbursement for separately payable 340B drugs to -- in the hospital outpatient setting. So it would potentially reduce the savings generated by the 340B discount.

There are other proposed changes to payments to -- through the outpatient prospective payment system included in that rule. So I don't have a way to say how that would net out.

Mr. Tonko. Mm-hmm.

Ms. Draper. We did conduct work in 2015, looking at the intersection of 340B and the Medicare Part B program and we did find that for DSH hospitals that their Part B spending on drugs

was substantially higher than non-DSH hospitals -- almost twice as much -- and we found that it was -- suggested prescribing patterns of providers perhaps prescribing more and more expensive drugs than 340B hospitals.

Mr. Tonko. Mm-hmm. The 340B discounts are also critical for disproportionate share hospitals which provide care to uninsured and under insured populations.

A recent study found that 340B disproportionate share hospitals provided some $23.7 billion of uncompensated care in 2014 alone.

So, Captain Pedley, the discounts provided through the 340B program are one reason why 340B hospitals are able to provide those services to patients who are under insured or uninsured. Is that your understanding?

Ms. Pedley. So the intent of the program was for the entities to purchase the drugs at a -- at a discount in order to stretch their resources. The statute is silent regarding whether the patient is insured or uninsured.

Mr. Tonko. But, obviously, it is going to help some in those categories?

Ms. Pedley. That was the intent of the program.

Mr. Tonko. Right. And GAO has previously found that for

all the covered entities it reviewed, 340B savings, and I will quote, "allowed them to support their missions by maintaining services and lowering medication costs for patients," which is consistent with the purpose of the program.

So, Dr. Draper, can you elaborate on the ways entities use 340B revenue to maintain services?

Ms. Draper. Yes. We talked to covered -- a small number of covered entities when we did our 2011 work and, for example, some federally qualified health centers talked about perhaps expanding -- you know, expanding their number of sites to reach more patients and to, you know, expand their services. So that was one example of how they -- how they use the money.

But, again, that is -- the money is not specifically tracked so we don't know how much of that was, you know, used specifically for that but that is what they told us.

Mr. Tonko. Mm-hmm. Thank you.

And, Captain Pedley, I understand the proposed rule was issued by CMS and not HRSA. But is it fair to say that a drastic reduction in payments to 340B hospitals would have a significant impact on covered entities in your program?

Ms. Pedley. I am unable to comment due to the fact that it is in proposed format.

Mr. Tonko. Right. Well, thank you.

Mr. Chair, I am all for finding solutions to rising drug costs. But this proposed rule does nothing to address that. It would be a disaster for 340B hospitals and certainly for the critical services they provide.

With that, I yield back.

Mr. Griffith. I thank the gentleman.

The gentleman from New York, Mr. Collins, is now recognized for five minutes.

Mr. Collins. Thank you, Mr. Chairman.

I want to thank the witnesses as well and maybe, you know, to start with a summary, we all understand the importance of 340B including the pharmaceutical companies, what the intent was in 1992.

I think the reality is that the landscape of the cost of drugs especially on the -- in the oncology world, especially as we have gotten into, you know, some of the biologics and the treatments, which are great for any and all of these patients.

But the costs are astronomical. And as a result then these discounts become very significant and much more so than, you know, a generic drug type of thing.

So it has been a very changing pharmaceutical world, certainly the last 10 or 15 years compared to '92. I think all of us are worried about the transparency -- clearly, the lack thereof. The definition of a covered patient -- because none of us want to see this program implode unto itself.

And I guess the example I use, if you are an airline and you are flying a plane with, you know, 200 seats and the average price on the plane is $400 but you do know that you have got to discount 10 seats on that airplane.

So you have got a revenue piece that gets into your pricing model that, you know, you have got 190 seats at $400 and 10 seats at $200, you got that model.

But what we are starting to see, especially in the oncology world, is private hospitals buying up oncology practices.

There is only one reason they are buying the oncology practices. Those are the most expensive pharmaceutical drugs prescribed and a 50 percent discount on a $60,000 drug is real money, and we don't know where the money is going. We don't know of the patients are getting it properly or whether there is a diversion.

But as that percentage goes up, think of the airplane taking off now with 200 seats and half of them are at $400 and the other

half are at a 50 percent discount.

There is only one thing that is going to happen. The $400 price is going to $500. So here we are. We always are worried about the cost of pharmaceutical drugs but potential abuse in the 340B program -- there is no free lunch in America.

At least that is what we were taught growing up. The price of the drugs will go up because the abuse results in the most expensive drugs grabbing this discount.

So the transparency is critical and I think our committee can work together on that. I do know factually there are hospitals that have a line item in their P&L and it is called 340B pricing -- discounts.

340B discounts is an actual line item on their profit and loss statement and they don't use it for additional services. It is simply a line item on the P&L and that is where we need to know where the money is going.

These are not the grantees. The grantees, the Ryan White AIDS clinics, we know exactly what they are doing and that was the intent back in 1992.

And the -- and some of the grantees are very worried -- because I have met with them -- that if we don't get this under control there could be impacts on them and nobody wants to impact

any of the grantees.

So I guess it comes back, Captain Pedley -- you know, as we have heard the others, the OIG and the GAO state, we need this clarity on patient definition.

We need clarity on requirements for transparency and we need perhaps clarity out of HRSA. What do you need from us? Because guidance is guidance. Regulations and regulatory authority is that.

But there seems to be almost a disconnect of what you are allowed to do, what you are not allowed to do. Do you need more regulatory authority for Congress or don't you? I mean, you see my worries and I hope -- I tried to give you an example of why we have got to get this under control.

Ms. Pedley. Based on the court ruling in 2014, the court held that the statute only provides HRSA regulatory authority in three specific places and that is the ceiling price and civil monetary penalties for manufacturers and administrative dispute resolution process. The first two are combined.

All other areas of the program we do not have specific regulatory authority. We do propose in the fiscal year '18 president's budget to provide that regulatory authority for HRSA.

Regulatory authority does provide us the ability to be more clear and the requirements of the program, which is why we did include that in the president's budget.

Mr. Collins. So are you saying right now -- for instance, I also serve on the Health Subcommittee of Energy and Commerce -- do we on the Health Subcommittee have the language you would like?

Because I would think fairly quickly we could move that language into a bill and I think, in a bipartisan way, move that through Congress. Have they been that specific? Has HRSA been that specific?

Ms. Pedley. I would have to check with my department colleagues on whether there has been specific language.

Mr. Collins. If there is, could you provide that to the committee and to myself? Because I think that could be a very quick starting point.

Thank you, Mr. Chairman. I know my time is up. Thank you all for your testimony.

Mr. Griffith. Thank you.

The gentleman from California, Mr. Ruiz, is recognized for five minutes.

Mr. Ruiz. Thank you, Mr. Chairman. Thank you for this

conversation. I have worked very closely with FQHCs and rural clinics. In fact, my medical career -- I grew up in an FQHC, essentially, that was a block from my house, that took care of farm workers and I have seen patients that go in that couldn't afford their medications, and the 340B program is very essential for a clinic to be able to provide lower cost or at least cover the uncompensated under insured patients' costs and expand their services. So this is something that we definitely need to strengthen and to get right.

But we are not talking about the big picture here. I mean, why are drugs so expensive to begin with? That is the common sense question.

This is another band-aid approach to figuring out how can we make medications more affordable. But we are really not addressing the elephant in the room, which is why are these medications so expensive and perhaps in addition to transparency for this program where we want information from FQHCs and people that are struggling to meet the needs of underserved communities we should also have transparency on the big pharmaceutical companies on their costs and their pricing and where are their moneys going to so that we can figure out how we can help protect patients and other entities who have the focus on providing care

for our neediest patients throughout America and our middle class families who are under insured and who are still struggling to make ends meet.

So we need to protect this crucial program which allows thousands of entities across the country to provide lifesaving prescriptions and care for the most vulnerable in our communities.

And we know that these providers operate on very narrow margins and this program allows them to stretch their money to serve more patients. For example, the Desert AIDS Project in my district has a Hepatitis C program through which patients have access to the medication to treat their disease that otherwise can be cost prohibitive.

And I have seen day in and day out how not having access to the proper medication is devastating to overall -- to the overall health of patients.

Ms. Bliss, you talk about transparency. What -- if you were to have a wish list of what you want to know in transparency within these programs, what would that wish list be like and what is the number-one information that you would most advocate for in terms of transparency?

Ms. Bliss. Thank you.

In the current program as it stands, we are advocating for increased transparency in the ceiling prices and identifying which claims are subject to the 340B discount and that is because there are existing program rules around those features of the program.

So coming from an oversight entity, our link is to those criteria. Where we advocate that there be new information, new guidance is where there are missing rules.

So at this point, we are focused on the program as it stands. But we would, in an environment with additional rules, then we would certainly recommend transparency go hand in hand with new requirements so that we would be able to tell whether the program is working as intended.

Mr. Ruiz. For example, what kind of transparency would you place on hospitals and clinics?

Ms. Bliss. Well, at this point, there are no reporting requirements, as Captain Pedley has described, about how those savings get spent.

But there are also no requirements about how they should be spent. So if hospitals were to start reporting those today, we wouldn't have a measure to judge the success or the outcomes or whether they would meet program intent.

So reporting requirements tied to actual program criteria and goals are what would be most effective.

Mr. Ruiz. What would be most helpful for you, Captain Pedley, in being able to enforce these in terms of transparency?

Ms. Pedley. So the statute is silent on the savings piece. But we did propose in the budget to work with Congress on ensuring that the program does benefit patients, especially those that are low income uninsured.

We are also working in terms of transparency, as mentioned, on the 340B ceiling prices. We are working on a system to provide those ceiling prices to the covered entities so that they can see the prices that they are to be charged.

Mr. Ruiz. Well, I certainly appreciate and would advocate fiercely in order to see those cost savings translated into real patient out-of-pocket savings.

I do also know as well that some of those savings are used for other programs that are in dire need in those underserved communities.

And so, you know, I think that a combination of both are very wise for these entities who work under very strained under resourced conditions to provide an enormous amount of help for patients who actually need it.

So thank you very much for your efforts.

Mr. Griffith. Gentleman yields back.

The gentleman from Michigan, Mr. Walberg, is recognized for five minutes.

Mr. Walberg. I want to start by thanking the chairman for holding this hearing.

The 340B program assists some of the most needy patients in our communities, including those who receive their care at community health centers, hemophilia treatment centers, and HIV clinics.

As the number of entities participating in the 340B program has quadrupled since 2011, we have learned of greater oversight challenges and we are hearing of those today.

I am hopeful and expectant that this hearing will help us clearly identify those challenges as we seek to preserve and strengthen this 340B program. So it continues to truly meet needs.

Captain Pedley, I see that HRSA first began auditing covered entities in 2012, as recommended by a 2011 GAO report.

As has been noted, HRSA has fewer than 30 staff devoted to oversight of the 340B program. So it is understandable that HRSA has conducted relatively few audits over the years when compared

with the size of the program -- 51 audits in fiscal year 2012, building up to 200 audits in fiscal year 2016.

What concerns me is the high rate of noncompliance that HRSA uncovered in a very small sample size of the program. Based on the available data, HRSA found noncompliance in 63 percent of 2012 audits.

In 2013, that number rose to 79 percent of audits showing noncompliance in 2014. Eighty-two percent of audits in 2015 -- that number dropped slightly to 78 percent.

And finally, in 2016, of the audits that have been completed so far, 66 percent show noncompliance. Those numbers are just staggering.

Can you explain to me how HRSA selects the entities it audits and why those numbers are so high?

Ms. Pedley. So HRSA determines the audits on two different models. The first is a risk-based approach whereby we factor in certain risk factors and then randomly select based on those risk factors.

We then separately specifically target audit some of the entities either based on specific allegations we have received about the entities already being in noncompliance or information that we have that we are unable to resolve an issue with an entity.

Then we may go in and target audit an entity already known with an issue. So the entities that we choose are already at higher risk.

Mr. Walberg. Am I correct that the audits only cover small number of the drugs that an entity might purchase through participation in the 340B program rather than a full audit of all drug purchases by that entity?

Ms. Pedley. So we use the standard auditing process whereby we do sample based on a statistical methodology, a certain percentage of the drugs to ensure that they meet program requirements specific to diversion and duplicate discounts.

However, we do review all other aspects of the program outside of the sample in addition to looking at their policies and procedures, interviewing staff, and looking at all other documents necessary to ensure that compliance beyond just the sample of drugs.

Mr. Walberg. So even the small number of audits connected by HRSA only cover a fraction of that entity's participation in the program?

Ms. Pedley. So the sampling is specific to the diversion and duplicate discounts that we sample and that is a standard

process used in auditing.

But we look at the entire program to ensure compliance, policies and procedures, interviews, looking at their software systems and how they track drugs.

Mr. Walberg. Okay. Thank you.

Ms. Bliss, has the OIG considered whether the 340B program encourages the use of brand drugs and discourages the use of generic drugs?

Ms. Bliss. We have not studied that particular issue.

Mr. Walberg. Is there any incentive to study that? An incentive to prescribe more drugs and more expensive drugs because the entity has received those drugs that reduce price?

Ms. Bliss. In theory, there is certainly financial incentives to maximize the spread and your payments and your reimbursements.

Mr. Walberg. Has -- Ms. Bliss, had the OIG reviewed whether the 340B program has created an incentive for hospitals to acquire practices?

Ms. Bliss. We have not specifically examined hospital incentives. I believe my colleague from HRSA had some work touching upon that issue.

Ms. Draper. Yes.

Mr. Walberg. Ms. Draper.

Ms. Bliss. Oh, I am sorry.

Ms. Draper. That is okay. Actually, in 2015 we did look at the -- looked at Medicare Part B, the intersection of that with the 340B program and we did find the average number of oncology patients increased for all hospital groups but the most for the 340B DSH hospitals.

And we also found that the Part B spending -- drug spending was substantially higher at 340B DSH hospitals which suggests that the prescribing patterns may -- the financial incentives may influence prescribing patterns to prescribe more and more expensive drugs.

Mr. Walberg. Okay. Thank you.

I yield back.

Mr. Griffith. I thank the gentleman.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. Schakowsky. Thank you.

Well, I am happy to see that everyone on the committee says -- has expressed their support -- just about everybody -- for the 340B program because it certainly is a vital source for health care providers that really underpins our safety net programs.

And I am all in favor of doing everything we can to make

sure that we provide the proper oversight. But I wanted to make a couple of comments.

One may seem irrelevant but I would hope that members of this committee would have as great enthusiasm for audits of the Defense Department and where big money is really spent.

And I would also like to comment my support for and associate myself with the remarks of Dr. Ruiz, who was talking about hep C patients being able, under this program, to be able to afford drugs that could offer a cure, but that we also want to look at why the pharmaceutical companies are charging tens of thousands of dollars for this drug and charging so much for other drugs and I think that this committee needs to look at more than -- this is really not, I don't think a discussion about the price of drugs as much it is a particular small program.

But I do want to -- I am concerned with the CMS-proposed rule and I know, Captain Pedley, that you said it is under advisement and so you can't talk about it.

But can you describe it so that I understand it better what this proposed rule would do? Because what it sounds to me is at the end of the day that the entities like hospitals and federal -- FQHCs would receive less money. Can you describe it?

Ms. Pedley. I don't know the details of that rule. That

is under the purview of CMS and we could help connect you with them. But I would be unable to go into any detail.

Ms. Schakowsky. Okay. I -- and you were also asked the question describe the types of comprehensive services 340B covers. You were just strictly talking about the discount drugs. Are there anything else that you can add about that?

Ms. Pedley. HRSA does not track or have information on how the entities use the savings to provide or care to more patients.

Ms. Schakowsky. Okay. The 340B program has a demonstrable effect in helping disproportionate share hospitals and rural hospitals save their patients and that is a key part of the program that they are able and actually required to spend that money into engaging in meaningful and beneficial work to support the most -- the most vulnerable.

So let me ask you then what you think then are the key -- Captain Pedley, the key areas that we ought to be looking at to support your work in making sure that your audits are as effective as they can be and that this program is as effective as it can be.

Ms. Pedley. As proposed in the -- in the fiscal year '18 president's budget, HRSA only, again, has regulatory authority in the three specific areas and we have proposed guidance in all

other areas.

The regulatory authority across the program is critical for us to be able to provide clarity in our program requirements and assist HRSA in our oversight efforts to be able to then enforce those requirements. So regulatory authority is key.

Ms. Schakowsky. So this program has just been described as a real mess by some others on the other side of the aisle. Dr. Draper, would you agree that that is accurate, based on what GAO has looked at?

Ms. Draper. Well, we have identified weaknesses in oversight and we believe that the oversight needs to be improved and there are things that can be undertaken to make that happen.

Ms. Schakowsky. What is the most important thing that we ought to do?

Ms. Draper. Well, we talked a little bit about -- I want to reemphasize about hospital eligibility. I think it is really important to think about HRSA's role with oversight related to participating hospitals.

In 2011, about a third of U.S. hospitals were participating in the 340B program and by 2015 they are 40 percent. HRSA may have more updated numbers.

But, you know, I think the issue, because other grantees

have specific requirements based on their grants that they have to follow, like, in treating under insured or uninsured patients, you have a range of hospitals participating in this program and they operate in settings that provide both inpatient and outpatient services.

So the risk for diversion is really -- there is more risk. Because this is an outpatient program, drugs are not to be used for an inpatient setting.

Hospitals also tend to have more complex contracting arrangements in organizational settings, which is really different than the federal grantees, and then they also serve -- you know, they provide a larger volume of drugs in multiple settings.

So I think the risk is probably higher for a hospital and that is why I think that the hospital eligibility criteria is really critical as well as the patient -- the definition of a patient.

Ms. Schakowsky. You know, in my home state of Illinois there are over a hundred hospitals participating in the 340B program, and by and large, I think, and I am not disagreeing that we want to look at this carefully, but that helps those institutions better serve their patients.

We have -- the 340B program helped a nine-year-old patient with a brain tumor who receives care at the University of Illinois, Chicago -- in Chicago and they were able to afford a drug that she needed for her chemotherapy regimen that is not covered by her insurance.

So, you know, we all have anecdotal information, I think. But I just worry that we don't want to throw out the baby with the bath water.

Ms. Bliss, what would you say is the most important thing?

Ms. Bliss. Clear program rules are fundamental to ensuring program integrity, accountability, and even assessing to what degree the program is working.

Ms. Schakowsky. Okay. I yield.

Mr. Griffith. I appreciate that. Thank you very much for yielding back and I now recognize the gentlelady from California, Mrs. Walters.

Mrs. Walters. Thank you, Mr. Chairman, and I would like to thank the panelists for being here today.

Captain Pedley, I understand that the number of entity child sites has more than doubled in the past six years, rising from roughly 16,500 in 2011, according to GAO, to 41,132 as of yesterday, according to HRSA.

Two weeks ago on July 5th, HRSA listed the number of registered child sites at 40,745. Yesterday, July 17th, that number had increased by almost 400 sites. That is a drastic increase in child sites.

And I would like to get a sense of what is driving that increase in sites and how that affects program integrity. How much can this rise in child sites be attributed to consolidation -- that is, the trend of larger entities often DSH hospitals find smaller clinics and physician practices that as a result fall under their 340B umbrella?

Ms. Pedley. The statute is very specific as to which entities are eligible for the program and HRSA's role through that process is to ensure that when an entity applies that they do meet the statutory requirements.

So everyone that we do list in the program does meet the statutory requirements and are eligible.

Mrs. Walters. Okay. When a covered entity acquires another practice as a child site, it is my understanding that the drugs dispensed to that child site's patients often becomes eligible for 340B discounts.

Does that child site take on any new statutory or regulatory obligations such as providing the kind of care that originally

qualified the parent site for 340B status?

Ms. Pedley. So specifically for a hospital, and it may be different for a grantee, but for a hospital if they do acquire an outpatient facility they do first have to be reimbursable on that hospital's Medicare cost report before they are eligible for the 340B program because that is our test to ensure that they are an integral.

Once they are in that cost report then they also have to enroll, be listed on our database. They can then purchase drugs at that clinic as well and they have to meet all other 340B requirements just as the main facility does.

Mrs. Walters. Okay. And to what extent is consolidation guided by perverse incentives? For example, a recent report has shown that there has been 172 percent increase in the consolidation of community oncology practices into hospitals since 2008.

Ms. Pedley. HRSA's role is to ensure that everyone that does register does meet statutory requirements. I am unable to speculate on business decisions a hospital may make to acquire those facilities. Our role is to ensure that they are eligible for the program.

Mrs. Walters. Okay. And as you know, oncology drugs can

be quite expensive, and I know we talked a little bit about this before.

If the covered entity is purchasing oncology drugs at the 340B discount but not charging the patients at a discounted rate for those drugs, this can be profitable for the covered entity.

Does this function to serve vulnerable patient populations and, if not, does it run counter to the intent of the program and how does this consolidation affect patient care?

Ms. Pedley. The statute is only specific around the different compliance elements related to the 340B program -- for example, the patient definition and duplicate discounts. It does not provide HRSA the authority around how the entity uses those savings.

Mrs. Walters. Okay. And how does this consolidation affect patient care?

Ms. Pedley. I am unable to comment on those business decisions made by the hospital.

Mrs. Walters. Okay. I yield back the balance of my time. Thank you.

Mr. Murphy. Ms. Clarke, you are recognized for five minutes.

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Ms. Clarke. I thank you, Mr. Chairman, and I thank our panelists for enlightening us today with this discussion.

I have been an ardent supporter of the 340B program. In fact, I have six nonprofit safety net 340B hospitals as well as multiple federally qualified community health centers and clinics in my district.

Having the access to affordable medications provided through this program has saved countless lives in my district as well as improved the quality of life for many of my constituents.

It is due in large part to this program that one of the hospital systems in my district was able to increase uncompensated care by 34.68 percent.

With the current debate raging around the repeal of the ACA and my Republican colleagues' attempt to systemically dismantle the Medicaid program by their health care reform bills, the 340B program is needed now more than ever.

However, I can't overlook numerous government reports citing the vulnerabilities in this program. Drug manufacturers have also expressed their concerns about the reports of such vulnerabilities.

To be clear, I support the intent of the program, but I do believe that more transparency and accountability is required.

Therefore, additional oversight and reasonable checks and balances are needed to strengthen the program.

So my question is to you, Captain Pedley. The first question is can you provide me with the dates by which some of the oversight tools stemming from the GAO and OIG recommendations will be fully implemented?

Specifically, what is the estimated completion date for the ceiling price website which can be helped -- which can help ensure that over -- excuse me, that covered entities are paying the appropriate drug price?

And can you tell me the date by which a centralized mechanism similar to the 340B Medicaid exclusive file will be up and running for Medicaid managed care organizations?

Ms. Pedley. The 2011 study from GAO did recommend information for us but specific to the ceiling price system that you mentioned we received funding in fiscal year '14.

We honored that and we had a contract put in place that September in order to start development of that system. It is complex. There are over 40,000 drugs as part of that system.

We also have to ensure that it is developed in a way to ensure the confidential and proprietary nature of those prices and to

ensure that the information in that system is not redisclosed.

We are getting close to the release of that system and plan for it to be released in the coming months so the covered entities are able to view the ceiling prices.

Ms. Clarke. So that would be this year?

Ms. Pedley. In the coming months.

Ms. Clarke. 2017. Coming months. Months are always coming.

[Laughter.]

Ms. Pedley. We do hope that it is soon and we have an education plan in place to ensure that those that are going to be able to use the system have adequate time to learn it so they can understand more about that system and the information it will contain.

Ms. Clarke. The 340B Medicaid exclusive file -- is that part of the system that you are speaking of?

Ms. Pedley. No. That is a separate document -- the Medicaid exclusion file.

There is currently one in place for Medicaid fee for service and the purpose of that file is to ensure that states and manufacturers have the information necessary to prevent a

duplicate discount in the program, meaning to prevent a 340B drug discount and a Medicaid rebate on the same drug and the file is used for that purpose.

We are separately going through the process of developing policy around duplicate discounts and Medicaid managed care.

Amendments were added to the statute in 2010 that did include now Medicaid managed care under the duplicate discount provision. We proposed in our 2015 omnibus guidance policy related to that matter and we received comments.

We are also in discussion with CMS related to that as there will also have to be policy in place by CMS in the states in order to make that process work.

Ms. Clarke. Well, that process is of interest to me since I have a significant portion of my -- of the recipients in my district are now in Medicaid managed care plans.

Is there no completion date -- are there no completion dates that are up and running and when can those dates be really confirmed for us?

Ms. Pedley. So we first have to address the policy matters as to how to handle duplicate discounts related to Medicaid managed care and we are working with the administration currently on next steps related to that policy.

And then from there we would develop some type of file or information that would be used to prevent those duplicate discounts.

Ms. Clarke. Well, let me close by congratulating you because I know that HRSA has been working on this item for a while and I am happy to see them finally done.

I yield back, Mr. Chairman.

Mr. Murphy. Thank you, Ms. Clarke.

I recognize the gentleman from Pennsylvania, Mr. Costello, for five minutes.

Mr. Costello. Following up on Ms. Clarke's line of inquiry, Captain Pedley, do you agree that given that two-thirds of the more than 70 million Medicaid enrollees are in managed care that whatever policy changes you are proposing there would probably go further in terms of addressing the issue of duplicate discounts than anything else?

Ms. Pedley. So under Medicaid managed care we do have to first develop that policy for how duplicate discounts are to be prevented under Medicaid managed care and that involves many parties through the process.

Our authority specifically over how an entity prevents those duplicate discounts. CMS would have to separately address this

issue with the states and the Medicaid managed care organizations.

Mr. Costello. Do you agree that the policy change can occur within the regulatory realm and that no legislative action will be required?

Ms. Pedley. HRSA does not have regulatory authority related to duplicate discounts.

Mr. Costello. CMS?

Ms. Pedley. I do not know the answer.

Mr. Costello. So at this point, you do not know, and I don't -- this isn't -- I don't mean this to be an unfair question -- you don't know whether this will require legislative action in order to address the policy change required in order to drill down and prevent duplicate discounts in the managed care realm?

Ms. Pedley. We have the authority to present guidance as we have presented in our proposed guidance. In order to regulate on this issue, we would need a legislative change.

Mr. Costello. Okay. Do you have an opinion on what policy is required or legislative change is required in order to address that?

Ms. Pedley. So in the fiscal year '18 proposed budget we did propose for broad regulatory in the program in order for HRSA to better clarify our policy and to ensure that those policies

are enforceable.

Mr. Costello. Shifting gears, HRSA -- this is in -- this is in the testimony of Ms. Bliss -- HRSA worked with CMS and with Congress to obtain any needed authority to share ceiling prices with state Medicaid agencies.

Do you have sufficient statutory authority to carry out that recommendation of providing ceiling prices to state Medicaid agencies?

Ms. Pedley. The statute is very specific to allow HRSA to provide the ceiling prices to covered entities. Therefore, we would need a legislative change to provide that information to the states.

We are currently in discussion with CMS regarding some possible administrative options. But we would need up front a legislative --

Mr. Costello. Okay. So let us talk about that for a second. Let us assume that state Medicaid agencies have the ability to learn of the ceiling prices. Can you share for this subcommittee how that would positively impact the program integrity?

Ms. Pedley. So in terms of providing the ceiling to states, it would not address any issues around duplicate discounts under the 340B statute.

The ceiling prices would be in place to help inform the prices being paid for those drugs so that the states could reimburse the covered entity according to CMS rules.

Mr. Costello. Can you share with me if you were to use claims level methods to identify claims for 340B purchased drugs and HRSA's guidance were updated related to same, what would that do in terms of program integrity? Would it improve it?

Ms. Pedley. So claims level data as suggested by the OIG in their study would make transparent the specific 340B drugs that are being purchased in order to prevent duplicate discounts.

Mr. Costello. Do you believe that there is an insufficient technology platform right now in order to provide the type of transparency and accountability in order to make sure that this program operates the way that it should?

Ms. Pedley. So related to the recommendation made by the OIG for HRSA to provide more clarity regarding Medicaid managed care and how to prevent duplicate discounts we have been working very closely with CMS and we have convened many of the stakeholders in this space regarding how a solution may play out to prevent duplicate discounts --

Mr. Costello. Right.

Ms. Pedley. -- and an IT solution is very important to

that process.

Mr. Costello. So I understand -- look, there is the clarity issues. The clarity issues are -- creates -- because there is ambiguity, people can interpret things differently and thus you have different results with -- given the same set of facts.

The question I have is for the enforcement side of this, you are doing -- you are doing, I think -- less than 1 percent of all of these 340B facilities get audited, right, because of a manpower issue.

If you have the right IT in place, a lot of that sort of speaks for itself, does it not? And so the question is really geared more towards the IT side of this and if you have the right IT platforms in -- well, here is a question.

I know my time has expired. If you had the right IT platform, do you feel that you could perform more audits in the same amount of time or in the same -- could you provide more audits in a given year if you had a better IT platform?

Ms. Pedley. We have not explored IT related to whether we could conduct more audits or not. But that is something that we could -- could look into.

Mr. Costello. Well, the IT would be on the side of the reporting, right?

My time is up. I yield back.

Mr. Murphy. Mr. Carter, you are recognized for five minutes.

Mr. Carter. Thank you, Mr. Chairman. I thank all of you for being here. This is an extremely interesting subject on a very important subject as well.

I am going to start with you, Dr. Pedley, and by the way, Mr. Chairman, she is a doctor. She had a PharmD degree so as well as being a captain.

And I want to ask you -- I know that Dr. Draper mentioned earlier when she was asked a question about what could we do to improve the program she mentioned about the hospital eligibility.

But one thing that I am concerned about is about the patient eligibility. If I have heard to, Dr. Pedley, say once I've heard you say it 50 times during this hearing the statute is silent -- the statute is silent.

What do we need to do to clarify patient eligibility? Do we need to do it legislatively or can you do it?

Ms. Pedley. So the statute is silent on what entities do with their savings. It is -- it does, however, mention that it has to go to a patient and HRSA does have authority related to creating guidance on who is an eligible patient.

And we have done that. We have a guidance currently on what defines a patient from 1996 and we proposed in 2015 additional guidelines related to the definition of a patient.

However, we do not have regulatory authority to regulate on what --

Mr. Carter. That comes from Congress? So we need to do that?

Ms. Pedley. We would need a legislative change.

Mr. Carter. Okay. Count on it.

I want to go to you, Dr. Draper, because something is very important to me and that is -- and I know that Representative Collins mentioned this and it is just something that I want to get clarified here because I think that there is a lot more that goes on here than we recognize -- a lot more ramifications, if you will, and that is the GAO has released a number of reports including the report in 2015 -- in June of 2015 -- that said the financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns. You acknowledge that.

You acknowledge that you have seen a tendency for more expensive drugs to be used -- for more 340B drugs to be used in those hospitals that are eligible for this.

Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has a direct financial effect on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B drugs.

This is something that is very important. Throughout this hearing, I have heard, well, this isn't really talking about prescription drug costs.

Well, it is really talking about prescription drug costs because I can assure you this is helping to increase prescription drug costs.

One of the things that you were -- you were asked by Representative Collins is about the incentive for hospitals to buy up physician practices in order to gain that authority or in order to gain that ability to have them participate in 340B programs. Is that something that you see happening?

Ms. Draper. On our 2015 work we did find that the average number of -- I know there is been a lot of discussion about oncology practices in particular, but the number of oncology patients increased for all hospital groups but the most for 340B hospitals.

Mr. Carter. Absolutely, and the more -- the less competition we have within the healthcare system the higher the

prices are. So it is just a merry-go-round here.

You know, this is -- I am not naive enough to believe that this is the worst administered program that we have in the federal government but I think it is an example of how a program that was set out with the best of intentions can mushroom into a program that is just out of control.

Listen, it is not just -- it is not just the pharmaceutical manufacturers who aren't making as much money as they will. If I have insurance and I am being charged through the 340B program, the hospital is making money off of me.

They are making money off my insurance. They are causing me to have higher premiums in the end. It has just as much an impact on me as it has on anyone.

Even though I have insurance, it is causing insurance to go up. It's causing prescription drug prices to go up. Hospitals are right when they say, we are in compliance. They are in compliance because what is compliance?

Nobody can really define what compliance is. They can point to just about any program that they have and many of them have fine programs that they are administering.

But until we clarify -- until we make sure that we are setting the record straight on what they are supposed to be doing with

this, no one is going to be out of compliance.

Not only that, but the repercussions when we do find someone who is out of compliance there aren't even there -- there aren't even any penalties there. You have said that over and over again.

You know, there is one word that we can sum up prescription drug pricing, that we can sum up this program with, and that is transparency.

We need transparency within prescription drug pricing. We need it here. We need it in the individual markets -- transparency. Whatever happened to the ability to just buy directly from the pharmaceutical manufacturer?

Right now there has got to be all kind of discounts, and I apologize for getting on my soapbox here but I am telling you it is out of control. Until we have transparency, we are never going to get this under control.

This program is a good program but it lacks clarity and it lacks oversight, and we have got to do something about it.

Mr. Chairman, I yield back.

Mr. Murphy. Gentleman from Virginia for five minutes.

Mr. Griffith. Thank you very much, Mr. Chairman. Thank you all for being here today to testify.

Let me start with Ms. Draper. The -- by the way, it is always

nice to have you here and always love it when I see the Medical College of Virginia listed in your bio.

Ms. Draper. Great school.

Mr. Griffith. Great school. Yes, ma'am.

The -- this metric for qualifying DSH hospitals is an inpatient measurement yet 340B is for outpatient drugs. So does it make sense for us to use an inpatient metric for an outpatient program?

Ms. Draper. Well, we do believe that that is a -- that is one of the weaknesses of the DSH measure. The other is that it really -- the formula is based on covered patients and that would be those covered by Medicare and Medicaid. So, you know, there are weaknesses inherent in that measure.

Mr. Griffith. That's just another one of the many things that you all -- many stones you all have turned over and said, whoops, we can't see anything there.

Ms. Draper. Mm-hmm.

Mr. Griffith. Yes. And what is the DSH threshold? Do you know?

Ms. Draper. Well, it ranges for different hospital types. For some hospitals, it is 8 percent -- the DSH adjustment -- and for others like the general DSH hospitals it is 11.75 percent.

So that is another issue -- whether or not that is an appropriate level or not and, again, that has been pretty consistent over time with the program.

So, you know, whether that needs to be reassessed that would also be a question.

Mr. Griffith. Yes, ma'am. Thank you so much.

Captain Pedley, earlier Ms. Draper referenced that prior to the shift or the change there were 1,300 -- and if I get the numbers wrong you all correct me -- 1,300 contract pharmacies with the various entities or hospitals and now there are 19,000, if I wrote it down correctly when you said that earlier.

I got all kinds of complicated questions on that that I have been given. But why the great expansion in the number of contract pharmacies? Is it just because we lifted the cap of one or how did that happen?

Ms. Pedley. The 340B statute is silent on how these covered entities dispense and get these drugs to their patients. We had understood that through state law entities were contracting with pharmacies.

So in recognition of that, we did develop guidance in 2010 that stated if they were going to have these contract pharmacies they needed to ensure they were also complying with the statutory

requirements of diversion and duplicate discounts and we audit that information on those contract pharmacies when we go in to audit a covered entity.

Mr. Griffith. All right. I am going to get to that in a second. But I have also heard that the contract pharmacies are not only allowed to charge a dispensing fee but some of them ask for part of the savings on the drug. Is that correct or is that incorrect?

Ms. Pedley. I don't have the information on that. That's a business matter between the parties and their contract.

Mr. Griffith. But it is not prohibited?

Ms. Pedley. It is -- it is not prohibited.

Mr. Griffith. Okay. Now, let us get back to the audits. You know, you have asked the hospitals to do the audits of the contracting pharmacies.

When you go in and you check on those, obviously, you don't have enough people to check on 19,000 individual contracts with the various providers to the various entities. So have you uncovered problems and if you do, do you -- do you suspend somebody?

Do you suspend the pharmacy or do you suspend the entity if they are not doing the proper oversight of the contracting

pharmacies?

Ms. Pedley. So we have audited now over 800 covered entities but it doesn't stop there. We also do conduct the audits within those of their contract pharmacies.

So we have audited over 18,000 contract pharmacy arrangements related to those audits. We do ensure that the covered entity is providing oversight.

We sample 340B drugs dispensed from those pharmacies to ensure that they have not been diverted or have a duplicate discount, and if we do find the entity is not providing oversight of those contract pharmacies we will remove the pharmacies from the program.

Mr. Griffith. All right. Now, that raises an interesting issue. If you have done the audits, and you touched on 18,000 contract pharmacies, those audits didn't reveal to you if some of them were getting a split of the savings with the entity?

Ms. Pedley. That is a matter outside of our authority so we don't review it when we -- when we audit them.

Mr. Griffith. Okay. Would you like to have that authority? I mean, as long as we are going in to look at this, and it looks like it is a bipartisan way, should we give you that authority as well?

Ms. Pedley. We would be happy to work with Congress on a specific proposal.

Mr. Griffith. I appreciate that very much. Yes, ma'am.

All right. I might be the last one up. I have got about 40 seconds left. Anybody have something that they really want to --

Mr. Carter. I do. I do.

Mr. Griffith. I yield to the gentleman from Georgia. Oh, okay. I yield to the gentleman from Georgia, though.

Mr. Carter. Dr. Pedley, I just want to make sure and understand. Most of the problems that you see, are they with the contracting pharmacies?

Is it not true that most of the hospitals dispense these medications that are covered under 340B through their own pharmacies -- through their own providers, especially with oncology? I mean, they dispense them out of the -- out of the office.

Ms. Pedley. It is a combination of their in-house pharmacy and whether they contract with pharmacies. I think, as you mentioned, it also depends on the types of drugs. But it is a combination of both.

Mr. Carter. Thank you. I yield back.

Mr. Murphy. I yield back to myself. Okay.

That being done, we are finished with the regular committee members. We have Mr. Welch, who, I assume, by unanimous consent, is allowed to participate today.

So I recognize the gentleman from Vermont, Mr. Welch, for five minutes.

Mr. Welch. Thank you, Mr. Chairman, I appreciate it, and I thank the panel.

A couple of things. One, Mr. Chairman, with respect to transparency, I am all on board. We need that across the -- across the board.

Number two, with respect to whatever auditing has to be done in order to get our hands around this program, I am all for that and I think you are doing a good job.

But I want to bring this back to what this means to rural Vermont and I think rural America. We are talking about the audit as though these nonprofit hospitals, like North Country Hospital in Newport, Vermont, is playing some kind of game and that just ain't the case.

I mean, folks there in a hospital are working hard, not making a lot of money, and are, like, the vital community institution in Newport, Vermont.

And I know, Mr. Chairman, you have got that and, Mr. Carter, I know you have that as well. They are, like, focused on trying to get costs down. That is their focus, and that cost going down means that they can serve other people in this rural and pretty poor community.

The pharma companies, frankly, are focused on shareholder profit. That is their job. But there is a tug of war here, and whatever it is we do -- transparency, better audits -- I do not want to compromise the ability of those rural community hospitals to do the job and get the services out to folks, and that has got to be the bottom line. For me, that is the bottom line. Rural America is getting hammered and it is not just Vermont.

The other issue, Mr. Griffith, you and I worked on to some extent -- the 340B issue where these orphan drugs get mislabeled and the pharmaceutical companies take advantage of the fact that there is an orphan designation for a small component of what the use of that drug is and then they get the higher price on everything -- and I would hope that would be part of it.

But just let me tell you about the North County Hospital. If we lost the 340B designation, that would be $2.7 million a year. That is what it would -- that is what would happen to them.

When Porter Hospital in Middlebury, Vermont -- the nearest

other hospital is about 40 miles away -- when the orphan drug rule change was made that cost them $500,000. That is, like, big money in a rural community hospital.

So that is the focus here -- that I -- I think ultimately at the end of the day whatever we do in transparency and on the audit and oversight, the bottom line for me is those community hospitals.

Commander Pedley, I do want to ask you about some of the challenges that you face in regulating in this area and share your best understanding of what you believe Congress intended when it enacted the provision on 340B.

Ms. Pedley. In terms of regulatory authority, due to the district court ruling in 2014, the courts did hold that we only have explicit authority in three areas -- that is related to the ceiling price, civil monetary penalties for manufacturers, and the administrative dispute resolution process.

But we do not have that authority for all other areas of the program. We have developed guidance in those areas but we did propose in the budget to provide comprehensive regulatory authority for HRSA to oversee around.

Mr. Welch. All right. Now, on the current application of the exclusion that has an effect on access to products in the

340B, is that something you have the ability to track?

Ms. Pedley. I am sorry. Did you say orphan drugs?

Mr. Welch. Yes.

Ms. Pedley. So related to orphan drugs, there was an amendment in the statute in 2010 that the newly eligible hospitals, mainly, rural hospitals, are unable to purchase orphan drugs under the program at the 340B discount.

We -- there was a lawsuit involving HRSA's interpretation related to that matter. Currently, under the program the policy is that the manufacturer does not have to provide the 340B discount to those newly eligible hospitals for drug --

Mr. Welch. All right. Thank you.

Let me ask -- Ms. Draper, it is very nice to see you. Thank you.

Is the -- on the orphan drug issue, and the specific question of how many drugs have been recently pulled out of the program, is that something the GAO has reviewed?

Ms. Draper. We have not reviewed that.

Mr. Welch. Is that information -- that information would be helpful and important, given the anecdotal evidence about real access. Is that something you would agree with?

Ms. Draper. I think anything that would help improve the

transparency and integrity of the program would be good.

Mr. Welch. Okay. Thank you.

I thank the panel. Mr. Chairman, thank you for allowing me to participate.

Mr. Murphy. Thank you very much.

That concludes this committee hearing. I would like to thank all the witnesses and members who have participated in today's hearing.

I would remind members that they have 10 business days to submit questions for the record, and I ask that the witnesses all agree to respond promptly to those questions.

Hearing nothing else, the Committee is adjourned.

[Whereupon, at 12:31 p.m., the Subcommittee was adjourned.]