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OPPORTUNITIES TO IMPROVE THE 340B DRUG PRICING PROGRAM

WEDNESDAY, JULY 11, 2018

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Michael Burgess [chairman of the subcommittee] presiding.

Members present: Representatives Burgess, Guthrie, Barton, Upton, Shimkus, Latta, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden(ex officio), Green, Engel, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, Schrader, Kennedy, Cardenas, Eshoo, DeGette, and Pallone (ex officio).

Staff present: Jennifer Barblan, Chief Counsel, Oversight

& Investigations; Mike Bloomquist, Staff Director; Adam Buckalew, Professional Staff Member, Health; Daniel Butler, Staff Assistant; Karen Christian, General Counsel; Margaret Tucker Fogarty, Staff Assistant; Adam Fromm, Director of Outreach and Coalitions; Caleb Graff, Professional Staff Member, Health; Brighton Haslett, Counsel, Oversight & Investigations; Ed Kim, Policy Coordinator, Health; Caprice Knapp, Fellow, Health; Drew McDowell, Executive Assistant; Mark Ratner, Policy Coordinator; Austin Stonebraker, Press Assistant; Josh Trent, Deputy Chief Health Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Jeff Carroll, Minority Staff Director; Evan Gilbert, Minority Press Assistant; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Rachel Pryor, Minority Senior Health Policy Advisor; Samantha Satchell, Minority Policy Analyst; and Andrew Souvall, Minority Director of Communications, Outreach and Member Services.

Mr. <Burgess.= Let me ask all of our guests to take their seats.

The Subcommittee on Health will now come to order. I now recognize myself five minutes for the purpose of an opening statement.

And this morning, we are convening today to learn about opportunities to improve the 340B Drug Pricing Program. This hearing builds on previous work done by the Committee on Energy and Commerce and the Oversight and Investigations Subcommittee in this Congress and the last Congress.

The Subcommittee on Oversight and Investigations has held hearings on aspects of the program over the past several years. That subcommittee also issued a comprehensive oversight report on the program earlier this year.

As we start this morning, it is important to emphasize that members of this committee both sides of the dais each understand the importance of the 340B program to safety net health care providers and many communities large and small across our nation.

The program enjoys strong bipartisan support and it helps many health care providers give care to vulnerable Americans. At the same time, it is worth noting that Congress established the 340B Drug Pricing Program over 25 years ago through the enactment of the Veterans Health Care Act of 1992. So just for purposes of references, the Cold War was still going on or right at the end of the Cold War, right at the beginning of the internet

age.

Certainly, we can all agree that our health care system has evolved significantly since that time, and it is reasonable to review how the program is working with today's realities.

The 340B program is a success. At the same time, there are ways in which the program's current operation raises valid concerns. Multiple reviews by nonpartisan auditors have identified challenges within the program's current operation and oversight.

For example, we know that the Health Resources and Services Administration, the agency charged with oversight of the 340B program, lacks some key regulatory authorities.

Additionally, the Health Resources and Services Administration has delayed multiple program regulations repeatedly without a compelling and clear rationale.

We have learned that, in 2016, HRSA audited less than 2 percent of total entities participating in the program. There has also been uncertainty about where the savings from this program are going and how certain covered entities may be utilizing the revenue generated from the program.

The newest concern with the program's oversight has been highlighted by the Government Accountability Office. Today, we will hear from Government Accountability Office, who recently released a ground-breaking report on contract pharmacies. We all know that the number of contract pharmacies has grown rapidly

since HRSA issued guidance in 2010 that allowed covered entities to contract with multiple pharmacies.

Since then, the number of pharmacies that covered entities have contracts with has increased from 1,300 to over 20,000 last year.

I think Government Accountability Offices raises a number of serious challenges with HRSA's current oversight of contract pharmacies.

I think we all should be concerned by the fact that many of the covered entities that the GAO reviewed do not have in place a policy that ensures uninsured low-income patients are not hit with a big hospital bill for their outpatient drugs.

Certainly, concern about health care costs, drug costs, hospital costs, other costs, is an ongoing concern. I have a discussion draft today which outlines one possible solution to this issue--to ensure that covered entities stretch resources through the 340B program while making certain that some of the most vulnerable patients see financial benefit.

Overall, I found this is an eye-opening report and I hope we will each review it carefully as we seek to ensure it is effectively implemented.

I appreciate that members here approach the 340B program with different backgrounds and a variety of perspectives. I trust we all share the same goal of ensuring that this federal program operates with integrity and that the program is

appropriately transparent and accountable to patients.

Ultimately, today's hearing is an opportunity to engage in a dialogue and exchange ideas about what may be the best way to move forward with improving the accountability and transparency of the 340B program.

In addition to what I anticipate will be a lively debate, we will be evaluating more than a dozen legislative proposals that address some of the concerns that members have.

These bills, whether drafts to generate discussion or introduced bills, are members' ideas from both sides of the dais to improve the 340B program.

I support several of the policies outlined in these bills. Others have caused me to have some questions. But we also need to hear from the wide range of stakeholders impacted by this program.

We do want to welcome Debra Draper, the director of Health Care at the Government Accountability Office. Thank you for your time this morning and welcome to our hearing and want to thank you in advance for your willingness to testify before us and answer our questions.

I also want to give a welcome to Dr. Fred Cerise, the CEO of Parkland Hospital in Dallas. I wasn't born at Parkland Hospital but I spent the better part of my life there, or it seemed like the better part of my life for four years, during my internship and residency.

I also want to welcome Dr. Debra Patt, vice president of Texas Oncology. Both of those witnesses will be on our next panel, as well as Dr. Charles Daniels from California.

Today's hearing promises to offer a thought-provoking--a number of thought-provoking ideas to inform our next steps to improve the 340B program. Thanks to each of our witnesses.

I now yield to Mr. Green of Texas, the ranking member of the subcommittee, five minutes for an opening statement, please.

Mr. <Green.= Thank you, Mr. Chairman, for holding today's hearing. I thank all of our witnesses for coming here to testify on this important issue.

The 340B Drug Pricing Program was created by Congress in 1992. It helps safety net providers care for their most vulnerable patients and afford drugs that would otherwise be out of reach.

Since its creation in 1992, stakeholders and policymakers have debated the intended purpose and appropriate scope of the 34B program.

And Mr. Chairman, I am glad we are having this hearing. Since I've been on the subcommittee this is our first, I think, oversight hearing on 340B, and I agree with you. It was created in 1992. I didn't get here until 1993, so I don't remember us having an oversight hearing on this.

But I think we ought to share how important the 340B program is needed to stretch scarce federal resources as far as possible

to reach more eligible patients and provide more comprehensive services.

The law does not specify how savings incurred from 340B discounts must be used by covered entities, a point that's highlighted both by the supporters and opponents of the program.

GAO studies have confirmed that large and covered entities use these savings to provide more care to more patients, including medications that otherwise would be unaffordable to those who serve.

For example, the Harris Health System--our public hospital system in the Houston area--primarily serves the indigent population of Harris County, Texas, saves $90 million a year through its participation the 340B program.

Harris Health uses the savings from the program on patient care services which include the cost of treatment, administration, management of services and facilities, and improves access to health--quality health care for our community.

We also have MD Anderson Cancer Center, Texas Children's Hospital, and Memorial Hospital Systems who benefit from that. Harris Health System and the other safety net hospitals across the United States provide access to cost-effective quality health care delivered to their patients regardless of their ability to pay.

There will always be more patient need than capacity to provide and the community's access to care depends upon the

contribution of every possible source of funding, including 340B.

The 340B program has grown significantly in recent years and oversight is appropriate. Our uninsured has grown over the last number of years, too.

According to the GAO, the number of 340B entities have nearly doubled in the past five years to over 38,000. Similarly, the number of contract pharmacy agreements have grown dramatically since 2010 from 1,300 to 18,700 in 2017.

It's important that Congress protect the integrity of 340B and ensure the program will continue to serve low-income Americans in need of care.

I look forward to hearing what the GAO found in its latest investigation and from our stakeholder witnesses on the importance of 340B.

I think we can always improve the program. I'd like to add this record of statement from the American Hospital Association and the Association of American Medical Colleges in today's hearing.

Mr. <Burgess.= Without objection, so ordered.

[The information follows:]

**********INSERT 1**********

Mr. <Green.= Thank you, Mr. Chairman, and I yield the remainder of my time to my colleague, Congresswoman Matsui from California.

Ms. <Matsui.= Thank you very much for yielding.

I hope we can all agree that the 340B discount drug program is incredibly vital to low-income and vulnerable communities.

Hospitals and clinics serve our communities every day. They are on the front lines of the opioid crisis right now and this program supports that work.

Unfortunately, there seems to be some misunderstanding about the original intent of the program. 340B was intended as a creative and flexible way to allow community providers to stretch scarce resources without using taxpayer dollars.

It was never intended to be a drug discount program directly for patients. Rather, it is discounted to providers so that they may better serve patients.

For example, Ryan White HIV Clinics can use the savings to truly address the social determinants of health surrounding medication adherence. That is not always direct medical care.

Instead, it is a public health approach that addresses the barriers that keep people from taking their medication appropriately.

I have concerns about some of the bills and drafts we are discussing today. No one has a problem with the concept of transparency. I am afraid that the true purpose of this

legislation is just to narrow the scope of the program rather than to increase transparency.

There is also very little discussion about drug manufacturer transparency in the program despite the fact that only a handful of audits have been conducted on manufacturers and the civil monetary penalties for noncompliance have not been implemented.

The 340B program keeps drug prices lower for providers serving low-income and vulnerable patients. Changing the 340B program would do nothing to reduce high drug prices, as some claim.

It is important to recognize a good thing when you have it, and the 340B Drug Discount Program is exactly that, and that's why I authored H.R. 6071, the Serve Communities Act, which will codify the program's true intent, improve program integrity, and further extend it to mitigate the opioid crisis.

I look forward to continuing to work with the committee to support the services provided by the community health providers, and thank you, and I yield back.

Mr. <Burgess.= The gentleman yields back?

Mr. <Green.= Yes.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman from Oregon is now recognized, the chairman of the full committee, Mr. Walden, five minutes for an opening statement, please.

Chairman <Walden.= Thank you very much, Mr. Chairman, for holding this legislative hearing to examine ideas to improve the

340B program. Since its creation by Congress more than 25 years ago, the 340B program has helped provide lifesaving medicines that reduced prices to certain safety net health care providers.

Now, through this program, many providers have been able to reach more patients, serving more uninsured and underinsured patients due to the savings this program enables.

The Health Resources and Services Administration estimates that in 2015 covered entities saved about $6 billion--$6 billion--on 340B drugs through their participation in the program.

For some participating health care providers known as covered entities, though, this program and the savings it generates are critical not just to their mission to help patients, but also it undergirds their financial viability and their ability to keep their doors open.

And I've met with hospitals. I've met with health centers in Oregon, including those in Bend and Germiston, among other locations, and they've told me about how they are using 340B savings to increase access to health care for the underserved. So it is really an important program.

But it's important to note that a lot has changed since the program was created. The number of unique hospital organizations participating in the program has nearly quadrupled in just five years, from 3,200 participating hospitals in 2011 to 12,148 in October of 2016. So quadrupling in five years.

While the actual number of 340B contract pharmacy arrangements is unknown because it is not tracked, the Government Accountability Office has informed us that 1,645 covered entities had a total of 25,481 registered contract pharmacy arrangements.

GAO warns this sprawling complex of arrangements increases the likelihood of covered entities being out of compliance with federal law.

GAO's latest report follows others from nonpartisan auditors expressing concerns about a variety of issues that are a challenge to the integrity and the accountability of the program.

For example, both HHS' Office of the Inspector General and GAO have identified the lack of a clear definition of the 340B patient as a structural challenge to HRSA having clear rules of the road.

We've also heard serious concerns from stakeholders. Because the 340B program does not specify how program savings must be utilized by a covered entity, many have questioned whether or not all covered entities are sufficiently transparent with how their participation in the program ultimately benefits patients.

Others suggest this program is in need of a tune up. Regulations need to be finalized, rules of the road need to be made clear, audits need to be more comprehensive, and enforcement needs to be more consistent.

There are also reports following the committee's two-year investigation by our own Oversight and Investigations

Subcommittee. That report detailed a lack of oversight, a lack of reporting requirements, and a lack of reliable data.

Earlier this week, HHS Secretary Azar spoke about the department's plans to move forward with finalizing regulations that have been repeatedly delayed.

I am encouraged by his comments, but also know there is more HHS should do to improve the oversight and operations of this program.

Our committee has an important responsibility to carefully evaluate a number of ideas from members on both sides of the aisle about how to improve this program.

I fully expect my colleagues will bring different views and ideas forward in examining these bills to improve the 340B program. I hope we will examine the bills from the shared premise that we all want to ensure some of our most vulnerable patients receive the care that they need and that they deserve.

Finally, I would like to highlight one bill in particular--that's H.R. 6273. It's a bill I've introduced along with Representative Mimi Walters.

This bill would require 340B DSH hospitals that have an emergency department to establish a plan for getting victims of sexual assault access to a Sexual Assault Forensic Examiner facility so they can be properly examined and treated by a qualified health provider.

I'd also like to highlight Mission Health Systems in North

Carolina, who told us how they are already using their 340B savings to provide care and examinations to sexual assault victims.

And, Mr. Chairman, I request that this letter from Mission Health Systems in North Carolina be entered into the record.

Mr. <Burgess.= Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 2**********

Chairman <Walden.= So I'd like to thank our two panels of witnesses for being with us today. I appreciate your feedback on these pieces of legislation.

We know we have a lot to discuss and will learn a lot by your testimony as we work to strengthen this program in a bipartisan manner.

And with that, Mr. Chairman, I'll yield back and give the caveat that I think we have multiple hearings going on and so I have to jet between them and a meeting over in the Capitol. But we do appreciate your participation in this. We want to get this right and modernize this program.

Thank you, Mr. Chairman. I yield back.

Mr. <Burgess.= Thank you, Mr. Chairman.

The chair now recognizes the gentleman from New Jersey, Mr. Pallone, the ranking member of the full committee, five minutes for an opening statement, please.

Mr. <Pallone.= Thank you, Mr. Chairman.

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

Congress created this program with the intention of helping health care providers expand their capacity to serve low-income, uninsured, and under insured patients in their communities.

By purchasing drugs at a discounted rate, 340B providers

can stretch resources to provide more comprehensive health services and, after all, many of these drugs have experienced dramatic prices increases over the years.

So I commend the work that our hospitals, community health centers, and all our safety net providers do and, make no mistake about it--they do a lot.

What I do not support is the process for this hearing. It is not thoughtful, it is not bipartisan, and is it not productive.

Having one hearing for a 65-page GAO study and 14 bills, many that are drafts that were given to us just days ago is ridiculous. We should be working closely with each other and with stakeholders on such an important issue.

First of all, the GAO study should have a hearing on its own. Second, we should have had actual witnesses who are part of the 340B program or who run the program that can give their expert opinions on the consequences and effects of these policies.

Today's hearing is counter to the purpose of why we hold legislative hearings at all. Democrats are, clearly, interested in working to strengthen the 340B program, but this is certainly not the approach I would take to find bipartisan consensus.

In the past, I've worked in a bipartisan fashion to try to address the concerns from stakeholders on all sides of this issue in a balanced and measured fashion to strengthen and support the mission of 340B.

But it's simply too difficult to be appropriately

substantive with this many items before us in so short a time frame.

That said, let me comment briefly on some of the bills. I want to commend Representative Matsui for her leadership on H.R. 6071, the Serve Communities Act. This bill would ensure balanced oversight of both 340B-covered entities and manufacturers.

It would also ensure that HRSA implements the regulations they were required to issue eight years ago and includes many other provisions that will strengthen the program.

There are also bills that would enhance 340B operations and give HRSA more resources and authority to operate the program and collect covered entity and manufacturer information.

This is an important--this is an example of an important area where we could have a realistic conversation about strengthening the 340B program had this process looked a little differently.

As the investigation of our Oversight and Investigations Subcommittee found, the 340B program is working as intended. Savings on the cost of outpatient prescription drugs makes it possible for these providers to shift resources to services that benefit the entire community--services such as offering primary care clinics at little to no cost--delivering medication to patients with limited transportation and maintaining a traveling children's dental clinic.

It was clear from the responses we received from the 340B providers they are using their savings to serve the community and Congress should commend and support these efforts.

Limiting the 340B program would severely undermine covered entities' ability to support this critical work. That's why I do not support legislation that would curtail or restrict the program.

Legislation like H.R. 4710 that includes a two-year moratorium on new hospital enrollment in the program is unnecessary and unfounded. Or the Protecting Safety Net 340B Hospitals Act, which would not actually protect anyone at all.

Instead, this bill would lead to the termination of 573 DSH hospitals. That's 51 percent of all DSH hospitals currently enrolled in the program.

I would note that these hospitals provided, roughly, $10.8 billion in uncompensated and unreimbursed care. If this bill ever became law, nearly 75 percent of our states will see 50 percent or more of their DSH hospitals cut from the program with five states having all the DSH hospitals cut from the program.

And these types of bills are not about improving or strengthening the 340B. They are about gutting the program, which I, obviously, will not support.

Instead, I remain dedicated to finding ways to strengthen the 340B program and ensure that it continues to fulfill its vital mission.

I yield back, Mr. Chairman. Thank you.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

This concludes member opening statements. All members are reminded that their opening statements will be made part of the record.

I certainly want to thank our witness for being there this morning and taking time to testify before the subcommittee.

So we have two panels of witnesses and each witness will have an opportunity to give an opening statement. This will be followed by questions from members.

On the first panel today we will hear from Ms. Debra Draper, the director of Health Care Team, the United States Government Accountability Office. We appreciate you being here with us this morning, Ms. Draper.

You're recognized for five minutes for the purpose of your opening statement, please.

?STATEMENT OF DEBRA DRAPER, DIRECTOR, HEALTH CARE TEAM, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

= Ms. <Draper.= Chairman Burgess, Ranking Member Green, and members of the subcommittee, thank you for the opportunity to be here today to discuss our recently issued report on the use of contract pharmacies in the 340B program.

We are going to be projecting some slides to go along with my opening statement so that--to provide some illustrative examples.

So the 340B program requires drug manufacturers to provide discounts on outpatient drugs to certain hospitals and federal grantees, also known as covered entities, who have their drugs covered by Medicaid.

A covered entity typically dispenses 340B drugs through pharmacies, either in-house pharmacies through contracts with outside pharmacies, or both.

In March 2010, HRSA lifted the restriction limiting the use of contract pharmacies, allowing any covered entity to contract with an unlimited number of pharmacies.

As a result, the number of contract pharmacies increased significantly from 1,300 to 20,000. For our report, we examined a number of issues.

We first examined the extent to which covered entities contract with pharmacies to distribute 340B drugs.

We found that about a third of the more than 12,000 covered entities in the program had at least one contract pharmacy. A number of contract pharmacies range from one to 439 with an average of 12 per covered entity.

Compared to other covered entity types, hospitals will more likely have contract pharmacies and have a larger number of them.

The distance between covered entities and their contract pharmacies range from zero to more than 5,000 miles with a median distance of 4.2 miles.

Second, we examined the financial arrangements that covered entities have with contract pharmacies and third-party administrators related to the dispensing of 340B drugs and program administration.

Of the 30 contracts we review, we found that covered entities generally pay their contract pharmacies a flat fee ranging from $6 to $15 per 340B prescription.

Some covered entities paid additional fees based on a percentage of revenue. We also found that covered entities reportedly paid their third-party administrators using one of two main payment methods--either per prescription process or per contract pharmacy.

Third, we examined the extent to which covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income uninsured patients.

We found that 30 of the 55 covered entities responding to

our questionnaire reported providing discounts at some or all of their contract pharmacies, with federal grantees more likely than hospitals to provide discounts.

And finally, we examined HRSA's efforts to ensure compliance with 340B program requirements at contract pharmacies.

We found that, first, HRSA does not have complete data on all contract pharmacy arrangements, which is critical to informing its oversight efforts, including audits of covered entities.

Specifically, HRSA does not require covered entities to specify which of its sites have a contractual relationship with each pharmacy.

Second, HRSA's audits identified a number of issues at contract pharmacies. However, the audits understate the extent of the noncompliance with a 340B program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries because they do not assess the potential for duplicate discounts in Medicaid-managed care where the majority of beneficiaries are enrolled.

HRSA requires covered entities with noncompliance issues identified during audits to assess the extent of the noncompliance, it does not provide guidance as to how these assessments should be made nor does it review the methodology used.

Fourth, HRSA does not require most covered entities to

provide evidence that they have taken the necessary corrective actions and are in compliance with program requirements prior to closing an audit, relying instead on entities self-attestation of compliance.

And, lastly, HRSA's guidance on contract pharmacy oversight lacks specificity, providing covered entities considerable discretion on the scope and frequency of their oversight practices with some performing very minimal activities.

In conclusion, we made several recommendations for HRSA to strengthen its oversight of the use of contract pharmacies in the 340B program.

HRSA did not concur with three of these, stating that implementation would be burdensome for covered entities and the agency.

We disagree and believe that the implementation of these recommendations is critical to improving the integrity of the program.

There are also two additional points that I wanted to make. First, it is critical that HRSA ensure that it has the necessary oversight, infrastructure, and resources when making major programmatic changes such as lifting the restriction on the number of contract pharmacies.

And second, it is essential that HRSA optimize the value of its oversight activities including audits of covered entities conducted through a contract costing nearly $4 million annually.

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

[The prepared statement of Ms. Draper follows:]

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

Mr. <Burgess.= Our thanks to our witness this morning. We'll move to the question and answer part of the hearing and I will recognize myself five minutes for questions.

So I have the report that the GAO published and the recommendations for executive activities. Let me just ask you, on the issue of the contract pharmacies, is there any evidence that--and this program was expanded, correct, in early March of 2010?

Your microphone may need to be on.

Ms. <Draper.= Prior to March 2010 an entity was allowed to have a contract pharmacy if it did not have--one contract pharmacy if it did not have an in-house pharmacy.

After that, the restriction was limited so that entities could contract with an unlimited number of pharmacies.

Mr. <Burgess.= So do we have evidence that increasing the number of contract pharmacies has happened in 2010? Do we have evidence that more patients now are reached with the increases in the contract pharmacies as they were expanded in 2010?

Ms. <Draper.= Yes, that's difficult to monitor. But, I mean, HRSA would say that one of the reasons for lifting that restriction was to increase access points for pharmacy for patients.

We also know that there's--you know, it does create some oversight issues around--a rapid increase in the number of contract pharmacies as we know from the audits that a lot of the

issues around diversion are really related to diversion at contract pharmacies.

So of the 813 audits that have been conducted, there were 380 incidents of diversion found in those audits and 249 were at contract pharmacies.

Mr. <Burgess.= And is it a concern that when the expansion occurred in 2010 there was not a commensurate increase of resources for HRSA to be able to adequately monitor that?

Ms. <Draper.= For HRSA, the group that oversees the 340B program or administers the program is a very small group of--it's a very small group and they really haven't had any major increases in staffing related to--not commensurate with the increase in the number of covered entities and contract pharmacies through the years.

Mr. <Burgess.= So is it safe to say they're still at 2010 levels as far as their funding or their resources?

Ms. <Draper.= I don't believe they're at the 2010 level but they're not far from that.

Mr. <Burgess.= Okay.

Ms. <Draper.= So they made some increases but they're still a very small shop.

Mr. <Burgess.= So of your seven recommendations--and, again, thank you for providing those--recommendation number two is one that, certainly, caught my eye about the duplicative discounts under Medicaid-managed care.

So, obviously, there are unintended consequences of not having the guidance that has been recommended. Are there currently any incentives to encourage states to oversee the 340B program in their managed care environment?

Ms. <Draper.= Well, currently, there is no--HRSA has not issued guidance on how to handle duplicate discounts in Medicaid-managed care.

Now, there are--60 percent of the Medicaid drug spending is--currently in Medicaid is in the managed care program. Seventy percent of the Medicaid prescriptions are written for managed care--Medicaid-managed care beneficiaries.

So this is where the bulk of the beneficiaries are enrolled and a large--where the greatest level of activity is located in Medicaid-managed care, and when we were doing our audits we did find evidence that there was--you know, there's evidence of duplicate discounts.

In one of the audit files we found there was a letter from a state that recognized that there was--duplicate discounts were found in Medicaid-managed care, and because there's really no guidance at this point from HRSA, it's not clear to covered entities how they're supposed to handle that and it also creates, I think, issues for manufacturers who--you know, it puts them in the middle of whether they go after the state or the covered entity to regroup there to reclaim the duplicate discount.

So it creates a lot of different issues.

Mr. <Burgess.= And just to be clear, when we are talking about duplicate discounts we are talking about discounts in the 340B program and discounts in the Medicaid drug rebate program?

Ms. <Draper.= That's correct. And it is a prohibition in the 340B program that the covered entities are not to subject manufacturers to duplicate discounts.

Mr. <Burgess.= But there is a concern that it may be happening and it would not be intuitively obvious to the casual observer because of the structure of a Medicaid-managed care contract?

Ms. <Draper.= I would say it's unclear to the extent that it's happening. I know that it's happening to some extent and I think that entities that we talk with express concern.

You know, it's anecdotal evidence but they express concern about, you know, the extent to which this is happening and how they're supposed to, you know, address it.

Mr. <Burgess.= I can see how it could be completely unintentional if you have a capitated contract with an MCO and you also have a discount how--how do you allocate where that--whether that discount is coming from a 340B program or the Medicaid drug rebate program.

So I can see how just the bookkeeping could be difficult and an unintentional violation could occur. But do you think it possibly is more than that?

Ms. <Draper.= It's hard to say. I think that, you know,

that was why we made a recommendation. HRSA will need to work with CMS to provide guidance on how to deal with, you know, potential duplicate discounts in Medicaid-managed care.

It has not yet happened and I think it's something that's really important that that needs to happen and, as you noted, that was one of our recommendations.

Mr. <Burgess.= And I agree with you.

That concludes my questions. Mr. Green, you're recognized five minutes for questions, please.

Mr. <Green.= Thank you, Mr. Chairman.

Dr. Draper, thank you again for your excellent work on this issue and I am particularly interested in the discounts provide for drugs to low-income and uninsured patients.

While 340B is not a program based on actually giving discounted drugs directly to patients, I think it still wouldn't sit right with most people to think about anyone gaining revenue from people that need medications and cannot afford them.

Regarding three of the GAO recommendations, HHS disagrees, says that they don't have enough resources, and two, the requirements would be significantly burdensome on covered entities, especially smaller providers such as federally-qualified health clinics.

In your report did you examine whether that's a major hospital system or a community health center, the difference in the--in how they would comply with that?

Ms. <Draper.= So they disagree with three of our recommendations, one of which was the extent--well, the first one was to register all their contract pharmacy arrangements so that would mean that they would register each or have some record of each--besides the parent entity, each child site as well that has a relationship with each pharmacy. They said that that would be burdensome.

Our point was that they already require that when they register their--when they register their entities. So we didn't feel like that was really excessively burdensome to ask to be done.

So that was one issue that they had. The other issue that they didn't comply with or didn't concur with is that looking at the--when we talk about the extent of noncompliance, looking at the methodology used and the extent of noncompliance.

So what they talked about was that, you know, they thought that that would be administratively burdensome. The entities--when there are issues of noncompliance that come up they have to do a corrective action plan.

So, really, that information is detailed and what we were asking for is just additional information about specific methodology and how that--how that was reviewed. So, again, we didn't feel like that was excessively burdensome.

Mr. <Green.= Didn't some covered entities then proactively note some of the other ways they care for patients?

Isn't it true that some covered entities that do not provide discounts on 340B drugs at their contract pharmacies actually, for instance, provide free or discounted prescriptions elsewhere and oftentimes broader free medical care?

The GAO's report on 340B contract pharmacies was published last month. HHS agreed--disagreed again with those recommendations and, again, it seemed like they did a blanket rejection of the recommendations.

But I think our subcommittee and the committee can decide what needs to be done. But, again, HHS is the one who deals with that on an everyday basis. So we need to--

HHS stated that many of the GAO's recommendations impose a significant burden on covered entities, especially smaller entities which are resource constrained. That's why I said it's different between a five-hospital system and federally-qualified health clinic that may only have one facility or maybe two or three and on a much smaller scale.

Ms. <Draper.= And to answer that partly as well is that most of the covered entities that have child sites they're going to be the larger entities. So it's going to be hospitals and federally qualified health centers.

Most of your smaller grantees are not going to have child sites. So, really, these are larger entities that most likely have the capacity and the capability to, you know, have the resources to do what we are asking to do.

Mr. <Green.= Since HRSA implemented a systematic approach to auditing covered entities in 2012, has oversight of the 340B program improved?

Ms. <Draper.= Well, the implementation of the audits came as a result of our 2011 report and recommendation. So we believe that the audits have been beneficial.

I think one of our concerns is that, you know, in 2012--so for the last several years they have audited 200 entities annually and that represents about 1.5 percent of total covered entities.

So the pace of the audits are not keeping--it's not keeping pace--the number of audits are not keeping pace with the growth in the number of covered entities.

Mr. <Green.= You believe--

Ms. <Draper.= They have found quite a number of issues with diversion, duplicate discounts, and also some entities not providing the oversight of the contract pharmacies as they're supposed to.

Mr. <Green.= Do you think as part of the oversight for 340B would improve if Congress appropriated additional funds for HHS for those--specifically for those purposes?

Ms. <Draper.= Well, you know, it's difficult to say but my thought is that probably resources are an issue about why the number of audits haven't been expanded.

They have a contract with--that they've had in place for the last two years for a contractor to conduct the audits. So,

you know, they do have limited resources. So I would expect that it's probably something to do with the resource limitation around, you know, whether or not they're able to increase their oversight activities.

Mr. <Green.= Thank you, Mr. Chairman.

Mr. <Burgess.= The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Kentucky, vice chairman of the Health Subcommittee, Mr. Guthrie, five minutes for questions.

Mr. <Guthrie.= Thank you. Thank you, Chairman.

Thank you, Ms. Draper, for being here. And you touched on some of this in your testimony but I will give you a chance to kind of expand.

So in your testimony you stated that the number of contract pharmacies increased from 1,300 in 2010 to approximately 20,000 in 2017.

Why do you think the number of contract pharmacies increased dramatically within this time frame, particularly in the last couple of years?

Ms. <Draper.= This really has to do with HRSA lifting the restriction about having--you know, lifting the restriction to now allow covered entities that have an unlimited number of contracts with pharmacies--outside pharmacies.

Mr. <Guthrie.= Okay. And then bases on your knowledge of

these types of contracts between covered entities and pharmacies, do you think HRSA should regulate how contract pharmacies are paid?

Ms. <Draper.= Well, HRSA has no legal authority over that and they will tell you that it is a private business decision between the covered entity and both contract pharmacies and in cases where they use a third party administrator as well as with third party administrators.

Mr. <Guthrie.= Well, yes, I understand they don't have any legal authority. But that would be something we would look to address. Do you have an opinion on that, whether we--it should be regulated by HRSA?

Ms. <Draper.= Well, that's an interesting question because in their comments to us when they were responding to our report, they were very concerned. We looked at the authority contracts and looked at the financial arrangements between covered entities and their contract pharmacies and third party administrators, and HRSA is very concerned about us publishing the payment rate information.

That information had never been made public and they were concerned about it being disruptive to the drug pricing market and would cause fluctuations in the prices charged for covered entities.

We disagree because the sample size was pretty small--30. But, you know, I think it would be something that, you know,

probably would need to be addressed if you're thinking about more broadly making that more transparent across all contracts.

Mr. <Guthrie.= Well, in your study, did you--did you notice or see or could you identify any best practices and payments that probably should be adopted across the board?

Ms. <Draper.= Well, we saw--we saw a wide variation. So it's really difficult to say, and we really didn't look at the impact. So the--we looked at the financial arrangements but not what--at the back end what were the most effective.

Mr. <Guthrie.= Okay. Well, thank you, and that does conclude my questions. I know I have two and a half minutes. I will yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from California, Ms. Matsui, five minutes for questions, please.

Ms. <Matsui.= Thank you, Mr. Chairman.

Dr. Draper, GAO asserts in the report that the study was conducted in part because a number of pharmacies that covered entities have contracted with has increased a substantial amount since 2010.

I know we've been having a discussion. Now, critics do cite similar statistics, saying that the program has exploded because the number of covered entities had increased since 2010.

Now, I would just like to set the record straight that

Congress intentionally expanded the 340B program in the Affordable Care Act.

We recognize the success of the program in allowing hospitals and clinics to better serve their communities and we extended that success to rural hospitals, which I believe is really very important.

I am going to talk some about the audits here. Much of this GAO report uses data recovered from HRSA audits of covered entities.

Dr. Draper, is that correct? Yes or no.

Ms. <Draper.= Yes. Our report talks about covered entities audits.

Ms. <Matsui.= Okay. How many audits did you find HRSA conducted on covered entities from 2012 to 2017?

Ms. <Draper.= There were 831 conducted in the last few years. It's been 200 each year.

Ms. <Matsui.= So a total of how many?

Ms. <Draper.= Out of 12,050. That's about 1.6 percent, 1.5 percent of total covered entities.

Ms. <Matsui.= Okay. So in your work at GAO studying the 340B program, have you received any audits of drug manufacturers in the program?

Ms. <Draper.= We have not done that work, no.

Ms. <Matsui.= And why is that?

Ms. <Draper.= We've not had a request or, you know, a mandate

to look at that issues.

Ms. <Matsui.= So we should request that it be done if we wanted to have that done. Is that correct? Because my records show that there were less than 20 audits of drug manufacturers in the history of the program.

Ms. <Draper.= Yes, actually there were--I think Dr. Pelley said at a recent hearing that there have been 12 conducted to date. There was one in 2015 and five in each of the years 2016 and 2017 and I think they're at or doing five this year.

And according to the website, there have been no findings related to--you know, they've had no findings on those manufacturer audits.

Ms. <Matsui.= So--

Ms. <Draper.= Out of 600 manufacturers, about .5 percent.

Ms. <Matsui.= Okay. So we have had many audits on the covered entities but very few or nothing on the drug manufacturers then?

Ms. <Draper.= Well, compare 831 versus, I guess, 12 have been completed.

Ms. <Matsui.= Yes. Right. Okay.

Does HRSA required that drug manufacturers take corrective action if found in noncompliance with program requirements?

Ms. <Draper.= That's correct.

Ms. <Matsui.= Okay. Since GAO's 2011 recommendations, has HRSA taken steps to improve its oversight of covered entities

in the program including a systematic approach to conducting audits of covered entities?

Ms. <Draper.= Yes.

Ms. <Matsui.= Okay. Has HRSA taken any steps to improve oversight of drug manufacturers in the program?

Ms. <Draper.= I can't answer that. We haven't looked at that issue.

Ms. <Matsui.= Okay. And I understand that you have not studied this or made any recommendations, and I would think that we should plan to have more oversight on the drug manufacturers if we are going to be looking at the contribution of drug manufacturers and also the use from the covered entities.

Ms. <Draper.= That may be some potential work that we do in the future.

Ms. <Matsui.= Okay. Great.

Mr. Chairman, I would like to ask unanimous consent to submit a few letters for the record. The first is a letter to leadership from a long list of patient groups that emphasizes the importance of the 340B program for people living with diseases like hemophilia, HIV/AIDS, epilepsy, hepatitis, mental illness, lupus, and more, and I also have letters from 340B health a long list of doctors from across the country and the American Society of Health System Pharmacists, again, emphasizing the importance of the program.

Mr. <Burgess.= Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 4**********

Ms. <Matsui.= Thank you, and I yield back.

Mr. <Burgess.= The chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentleman from Texas, vice chairman of the full committee, Mr. Barton, five minutes for questions.

Mr. <Barton.= Thank you, Mr. Chairman, and thank you for holding this very important hearing.

You know, there's a saying that a lot of us use quite a bit. It's called no good deed goes unpunished. The 340B program was set up to be a really good deed, and word spread and now, in my opinion, that program is being abused.

In the report that GAO did, they claim that the number of hospitals that are participating in 340B is up to 12,722 and it's tripled in the last four years.

The report further states that that's about 40 percent of the hospitals. But according to the American Hospital Association, there are only 15,598 hospitals in America. So if the AHA number is right, 82 percent of the hospitals in the United States are now participating in the 340B program.

This is a program that's supposed to help lower drug costs for hospitals that serve a disproportionate share of low-income patients or patients that participate in low-income Medicare and Medicaid.

It's obvious that--to me, anyway, this program is being abused. So the question is what do we do about it. Well, in

a perfect world, which this is not, the Republicans and the Democrats on this committee would work in a bipartisan basis and we'd come up with a solution, and there's a chance, Mr. Chairman, that we may actually do that. I don't know. But--

Mr. <Burgess.= Will the gentleman yield?

Mr. <Barton.= I will be happy to yield.

Mr. <Burgess.= Hope springs eternal. Yield back.

Mr. <Barton.= Okay. And I am a hopeful guy, Mr. Chairman.

But in any event, I, with committee staff, have put forward a discussion draft that says one thing we could do is just raise the percentage of disproportionate share patients that the hospital serves.

And, like, we are going to have Parkland Hospital, which is a low-income hospital for Dallas County and Dallas, Texas--their chairman is here on the next panel--they serve over 50 percent of their patients would qualify, and the current law says you only have to have 11.75 percent. So the discussion draft says let's raise that percentage a little over 18 percent. I don't think that's a draconian increase, and I could be wrong.

But let me ask you, ma'am, do you believe, based on the study, that it would be good public policy to raise the DSH percentage requirement a little bit, or maybe a lot?

Ms. <Draper.= Well, I've testified on this several times before. I think a major issue with this program is that the intent of the program is not very clear. Intent was set up when the

program was first set up in the early '90s.

A lot has changed in the health care landscape over that time and whether that intent is still, you know, relevant today I think that is something that is one of the first things that need to be done because a lot of people assume that it's a program for low-income people.

That's not explicit in the intent and so then that gets to the whole issue about discounts and, you know, whether discounts are supposed to be provided and--

Mr. <Barton.= Well, is there any question that the intent was not to let every hospital in America participate?

Ms. <Draper.= Well, at the time I think it was more that--I mean, the intent was really, to me, closer to what a covered--like, a grantee.

It was to stretch scarce federal resources to reach--provide more comprehensive services and reach more patients, really using the federal grants that were available to the covered entities at the time.

Mr. <Barton.= Well, I agree with you. The intent was not clear. There's enough ambiguity in the program you can drive a Mack truck through, and word's gotten around in--not every hospital. There's still 18 percent that, apparently, don't read the newsletters so--

Ms. <Draper.= Well, the 12,000 I think--if you're talking about the 12,000 covered entities, that includes both hospitals

and federal grantees. So it's not just hospitals.

A hospital is probably a little bit more than 50 percent of that number and--

Mr. <Barton.= Okay.

Ms. <Draper.= --the federal grantees are the remaining.

Mr. <Barton.= So the 40 percent number--

Ms. <Draper.= It's probably 40--you know, the last number I saw was 45 percent.

Mr. <Barton.= So pure hospitals would be 6,000?

Ms. <Draper.= Something along that line.

Mr. <Barton.= Okay. Well, my time has expired, Mr. Chairman, so I am going to have to yield back.

I think it's good to have this and I think it's very good that we try to work to tighten up and, as the gentlelady just said, let's determine what the real intent is and then legislate accordingly.

With that, I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Florida five minutes for questions, please.

Ms. <Castor.= Thank you, Mr. Chairman.

Dr. Draper, I want to return to GAO's recommendations on audit process--on the audit process for 340B covered entities. These recommendations appear to create a lack of parity between

HRSA's audit process for covered entities and the agency's audit process for manufacturers.

For instance, I do not think that HRSA has any requirement or guidance regarding how long manufacturers must look back for 340B overcharges nor are manufacturers require to submit any documentation demonstrating that an error leading to 340B overcharges to covered entities has been corrected.

Did GAO consider this lack of parity in manufacturer audits when they were constructing their recommendations?

Ms. <Draper.= We did not, because the scope of this work really related to contract pharmacies--the use of contract pharmacies and, you know, we haven't done--as I mentioned earlier, we have not done work looking at audits of manufacturers and, you know, HRSA does post that on their website and, as I said, they've done--I think they talked about 12 completed today.

Ms. <Castor.= So GAO has--that wasn't in your scope this time and then you haven't been--that hasn't been a focus in the past at all?

Ms. <Draper.= It hasn't been a focus. Audits of manufacturers, from my understanding, started in 2015. So this most recent report that we did really looked at the use of contract pharmacies in the 340B program.

Ms. <Castor.= So you would need the Congress to suggest that that would be a good idea if we are going to do it?

Ms. <Draper.= Yes. I mean, we do our work either through

mandate or congressional request.

Ms. <Castor.= I just think it's an important piece of it because it seems like something is afoot here--that the manufacturers have--and drug companies have really been playing offense when it comes to 340B and I think it would be fair to take a look at their overcharges.

I mean, this is--we are struggling right now in America with how to contain these huge cost increases for drug prices.

When I am at home and I sit down with my neighbors and talk--and ask them what's important, this is always the top of their list and it seems--it's a little bizarre to me that the committee is having a hearing on this rather than really doing a much broader look at how we contain the escalating cost of prescription drugs for folks.

There are some great Democratic bills out there. We've tried to get some Republican support. But it is--it's just--there seems to be a real disconnect here. The 340B is so vital to my hospitals.

It's the one initiative out there that helps our safety net hospitals and community health centers provide affordable prescription drugs and it seems like the big drug manufacturers and drug companies just--they're never satisfied, and I don't know why we are taking up a great deal of time.

I appreciate GAO's work. It's important. You can always improve certain initiatives but. It really gives me pause that

this is the direction of the committee rather than really tackling the bigger issue for folks back home, which is much broader, much more severe. And I know you all are hearing it like I am hearing it.

So thank you, again.

Ms. <Draper.= Yes. I would just want to add that I think, you know, clarifying the roles, rules, and responsibilities of all the stakeholders in this program is really critical for this program to be--to have this program to be of the highest integrity and I think that, you know, the growth in this program--the pace of the oversight has not kept pace with the growth and I think there are a lot of ambiguity and lack of transparency in this program--that, you know, improving those will go a long way to helping improve the --

Ms. <Castor.= I agree with that. I agree with that strongly, because we have to protect program integrity because it is so vital for folks back home and it enables our safety net hospitals and community health centers to make sure that they are serving their broader mission.

But I am talking about the larger context. So I appreciate GAO's work here and, really, I would hope the committee would be bolder in tackling this critical problem for our folks back home and their pocketbooks.

Thank you. I yield back.

Mr. <Burgess.= The chair thanks the gentlelady. The

gentlelady yields back.

The chair recognizes the gentleman from Illinois, Mr. Shimkus, vice chairman of the Energy and Environment Subcommittee, five minutes for questions.

Mr. <Shimkus.= Thank you, Mr. Chairman.

I appreciate you being here and I appreciate your opening statement.

There is a concern in why it's important because in your opening statement we saw hospitals grow from, I think, 1,300 to 20,000 people in the program.

We saw contract pharmacies go from one to 439--I just was scribbling--based upon your opening statement. The distance of contract pharmacies from zero to 5,000 miles away from a hospital--I don't know what the 30 to 55 was.

I also wrote down that there was--I was going to get the definition of diversion, which is not knowing who the drug pricing really follows, from what I understand, in trying to get staff definition--and no patient definition.

Is that all part of that opening statement, Ms. Draper, that you said?

Ms. <Draper.= Yes. The patient definition is pretty ambiguous. So--

Mr. <Shimkus.= So if you want to serve underserved--if you want to serve people who can't afford it, it might not be bad to ask the person what--

Ms. <Draper.= Well, one of our recommendations from 2011 that still remains to be implemented is to clarify the eligibility criteria for our patient.

Mr. <Shimkus.= And that's why I am not--I am not adverse to talking about and getting in this debate. Listen, I am from rural small-town America. I have hospitals that rely upon this because of the patient area and who they cover.

They're unafraid about being in this debate because they know they're covering the right people. The question is about the other ones and the expansion and getting some type of confidence.

I got a letter from a state rep who talks about evidence of taking advantage of a system for their financial benefit and not properly serving vulnerable uninsured populations. We ought to look into that.

This is State Rep. Charlie Meier. This was sent in September of 2017. I have a letter from a pharmacist who's concerned about disproportionate hospitals--he says these pharmacies will bill the patient's private insurance at usual and customary pricing but can fill that prescription using 340B medications at significantly lower cost, kind of like gaming the system.

The challenge in health care policy is that the national government--we are a big payer--Medicaid, Medicare. Also with Medicaid we participate with the state but we always really underpay.

So then health care providers try to find other ways to make up the cost and that maybe billing higher to private insurers and all sorts of stuff, and I think that's kind of what's going on here to some extent.

It's another way for hospitals to make up the shortfall from the federal government not compensating, and it is right that we looked into this and follow this discussion--this debate.

So a couple questions in my time remaining. In your report it states that 69.3 percent of hospitals versus only 22.8 percent of federal grantees had at least one contract pharmacy arrangement. Why do you think that is?

Ms. <Draper.= Well, hospitals are much larger. They serve--their catchment areas are much larger, probably than federal grantees. They also have much more complex organizational structure than they're more likely to have and some of the grantees have, you know, multiple child sites that may be, you know, a far distance from--

Mr. <Shimkus.= Could it be that the grantees have in-house pharmacies?

Ms. <Draper.= Well, they could. Yes.

Mr. <Shimkus.= I think that's probably something we should look at. The report states that some covered entities maintained contracts with pharmacies that they do not use to dispense 340 drugs. Why would a covered entity maintain this arrangement?

Ms. <Draper.= Yes, that was an interesting finding for us,

and what the--what the covered entities talked about, like, when there are very expensive drugs, like, for hepatitis C or a hemophilia drug or HIV, that what happens is even if a patient rarely needed it maybe once every two years, that it was more advantageous to keep that arrangement, in the case where that one patient might need that very expensive drug.

Mr. <Shimkus.= And I think you answered this before, but just for the--before registering contract pharmacies with a given covered entity, does HRSA review the covered entities' plans for oversight to ensure it is sufficient?

Ms. <Draper.= They do not. But they will collect those policies and procedures if they conduct an audit of the covered entity. So at that point they'll pull the policies and procedures and look at those.

Mr. <Shimkus.= I appreciate your testimony.

Mr. Chairman, I yield back. Thank you very much.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Oregon, Dr. Schrader, five minutes for questions, please.

Mr. <Schrader.= Thank you, Mr. Chairman. I appreciate it. I appreciate Ms. Draper being here and the work that GAO does.

A question that came up in the hearing so far about, you know, why do we--why do we have this program, and I think it's pretty clear, frankly.

We established back in 1992 and supposed to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. End of discussion.

Now, if we don't think that's the appropriate use of the resources of the discounts, then let's have that discussion. I am okay with that.

But I think it's pretty clear that the goal of the program is to, frankly, allow people and allow modern medicine to use the discounts from some of our pharmaceutical friends who saved millions and millions of lives in a much more--much more conducive setting than being in a hospital by making sure people have access to these medications that we should embrace that. I mean, that's a good thing.

The other piece that I am a little concerned about and the tone of the conversation so far is that having this vast increase in people using the 340B program is wrong. I would argue that's a success. It means that hospitals are beginning to realize, especially with the advent of the Affordable Care Act that brought services to a lot of very vulnerable people that there's an opportunity for them financially and for them from the standpoint of their Hippocratic Oath providing excellent care to my constituents that they're able to do those wraparound services.

You know, we don't have the money in our system right now to give these folks the opportunity to develop this wraparound

service and it's paid for, largely--at least some of it--out of the 340B discount program, and what population is served by that is not specified, although I think your audits show, hopefully, for the most part, it seems like, at least in my state, that the program is being used appropriately.

You know, the discounts are on drugs for those people that are eligible. I think that's great. So far in my state, I am not aware of a lot of problems. We've had some audits.

I've met with some of my providers, you know, just a few weeks ago and they've been recently audited. They seem to be indicating they're getting audited on a little more regular basis than you have talked about so far and they're meeting their goal.

So I would argue respectfully that since we do have a lack of resources--well, fairly significant lack of resources here in Washington, D.C., to help our hospitals deal with our Medicaid population and those other low-income folks with this wraparound service prevents them from coming in and actually costing the system and the taxpayer a lot more, and that's a discussion I think we have to have a little more of before we start adding new rules and regulations.

I came in a little late and I apologize for that, and haven't gotten through the entire report. What was the finding on terms of duplicate discounts by the different hospitals and covered entities?

You know, they're not supposed to have a Medicaid rebate

discount and take 340B. What was the finding in that regard, Ms. Draper?

Ms. <Draper.= Well, there is evidence that there are duplicate discounts in Medicaid-managed care and HRSA will say that they haven't issued guidance to covered entities.

Covered entities express concern that, you know, that may be occurring. But they don't really have guidance as to how they handle it.

Most recently, HRSA added a change so if they become aware of a duplicate--a potential for duplicate discount in one of their audits, they will put it in the audit finding letter but they will not require the entity to really do anything about it unless there are other findings related to audits.

Mr. <Schrader.= I would like to see those specific instances that your report identified, you know, what percentage of the hospital/other--there's other entities, too.

You know, hospitals are a smaller percentage of the covered entities that the program applies to. So I would like to see if it's possible where you found that and also if there's some geographical differences--you know, there's more prevalence.

Ms. <Draper.= So we did--this was based on 20 completed audits and we found it in one of the files.

Mr. <Schrader.= One out of 20?

Ms. <Draper.= Out of 20, yes.

Mr. <Schrader.= All right. Well--

Ms. <Draper.= And then HRSA--

Mr. <Schrader.= To your point earlier, I think we need to do more audits. That's hardly--it's hard to get statistically relevant information out of 18,000 or 16,000 covered entities or hospitals. It's--

Ms. <Draper.= Right. I think the other issue is that, you know, the majority of beneficiaries in Medicaid are in managed care. So that is an important place for, you know, that--

Mr. <Schrader.= Last question. I am sorry. I am running out of time.

Ms. <Draper.= That's okay.

Mr. <Schrader.= You know, you talk about an increase in 25 percent of the discounts paid. What portion of that is a result of the increase costs to the pharmaceuticals over the same, you know, time period from 2010 until now?

Ms. <Draper.= The 25 percent increase in costs paid?

Mr. <Schrader.= Yeah.

Ms. <Draper.= Well, we look at the--you know, you have to look at the proportion of the--you know, the cost of the--

Mr. <Schrader.= I mean, if the program is costing us 25 percent more since 2010, you know, some of that is, obviously, increased in popularity. People are realizing they can actually do that nice wraparound service.

The other piece is, you know, potentially increased costs as a result of new age drugs that are, again, maybe very, very

good.

But I think we need to have that information, Ms. Draper. That would be really helpful for us to decide how much of this is appropriate and how much is not.

So I am fine with clarifying the rules. I think they're pretty explicit at this point and make sure that everyone's following and being enforced, do more audits that we are currently are doing.

They seem to be working. But I would rather that than have a whole bunch more of new regulation. Let's enforce what we already have.

And I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Ohio, Mr. Latta, five minutes for questions, please.

Mr. <Latta.= Thank you, Mr. Chairman, and Director, thanks very much for being with us today. If I could maybe just touch on some questions in the transparency area.

In the report, GAO states that HRSA does not require covered entities to share contracts made with pharmacies to the agency. Do you believe that sharing this type of information for all contracts would improve program oversight?

Ms. <Draper.= Well, it's--you're probably talking about tens of thousands of contracts. So it would be--it would be

probably pretty burdensome.

The other issue is that HRSA doesn't have legal authority to--over those arrangements. They discuss it as a private business matter between the covered entity and contract pharmacies and third-party administrators.

Mr. <Latta.= Well, let me follow up on that then. Should such contracts be made public to ensure that the financial arrangement between the covered entity and the contract pharmacy are consistent with the requirements and purpose of the program?

Ms. <Draper.= Well, as I mentioned before, HRSA was very concerned about us publishing the financial information from the 30 contracts that we had--we reviewed, discussing that it could be potentially disruptive to the drug pricing market and, you know, cost fluctuations and the fees that covered entities pay.

We disagree with that, but I think it's something that--if you're thinking about this on a larger scale it's something that would have to be looked at and, you know, probably include HRSA in the discussion about that, what their concerns are and whether they're valid.

Mr. <Latta.= All right.

In the report, GAO states that the covered entities must have a plan with the contract pharmacy to ensure compliance with the statutory prohibitions on the 340B diversion of duplicate discounts.

Should Congress require such plans be made public?

Ms. <Draper.= Currently, they are--they're--HRSA does not require those until they--unless they do an audit of the covered fee and then they--then they collect that information.

I am not sure what the public would do with that information. It would seem that that would be something more important for HRSA to have rather than, you know, the general public. But it seems like an administrative process--a oversight issue with HRSA.

Mr. <Latta.= On Page 19 of the report, GAO states that the number of contract pharmacy arrangements is unknown because HRSA does not require a covered entity to register pharmacies with each of its child sites.

And should such registration be required?

Ms. <Draper.= Well, that's what we recommended. So I can give you an example. So of the covered entities with one contract--that register only one contract pharmacy, there were, like, 1,645 of those.

They had 25,000 arrangements. So that could have resulted in more than 800,000, you know, separate contract pharmacy arrangements.

So HRSA does not have really that information and it does go to inform, you know, the complexity of the covered entities and the different arrangements that they have. It does inform their oversight efforts, particularly the audits of covered entities.

It also makes it difficult for manufacturers to know whether a particular entity is actually included on the contract and it's a valid contract so that they can, you know, actually provide the drugs to that entity.

Mr. <Latta.= Okay.

What is the most important recommendation to improve the program integrity?

Ms. <Draper.= What's the most important one?

Mr. <Latta.= Right.

Ms. <Draper.= I would say all seven are important. I mean, they all go to, really, program integrity.

Mr. <Latta.= Anything you have listed at the very top of your--as you were putting them in the report, one to seven?

Ms. <Draper.= Well, it's really hard to distinguish because I think they all address different areas but they all culminate in improving the integrity of the program, which is really critical, and I would hate to say one over the other because I think they're all equally important, and we agonize over recommendations before we make them to make sure that they are valid. And so I would like to say that all seven are important.

Mr. <Latta.= Okay. Well, as you're looking at the GAO side, on the HRSA side, how would--how should HRSA prioritize the implementation of your report of the GAO recommendations?

Ms. <Draper.= Again, I think that they disagree with three of them and we disagree that they disagreed. I think that they

need to implement all of them.

I think one of the big ones is the duplicate discounts. They need to--that needs to be clarified because there is--no one knows the potential for the amount of duplicate discounts and that's definitely a clear prohibition of the program.

So I think that's one area and that's going to probably require--they're going to have to work with CMS on that to get that implemented.

So I think just the time line for that and the importance of that--that that would be one that I would probably focus on initially. But I think all seven are important.

Mr. <Latta.= Well, thank you very much.

Mr. Chairman, I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Indiana, Dr. Bucshon, five minutes for questions, please.

Mr. <Bucshon.= Thank you, Mr. Chairman.

I would just remind everyone, 1992, no internet, and the Cold War was just ending. Times have changed, and the original intent of the program is important. But, again, today is today. It's not 1992.

I just want to make it clear that I am a strong supporter of the 340B program. It's critical to many of the rural hospitals in my district.

I called every CEO of every hospitals and, honestly, all

of them talked about the critical nature of the program but also none of them had a problem with more oversight.

You know why? Because they're doing what they're supposed to be done. You know, if everyone out there is following the intent of the program, either original intent or in its current goals, then no one--I repeat, no one has anything to worry about with increasing oversight of the program, being required to report their activities.

And those that are not, honestly, should be ashamed of yourselves, and you know who you are. It's ridiculous. As a provider, the intent of this is to get low-income fellow citizens access to very important critical lifesaving medications.

And so those of you who are opposing more transparency, the lady doth protest too much, me thinks. So you can Google that and see what that means.

But we know--we know what the reason behind this is, okay. The reason is money, and so we need to get the focus off money and back onto the intent of why this program was put in place and we've lost that, and it's appalling.

Again, I want to say people that are fighting against more transparency, in my view, it's shameful, and if they ought to quit doing that and cooperate with the committee and help us--help us improve the program for everyone.

So, Ms. Draper, I mean, the reach has expanded way beyond the--and has led to the creation of, in my view, a cottage industry

almost to maximize the profits including vendor, software developers, consultants, contract pharmacies.

Again, I know you have said this but would you agree that further oversight of entities beyond the program's covered entities is warranted.

Ms. <Draper.= I would say there should be oversight of all the--all the stakeholders in this program.

Mr. <Bucshon.= Agreed. So I don't think we have any partisan issue with that. From your perspective, considering the lack of transparency about the vendors, is there potential for program abuse there?

Ms. <Draper.= Well, I would say that--

Mr. <Bucshon.= Third party vendors.

Ms. <Draper.= I would say when things are not transparent or they're--you know, the rules are ambiguous that there's always, at least a lot of interpretation and why the interpretation.

So I think, you know, if you don't have clear roles and responsibilities and rules then, you know, there is a lot to be interpreted and it does pose a risk for potential undesirable effects.

Mr. <Bucshon.= Do you know how many third party administrators there are?

Ms. <Draper.= I don't know.

Mr. <Bucshon.= You have no idea? And does the GAO have any information regarding how much money on average covered

entities spend on contract pharmacies and vendors, because these costs presumably could limit--presumably could limit the amount of care provided to low-income and uninsured patients?

Ms. <Draper.= We don't have that information. That information, as far as we know, is not available.

Mr. <Bucshon.= So it's not transparent so there's no way to know. And then the final thing I will say is I think someone mentioned--I think you mentioned it's important to have transparency to HRSA. I am going to argue that it's important to have transparency to constituents that I represent.

The only way that things change is if the people that I represent and every member here represents know what's happening out there.

Things don't change, in my view, is if a federal agency understands better what's happening because as you see, HRSA has said they don't agree with three of your recommendations, and you have made recommendations.

When's the first time there were recommendations made about this program? I mean, what year do you think?

Ms. <Draper.= Yes. We made recommendations in 2011 and they still have two to--yet to be implemented.

Mr. <Bucshon.= Okay. So you're--that's, roughly, seven years, right, depending on the time of year that they're implemented.

So my point is transparency to HRSA to get more information

to the federal agency hasn't worked. It's not working, right. Nothing's been changed. Is that true?

Ms. <Draper.= Well, some things have changed but, you know, a lot of it is we haven't had this discussion about HRSA needing--whether they can issue rules and responsibilities through guidance or regulation.

Mr. <Bucshon.= Right.

Ms. <Draper.= Their belief is that they need regulation--on the two open recommendations that we currently have that they need regulation versus guidance.

Mr. <Bucshon.= Okay. And let me guess--they're blaming it on Congress, saying that we need to do a legislative fix. This is a classic agency approach where when they're not acting on recommendations from you or others that they hide behind the, quote, unquote, "legislative fix'' so they can't improve things.

So my major push is this. In health care in general, not on--only in 340B the only way that we are going to get health care costs down and ensure all of our citizens is if everyone in this industry is completely open and transparent to the people that I represent and to the people of America.

Thank you, Mr. Chairman. I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Missouri, Mr. Long, five minutes for questions, please.

Mr. <Long.= Thank you, Mr. Chairman.

Dr. Draper, the GAO report indicates that disproportionate share hospitals have, on average, 25 contract pharmacies per hospital with 45 percent have at least one contract pharmacy that is more than 1,000 miles away from the hospital itself.

Your report also notes the guidance from HRSA--the Health Resources Services Administration--gives covered entities discretion on how to determine compliance for contract pharmacies.

Could you discuss the effectiveness of covered entities' current oversight practice of contract pharmacies, given the lack of specific guidance from HRSA?

Ms. <Draper.= Well, when a contract--when a covered entity contracts with a pharmacy they are to have rules--specific policies and procedures how they're going to conduct that oversight. HRSA does not collect that information. They do collect it during the course of an audit. If an entity is audited they will pull that information and make sure that they're in compliance.

HRSA gives wide discretion about what that oversight means and, just for example, it says--you know, their 2010 guidance says that the exact method of ensuring compliance was left up to the covered entities.

So we found wide discretion about how entities are implementing--overseeing contract pharmacies. So, for example,

one covered entity reported auditing claims of five randomly selected patients quarterly when they serve 900 patients on a monthly basis.

And then one critical access hospital that serves about 21,000 patients annually, their independent audit review of five claims per year. So a wide variation.

I mean, there's no--you know, again, this is not specific guidance as to how entities are supposed to conduct this--conduct oversight.

Mr. <Long.= Yes. Well, that was my question. Excuse me.

In your report, you also note that weaknesses in HRSA's audit process impede effectiveness of its oversight, mainly, that HRSA does not have complete data. How is HRSA able to determine the contract pharmacy complying with--that contract pharmacies are complying with program requirements?

Ms. <Draper.= Well, you know, again, the audits are a major oversight mechanism.

Mr. <Long.= Their what? I am sorry.

Ms. <Draper.= Their audits of covered entities. So what happens is that when a covered entity contracts with the--with the pharmacy, there's one or two ways that they can contract.

One is that they can do a comprehensive contract, so the contract is with the covered entity and the pharmacy and then at their child sites, and all the child sites have to be listed on that one contract.

The other method is to individually contract for each parent and child site with that covered entity. So that's one of two ways. That's how they contract.

But when they register the pharmacies with HRSA, HRSA, again, they can register the pharmacy for parent and child site or they can just do a comprehensive--just register the parent site alone, which doesn't cover--it doesn't tell them who they child--individual child sites are. So they don't really have that information readily accessible in their records.

Mr. <Long.= Okay. Grantees such as community health centers typically must demonstrate that they are serving a specific vulnerable population and are required to reinvest in additional resources into services for those populations.

They also have substantial reporting requirements on how they use their funding. However, no similar requirement exists for hospital entities even though we've seen a significant growth in the number of hospitals participating in the program.

Would it make sense to put in place similar requirements for all participating entities?

Ms. <Draper.= Well, I can tell you that grantees--many of the grantees have specific requirements as part of their grants to how they use their revenue or savings and what discounts they might provide--you know, provide patients. There's not similar requirements for--necessarily for hospitals that participate in the program. So that's the difference between the two.

Mr. <Long.= Okay. Do you believe the consistently stringent oversight across all entities is necessary for appropriate governance of the program?

Ms. <Draper.= Yes, I do.

Mr. <Long.= Okay. Thank you.

And, Mr. Chairman, I yield back.

Mr. <Burgess.= The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from New York, Mr. Engel, five minutes for questions, please.

Mr. <Engel.= Thank you, Mr. Chairman.

340B is a small but essential program that lets qualified providers stretch limited resources to better serve their patients and communities, and in my district at more than a hundred New York safety net hospitals 340B discounts allow for greater access to prescription drugs and more comprehensive care for patients, many of whom have nowhere else to turn.

Now, I am all for ensuring program integrity. It's essential if we want the 340B program to continue helping vulnerable patients get the care they need, and it's my understanding that hospitals are subject to random audits of the Health Resources and Services Administration to make sure that 340B is working as it should.

Some of the policies we are considering today, though, don't seem to be aimed at better program integrity. Rather, it seems

to me that the goal is really to make participants' participation in the 340B program more onerous for providers or cut providers from this program altogether and I am concerned that were these policies to go into effect providers would be forced to cut back on the care they offer to patients and curtail the work they're doing to improve the health of our communities overall.

Now, this would come on the heels of the Centers for Medicare and Medicaid Services' decision earlier this year to slash the amount Medicare reimburses for drugs purchased through 340B.

In New York, this will result in more than $100 million in cuts to eligible 340B hospitals. That, in turn, leaves these providers with fewer resources to care for the same patients 340B is supposed to benefit in the first place.

So I am a co-sponsor of Congressman McKinley's bipartisan bill to reverse these misguided cuts and I hope this committee will act on legislation quickly.

Dr. Draper, I want to ask about GAO's recommendations that HRSA should mandate additional registration requirements for contract pharmacies.

It's my understanding that HHS did not agree with this recommendation, something that does not happen frequently, as there are already contract pharmacy registration requirements in place.

HHS argued that new needless burdensome requirements wouldn't do much to improve program integrity. I think we can

all understand why contract pharmacies are important. Forcing patients to visit a hospital pharmacy when there is a more convenient option just doesn't make much sense.

But I worry that the policies GAO has recommended would ultimately result in the loss of 340B discounts eligible patients just because of where that patient chooses to get their drugs and, as a result, hospitals will lose out on savings that allow them to better care for these vulnerable patients.

So, Dr. Draper, isn't it true that HHS had, quote, "significant concerns regarding many of the findings in the draft report,'' unquote, and did not agree with three of the seven GAO recommendations because they felt that it wasn't the best use of resources to actually improve program integrity?

Ms. <Draper.= They did not concur with three of our recommendations and the one that you were talking about specifically about registering, making sure that each site was registered with each contract pharmacy, they already have that information available and that part--when a contract--when a covered entity registers their contract pharmacies that information is available.

It's just not available in their database, and the problem with that is that, you know, they use that information to--the complexity of a covered entity is used in their decision about the--90 percent of their audits are risk-based audits.

So they use that information of the complexity of an entity

to determine which entities get selected for audits. So that's really important information to have.

The other--the other piece of that is that, you know, it's important for manufacturers to have that information available to them because if they don't have that that they're not really--they can't really verify that the entity that they're providing drugs for is really a covered entity under the contract.

Mr. <Engel.= Thank you. Thank you.

I yield back, Mr. Chairman. Thank you.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from New Jersey, Mr. Lance, five minutes for questions, please.

Mr. <Lance.= Thank you, Mr. Chairman. Good morning to you and thank you for your public service.

As I have read your report, there is an indication that flat fees paid by pharmacies--paid to pharmacies by covered entities for brand name and specialty drugs were higher than going the other way.

Does this make sense and could you just explain that a little more to me?

Ms. <Draper.= Yes, it made sense because, you know, those drugs are much more expensive. So, you know, the flat fee for a generic, which probably is much lower cost--the thing that you want to do is make sure that the fees are proportional to the

cost of the drugs. So, you know, I think there was--there's been some talk about making the fees the same--

Mr. <Lance.= Mm-hmm.

Ms. <Draper.= --and the problem with that is that then you might end up in a--you know, that a patient pays more for being in the 340B program than if they weren't because--you know, the--it gets out of proportion.

So that would make some sense.

Mr. <Lance.= Thank you.

But it also states that some contracts exclude generic drugs from being purchased at the 340B price. Why would contracts only allow for the purchase of brand name drugs?

Ms. <Draper.= And, again, it's the same kind of issue that it may put the drug into a negative revenue situation for the covered entity. If the--if the fee associated with that and the costs of the drugs puts it into a negative revenue or savings, then that really sometimes doesn't work.

And what we've heard from some contract pharmacies that they--if they find that that happens, then they may--they will consider it not to be a 340B prescription but a regular prescription so it doesn't put the covered entity into a negative revenue or savings situation like that.

Mr. <Lance.= Should we go to a system where they can decide which to choose or is the system as it currently exists the better system, from your perspective?

Ms. <Draper.= Yeah, I think that will require more study to find out how best to do that because, again, you don't want to create negative incentives related to this.

You want to make sure that, you know, whatever fee that's being charged is not creating--you know, that the patient would come out in a worse situation by participating in the 340B program than not.

Mr. <Lance.= Thank you, and I look forward to continuing to work with you and, Mr. Chairman, I yield back two minutes and 27 seconds.

Mr. <Burgess.= The chair rejoices.

The chair is prepared to recognize the gentleman from North Carolina if he is ready.

Mr. <Hudson.= I will be ready in just a second, Mr. Chairman. Thank you for that.

Thank you, Ms. Draper, for--

Mr. <Burgess.= Five minutes.

Mr. <Hudson.= --providing your testimony. In the 8th District of North Carolina, I have four major hospital networks, each of which uses the 340B program. I've toured their facilities and they've shown me ways that they use the 340B program to better serve their patients.

I believe this program is vital to our communities and I believe in its mission. But the program can and should be improved.

I applaud Chairman Burgess and Ranking Member Green for holding this hearing to allow us to explore solutions to help preserve and strengthen this program for the next generation.

One idea that I've been exploring is elevating the 340B program to an administrator level program within HRSA. Right now, the 340B program is administered by the Office of Pharmacy Affairs within HRSA. But there's no figurehead for Congress to address its concerns to.

A recurring theme I've heard from both covered entities and pharmaceutical manufacturers who've come in to talk to me about changes they'd like to see in the program is that they want to see more transparency and accountability.

Further, both in the GAO and Energy and Commerce Oversight and Investigations Subcommittee reports recommended this program be given more authority to conduct oversight and resources to ensure proper implementation.

The 340B program is utilized by over 12,000 covered entities and there are close to 20,000 contract pharmacies. It plays a vital role in our health care system.

However, it's critically under resourced to appropriately administer this program. By elevating the 340B program to a Senate-confirmed administrator level program, I believe we can make this program more accountable to Congress, proving more visibility to the program, and improve the administration of the program. I believe these are goals that hopefully we can all

support.

Ms. Draper, do you foresee any issues with elevating the 340B program to a Senate-confirmed administrator level program within HRSA?

Ms. <Draper.= I haven't really thought about that. But I think the more visibility that that position has will be--would be helpful.

Mr. <Hudson.= Great. Well, if you have any further thoughts I would love to hear your feedback. I appreciate the work you put into this and I think it's benefited this committee.

Ms. <Draper.= Thank you.

Mr. <Hudson.= With that, Mr. Chairman, I will yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from New York, Mr. Collins, five minutes for questions.

Mr. <Collins.= Thank you, Mr. Chairman.

I think, you know, Ms. Draper, you have actually answered a lot of our questions. The GAO report was a very specific audit on the contract pharmacies and I think we've kind of covered that.

So maybe I will spend a few minutes just stepping back for a second, I think, sometimes, you know, to summarize things.

Everyone in this room agrees 340B is a great program. It's been around 25 years. But in 25 years, a lot has changed.

Certainly, the types of drugs and the treatments we have

to cure diseases, treat diseases, very significantly different today than 25 years ago and many of these drugs are extraordinarily as they've gone through billion-dollar trials and the like, and I think all of us have the same concern--that the bad actors are identified and we stop those actions.

Certainly, you identified some of the issues with contract pharmacies a thousand miles away, diversion, getting double discounts and so forth.

So I think, you know, as we are going to maybe nuance some things we should always keep stepping back and saying this program has been there 25 years--it's a good program--the pharmaceutical companies support it. Covered entities need it, the grantees need it, et cetera, et cetera.

So it comes back to--you know, there's a saying there's no free lunch and as we have seen some bad actors take advantage of the 340B, 50 percent discounts and they're providing them to patients who are fully insured, so Blue Cross-Blue Shield is paying the full bill.

The hospital is taking that money, adding it to their operating income, if you will, to cover expenses not--in some cases, the bad actor not telling us what they're using it for versus grantees who do, in fact.

So I absolutely think the transparency is important here. I think we should all remember because of what you're saying--one of my bills is a one-tenth of 1 percent user fee for hospitals

using the program to get into HRSA.

While they may not like it actually the fewer bad actors we have the more confidence we'll have this program will continue, and I think we've all heard HRSA needs the resources.

You, I am assuming, agree with that. So that one-tenth of 1 percent, which is one of the things we'll be talking about is to address that need.

The other one is patient definition. I have a bill here on patient definition that's quite controversial but it says this program was intended for the uninsured, the low income, and we are seeing some folks talking advantage and buying, in many cases, oncology practices where the vast majority of the patients are fully insured, and today those are not 340B entities.

They are getting purchased and the next thing you know all these patients with full insurance, the person who's purchasing it is pocketing that difference. I would call that an abuse.

So under the, you know, patient definition that I am pushing, the qualified patient would be a person who's uninsured or low-income. If someone has insurance they would not be covered by 340B.

I am not sure if you have an opinion on that. That's probably one of the most controversial pieces because, clearly, if it only applied to the uninsured and the low income, that would, certainly, today be removing money from hospitals who use the funds for their operation expenses. Do you have an opinion on

that patient definition piece being only the uninsured and the low-income?

Ms. <Draper.= I would just say that the patient definition needs to be clear and it needs to be clear--I mean, I think that's a major issue with the program overall.

There's a lot of ambiguity in the rules and regulations and it leaves a lot to interpretation. So if that's what Congress intends then, you know, that should be clear in the program. That should be a clear definition.

Mr. <Collins.= Well, and I think that's why, again, Mr. Chairman, this is such a good hearing because we are covering these things from A to Z to start a dialogue, starting with the fact everyone wants 340B to continue to serve what it was intended to serve.

But we need to know where it's going and what we can't have are the bad actors taking advantage of loopholes or otherwise to pad their bottom line when in fact there's--they should have a responsibility to run their operation and everyone needs more money.

Everyone would like more money. But to take it off the backs of pharmaceutical companies inappropriately could lead to higher prices overall. At some point, if people are taking the money out, you're going to see increases, just the opposite of what we want to see today.

Ms. <Draper.= And I would say what will go a long way is

the intent of the program clarify that, clarify the rules, and make sure that there's a really strong oversight infrastructure in place.

Those will go a long way to improve the integrity of the program.

Mr. <Collins.= Which is what all of us want. So thank you for your testimony.

And, Mr. Chairman, this is a great hearing. Thank you for holding it. I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Indiana, Mrs. Brooks, five minutes for questions, please.

Mrs. <Brooks.= Thank you, Mr. Chairman. And I apologize--I was in another hearing as well.

A May 2018 brief by MACPAC highlights the Medicaid exclusion file that HRSA maintains to help prevent duplicate discounts does not apply to the drugs dispensed by contract pharmacies, and while certainly recognize that identifying and preventing duplicate discounts is the legal responsibility of the covered entity, given your research and the complexity of the program, do you think it is likely that a significant percentage of covered entities with contract pharmacies are at risk of violating the law by providing those duplicate discounts?

And if you could go into a little bit of detail.

Ms. <Draper.= I think there's certainly a risk related to Medicaid-managed care. Sixty percent of all Medicaid drug spending is in managed care and 70 percent of all Medicaid drugs prescriptions are written for Medicaid beneficiaries and managed care.

So I think the potential risk is pretty large. We don't know the extent. We haven't looked at it. But we actually will be starting work very soon looking at duplicate discounts in the 340B program.

Mrs. <Brooks.= Is that a separate study you're doing?

Ms. <Draper.= Yes, and we--we are--the team that did this work we will be moving over to that work very soon.

Mrs. <Brooks.= And what--can you talk to us a little bit about the parameters of that work?

Ms. <Draper.= We haven't really scoped it yet but we will be looking at, you know, basically, duplicate discounts related to the 340B program including managed care.

So we are just--we just staffed it--we actually haven't staffed it yet but the staff from this job will move over to that job and we'll begin work very soon.

Mrs. <Brooks.= And do you have any sense of the approximate timing of how long that work might take?

Ms. <Draper.= Yeah. It's hard to say. But I would say nine to 12 months, something like that. It depends on how--you know, we'll have to scope it and see, you know, how broad the

scope will be. We will be happy to, you know, provide that information subsequently.

Mrs. <Brooks.= I think that would be very helpful to this committee.

Let me shift with respect to third party administrators. To your knowledge, does the use of third-party administrators prevent findings of noncompliance and, if so, at what cost to the covered entity?

Ms. <Draper.= Well, the role of third party administrators is to review claims to make sure that patients are 340B eligible.

So, you know, it is--it is a risk--I guess a risk-aversion process and if the TPA doesn't do it then someone within the covered entity needs to make--needs to ensure that those patients that are getting the drugs are actually eligible patients.

So what we found is that, you know, we had a limited number of TPAs but they charge anywhere from, like, $3.50 to $10 per prescription I think is what they told us, or they do it also--they may do it on a per contract basis or per covered entity, like, $25,000 for a year.

Mrs. <Brooks.= So if you--if the TPAs are paid a flat fee for contract pharmacy, do you believe that incentivizes less oversight and/or increase noncompliance of that contract pharmacy when it is a flat fee?

Ms. <Draper.= Yes, it's hard for me to say. I don't think we really had the evidence to suggest either way.

Mrs. <Brooks.= Okay.

Ms. <Draper.= It was really more of a descriptive piece to really get some insights into the financial arrangements.

Mrs. <Brooks.= Thank you. I have no further questions.

Yield back.

Mr. <Guthrie.= [Presiding.] The gentlelady yields back.

I now recognize Mr. Carter from Georgia, five minutes for questions.

Mr. <Carter.= Thank you, Mr. Chairman.

Ms. Draper, thank you for being here. This has been very informative and I appreciate the work that you have done.

Just full disclosure, before I became a member of Congress I was a practising pharmacist, actually participated in some 340B programs.

But I will be quite honest with you, I did not know the extent to what this program was being done until I got into Congress.

I thought it was for rural hospitals and for low-income patients to get discounts on medications, and it was only until I got here that I discovered that it was being exploited, if you will, not illegally, but just it wasn't defined well enough to call people to not be able to exploit it like they were.

I am not saying that they were doing anything illegal. They were just simply--I am just simply making an observation and it appears to me that Congress never made it clear exactly what we intended for the program to be.

One of the things that's been discussed here today has been the number of contract pharmacies, and I want to make sure I understand.

You know, accessibility to these medications is very important. So it appears that the theme has been is if we can cut down on the number of contract pharmacies we can control the program better.

Whereas, I would submit that it would be better if we could have a better patient definition of who is eligible and who is not eligible and not necessarily to have to cut down on the number of contract pharmacies.

Would you agree with that?

Ms. <Draper.= Yes, I don't think their work suggests cutting down on the number of contract pharmacies. I think it just suggests having more rigorous oversight and the rules be clear.

Mr. <Carter.= Well, and I appreciate that. One of the things that concerns me is that there's legislation being proposed now to codify the patient--the current patient definition that dates back all the way to 1996. I mean, we've got staff members who weren't even born then.

So, you know, I mean, that's, to me, ludicrous to even think about doing that. It has to be updated. But as I understand it, GAO and HHS have both identified the unclear patient definition as being one of the major problems. Is that true?

Ms. <Draper.= Yes.

Mr. <Carter.= And that's one of the problems that HRSA is having with, really, overseeing the program is that the patient definition is not clear.

Ms. <Draper.= Well, it isn't clear and that's one of the--that's one of our outstanding recommendations from 2011 that still needs to be implemented.

Mr. <Carter.= Right. Let me ask you something. Are you aware of a memo from the Congressional Research Services to Senator Cassidy that was dated on June 18th of this year?

Ms. <Draper.= Yes, I am.

Mr. <Carter.= So is it fair to say that the gist of that memo was to confirm that under the current patient definition that is being proposed to be codified into the system that it's possible for a 340B hospital near Hollywood to get a discount from Botox to be given to a--and then to be given to a movie star and then to get a discount--a 340B discount?

Ms. <Draper.= Well, the--you know, outpatient drugs are covered.

Mr. <Carter.= So that--yes--I mean, yes or no?

Ms. <Draper.= Yes. I mean, it's possible.

Mr. <Carter.= Yes. So it's possible for Botox to be under the 340B program and for a Hollywood start to get a discount and for that hospital to get a discount of that drug.

You know, the thing is, Mr. Chairman, I don't think there's anyone here who doesn't think that this is a good program. It

is a good program.

But, obviously, it needs some safeguards. Obviously, we need guardrails on this program. We need to do some things and change some things to make this program better. If, indeed, when the program was established in 1992, as some have suggested, that it was not clear exactly what it was intended for we need to make that clear in Congress. This is incumbent upon us in Congress to make that clear and that's what we--I want us to do.

Let me ask you one other thing and that's about the--about the duplicate payments and the claims modifiers. I understand that some hospitals are getting discounts for both Medicaid and for the 340B program.

Would a claims modifier not work to solve that problem?

Ms. <Draper.= The guidance isn't clear. There's been no guidance issued around--related to Medicaid-managed care. That's where the issue is. It's not--so there is--you know, there is a process in place for Medicaid fee for service but there is no process for Medicaid-managed care, which is--

Mr. <Carter.= Right.

Ms. <Draper.= --where the problem is.

Mr. <Carter.= And that's what you said in your report. It says the potential for duplicate discounts related to Medicaid-managed care has existed since 2010 when manufacturers were require to pay Medicaid rebates under managed care and currently there are more Medicaid enrollees prescriptions and

spending for drugs under managed care than for fee for service.

Ms. <Draper.= Yes, that's correct.

Mr. <Carter.= So that just needs to be clarified, right?

Ms. <Draper.= Right. There needs to be--

Mr. <Carter.= You know, I mean, this--the resolution to all this seems to be simple. We just need to update the code.

Ms. <Draper.= Somebody mentioned this, that, you know, covered entities--I mean, they would like to have the guidance issued--

Mr. <Carter.= Absolutely.

Ms. <Draper.= --so that they're clear about what they're supposed to do as well.

Mr. <Carter.= Well, I hate to put this on record but this is one time I kind of feel bad for the agency because we certainly haven't given you any guidance at all and we need to do something about that.

And I want to thank you, Mr. Chairman, for holding this hearing and for us addressing this issue, and I yield back.

Mr. <Guthrie.= Thank you. Appreciate that. The gentleman's time has expired and yields back.

The chair now recognizes Ms. Eshoo of California five minutes for questions.

Ms. Eshoo, you're recognized.

Ms. <Eshoo.= Thank you. I was just in deep thought for a couple of seconds there.

Thank you, Mr. Chairman, and thank you, Dr. Draper.

I hope that you will be able to enlighten me in the following area. Do you think that the reporting requirement relative to the qualification for how 340B savings are spent differently among the types of hospitals currently eligible to participate in the 340B program? Do you think that anything needs to be done relative to reporting requirements?

Ms. <Draper.= Right now, there are no reporting requirements. So--

Ms. <Eshoo.= There are what?

Ms. <Draper.= There are no reporting requirements around--are you talking about savings and revenues generated from the 340B program?

Ms. <Eshoo.= Well, they all have reporting requirements when they have the 340B program. But I don't believe that the three--that the reporting requirements are all the same.

Is there--do you think in--that something needs to change with that?

Ms. <Draper.= Well-

Ms. <Eshoo.= Or do you think that what's in place is appropriate?

Ms. <Draper.= Well, there are no--there are no requirements for covered entities to account for how--you know, what savings or revenues they generate from the program.

Ms. <Eshoo.= Do you think that there is an inconsistency

in reporting requirements that limit HRSA's ability to effectively oversee and administer the 340B program?

Ms. <Draper.= I am not aware of anything that's inconsistent there.

Ms. <Eshoo.= Does GAO have recommendations regarding what information should be reported by all covered entities?

Ms. <Draper.= We have not made recommendations around that issue.

Ms. <Eshoo.= What do you think the major issue is--let me ask it this way. What do you think is broken, if anything?

Ms. <Draper.= I think the--you know, as I said, I think there's--the intent of the program needs to be clarified that the rules and regulations--

Ms. <Eshoo.= What does that mean? Clarify it.

Ms. <Draper.= So the intent is, you know, was developed in the early '90s when the program first became operational. There's a lot that's happened in the--in the landscape--health care landscape.

I think some folks have talked about the increase in the price of drugs, the new technologies in health care. I think just the types of entities that are--that are currently serving people--you know, these entities, particularly hospitals are much more complex organizations than they--than they used to be.

So there's so much that has changed and I am not sure that the intent of the program has--and also health care reform is

a big piece. So it's not clear that the changes in the landscape--health care landscape have really--really support the current intent of the program.

And, you know, it's funny because we talk to folks and they think that the intent of the program is to serve low-income people. Well, that might an indirect--

Ms. <Eshoo.= But it's not to--it's not to track individuals. It's for institutions that are--

Ms. <Draper.= Right. Covered entities.

Ms. <Eshoo.= --the entities that are responsible for taking care of poor people. But that principle hasn't changed. That's why I am not so sure what you're specifically recommending.

Ms. <Draper.= Well, I think we are recommending that the intent, the oversight, the more rigorous oversight, which will help improve the integrity of the program.

Ms. <Eshoo.= You're saying that Congress should do more oversight?

Ms. <Draper.= No, I am talking about the HRSA should do--you know, they should have more rigorous oversight of the program and--

Ms. <Eshoo.= How? I mean, give me something specific. I asked you about--

Ms. <Draper.= I think we made--

Ms. <Eshoo.= --reporting and that I think that there are different reporting requirements of institutions. But give me

a specific.

Ms. <Draper.= So we've made several recommendations in the current report. You know, one was to institute a process for ensuring that duplicate discounts don't happen in Medicaid managed care. So that's a clear prohibition of the program that they don't--they don't have guidance for at this point.

I think that's one. I think making sure that they have--you know, another recommendation was that they have clear--that the number of contract pharmacy arrangements is clear that they--that they, you know, track each one of those because right now they're really understated.

So the--HRSA understates the number in their database of the number of contract pharmacy arrangements that currently exist and that's an important piece for oversight because that information is helpful to inform, you know, which covered entities they select for audits because it does increase--you know, the complexity level of an entity does factor into their audit selection.

So those are a couple issues.

Ms. <Eshoo.= Thank you.

Thank you, Mr. Chairman.

Mr. <Burgess.= The chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentleman from Virginia, Mr. Griffith, five minutes for questions.

Mr. <Griffith.= Thank you very much, Mr. Chairman.

HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit.

Instead, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity came into compliance with the 340B program requirements.

Ms. Draper, does HRSA reaudit a covered entity after a corrective action plan is submitted to ensure compliance before they close the audit?

Ms. <Draper.= They don't before they close an audit but they have conducted 21 reaudits over the course of, I don't know, a couple years. So and one--in the findings of those, one, they found the covered entity in one of the audits where the entity did not implement their corrective action plan, as they said.

They found 12 other instances where the noncompliance findings were similar. Three were for the exact same issues. So, you know, even in the reaudits they find, you know, that--you know, the audits probably should not have been closed.

Mr. <Griffith.= The audits still exist. And so wouldn't it be a better practice if they would at least do a mini audit or something to make sure that the problems were addressed before they just close the audit and say, here are your problems but we are not coming back to check on you, you know?

Ms. <Draper.= Or require some kind of documentation. You know, at GAO, I mean, it's a very similar process. We don't close a recommendation unless we have specific documentation that something has actually been implemented.

A lot of times an agency will submit to us that they have a plan. Well, a plan doesn't do it. It has to be actually implemented.

So I think, you know, more rigorous information that they require from the--from the covered entities as to what they've done.

Mr. <Griffith.= I would agree with that, and I know that some of the hospitals are, you know, saying that they used the--I am switching gears on you--but they used the moneys that they generate or that they get from using the 340B program to help somehow.

But I notice that about half of the covered entities that you all reviewed the uninsured patient discounts just didn't go to the patient.

And I know they may be using it somewhere else, but don't you think that's a little bit of a problem--that we ought to have some way to track that to see that it's at least going to help folks who are low income?

Ms. <Draper.= Yes. So what we found of the 55--so we sent out--55 respondents that responded to our questionnaire, 30 said that they provide discounts at some or all of their contract

pharmacies.

Twenty-five said that they did not. But of those, four actually provided discounts at their--in their in-house pharmacies and so and then some others talked about that they provide benefits through, like, their charity care program that may cover--

Mr. <Griffith.= And I get that. I just think that we--

Ms. <Draper.= --that as well. So--

Mr. <Griffith.= --that since we are putting this program out we ought to have some way to track that to make sure, in fact--

Ms. <Draper.= Yes. There are no requirements for discounts--that the program provide discounts.

Mr. <Griffith.= Right. And I noticed that on Page 32 of your report you all found that some patients are even required to cover the cost of a 340B dispensing fee.

So not only are they maybe not getting the benefit but then they're having to take money out of their pocket to pay the contract pharmacy a dispensing fee.

Should Congress establish a new policy prohibiting that practice?

Ms. <Draper.= Well, I think--so what we did find was some of the covered--I mean, some of the contract pharmacies said that if a patient is uninsured or low income that they would discount that fee or just eliminate it altogether.

So, again, there's a wide range. I mean, it's hard to make

generalizations because there--we saw so much variation in how these arrangements worked and the financial arrangements. So it's just--

Mr. <Griffith.= I will tell you it troubles me when I see that we've put the program together to make it less expensive for folks and then we find that through the process in some places they're actually charging these folks a dispensing fee. That troubles me.

Ms. <Draper.= Well, you certainly don't want to discourage people from getting the drugs that they need.

Mr. <Griffith.= Exactly.

I am looking at my various questions and my time runs out. Do you think that or what do you--what would the effect be of limiting the fair market value of the fees a contract pharmacy could charge a covered entity?

That is, what if HRSA were to take the profit motive away from contract pharmacies and ensure that the benefits of the program would actually flow to the covered entities and not the contract pharmacies?

Ms. <Draper.= Yes, that's a--again, that's a really difficult question. I think the issue is--

Mr. <Griffith.= I try not to ask all the easy ones.

Ms. <Draper.= --that you don't want to create negative incentives that the program doesn't work as intended and I think that, you know--so it's just--it's hard to make a blanket

generalization because I think it--some of these things really do require further look see to see what the impact actually is.

Mr. <Griffith.= All right. And I think that's fair and I appreciate your time and your testimony here today and I appreciate it, and thank you very much.

And I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair would observe that as we finish the first panel we will go immediately into the second panel. So to the members of the second panel, consider this your five-minute warning that if you need to take a break before we go into the second panel this might be the time to do it.

The chair is now pleased to recognize the gentlelady from Illinois five minutes for questions, please.

Ms. <Schakowsky.= Thank you, Mr. Chairman, and I want to thank you so much for being here. 340B is absolutely essential to people in my district. With skyrocketing drug prices, 340B is literally a lifesaver.

In my district, Advocate Health has used its 340B savings to provide support for uninsured or under insured patients through the child vaccination programs and the medication assistance program.

340B is not the driver of high drug prices. The pharmaceutical corporations' unlimited power to set the list

price is the driver. The 340B program is one that actually attempts to lower drug prices.

There are many things Congress could be doing right now to lower drug prices. For example, a California law went into effect earlier this year that requires drug makers to give advanced notice of large price increases.

In response to that, Bloomberg reported that in the past three weeks Novartis, Gilead, Roche, and Nova Nordisk sent notices to California's health plans rescinding or reducing previously announced price hikes on at least 10 different drugs.

If we really want to get serious about lowering drug prices a first step would be a bill that I have, H.R. 2439, the Fair Drug Pricing Act. Like the California law, this bill would require basic transparency for drug prices spikes.

There's been a lot of discussion about greater transparency in the 340B program and we can strengthen the 340B program by increasing accountability for pharmaceutical corporations that currently have very little oversight.

I want to follow up on Representative Matsui's questions because I am also concerned with the disparity between audits of covered entities and pharmaceutical manufacturers.

So, Ms. Draper, would you--you stated that 831 covered entities have been audited where only 12 pharmaceutical manufacturers have been audited. So I am wondering when a pharmaceutical corporation is audited by HRSA, what is being

evaluated?

Ms. <Draper.= Yes. So I would correct--it was 813 covered entities.

Ms. <Schakowsky.= Oh, I got the numbers changed around. I am sorry.

Ms. <Draper.= I said it wrong to begin with.

Ms. <Schakowsky.= Okay. Thirteen. Maybe I read it wrong.

Ms. <Draper.= So, we haven't looked at the--we haven't looked at manufacturer audits. But our understanding is that when HRSA--HRSA has done 12 to date. They began in 2015 with one and then five each year thereafter and I think they're on schedule to do five this year.

So our understanding is they--that they look at the drug pricing, the ceiling, and some other policies and processes and, you know, it's also our understanding, just based on the information that we found from their website is that they have found no--they've had no findings related to the manufacturer audits to date.

Ms. <Schakowsky.= Say that last sentence.

Ms. <Draper.= They've had no findings related to the manufacturer audits. So I don't know the extent that they--we haven't looked at that so I don't know the extent to which they--what they've looked at or the extent, their scope, or methodology.

Ms. <Schakowsky.= So, in other words, as far as you know,

HRSA has not punished or penalized or otherwise fined a pharmaceutical corporation participating in 340B for exceeding the statutory ceiling?

Ms. <Draper.= Not based on the audits, that I--that I understand. There's still some things that--you know, they have statutory authority to do--you know, they're supposed to do the--posting the ceiling prices on a website, creating civil monetary penalties, and also dispute resolution process.

Those things have, you know, been delayed. So those are things that are still outstanding for HRSA to implement related to manufacturers.

So I don't know when those are projected to be implemented. But they have been--you know, there have been continual delays in getting those implemented.

Ms. <Schakowsky.= So would you expect that if they actually did those kinds of inspections that maybe at least one or two might have exceeded the--you know, the fact that there's no--nothing, no action?

Ms. <Draper.= Yes. It's hard for me to say because, as I said, we haven't looked at it. But there are 600 manufacturers. So to do, you know, five annually that's about .5 percent.

The covered entities is about 1.5 percent of the audits.

Ms. <Schakowsky.= You stated that compliance measures have been required of pharmaceutical manufacturers. What were those compliance measures and were those in response to an audit?

Ms. <Draper.= I am sorry. What was the question?

Ms. <Schakowsky.= That you stated the compliance measures have been required of pharmaceutical manufacturers and were those in response to some audit?

Ms. <Draper.= Well, manufacturers are required not to discriminate based on 340B participation and so, you know, as far as I know, I don't--I assume that that's what--one of the things that HRSA is looking at.

They did revises their guidance on that a few years ago based on a recommendation that we made. But I really can't give you details about, you know, what their audits entailed or, you know, so--

Ms. <Schakowsky.= Thank you very much. I appreciate it, and I yield back.

Mr. <Burgess.= The chair thanks the gentlelady. The gentlelady yields back.

Seeing that all members of the subcommittee have had a chance to ask a question, it's now in order to recognize Mr. Welch of Vermont, a member of the full committee, five minutes for questions.

Mr. <Welch.= Thank you very much, Mr. Chairman, for having this hearing, and I've been listening to the questions of my colleagues and have been in agreement with a lot.

The transparency that Dr. Bucshon mentioned is important and, Mr. Griffith, the point you made about the benefit going

to the patient actually raises a pretty serious question because I bet a lot of the hospitals in your district and mine are similar.

For them, for those hospitals, this is really not a question of exploitation. For them, it's a question of survival, and there's a tough call to make because most of these folks who were dependent on that hospital are relatively--really quite low income in my state.

These are nonprofit hospitals in every case in my state and this question of whether the benefit goes directly to the patient where they're getting significant taxpayer help for the health care versus the institution which, in Vermont, is so critical. So that's a challenge. I just want to say I appreciate your point. But this is about survival.

Mr. <Griffith.= If the gentleman would yield.

Mr. <Welch.= This is about survival for many of our hospitals, and if they weren't in those communities we have some like in your communities where that not only--those local hospitals not only provide health care but they're like the center of life in many of our communities and we've got to--we've got to make them successful.

Mr. <Griffith.= And if the gentleman would yield for just a second.

Mr. <Welch.= I will for--

Mr. <Griffith.= I would just say to the gentleman that I appreciate that point and that was not directly where I was going,

although I think I needed to ask the question.

But I would like for us to be able to see that the benefit, if not going directly to the patient, is going into low income coverage as opposed to just speculation that it is.

Mr. <Welch.= Well, I am willing to work with you on that. But I--here's the way I see it and this is why this is important. Any program we have, whatever program it is, we should be monitoring it and making certain that it is doing what it's supposed to do.

And it might be something you propose or something I propose. Accountability matters. I believe that.

But there's also a larger issue here about the pharma prices that are just killing us. They are enormous, and it is the fastest rising cost of health care and it is--if this program is a small component of what the pharma--the pharma profits are very, very substantial and this program, for whatever issues people are raising, really is like 4 percent of the discounts overall for pharma and the prices to these hospitals are really pretty brutal.

One bill that Mr. Harper and I have, and as you know, Mr. Harper has good news, we hope--he's waiting for his first grandchild. Otherwise, he'd be here with us. So let's wish him well.

But he and I have the orphan drug bill and I think I will ask the witness about this. That orphan designation--talking about things getting a little bit out of control, when it was

originally passed by Congress it was to give a preference for drugs that were used to treat, quote, "orphan'' diseases--rare diseases--but the pharmaceutical companies have managed, through litigation, to have that designation apply even when the drug is being used for a very common disease and it's resulting in the congressionally-conferred benefit going for congressionally unintended consequences.

Do you have any information about how much the orphan drug bill is being utilized for nonorphan diseases?

Ms. <Draper.= I don't, other than to know that a lot of those orphan drugs are used for other indications. That's about the extent of what I know.

Mr. <Welch.= Yes. And Mr. Chairman and my colleagues, I would hope that we'd give some opportunity for the Harper-Welch bill to be considered by the committee to address that.

Thank you, Mr. Chairman.

Mr. <Burgess.= That is the purpose of the--will the gentleman yield?

Mr. <Welch.= Yes.

Mr. <Burgess.= The purpose of the hearing today.

Mr. <Welch.= Yes, I appreciate that, Mr. Chairman.

The other issue I just--this is more of a statement than anything--I appreciate your work, but these pharmaceutical prices are brutal for everyone, but these small hospitals, 14 of them in Vermont, if they lost the 340B program it would be the

difference between black ink and red ink.

It's really that dire, and somehow some way--Mr. Carter, you know, you have been talking about this too--we've got to address those pharmaceutical costs.

So I yield back and thank the chairman for this hearing and allowing me to participate.

Mr. <Burgess.= The gentleman yields back. The chair thanks the gentleman.

The gentleman would remind members of the committee that we did have a rather extensive supply chain hearing not too many weeks ago where a lot of these issues received a great deal of discussion.

In fact, there are legislative products that are in the works as a consequence of those--of those discussions.

Seeing no other members wishing to ask questions, this concludes our first panel.

Ms. Draper, thank you very much for your time and your testimony. You have answered a lot of questions this morning and given us a lot to--a lot to think about.

We will now not actually but recess but you are excused from the first panel and we will immediately seat our second panel and while we are gathering name plates.

And I don't mean to hurry things along but we will have votes on the floor and out of respect for our panellists, some of whom have travelled a great distance, we want to try to conclude their

testimony and questions before we get distracted with votes on the floor.

So as the second panel is being seated, each of our witnesses on the second panel will have five minutes to provide an opening statement and, once again, questions from members after that.

Today, we are very fortunate to have with us Dr. Debra Patt, who is the executive vice president of Texas Oncology, Dr. Fred Cerise, the president and CEO of Parkland Memorial Hospital, and Dr. Charles Daniels, pharmacist-in-chief and associate dean, University of California San Diego.

We appreciate all of you being here today. Dr. Patt, let's start with you and you're recognized five minutes for an opening statement.

?STATEMENTS OF DEBRA PATT, EXECUTIVE VICE PRESIDENT, TEXAS ONCOLOGY; DR. FREDERICK CERISE, PRESIDENT AND CEO, PARKLAND HOSPITAL; CHARLES DANIELS, PHARMACIST-IN-CHIEF AND ASSOCIATE DEAN, UNIVERSITY OF CALIFORNIA, SAN DIEGO

STATEMENT OF DR. DEBRA PATT

= Dr. <Patt.= Chairman Burgess and Ranking Member Green, thank you for the opportunity to testify today on the opportunities to improve the 340B program and the impact it is having on patients with cancer.

I am Dr. Debra Patt, a practicing community oncologist in the great state of Texas. I serve as a national leader in health care policy, clinical informatics, and cancer research within my practice and in partnership with national organizations like U.S. Oncology, the Community Oncology Alliance, and ASCO.

I also volunteer my time and work collaboratively with Seton, my local 340B hospital, and their medical school affiliate. As a clinical professor at the University of Texas Dell Medical School, I co-chair the Access to Care Working Group to serve vulnerable patients in my community.

I share in this committee's commitment to improve the 340B program and will illustrate why providing transparency oversight and accountability to 340B hospitals would help to ensure that the vulnerable patients that need it can benefit.

In recent years, the 340B program has experienced explosive

growth, exceeding $19 billion in drug purchases last year. This rapid growth suggests powerful economic incentives are at work as 340B hospitals and contract pharmacies get substantial economic benefits from participation.

In cancer care we have many oral drugs that cost more than $10,000 a month. Hospital and contract pharmacies may purchase the drug for $5,000, then sell the drugs to patients for $10,000. This 50 percent margin is pure profit for the hospitals without verification that it is helping patients.

Furthermore, GAO underscores that 340B contract pharmacies are also big businesses, sometimes with healthy 15 to 20 percent profit margins.

Some 340B hospitals have enjoyed more than a $100 million in savings and have used those profits to acquire independent community oncology clinics and increase market share. This arbitrage opportunity on drugs in 340B to buy low and sell high provides a clear incentive to do this.

A recent Community Oncology Alliance report indicates that nearly 700 private community oncology clinics have closed or become affiliated with hospital systems in the last decade.

When this happens, the cost of care for patients doubles and it costs Medicare billions. How do we know that this program is used to enhance care for vulnerable patients? This is by far the most important issue that we face today with the 340B program.

Parkland Hospital in Dallas is a great example of a hospital

that needs and is using the 340B program as it should be. It's almost 50 percent DSH, far exceeding the requirements, and clearly needing the program.

Unfortunately, Parkland is not the typical 340B hospital. As of 2015, there was only a 1 percent difference in the amount of uncompensated care provided by 340B hospitals compared to non-340B hospitals.

A National Academies report noted that nonprofit hospitals are increasingly displaying business characteristics of for-profit hospitals, and many nonprofit hospital executives have seven or even eight-figure annual salaries.

Because there is no mandate to spend profits on vulnerable patients, some hospitals may use these to build towers or enhance executive compensation.

Across the country, there are pervasive and deep access to care issues for vulnerable patients that I see every day in clinic, and I want to share with you some of these experiences, because in the end it's all about patient care.

In Longview, Texas, about two hours east of Dallas, a 340B hospital declines to provide chemotherapy to honor under insured patients without up front cash payments.

In Austin, there are widespread shortcomings, delays, and detours in care for uninsured patients with cancer who, for some example, are placed on wait lists for months.

Last year, I saw a 50-year-old Austin musician who had a

clinical stage three breast cancer and was refused services at the 340B hospital. She watched it progress in her chest for the next three months until she came to us for care.

A 34-year-old pregnant woman with stage four colon cancer had to start her chemotherapy during pregnancy. We treated her for five cycles as a hospital inpatient under emergency care because the 340B hospital took eight to ten weeks to get her an appointment.

Another 16 patients I am aware of sat for more than six months last year to wait for gynecologic oncology appointments in the 340B hospital. Some had curable advanced cervical cancer and presented to the emergency room while waiting for treatment.

In Kentucky in February, a lung cancer patient was refused treatment at the 340B hospital due to lack of insurance and waited three months before seeking treatment elsewhere.

In Boulder, a patient with aggressive lymphoma who had Medicare Part A but was waiting on Medicare Part B was referred to the local 340B hospital to receive therapy. They would not see or schedule him until he got Part B and he died several weeks later without ever being seen.

I urge the committee and Congress to support legislation to provide for the integrity and viability of the 340B program so that we can ensure that it's about helping patients, not hospital bottom lines.

Without action, the program will continue to grow, Americans

fighting cancer will have less access to care, and patients, payers, and taxpayers will pay more.

Once again, thank you for the opportunity to address the committee. I am happy to answer any questions regarding my testimony.

[The prepared statement of Dr. Patt follows:]

**********INSERT 5**********

Mr. <Burgess.= And thank you for your testimony. And Dr. Patt, I apologize. I mispronounced your name as I introduced you. So, again, thank you for your testimony today.

Dr. Cerise, you're recognized five minutes for an opening statement, please.

?STATEMENT OF DR. FREDERICK CERISE

= Dr. <Cerise.= Thank you, Mr. Chair.

Chairman Burgess and Ranking Member Green and members of the subcommittee, thank you for the opportunity to speak to you regarding the importance of the 340B program.

I commend your leadership in ensuring the integrity of the program and hope to give your committee meaningful feedback on our policy--on your policy proposals.

My name is Fred Cerise and I serve as the president and CEO of Parkland Health and Hospital System. I am a member of the Medicaid and CHIP Payment and Access Commission, the chair of the Teaching Hospitals of Texas and sit on the board of the Texas Hospital Association.

I am appearing here today on behalf of Parkland Health and Hospital System. My testimony reflects my views as Parkland's CEO.

Located in Dallas County, Parkland is one of the largest safety-net systems in the country. Our mission is to care for all who reside in Dallas County regardless of ability to pay.

Our system includes an 878-bed acute care hospital with an extensive network of primary care clinics across Dallas County. We also provide health care in the Dallas County Jail.

We are the primary teaching hospital for the University of Texas Southwestern Medical Center and are nationally recognized

for our Level I Trauma, Level III neonatal intensive care unit, one of the largest civilian burn units in the nation.

We are also proud to claim Chairman Burgess as one of our many excellent physicians who have trained at our facility.

Last year, we provided over $879 million in uncompensated care and 76 percent of our patients were on Medicaid or uninsured. We had more than 1.2 million outpatient visits and filled 1.6 million outpatient take-home prescriptions and dispenses over 8.6 million inpatient medications.

Our pharmacy department includes one inpatient, seven retail, one central fill, and 26 Class D clinic pharmacies. We do not have a contract pharmacy and our pharmacy payer mix is over 62 percent charity care.

Parkland has participated in the 340B Drug Pricing Program since its inception. You've heard a lot of testimony in previous hearings around the unaffordability of drugs. The 340B program is a lifesaver for our patients. We directly use the savings to provide free and low-cost drugs to our patients.

I want to share two patient examples today that will illustrate the importance of the program. The first patient is a 53-year-old male with diabetes and a kidney transplant. He's under 100 percent of federal poverty level and enrolled in our Parkland financial assistance program.

He currently takes nine prescription drugs, and under our

Parkland financial assistance program, he pays $5 per drug. So for comparison, for one month the 340B price would be $255, the GPO price was $451, and the total Parkland co-pay was $45.

This is an example where Parkland passes on more savings to a patient than even what the 340B program provides.

The next example is a 61-year-old female with rectal cancer, diabetes, a colostomy. She's enrolled in our Parkland financial assistance program and is on seven drugs. The one-month cost for the 340B price was $20, the GPO price was $1,544, and the total Parkland co-pay was $35.

So under this example, the patient's co-pay was more than the 340B price by $15. However, this patient receives her cancer treatment and manages her diabetes at Parkland. Our 340B savings go directly back into our system to help with the cost of care for individuals like this patient.

Here are a few additional facts about our program. Last year, the 340B program saved Parkland over $152 million. You can see additional savings information in our written response to the Subcommittee on Oversight and Investigations inquiry last years.

We take compliance very seriously. We have one manager directly dedicated to overseeing the program and a multi-disciplinary team to assist him with ensuring the integrity of our program.

We perform quarterly scheduled audits on both inpatient and

outpatient areas. We also perform other targeted audits throughout the year. Health systems like Parkland welcome enhanced transparency requirements and stronger oversight from HRSA.

Like Congress, we believe this program should benefit from the populations we serve. We think Congress should be proud of the 340B Drug Pricing Program and what it has done to improve the lives of so many Americans.

I know that this program has saved our Dallas County taxpayers hundreds of millions of dollars since its inception and something we all can be proud of.

Thank you.

[The prepared statement of Dr. Cerise follows:]

**********INSERT 6**********

Mr. <Burgess.= Thank you, Dr. Cerise. We appreciate your testimony.

Dr. Daniels, you're recognized for five minutes, please.

?STATEMENT OF CHARLES DANIELS

= Mr. <Daniels.= Good morning, Chairman Burgess, Chairman Walden, Ranking Member Green, and Ranking Member Pallone. Thank you for this opportunity to share my experience with the 340B Drug Pricing Program.

I also want to say hello to Congressman Peters, my own congressman, who serves on this committee, along with Congresswoman Matsui, who represents the people of our sister institution, UC Davis Health.

I've been able personally share with Congressman Peters and Matsui and value of 340B discount to UC San Diego Health patients.

My name is Charles Daniels. I serve as the pharmacist-in-chief for the University of California San Diego's Academic Medical Center, referred to as UC San Diego Health.

As pharmacist-in-chief, I oversee the UC San Diego Health administration and use of the 340B program. UC San Diego Health is a top-ranked public academic medical center serving the people of San Diego and surrounding communities.

We offer tertiary and quaternary services as well as the resources of an NCI-designated comprehensive cancer center. We meet the criteria for being both a Medicare DSH as well as a Medicaid DSH hospital.

Currently, nearly 40 percent of UC San Diego Health patients have Medicaid health care coverage, making Medicaid the most

common payer for UC San Diego Health patients, followed by Medicare.

UC San Diego Health has been a 340B provider since the program's inception. We have a very high DSH adjustment percentage of 34.77 percent. UC San Diego Health utilizes the 340B drug discount to furnish discounted or free outpatient drugs as well as to provide necessarily medical services.

For example, a benefit of the 340B program is being able to provide some patients direct discounts on their drugs. We also provide patients help reconciling their medications and better understanding how to take their prescriptions when they leave the hospital through our Meds to Bed program.

UC San Diego Health invests savings we generate from 340B and teams of physicians that make regular trips 100 miles inland to Imperial County to deliver much-needed medical care to some of the country's most underserved populations.

UC San Diego Health also runs one of the most successful HIV and AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS program and takes a whole person care approach to treating patients with AIDS or HIV.

They offer primary care and comprehensive specialty care services including addiction counselling and mental health care.

A great benefit of the program of the flexibility qualifying providers are afforded to decide how they can best use the discount

to serve the unique needs of their underserved populations.

Because the 340B drug discount provides critical access points for so many of UC San Diego Health's patients. We've put into effect numerous practices to promote compliance with 340B program rules. These practices are necessary investments to ensure we remain 340B compliant.

At UC San Diego Health, we employ dedicated pharmacy staff to conduct internal audits each month, a random sample of 340B transactions from our hospital facilities, child sites, in-house pharmacies, and contract pharmacies that's conducted to verify that those prescriptions meet all of the HRSA requirements to be eligible.

UC San Diego Health also hires an outside auditor to conduct an annual review of our 340B program compliance. We provide regular continuing education on 340B rule clarifications to our compliance staff, our pharmacy personnel who work directly with patients at the prescription counter.

Additionally, we tried to be very intentional about the pharmacies with whom we contract. The 340B outpatient drug discount is the lifeblood of so many services that UC San Diego Health provides to underserved patients.

Any efforts in rule making or legislation to scale back the 340B Drug Pricing Program would be consequential to our patients and the patients of safety net providers across the country.

I welcome this opportunity to answer your questions. Thank

you very much.

[The prepared statement of Dr. Daniels follows:]

**********INSERT 7**********

Mr. <Burgess.= Thank you, Dr. Daniels. We'll move then to the member participation portion I am going to recognize Mr. Barton of Texas the first five minutes for questions.

Mr. <Barton.= Well, thank you, Mr. Chairman, and I want to thank our panellists for being here, especially the two from Texas. It's good to have you all both here.

I am going to ask the first question to the gentlelady, Dr.--is it Patt? Is that right? Dr. Patt? If you wanted to subsidize operating cost of hospitals that serve low income patients, would you set up a system that uses a discount drug payment scheme to do that?

If that was your goal, if you were trying to lower the operating cost, would you--would you say the pharmaceutical suppliers of the drugs had to lower their payment so they could, in essence, subsidize the operating costs?

Dr. <Patt.= So it's--in a perfect world where I looked at health care funding that would not be an optimal system. However, I do believe that the 340B program is a really important program to provide services to hospitals that serve a high proportion of underserved patients.

In my opinion, given what we have, it would be optimal to make modifications to the current program to allow it to operate in alignment with its original intent, and to try to move away from some of the--some of the changes that render the potential for fraud and abuse, that would be beneficial for all parties.

Mr. <Barton.= It seems to me, and I am one of the few that was here when these programs were set up--if you're trying to help hospitals with their operating costs, you set up a program to subsidize operating costs.

This program is set up to--if you meet the minimum requirements for DSH--percentage of your patients--requires the pharmacy--the manufacturers to provide discounts to--in terms of drugs.

The assumption would be those discounts go to the patients. We are trying to lower the out-of-pocket cost to the low-income patients.

That doesn't mean we can't subsidize operating cost, whatever way the Congress wants. But we've had this discussion about what the intent was. There's no question in my mind the intent was to pass through these lower drug costs to the patients taking the drug.

Dr. Cerise, from your testimony, most of the discounts that your hospital receives do go to the patients but not all. Is that correct?

Dr. <Cerise.= In terms of the direct dollar for drug costs, I gave two examples where, one, the discount was not as high as the actual drug cost.

But in that case, that patient is getting--through our health system she's getting all of her other services at very low reduced costs in our health system. So I would say in virtually 100

percent of the cases, whether it's drug costs, most of the times it's fully through drug costs and more. But in those cases like that one example where it's not, they're getting the benefit through other services, seeing the doctor, and being in the hospital and those sorts of things.

Mr. <Barton.= Well, I have a discussion draft that the committee staff has put out, and a discussion draft requires that to participate in the 340B program a hospital has to have at least I think 18 percent of its patient load DSH eligible.

Your hospital is over 50 percent. What would--what would be a--well, first of all, should we increase the DSH percentage requirement under current law?

Dr. <Cerise.= So from Parkland's perspective, as you said, it's--we are going to meet that threshold whether you increase it, you know, a little bit or a lot because our DSH percentage is almost 50 percent.

So and if you asked us--if you were looking at options for the program and some of the things that have been talked about--moratoriums, decreasing Medicare reimbursement--for us, rather than have something like that that goes across the board it would be preferential to increase that threshold.

I am sure for other--we are different than other hospitals that are closer to that threshold. They have other concerns and but for us it would not impact our ability to --

Mr. <Barton.= But you do support increasing the DSH

percentage? The answer should be yes.

Dr. <Cerise.= Yes, sir. Again, it would not be the--the reason--the reason people are coming to the program is because of high drug costs. The--and so it would not be the first place I went, but because it is--it is an attempt to increase the--to allow hospitals to deal with that.

However, as you said--

Mr. <Barton.= My time has expired.

Dr. <Cerise.= If the purpose is to restrict it, it's better than--it's better than restricting across the board with reducing Medicare reimbursement.

Mr. <Barton.= I will ask Dr. Patt one last question. Should 100 percent of the 340B discount be passed on to the patient?

Dr. <Patt.= I think that we should have 100 percent transparency about where the money is being spent because shining a light--having sunshine on this situation I think would facilitate appropriate use of those funds.

Mr. <Barton.= Thank you, Mr. Chairman.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Texas, Mr. Green, for five minutes.

Mr. <Green.= Thank you, Mr. Chairman.

Eight years ago, Congress passed the Affordable Care Act to address the HHS Office of Inspector General reports of drug

manufacturers overcharging 340B drugs.

The ACA directed the HHS to impose civil monetary penalties on manufacturers and to implement a ceiling price website so providers could verify what they were being--where they're being overcharged.

And I understand the implementation of these regulations were delayed five times. For our members on the panel, from the hospitals and even Texas Oncology, do you have any way of knowing if manufacturers are following the rules and are charging your hospitals the right price?

I will start with you, Dr. Patt.

Dr. <Patt.= I am unaware, sir. I don't know.

Mr. <Green.= Dr. Cerise? Coming from Houston we have similar hospitals like Parkland. So--

Dr. <Cerise.= So explain to me again--I am sorry--the specific question.

Mr. <Green.= There--for hospitals, do you have any way of knowing that the manufacturers are following the rules in charging your hospitals the right price no matter what the--this program is?

Dr. <Cerise.= I can't tell you. I don't--maybe, Chuck, you have, as the pharmacist, would have a better--

Mr. <Daniels.= Thank you for the question.

At this point in time, we don't have clear access to what the 340B prices are across the board. We can't see what other

places are paying and we don't have access to the information that we have always thought should be available.

Mr. <Green.= Okay. In 2018, Medicare outpatient prospective payment system final rule included a policy to cut Medicare reimbursements for certain 340B drugs by nearly 30 percent from the average sale price plus 6 percent to the average sale price minus 22 percent--22.5 percent. CMS estimates this will reduce critical payments to safety net hospitals by $1.6 billion each year.

Dr. Cerise or Dr. Daniels or even Dr. Patt, can you both describe the impact this cut would be on your institutions?

Dr. <Cerise.= Yes. We project a $2.2 million reduction from that action.

Mr. <Green.= Dr. Daniels.

Mr. <Daniels.= Our estimate at the beginning of the year was $8 million negative impact on the organization. So that's the best number we have right now.

Mr. <Green.= Dr. Patt.

Dr. <Patt.= While I don't have direct impact on my organization, I can speak to three changes.

One, that it does decrease the financial incentive for practices to acquire--for hospitals to acquire community oncology practices while they still can enjoy, roughly, 30 percent margins on drugs.

Two it actually doesn't take away funds from the system

because it's a rebalancing. It's not really a cut. Those funds weren't brought back to CMS. They were given to other hospitals that were providing care.

And three, patients saved money because out-of-pocket patient co-pays diminished substantially.

Mr. <Green.= Okay. The recent GAO report confirms that the contract pharmacies play an essential role in helping uninsured and low income patients get needed care including but not limited to prescription drugs.

Covered entities are already subjected to high-level of oversight both internal and through HRSA audits. Even HRSA, which oversees the program, does not agree on all these recommendations, noting that many of them are overly burdensome.

However, the GAO notes that HRSA needs to provide additional oversight over contract pharmacies.

Dr. Daniels, can you describe how UCSD used its contract pharmacy arrangement to increase access for patients?

Mr. <Daniels.= Thank you.

And so for the group we have approximately 63 contract pharmacies. They go all the way from the North County, Oceanside near Camp Pendleton all the way to the Mexican border--Chula Vista.

Those sites were selected by us based on where our patients were and where their prescriptions were being filled, and we tracked that process from our electronic medical record. Each

prescription that was sent out we tracked which pharmacy it was sent to and those became candidates for inclusion in the contract pharmacy program.

What I can say is that there are two things that I believe are important that we've taken as very serious. This is an important program to UC San Diego Health.

We have no interest in putting the program or ourselves at risk. So we follow audit procedures very carefully, very rigorously.

We do audits on a monthly basis that includes a subset of each of the players in the--in the program--hospital, child sites, contract pharmacies, and our own in-house pharmacies--and that information then is provided back. We analyse it at the department level and at the hospital level to make sure that we've done that.

I guess I would be--also want to share with the subcommittee that over the last three years we've reduced from originally 119 contract pharmacies to 109 contract pharmacies to 63. That is our current number.

And that was based on our desire to make sure that we had full accountability. I am sure that you're all aware, but the covered entity is sole holder of the risk.

If there's a violation in the program, we have the accountability. And so we have set up our programs both for selection and well as auditing around making sure that there are

no violations.

Mr. <Green.= Mr. Chairman, if I could just have one minute because our colleague from Texas took a little over time.

On June 1st, HRSA--

Mr. <Burgess.= Charge it to his account.

Mr. <Green.= Oh, to his account? Well, I just wanted to make sure our side had that extra minute. Could I have that extra minute?

Mr. <Burgess.= You have already used it.

Mr. <Green.= I didn't. The doctor did.

[Laughter.]

HRSA issued a final rule delaying the implementation of the 340B Drug Pricing Program, sealing the price penalties until July of 2019. These latest delays in the mandate that these regulations was eight years ago.

If the administration cares about accountability for 340B, perhaps they should start with implementing the delayed regulatory guidance program, and I thank you for your patience.

Mr. <Burgess.= Does the gentleman yield back?

Mr. <Green.= Yes. I didn't know I had anything to yield back.

Mr. <Burgess.= The chair thanks the gentleman. The chair recognizes the gentleman from Indiana five minutes for your questions, please.

Mr. <Bucshon.= Thanks for the seven minutes, Mr. Chairman.

I appreciate it.

[Laughter.]

Anyway, well, first of all, I want to commend all of you for what you do on behalf of patients. I was a health care provider before I was in Congress--a cardiovascular surgeon--and I know what it takes every day to be out there helping people. So I commend all of you and the people that work for you for what you do every day.

And CMS, as has been pointed out, has already cut reimbursement, and my fear is if we--if we don't do something with transparency and other changes to the program, it's going to happen again because it's about the money.

With the exponential growth, CMS is looking at that--the outlay of funds and they'll cut it again and this time it's going to be--it's going to hit critical access hospitals and others like in rural Indiana that I represent.

Dr. Patt, in your testimony you gave examples of patients at 340B hospitals without insurance being treated differently than those with insurance, which I think is appalling, by the way, as a provider, and in some cases their cancer treatment is significantly delayed due to their insurance status. This is exactly why we need transparency and reporting to be required in this program.

Do you think there should be additional requirements for hospitals to report their patient mix and charity care activities

including at their child sites?

Dr. <Patt.= Yes, sir, I do. So I think there are three changes that are important in the program. I think that you need transparency because I think when you shine a light on anything the sunshine provides better behavior, in general.

Mr. <Bucshon.= Agreed.

Dr. <Patt.= Two, accountability, and three, definition of a patient. Because of the laxity in definition of a patient, it provides a lot of opportunities in variability of interpretation between qualifying entities, especially with the expansion of the contract pharmacy relationships.

So, for example, if you have an entity that's maybe seeing a hundred new cancer patients per year in a market where they have 50 percent market share and 19 contract pharmacy relationships, they might capture 50 percent market share in that community of oral scripts that are written just because of the lax definition of a patient, and that's not really appropriate because those patients aren't really being managed by a smaller oncology provider. So I think those three components are critical.

Mr. <Bucshon.= Thank you.

Dr. Cerise, obviously, I believe in more transparency and it sounds like both you and Dr. Daniels--you do it internally.

We appreciate that. I've introduced a bill probably everyone in this room is aware of--the 340B PAUSE Act--and I also

have a discussion draft, both of which address reporting.

Does Parkland track--and I know you have already answered this but just to reiterate it--does Parkland track how 340B savings are spent and do you have any ideas or recommendations to Congress about what type of additional reporting requirements for the program that might be reported to HRSA or to the Congress so that we can get a handle on this?

Dr. <Cerise.= We do track our savings and you know, when we are delivering over $800 million in uncompensated care, that savings is gone in to support that. We are fortunate to have Dallas County taxpayer support that lets us do that.

But with 8 percent commercial business, we have limited ability to generate revenue elsewhere and programs like 340B help us to do that. And so I think looking at a payer mix among health systems and seeing what that--what that mix is, including the uninsured, looking at outpatient metrics--you know, the DSH formulas and inpatient formula for an outpatient program.

So getting an idea of what people are doing on the outpatient elective side of the equation would be important as well and then tracking programs what the benefit of those programs is to the population that they're taking care of, reporting on that.

Mr. <Bucshon.= Dr. Daniels.

Mr. <Daniels.= So we have some data. Right now, we currently provide about $155 million in under compensated care, an additional $17 million in charity care.

For that our current estimated savings from the 340B program is approximately $87 million. UC San Diego--and I personally support greater transparency--the idea of sharing--we are not afraid to share and show what we've done.

The question will largely be how that transparency is generated, what the numbers might look like, and making sure that they're doable administratively.

Mr. <Bucshon.= Great, because some hospitals, including the largest health system in the state of Indiana have said that the reporting requirements in the PAUSE Act are too burdensome.

It sounds like that you all already have internal data that, you know--could we require things that are too burdensome? Sure. That's what the government sometimes times does.

That's why I would appreciate your ongoing input and anyone that has any ideas about what is practical, doable, but also gives us the information we need so that we prevent further CMS reimbursement cuts, which are doing to happen if we don't get a handle on the program.

Thank you. I yield back.

Mr. <Burgess.= The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from New Jersey, Mr. Pallone, five minutes for questions.

Mr. <Pallone.= Thank you, Mr. Chairman.

Dr. Daniels, I mentioned in my opening statement that I have

always deeply supported the 340B program and I've always tried to work in a bipartisan fashion to strengthen the program, ensure appropriate and thoughtful reporting and transparency, and give the agency the resources that it needs to oversee 340B.

And the program plays a critically important role in our health care system. I don't want it to be lost here today that the majority investigation on 340B and the countless hearings we've had in our committee have reaffirmed the point--the value of 340B on both sides of the aisle.

And I think it's a good thing that we expanded the types of hospitals that can participate in 340B and the Affordable Care Act because that means that more dollars are going to stretch medical and social services for those in need.

However, I agree that it's very important to make certain those dollars do in fact go towards expanding services as the statute dictates and that all covered entities are carrying out the 340B program with the people they're intended to serve at the center of any policy decision and in full and transparent compliance with the law.

It would seem like an easy concept to track and document the savings to ensure the statute is met. But I know that's actually quite complicated and I would like to understand this better, given the interest in the issue. So would you explain the--well, I will ask Dr. Daniels.

Can you explain the complexity of tracking savings in 340B

discounted drugs and how does the University of California at San Diego ensure these dollars go towards expanding services for vulnerable patients?

And then, similarly, for Dr. Cerise, if you could also answer the same questions to hear how Parkland handles this issue. So I guess we'll start with Dr. Daniels.

Mr. <Daniels.= Thank you.

Let me speak to the question of how they're applied. There's no doubt that the complexity of how the discounts are accrued makes it very difficult for us to identify exactly. I think I used the phrase estimated impact cost savings of about $87 million.

The flow of the information on the drug costs comes back and it's not associated specifically with a given patient. We can track the amount of discount that comes back into us and I think that's an opportunity for standardization over time.

But I think the biggest challenge that I see is having--being able to separate the payment that comes back to the organization from the payers. From the drug cost side we can--we can track that but it's not at the patient-specific level.

Mr. <Pallone.= All right.

And then I will ask Dr. Cerise the same thing with Parkland.

Dr. <Cerise.= The same response. We can track that in aggregate, looking at our--looking at our drug spend. But on an individual patient level, we don't track it that way.

Mr. <Pallone.= I mean, do you have any suggestions to change that so we can have better tracking?

Dr. <Cerise.= So we are a--all of our pharmacies are 340B pharmacies. We don't have mixed inventory, and so we--the patients that we serve are eligible for those discounts and so whether it's at, you know, our central site or child sites, we will look at the cost of drug, our GPO cost, or 340B cost, and you can calculate the difference there to understand the savings.

But what my pharmacists say, at an individual patient prescription level tracking, oftentimes you don't know what your reimbursement is at the time it dispenses anyway. It's very difficult to do it at that level of detail.

Mr. <Pallone.= All right. Well, let me just say I want to point out that so many of the bills here today focus on huge amount of reporting and I think we all need to remember that we have an agency with less than 10 people on staff dedicated to managing 340B and we need to set up our agencies up for success and we should give the agency what it needs to effectively oversee the program. So we'll look into that better.

But thank you both for your input. I appreciate it.

Thank you, Mr. Chairman.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, five minutes for questions.

Mr. <Guthrie.= Thank you. Thank you, Mr. Chairman. Thank you for the opportunity and for the panellists to be here.

And Dr. Patt, I will start with you. In your written testimony, you explained how consolation of private oncology practices might be an unintended and unwelcome byproduct of the 340B program.

What guardrails do you think Congress needs to put in place to hinder this and are there other specialties that we should be aware of where this same trend is happening?

Dr. <Patt.= Yes, sir. Thank you for the question.

So I think that if you make three changes to the program it will substantially enhance its integrity and change some of the misuses of the program and not promote consolidation.

Again, it's transparency, accountability, and definition of a patient. I think that those three things will substantially diminish program use in ways that are not beneficial for patient care, because I think nobody is going to argue with organizations that are using this to enhance the care of patients.

It's the lack of clarity in how organizations are using it, whether it's to benefit patients or for other strategic initiatives that remain challenging.

So I think those three things are important. I do think this isn't just an oncology problem. We've consolidated oncology practices, but actually there are many practices that have similar outpatient drug utilization characteristics--rheumatology,

ophthalmology, gastroenterology, neurology--that are all subject to the same issues.

I think actually the most consolidation in the last few years has been in ophthalmology practices as there is a tremendous benefit of doing that, and I would say, comparably--there are physicians in the room--there are other medical subspecialties that have also consolidated based on similar issues.

So if you look historically at cardiology where the rates--there's a site of service difference in rates of reimbursement for echocardiography, you have seen cardiology practices all align with hospital systems.

So I think that it is subject to more consolidation of other medical subspecialties and if we make the program more transparent, accountable, and define a patient in a more meaningful way, that those are things that we can do to make sure that the program is used to care for vulnerable patients.

Mr. <Guthrie.= Thank you. Thank you for your answer.

And then Dr. Daniels, I notice in your testimony that you mention that UC San Diego does pass on 340B discounts to low income but on a case by case basis.

How do you determine which case by case and should there be a standard that--

Mr. <Daniels.= Well, there is a standard. So the testimony--

Mr. <Guthrie.= Apply the standard on a case by case basis?

Mr. <Daniels.= The testimony may have misrepresented--

Mr. <Guthrie.= It's not inconsistent. You're right.

Mr. <Daniels.= We have an algorithm. Patients that come to the counter we have information on their payer. Those patients that come with either a low family income we use an algorithm where the pharmacist or the technician at the counter asks those patients what their annual income is.

It's an honor system. We don't check it. And depending on their percentage of the federal poverty level, we have an algorithm that either gives the whole package to them free, a separate category of--I think it's 350 percent of the federal poverty level to 400 percent--they get a different discount but the drug gets free and the--and they do the co-pay.

And then for those patients that have a high co-pay and have a low family income, then they also get the drugs for that discount. So it's not random, I guess I would say. And the procedure has been fully vetted by our compliance office to make sure that we are doing the right thing.

Mr. <Guthrie.= Good. That makes sense.

So also to you and then Dr. Cerise, you both mentioned in your written testimony performing self or internal audits to ensure compliance with the 340B program.

Can you take about 20 seconds--in 20 seconds what kind of audits you guys do--how you go about it? Or do you just want to do it, Dr. Cerise, go--I guess one of you answer and one shake

your head whether you agree or disagree?

Dr. <Cerise.= Yes, because I won't get to the details. We have a--we have a 340B pharmacist who's dedicated to this program. So he will look at all of our sites--our child sites and look for things like patient definition, for duplicate discounts, and we comply with Texas and Medicaid law, acknowledging on the scripts that they're a Medicaid patient--that sort of thing.

Mr. <Guthrie.= Okay. Similar, Dr. Daniels?

Mr. <Daniels.= So we have--and in the package--in fact, it was on the screen a little while ago during my opening, we do have an algorithm or, I should say a flow chart, that is used by each of the pharmacies to decide whether or not they meet the criteria.

But as far as the audits are concerned, let me just briefly comment that the audits that we look at are comprehensive. They go to all the areas of the program. They look at the patient eligibility.

They look at the location where the service was provided to make sure that it is part of our--of our rules--our HRSA rules and as a result of that, we get reports. They come first to our pharmacy leadership team on a quarterly basis and then at the end of the--at least once--twice a year then we--our pharmacy--our 340B executive steering committee meets and their job--that's a multi-disciplinary group and their job is to review it and--

Mr. <Guthrie.= I think I am getting --

Mr. <Burgess.= The gentleman's time has expired and I am just hurrying us along because we will have votes on the floor and I would like, for your benefit, to conclude this panel before we leave.

The gentlelady from California, Ms. Matsui, is recognized for five minutes.

Ms. <Matsui.= Thank you, Mr. Chair.

Thank you very much for joining us today. As you know, that UC Davis Medical center is in my district and but I consider all the UC systems an important constituent and thank you for representing UC Health as a whole today.

Your testimony specifically touches on original intent of the 340B program and I think that is really very important. The program was never designed to be a drug discount program for patients; rather, a discount for the providers to ensure they're able to best serve the vulnerable and low income patient population.

And particularly in California, which has been successful in implementing the ACA and extending health care to most of the population, the need to support community providers remains despite the intentional reduction in charity care across the state.

And that's why my legislation, H.R. 6071, codifies the intent of the program in order to eliminate confusion.

Dr. Daniels, what does a hospital like yours have to do to be eligible for the program?

Mr. <Daniels.= So we are one of the original DSH hospitals, going back to the 1990s legislation. In order to meet that target, we come it at a DSH discount percent or adjustment percent of 34.77, I think it is--substantially above the minimum cutoff and that results--that gives us, I guess, qualification as a DSH hospital and that's how we participate.

Ms. <Matsui.= Okay. Your testimony touches on the various practices UC San Diego Health has in place to promote compliance for the program.

Can you describe some of those practices?

Mr. <Daniels.= The compliance is very important to us. This is a really important program for UC San Diego Health, and so we've taken that seriously and, in fact, as we've gone through our compliance we've done two things specifically to help us assure compliance.

We follow the HRSA rules all the way through from patient eligibility and how they're qualified. We follow the process of making sure that we can verify and account for all of the steps in the program.

The audits include such things as looking at the patient prescription itself, making sure that all of the pieces are in place, that it's an eligible provider that is part of our contract or paid medical staff.

And in the process of doing that we also look at where the encounter was for that patient. So those are all elements of our regular--

Ms. <Matsui.= Exactly.

Mr. <Daniels.= --audits of all of our--

Ms. <Matsui.= And it seems to be very complete and I think there's a lot of transparency there already.

And I--Dr. Daniels, you indicated that you calculated approximate savings of about $87 million from this program. Is that correct?

Mr. <Daniels.= That's the best estimate we have right now.

Ms. <Matsui.= And the best estimate. And I understand that HRSA is supposed to implement a ceiling price website and which should have been done years ago with the ACA, and apparently it's stuck somewhere in OMB.

So there's a lack of transparency with--on the fact of the drug manufacturers as far as the ceiling price. And I imagine that makes it difficult for you to calculate some of the savings yourself, right?

Mr. <Daniels.= It totally is. We don't really know what the actual price is supposed to be. So we have to make estimates in order to identify the difference between the price that we are paying under 340B and what the next best price would be.

So the next best price is--for the record, the 340B prices is not always available to us.

Ms. <Matsui.= Yes. So I think we should have more transparency on the other side, too.

Mr. <Daniels.= I would agree.

Ms. <Matsui.= Your testimony provides a brief summary of how savings accounts are used. Can you talk further about what would happen if you lost 340B savings?

Mr. <Daniels.= So that is an important question and I've actually had that conversation more than once with our CEO to talk about sort of how this might happen because we go through the process on a regular basis of figuring out sort of what that might mean.

A fair amount of the funds of the Owen Clinic, which is our HIV/AIDS program that I described earlier, come from--not from payer reimbursement but come from decisions within the organization.

It would probably impact our ability to extend our care into the Imperial County, out to El Centro and the areas out there. It would also impact negatively our ability to provide the free drugs to patients that are part of our program.

Ms. <Matsui.= All right. Thank you very much and I yield back.

Mr. <Burgess.= The chair thanks the gentlelady.

The chair recognizes the gentleman from New York, Mr. Collins, for five minutes.

Mr. <Collins.= Thank you, Mr. Chair, and thank your

witnesses and also Mr. Hudson for letting me jump in. I've got a Boy Scout event I've got to go to in just a second.

One of my two bills here is a small one but, as Mr. Green, pointed out about the resources of HRSA, it's a user fee of one-tenth of 1 percent for hospitals using the program. So for every $1 million of drugs you'd have to pay $1,000.

So Dr. Patt, would you agree that HRSA needs more resources, and I hope you might agree that my one-tenth of 1 percent is not onerous?

Dr. <Patt.= So, obviously, I don't represent a hospital that would pay these fees. But, in my opinion, having 22 people employed by our HRSA to conduct audits of 1.6 percent of 19,000 qualifying entities is inadequate and there needs to be some mechanism to staff HRSA appropriately, to resource HRSA appropriately, to empower HRSA appropriately to make sure that the program can be maintained with integrity.

Mr. <Collins.= And, certainly, I would point out too, like our--all our fees like PDUFA and so forth it's not unusual to have other folks pay money into something for, in some cases, a service in the case of PDUFA and some of the other drug programs.

So would either of our other two witnesses, very quickly, want to comment on that?

Dr. <Cerise.= Sure. Well, obviously, we think compliance is a big deal. We want to understand the expectations. We want to comply with the expectations.

We support oversight and transparency in reporting. And so, you know, if you're going to--if you're going to do a fee on--based on your amount we have a big amount because we are a large safety net system and we have a very high DSH percentage. So you might look at scaling according to DSH percentage.

Mr. <Collins.= Something to be considered. Sure.

Mr. <Daniels.= The idea of appropriately staffing HRSA to do its job, I think, is clearly important and I support that and I think UC San Diego would.

My only concern when I--when I hear the statement user fees is whether or not that is likely to take away from the important mission that the 340B program conducts or supports. And so from that point, it's--the idea of losing those moneys for fees puts a little shiver.

Mr. <Collins.= That's why we did one-tenth of 1 percent. So $1,000 per million.

So, Dr. Patt, the other issue that I am covering is the patient definition--that's my bill--and I know it's very controversial right now. But if you look at some of the oncology practices and some of them, I think would have the appearance of being acquired because of 340B because nothing else changed. The doctors didn't change. The locations didn't change.

A lot of times they are serving primarily an insured population base and the minute they get scooped up by a DSH hospital then the discounts they're called a qualified patient.

So, you know, my bill--I know it's controversial--would say that the fully insured patient would no longer qualify for the discount. Do you have any comment on that?

Dr. <Patt.= I would say that I think that tying discounts to the patient is important and I think that definition of a patient is critical because of the laxity of definition of a patient today.

I think that many qualifying entities are receiving discounts for patients that they don't actually manage because--I will just say most cancer patients they're admitted to the hospital. And so if I see Mrs. Jones, who has a lung cancer, I refer her for an outpatient biopsy. But I am treating her in my private practice.

She has a hospital medical record. I have privileges at the hospital. It would be really easy for a post-hoc reconciliation vendor to say, hey, Mrs. Jones is a hospital patient.

So I think defining a patient is really critical. I would say that I think it would be a big stretch to say that it should only apply for low income patients only because then how would patient--how would hospitals that are seeing such a high percentage of disproportionate share make money to extend other services to low income patients.

So I think--I do think that would be a challenge. But I do think that when you look at patients and qualifying patients

we really need to not just look at the inpatient DSH metric because it's antiquated.

It's 1992, post-Cold War. We really need to think about outpatients and the outpatients that we are serving and that that would be a more meaningful way to make sure that this program, in my opinion, is in alignment with its original intent.

Mr. <Collins.= Thank you for that--those comments and, Mr. Chair, I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Oregon, Dr. Schrader, five minutes for questions, please.

Mr. <Schrader.= Thank you, Mr. Chairman.

Dr. Patt, just trying to get clarity here. You indicated in your opening remarks that the hospital group you worked with--Seton--you know, could charge $10,000 for a cancer drug and with the discount only be on the hook for $5,000 and they would pocket all that money. Is that a reflection of what happens at your hospital group?

Dr. <Patt.= So no. I was establishing in my introduction that I round at Seton Hospital. I made rounds there every day. I work with them collaboratively in dealing with poor and underserved patients.

You know, like--

Mr. <Schrader.= So this didn't actually happen?

Dr. <Patt.= Like most community providers, I work in collaboration with our hospital system.

Mr. <Schrader.= But, I mean--I have limited time. I apologize. But did this actually happen at your hospital?

Dr. <Patt.= So I would say I don't know a specific example. But, typically, hospitals, when they purchase $10,000 oncology drugs, get a 50 percent discount. And so as I think--

Mr. <Schrader.= And they pocket that money for salaries and all that sort of thing?

Dr. <Patt.= No. What I am saying it's a problem of lack of transparency. We don't know how they're using those funds.

Mr. <Schrader.= Well, I would suggest that that's the reason we have the audits. We heard earlier testimony from Ms. Draper that this--they have these audits. They're not doing enough of them.

We've heard good bipartisan testimony we could have more complete audits. But I worry--we don't want to give the impression to folks out there that the hospitals would just pocket this money for their own personal gain.

The real world is under the statute and under the statute and under the audits they are required to provide services for patients, either wraparound services or direct drug discounts to those particular patients that are Medicaid eligible.

So I just want to make sure there's clarity out there. The other thing that--

Dr. <Patt.= Respectfully, the evidence--

Mr. <Schrader.= If I may reclaim my own time.

The other thing that I am concerned about in some of the legislation?

Mr. <Bucshon.= Would the gentleman yield?

Mr. <Schrader.= No.

The other thing I am concerned about right now is the charity care nexus. Under the Affordable Care Act and actually, hopefully, through this particular program, the goals is to reduce the amount of charity care that's out there.

So if we base the 340B program on just those clinics and those hospitals, those outpatient service providers that have a high charity care load, we are missing the point.

We are actually penalizing hospital groups--coordinated care organizations in my state--that have actually reduced the cost of health care overall, provide those wraparound services and have reduced charity care.

With all due respect to my colleagues across the aisle, you know, frankly, they've increased charity care costs recently by undermining the cost sharing program, by not allowing reinsurance programs, taking away the mandate.

If there's an increase in charity care costs, you know, that's not a fault of the system and all the good work that your hospital groups are doing. That's, frankly, on us here in the United States Congress.

So I have problems with the charity care case. Dr. Daniels, when we figure out charity care, do those wraparound services that a lot of, you know, our great groups in this country have provided factor what constitutes charity care so we can compare apples with apples?

Mr. <Daniels.= Well, in California, because of the Medicaid expansion, we have minimal charity care. We have a fair amount of under compensated care as a result of Medi-Cal and, to a different degree, Medicare payment systems.

So but there is no doubt the answer to your question is that we include all of those sort of wraparound process as part of how we--what we count in the under compensated care. So--

Mr. <Schrader.= Yes, and I think that's an appropriate thing we have to focus on. The goal is to reduce charity care. Those--some folks did not choose the Medicaid expansion. Okay, you're going to have high charity care caseloads.

But those groups--those parts of the country that went that route, they're actually, hopefully, enjoying the benefits of the fact that they've been able to use these products--the 340B program for these wraparound services to provide good patient care, and I think that's sometime that we ought to focus on in a lot of the discussion here.

Dr. Daniels, furthermore, there's a big audit regimen that already goes on on 340B. Apparently, it's not perfect. There are some improvements. GAO indicates HRSA agrees with some of

those recommendations. Some of our colleagues here have some great ideas.

You know, what do you think of the current regimen and should there be some pieces that you might recommend that we should not be doing? Another, perhaps, audit processes that we should be going through?

Mr. <Daniels.= What I would say to that is that, speaking on behalf of UC San Diego Health, we've taken the program very seriously. We want to make sure that we are in full compliance.

Changes, I think, are potentially in order. We strongly support more transparency but it should be the right transparency, putting the light not only on the providers but also the manufacturers, making sure that the information that we collect as part of that transparency serves an important purpose for understanding the direction the program is going.

Mr. <Schrader.= Thank you.

And I yield back, Mr. Chairman.

Mr. <Burgess.= The chair thanks the gentleman.

The chair recognizes the gentleman from North Carolina, Mr. Hudson, five minutes for questions, please.

Mr. <Hudson.= Thank you, Chairman, and thank you to the panel for your written testimony and the time you have given us here today. It's very important.

I mentioned earlier when I was questioning Ms. Draper from GAO that I have four major hospital networks in my district.

Each one uses the 340B program. They've demonstrated to me how the different ways that the program enables them to better serve their patients.

I believe this program is vital for our communities and I believe in its mission. But the program can and should be improved. One idea that I've been exploring is elevating the 340B program to an administrator level program within HRSA.

By elevating 340B program to a Senate-confirmed administrator level program I believe we will make the program more accountable to Congress, provide more visibility into the program and improve administration of the program.

I believe these are goals that we all could support. I would just ask the panel, each one of you, to answer, do you foresee any issues with this legislation?

And, Dr. Patt, if you--start with you.

Dr. <Patt.= I think there are many different ways you could improve upon administration of the program. I can't speak to which one would be best.

Dr. <Cerise.= It's a critical program for us and for our patients and so anything that can support the program to make it viable and continue to work for us and for our patients we would be in favor of.

Mr. <Daniels.= So I concur it's an important program and worth making sure that it is done correctly. I am not in a position to be able to answer the question of whether or not an

administrator level is the right direction.

But I, clearly, support making it--organizing it so that it can be successful and help us be successful.

Mr. <Hudson.= I appreciate your answers, and I sprung this on you. So I really would be interested in your feedback--the feedback of your organizations. This is an idea that has some bipartisan support here and I think we'll continue to pursue. If you have thoughts--if you'd like to submit them in writing I would welcome that. Thank you.

And with that, Mr. Chairman, I will yield.

Mr. <Bucshon.= Would the gentleman yield for a few minutes?

Mr. <Hudson.= I yield the balance of my time. Yes.

Mr. <Bucshon.= And the point I was trying to make with my colleague was not allowing the witness to answer the question was in that the implication that we are assuming that everyone are bad actors out there is just factually not true.

The issue is is we don't know. That's the issue. The issue is not accusing anyone of anything. The issue is we just don't know, and it's unfortunate that that impression was created and then not allow the witness to answer the question.

I yield back to Mr. Hudson.

Mr. <Hudson.= Unless there's anyone else, Mr. Chairman, I will be happy to--

Mr. <Burgess.= Yield to me for just a moment, if you would.

And then the other aspect of what was brought up and,

unfortunately, the gentleman's already left, but I would just point out this committee--this committee provided 10-year authorization for Children's Health Insurance this year. This committee provided two years of authorization for community health centers. This committee provided reauthorization for teaching health centers.

True enough, cautionary reductions were not considered not because this committee would not consider them but because Senate Democrats killed that bill over in the Senate Health Committee.

So fair is fair. We can point out some things. But this committee has, I think, an exemplary body of work to point to in the last 18 months in the work that we've done to provide affordable care for people who need it.

With that, I am going to recognize the gentleman from--oh, do you yield back, Mr. Hudson? I apologize.

I recognize the gentleman from California for five minutes.

Mr. <Cardenas.= Thank you. Thank you very much, Mr. Chairman, Ranking Member. Appreciate the panellists coming forward and helping to educate us about what's going on in the real world when it comes to this very important program that we all--all of our communities depend on.

One of the first things--top lines I would like to remind everybody is this 340B program, has it--is it having a positive effect on rural health care--health care in rural America?

Just top line, is it?

Dr. <Cerise.= Yes.

Mr. <Cardenas.= Anybody disagree with that? Is everybody consistent with it? Okay. Good.

I just wanted to point that out because I represent Los Angeles, second largest city in the country. But I think it's important and incumbent upon all of us to always recognize that when something, on balance, is actually helping American citizens in our district or outside our district--people whose accents might be very different than the people that we represent in our district, what have you, I think it's important that we try to do our best to be good stewards in oversight and making laws to make sure that we try to figure out how do we keep something that, on balance, is doing good things--how do we keep it going and help to make it better.

One of the things that I would like to ask--again, a top-line question is are any state or federal dollars involved in the 340B program? Obviously, out in the field HRSA is federally funded, et cetera, but I mean, out there in the field?

Mr. <Daniels.= Our oversight is a mixture of local, state, and federal funds. So in terms of compliance and oversight, in terms of, you know, acquiring--and how we acquire drugs but--

Mr. <Cardenas.= Pretty minimal out there--the application.

Mr. <Daniels.= Yes. This is--this is a drug discount program. It's not federal dollars, right.

Dr. <Cerise.= Yes. I guess I would concur that the point

of the 340B program is--has been for 25 years that it doesn't cost the citizens in the United States directly.

Mr. <Cardenas.= That point being made, the intent--and it looks like the intent is following through. Because I've been a lawmaker for 20 some years and I've actually passed some laws that I had to correct because, oops, the intent was--so my--your point is 25 years ago the intent was, and when it comes to public dollars being utilized, by and large, it's following through with that intent, right, in your work? Yes.

Dr. <Patt.= So I would say that with--if you look initially that's absolutely true and if you look at some of the secondary consequences of consolidation, which have caused site of service shifts to sites of care that cost double, that costs patients more.

It costs taxpayers more. You know, health insurance premiums rise. We pay more in the Medicare system. And so there are secondary consequences that do cost all of us more.

Mr. <Cardenas.= Okay. But not having a 340B in and of itself would be disastrous compared to the environment that you just described?

Dr. <Patt.= I do think not having a 340B program would be disastrous. I completely agree with that.

Mr. <Cardenas.= Exactly. So basically, Dr. Patt, you basically pointed out--and thank you for doing that--that it's not perfect but--and there are some inadvertent consequences--but

in my personal opinion, those inadvertent consequences we should always close them as well as we can. By and large, the 340B program is a success, by and large, with its intent and its actual utilization in the field.

Dr. <Patt.= I think there definitely are successes in the 340B program. But I think to understand that better--

Mr. <Cardenas.= Overall?

Dr. <Patt.= --we need better transparency.

Mr. <Cardenas.= Yes, and transparency is something that I think we all need more of and one of the things that HRSA has not grown to the degree to have the proper oversight in the program since the program's inception.

My understanding when it started it was--the participants were in the hundreds--the facilities. Now it's in the--over 10,000, correct? It's some magnitude thereof, and HRSA has been a problem keeping up with that and I think it's incumbent upon Congress and policy makers to make sure that we try to figure out how do we make that happen--how do we make sure that HRSA actually can keep up so that that transparency is in fact real-time transparency?

Because all of the participants are required to report, and apparently they do. But at the same time, when reports are stacking up and those who are supposed to be looking at those reports and verifying them are behind, therein lies the problem.

Again, to me, that's--I think Congress has more to do with

trying to close that issue more than anybody else in the system.

Boy, does time go by fast. My question for Dr. Daniels--can you tell us very briefly and quickly about the reporting at your hospital?

Is the reporting for 340B is that quite involved with your organization? Is it kind of a--sort of a full time effort or is it just tertiary?

Mr. <Daniels.= We currently have two full time equivalent staff members that focus exclusively on that and then there are other administrative pharmacy support that are involved also.

Mr. <Cardenas.= Okay. Thank you very much. My time has expired.

I yield back.

Mr. <Burgess.= The gentleman yields back.

The chair recognizes the gentleman from Virginia, Mr. Griffith, five minutes for questions.

Mr. <Griffith.= Thank you very much, Mr. Chairman.

I appreciate my colleague mentioning that we have to look out for folks who might have different accents. I thought maybe he was talking about me.

Yeah, he says yeah, and others. But I do appreciate that because this is a good program and I think we all acknowledge that.

But, Dr. Patt, I agree completely and that was the dialogue I was having with my colleague from Vermont earlier that we need

more transparency.

We need to see where these savings are going so that we can make sure that this money and the intent is going to where we intended it to go.

It may not go directly to patient A but it ought to be going to patients in similar circumstances as patient A, who's entitled to a benefit.

So I appreciate your comments on transparency and we'll see what we can do to make that happen.

Dr. Daniels, I noticed in your answer on, you know, what is it costing the taxpayers, you said it didn't cost the taxpayers directly, which I agree with. I think that's--or close to agree with.

But let me see if I can clarify it for my own edification and education. So if you're receiving Medicaid and Medicare, which is a taxpayer benefit, and the hospital receives a discount for the drug, don't they still bill Medicaid and Medicare?

And I am not saying it's wrong. I am just asking to get educated. Don't they still bill Medicaid and Medicare for the full cost of that drug?

Mr. <Daniels.= We, certainly, bill according to the contract that we have.

Mr. <Griffith.= And that would be the way the 340B works, though, isn't it?

Mr. <Daniels.= Yes. I think we follow the rules.

Mr. <Griffith.= And I am not--and I am not being critical of that. I am just trying to make sure that--so that would be a little bit of direct money and then the indirect in that costs may be shifted elsewhere. But I appreciate that.

My understanding, and correct me if I am wrong--and I am looking mostly at our hospital folks, not Dr. Patt in this one--is that the child sites--those sites where a company has come in and purchased the practice--the child sites are actually growing faster for 340B in the last several years than have been the parent sites. Is that not correct?

Dr. <Cerise.= That's correct. We have the 83 child sites, and the way our child sites work is anything we have off campus--so we may have one building with five different clinics on a floor. That's five cost centers and five child sites.

So as we--you know, like we are dealing with now--we have a behavior health problem and we are trying to add some services in an extended observation unit that'll be a child site so we can get access to drugs to treat those patients.

Mr. <Griffith.= And but that's been--that's industry wide as well, isn't it?

Dr. <Cerise.= I can't speak for the rest of the world. Sorry.

Mr. <Griffith.= Okay. How about you, Dr. Daniels?

Mr. <Daniels.= Yes, just affirming that statement. If we have, in the same physical space, if on Monday we have cardiology

and on Tuesday we have endocrinology and on Wednesday yet another clinic, each of those would be registered as separate child sites.

So we follow the HRSA rules and that part of--part of the number--the large number of child sites is related to the fact that that's the requirement in order for us to be able to meet the HRSA rules.

Mr. <Griffith.= And I think one of the concerns--we had--not in--I don't believe it was this subcommittee--I believe it was one of my other subcommittees--we had a hearing previously on this same subject area and one of the concerns raised in that was a lot of hospitals were buying oncology sites in order to bootstrap or beef up their 340B capabilities.

Dr. Patt, can you speak to that?

Dr. <Patt.= I can. You know, it's--you have seen almost 700 community oncology practices close or align with hospital systems in the last decade, shifting the costs of the site of service.

And so let's say you have a hospital and two community oncology practices that are 30 to 35 miles away in a suburban area. If those qualify as child sites where it's, you know, the payer mix is predominantly private and Medicare, it allows them a tremendous economic advantage.

And so because they have such, you know, an arbitrage opportunity with purchasing power, it's really easy to say hey, community oncologist A--practice A and B, you know, you can either

align with us in the hospital system and let us purchase you or we are going to open something right next door and I can see half the patients because I can bleed for years because I have 340B discounts--I buy drugs at half the price--and we are going to push you out of the market.

And so that's happened to almost 700 community oncology practices. And so, you know, that's--it certainly alters market dynamics, and while I would say that's not great for community oncology and not great for some rural sites that have closed, but more so shifts the site of service to a more expensive cost of care.

And so, you know, we'd love to see some of that economic incentive be diminished over time and I think that that happens when you provide transparency, accountability, and appropriate patient identification because then you know that, you know, you can show sunshine on that behavior that qualifying entities have and then make sure that its alignment and value add to underserved patients.

And so I think that those are things that are in the best interest of health care in general.

Mr. <Griffith.= I appreciate that and I see my time is up, and I yield back, Mr. Chairman.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Illinois five

minutes for questions, please.

Ms. <Schakowsky.= Thank you, Mr. Chairman, and thank you all for your testimony.

As Dr. Patt rightly pointed out in her written testimony, that patients without access to health care have a higher--almost a 50 percent higher mortality rate--this is particularly true for those who can't afford the drug costs to treat their cancer.

In fact, not only are cancer patients two and a half times as likely to declare bankruptcy as healthy people but those patients who go bankrupt are 80 percent more likely to die from the disease than other cancer patients, according to studies from the Fred Hutchinson Cancer Center in Seattle.

The average cost of cancer treatment runs about $150,000 range. New cancer treatments emerge routinely but with new hope coming even more--comes even more cost. Eleven of the 12 cancer drugs approved by the FDA in 2012 were priced more than $100,000 a year.

So this is good business for pharmaceutical manufacturers. They have a lot of money and influence and they use it to attack programs that are aimed at lowering drug prices like the 340B program.

So, Dr. Patt, your testimony notes that many nonprofit hospital executives have seven or eight figure annual salaries. You also imply that such executive compensation is enhanced under the 340B program.

Texas Oncology is a member of the U.S. Oncology Network, which is a division of the McKesson Corporation. Is that correct?

Dr. <Patt.= No, ma'am. Texas Oncology is a private practice. We have a business relationship with the U.S. Oncology Network. They provide us electronic health record management services--a singularity in group purchasing, and so it is an affiliation.

But I work for a private practice in the state of Texas.

Ms. <Schakowsky.= Okay. Well, just to note that, you know, while you criticise nonprofit executives for their salaries, Forbes magazine recently published an article titled, "Ten Highest Paid CEOs'' and the CEO of McKesson came in as number one on the list with an annual salary of $131.2 million.

Now, you mentioned that you collaborate--you have collaborative relationships with 340B hospitals. But I am trying to understand the nature of that--of that collaboration.

We know that many of the uninsured patients that--at your center that you--that they have been directed to Seton and other 340B hospitals in your service area. Is that right?

Dr. <Patt.= So my collaborative relationship with Seton is extensive. For a decade I ran their breast cancer services for the network.

I chaired the breast cancer subcommittee. I still chair under the division of women's health, which is a collaboration between UT Dell Medical School and Seton.

Ms. <Schakowsky.= But isn't it also true that you have referred people to Seton and to the 340B program?

Dr. <Patt.= So I have referred people to the Seton outpatient clinic. It's called the Shivers Infusion Center, yes, and I round at Seton. So I rounded at Seton every day last week except for July 4th I had off. About a third of my patients that I saw were uninsured.

Ms. <Schakowsky.= So it isn't clear to me why your center is not treating those--your center treating those uninsured patients right there.

Is your center itself a safety net provider?

Dr. <Patt.= It's not a safety net provider. So we do provide care for Medicaid and uninsured patients. That's a little less than 10 percent overall of the percentage of payer mix that we have across the state.

It varies because our sites in McAllen and El Paso have a higher percentage of Medicaid and uninsured. But we don't receive funds from an intergovernmental transfer. We don't have 1115 waiver district funds.

We don't have 340B discounts. Being a private practice we are a PA. So being a private practice we don't have incremental funds to see and treat those patients.

Now, sometimes we do, of course, and we've been very fortunate to get some drugs donated for patients because, you know, as you mentioned, some cancer drugs are very expensive.

Actually, we've had a lot of success so we've--

Ms. <Schakowsky.= In your--in your experience have you seen the abuse of 340B in those hospitals with which you collaborate?

Dr. <Patt.= I don't know because I don't know how they use the 340B program. You know, I find it challenging because in my own practice--again, last week when I saw five uninsured patients each day it's a challenge to get those patients into the 340B institution and more so, you know, being an oncologist I know that actually those expensive drugs are some of the least important ways to cure cancer.

Screening for colorectal cancer and breast cancer and good primary care are some of the best things you can do to prevent cancer mortality and those programs for uninsured patients in my community are virtually absent.

And so that's a challenge that we have and, you know, we work together with the 340B hospital on many efforts to try to improve upon them and I've dedicated a lot of my volunteer time to those efforts.

Ms. <Schakowsky.= Well, it seems that your institution also relies on those 340B hospitals. I am happy that you said originally that you think it's an important program because--

Dr. <Patt.= I do.

Ms. <Schakowsky.= --I do, too.

And I yield back. Oh, wait. I do have more money--more money--more time.

Mr. <Burgess.= No. Your time is way--

Ms. <Schakowsky.= Oh, it's way over. Okay. I yield back.

Mr. <Burgess.= You're in arrears.

[Laughter.]

We are going to the next hearing.

So I recognize the gentleman from Georgia five minutes for questions, please.

Mr. <Carter.= Thank you, Mr. Chairman, and thank all of you for being here.

Dr. Cerise, I want to start with you. As you know, HRSA uses a hospital's DSH adjustment as--DSH adjustment percentage as one of the measures for eligibility for the 340B, and under current law the hospitals must report their low income utilization rate in the inpatient setting and not in the outpatient setting. And, of course, this can make a big difference.

Simply put, the--some of the low income utilization rate is an inpatient metric that is being used for an outpatient program.

Can you tell me, in your hospital what's been your DSH percentage for the last few years? Do you have any idea?

Dr. <Cerise.= Forty-seven percent.

Mr. <Carter.= Forty-seven percent in the inpatient. Do you have outpatient facilities as well?

Dr. <Cerise.= We do.

Mr. <Carter.= If you were to include those, do you have

any idea what it might be at that point?

Dr. <Cerise.= Yes. Well, I can tell you approximately. Our--

Mr. <Carter.= I understand. I won't hold you to it.

Dr. <Cerise.= --our Medicaid uninsured percentages would go up if you included the outpatient.

Mr. <Carter.= The outpatient clinics?

Dr. <Cerise.= Correct.

Mr. <Carter.= Okay. Dr. Daniels, what about you? Do you have any idea what your percentage is in the inpatient setting now?

Mr. <Daniels.= The inpatient setting we are at 34.77 percent.

Mr. <Carter.= If you were to include the outpatient, any idea?

Mr. <Daniels.= I don't have that information. I know that we also do provide a high level of care in the ambulatory to Medi-Cal patients.

Mr. <Carter.= Right.

Mr. <Daniels.= And so but I don't know what the number is.

Mr. <Carter.= Do you have child sites as well at Children's Hospital?

Mr. <Daniels.= Yes, we--

Mr. <Carter.= What's the patient mix there?

Mr. <Daniels.= I don't have that information. We don't

collect it that way, sir.

Mr. <Carter.= Okay. Dr. Cerise, do you?

Dr. <Cerise.= In general, our child--we don't have children's--actually, we do see a little bit of pediatrics in our primary care clinics.

Mr. <Carter.= Right.

Dr. <Cerise.= But most of our child sites are serving adults and the mix there is going to be, roughly, 75 percent Medicaid and uninsured.

Mr. <Carter.= So it's higher than in the inpatient setting in a hospital?

Dr. <Cerise.= Sicker patients in the hospital we tend to be able to get some coverage for sometimes better than the chronic patients who are seen in the outpatient clinics--

Mr. <Carter.= Right.

Dr. <Cerise.= --a higher percentage of uninsured.

Mr. <Carter.= Well, then, and, you know, I've gotten legislation that I am introducing that would require one of--would require the outpatient be factored in as well, because I think that's very important because, obviously, one of the abuses--I am not--you know, it's not illegal--it's just one of what we consider to be the--some of us consider to be the abuses is that a lot of the hospitals are using this in outpatient clinics and outpatient settings when it was intended to be used and based on the inpatient.

So Dr. Patt, if I could go to you. You talked about some of your experiences--they were really frightening to hear--of some of the patients who were having to wait and not--are being denied care and I was just wondering what can you--what can you suggest that we can do so that this doesn't happen--some of these examples?

What can we do legislatively in Congress?

Dr. <Patt.= So, again, in my opinion, reform focusses around three issues--having transparency, accountability, and definition of a patient.

So I think if you have transparency in how hospitals spend these funds it helps to solve some of these problems immediately, and accountability, I think, rests in not the--not just having this being a percentage DSH metric for inpatients but have some accountability for outpatients, because this is really an outpatient program that's measured by DSH inpatient.

And, again, if you look--as 340B programs have grown tremendously, 340B versus non-340B entities, on average, have only a 1 percent difference in uncompensated care.

And so I think that we need to--again, transparency, accountability, and patient definition, I think, you know, will bring up great actors in this program and give every hospital that's using this program an opportunity to provide excellent care to the patients they serve.

Mr. <Carter.= Right. I couldn't agree with you more. All

three of those are extremely important, especially patient definition. To me, that would clear up so much about who is--who is eligible and who is not eligible.

Mr. Chairman, at this time, I would like to ask that this document titled "How Abuse of the 340B Program is Hurting Patients'' by the Community Oncology Alliance be submitted into the hearing record.

Mr. <Burgess.= Without objection, so ordered.

[The information follows:]

**********INSERT 8**********

Mr. <Carter.= Thank you.

Let me ask you, Dr. Daniels, in your hospital what qualifies a patient for a 340B?

Mr. <Daniels.= First of all, they have to be under our care. That means that there is a relationship between the physician and the patient.

Mr. <Carter.= Okay.

Mr. <Daniels.= Secondly, it means that they have to have been seen by one of our providers and it means somebody with that contractual employment relationship.

And third, it relates to the encounter that generated the prescription being part of--being seen in one of our sites.

Mr. <Carter.= Being seen in one of your sites, whether it's inpatient or outpatient?

Mr. <Daniels.= It could be either.

Mr. <Carter.= It could be either?

Mr. <Daniels.= Yes.

Mr. <Carter.= But, yet, we base it on the inpatient?

Mr. <Daniels.= Yes.

Mr. <Carter.= Yes. That's--Mr. Chairman, I yield back.

Mr. <Burgess.= The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Oklahoma five minutes for questions, please.

Mr. <Mullin.= Thank you, Mr. Chairman. Thank you to the

panel for having a very long day with us. We really appreciate it.

This, obviously, is an important issue. I am just going to keep talking until the clock resets because I will just have much time as I want then.

Are we good? All right.

[Laughter.]

Anyways, I really appreciate you guys being here. I just got a couple questions and I am going to yield what time I have left to the--to my colleague from Indiana. He's going to need extra time because, obviously, he's pretty invested in this thing, too.

So my question is going to be to the whole panel. This committee has found that HRSA lacks significant regulatory authority to oversee the 340B program requirements. My draft bill allows HRSA to prescribe regulations as necessary or appropriate to carry out the 340B program.

Are there any 340B program requirements that each of you can think that HRSA should further clarify?

Dr. <Cerise.= I will start, and that is, again, we look for guidance. We want to follow HRSA guidance.

Mr. <Mullin.= Right.

Dr. <Cerise.= Some of the discussion around patient definition I would be concerned if we started parsing what that is. If that's a patient of our entity, those savings will accrue

to let us do services in entities.

So if you start to divide it by insured or uninsured status or the type of care, we do a lot of care. For instance, telemedicine will see--a dermatologist will see one of our patients that way.

So some of these programs had actually saved money and improved access. We won't--we would not want to restrict --

Mr. <Mullin.= So what type of clarification would you need on that?

Dr. <Cerise.= Well, I just would--I would be careful about how we limit something around patient definition. We'd be happy to participate in some of those conversations.

Mr. <Mullin.= We would love some recommendations. The idea is that we want to give clear guidance. The whole purpose of this is the fact that there isn't clear guidance, and as Buddy--or my colleague from Georgia had alluded to, that there's unclarity that is being--happening right now when it's designed even--what Dr. Daniels had just said--it's designed for inpatient but yet it's also being used for outpatient services, too.

So there needs to be clarification on that. Not saying that Dr. Daniels is bad--it just needs to be clarified. We want it to be used for the intended purpose.

Dr. <Patt.= I was just going to also add that I do think definition of a patient is critical, you know, in a way that allows qualifying institutes to use it appropriately.

But I think, given the tremendous growth in the contract pharmacy-hospital relationship, the variability and identification of a patient and especially laxity in that definition causes many challenges in inappropriate overuse of the program that, you know, could be brought in by--

Mr. <Mullin.= So what would that narrow scope look like?

Dr. <Patt.= So registration, looking at the provider status, making sure they're either employed by or have a contractual relationship with the hospital entity, looking at the origin of the prescription, looking at payer status--not that you have to determine by payer status but that way you can at least note it so it can be reported.

Mr. <Mullin.= Right.

Dr. <Patt.= And demonstration of a relationship. And so that's historically done by things like medical records.

Mr. <Mullin.= Dr. Daniels, do you have anything?

Mr. <Daniels.= Only the comment, and I agree that it's important to define the patient. One of the concerns that I would have on behalf of UC San Diego is that in the--in a redefined patient definition that it doesn't serve to eliminate the benefits that come to the covered entities through the process, so in that sense, to not reduce the number of patients that would be qualified necessarily as a way to reduce the benefit that goes to the covered entity.

Mr. <Mullin.= I will yield the remainder of my time to Dr.

Bucshon.

Mr. <Bucshon.= Thank you for yielding.

I want to talk about this criticism that what--what are we all worried about--it doesn't cost the government any money, and it didn't cost us anything. We just heard that from our colleagues.

I would make this argument. If we had transparency and we knew all the money was being used for the intent of the program you could make that--I think you could make that case.

When you don't have transparency, I think it would be hard to explain to my constituents why a hospital put up a new $100 million tower and part of the reason why they're able to do that is because they're using the revenue generated from the 340B program to support that activity.

Here's the problem. We don't know, and so, you know, I am hopeful that if we do some transparency that every 340B entity in the United States is in full compliance using the money for what they say.

But we have multiple reports, including GAO and an oversight committee report from Energy and Commerce that says that that's not true.

So anyone who wants to make the argument that what's the big deal--it doesn't cost the taxpayers anything--well, it's a matter of where the money is being spent.

If it's being spent for the intent, I would agree, because,

you know, the money is being redistributed. It's not being paid for the drug itself--that it's being paid to help support care of those patients.

But if it's being used by a system to support other activities, I would argue it's costing the taxpayer billions of dollars.

I yield back.

Mr. <Burgess.= The gentleman's time has expired. The buzzer is--votes have been called on the floor. So I am going to go Mr. McKinley.

All subcommittee members having had time for questions, I recognize Mr. McKinley for five minutes.

Mr. <McKinley.= Thank you, Mr. Chairman. I am not member of this committee but am the sponsor of the House Bill 4392, I appreciate the chance to chat here a little bit with you.

I think it's been enlightening to listen to some of the debate--some points--and it's where I wanted to make my remarks and that was about the intent of this 25, 26 years ago, and that was--the intent was to provide discounts to drugs to providers to, quote, "reach more eligible patients and provide more comprehensive services.''

I think that's pretty basic. We have--just for the record, we have a 199 co-sponsors on our piece of legislation. That's more than any of the other pieces that have been debated here.

We want to--we want to put a moratorium on that rule because

there are consequences for that rule as it goes forward with it, because unless this rule is modified quickly, it's going to cut $1.6 billion from health care providers across America and that--there are going to be consequences.

Hospitals and health systems are going to cut back on their services. We all see at one of the hospitals in West Virginia--WVU Hospital--they use the facilities.

I listened with interest all the way the program is being used and I know at WVU they used it to fund a bus. It goes around to be able to do mobile mammograms throughout West Virginia, and the cancer rate in West Virginia is the highest in the country and they're trying to reach that using the 340B program with it.

But yet, WVU Hospital is going to lose $10 million through this--if this program isn't modified.

Now, I could go on with it--that the--a Kentucky hospital in Louisville with nine hospitals is going to lose over $5 million.

A clinic or a hospital in Cleveland is going to lose almost $7 million annually and a large system in Greater Atlanta is going to lose over $5 million.

I am sure I could go on example after example. There are consequences when we start reducing the funds from these hospitals.

So I guess the question, Mr. Chairman, comes back is, has the mission of this program 25 years ago to, quote, "reach more patients to provide comprehensive services,'' has it been

accomplished?

Can our health care system afford nearly 30 percent reduction in health care funding and still survive? I think the answer is of course it can't, and we have not achieved the mission.

So our access to health care from both sides of the aisle, we have to have more increased health care access if we are going to take care of the folks in this country.

So while we can continue to debate this rural or 340B program, but all the while people aren't getting health care because of the $1.6 billion in cuts.

So we can continue to debate this. But what we are trying to say--and I agree completely with Congressman Bucshon as trying to reach the transparency--but I also say that the transparency is not only just for the providers, it's also for the drug manufacturers.

So what I am hoping by issuing this legislation the way we did is to try to force everyone to come to the table. Not just to debate forever--come to a conclusion.

So, Mr. Chairman, I am calling on you to keep the focus on this, please. Hospitals across this country, in West Virginia, $10 million at just one hospital.

Mr. <Burgess.= Perhaps the gentleman would like to let the witnesses respond to his observations.

Mr. <McKinley.= So I am hoping that we can keep this focus, and I know I've talked to the chairman about this. I feel we

will. But the sooner we can come to a conclusion and something that can pass the House and pass the Senate, I hope we can do that.

So I yield back the balance of my time.

Mr. <Burgess.= You don't have to yield back. You have three witnesses here who are experts. They may have opinions about what you just said.

You have got 42 seconds left. Dr. Cerise, do you have an answer or an observation?

Dr. <Cerise.= So the change in Medicare reimbursement definitely has an impact on us and I would suggest if there were concerns about the growth of the program or the oversight of the program that we address it that way and not by reduction in the Medicare reimbursement for eligible providers who are using those savings.

We--obviously, we get $152 million in savings in the program. It's a significant impact for us to be able to take care. There are a million people in Dallas County who are either uninsured or on Medicaid and those funds allow us to take care of that population.

Mr. <McKinley.= Dr. Daniels.

Mr. <Daniels.= The process of trying to restore the OPP reductions is very important to us at UC San Diego.

Mr. <McKinley.= Thank you. I yield back the balance.

Mr. <Burgess.= The gentleman's time has expired.

The chair observes that the chair has not taken time to ask questions but, as luck would have it, any questions that I could have possibly asked have already been asked at least three times and you have answered them at least three different ways. So that's been instructive.

It really--forgive me for a minute, Dr. Daniels. Let me just talk to my two Texans. We have two very different practices types, both impacted by the 340B program in different ways, and I think it is becoming--it's just quite apparent today during today's discussion that, Dr. Patt, we need to take your considerations--that they're very serious and we need to take them under advisement.

Dr. Cerise, we know you're the gold standard and anything that we do should not disrupt what you have built at the Dallas County Hospital district because it does provide an unbelievable service.

You're unique. I mean, most of the other places throughout north Texas do not have an in-house pharmacy, strict formularies. I mean, there are--there are reasons why what you do cannot be extrapolated across the entire north Texas community.

Still, you work well with--you get your mission and you perform your mission and that's to be well commended.

Dr. Patt, I am concerned about the consolidation. I am concerned about the fact that we are perhaps driving that consolidation with some of our activities.

So I want us to work with both of your practices in mind. I certainly appreciate the accountability, the transparency, and patient definition message that you have brought.

You can see that that message delivered as well, of course, as the GAO previously had their seven recommendations, all of which are worthy of our consideration.

I am going to yield back my time to conclude the hearing at this point. I have, what--seeing that there are no other members wishing to ask questions, I again want to thank our witnesses for being here today.

I would like to submit the documents from the following for the record: America's Essential Hospitals, Ascension, Texas; American Society of Clinical Oncology; Catholic Health Association; the Association of American Medical Colleges; Vox 340B article; U.S. Oncology; and Children's Hospital Association.

[The information follows:]

**********INSERT 9**********

Mr. <Burgess.= One last commercial before we conclude--I ran through a litany of positive things that this committee has delivered for health care and in this country and, Dr. Cerise, you reminded me, or maybe it was Dr. Patt--you reminded me of the district funds in the 1115 waiver, also worked on through this committee--the extension or the prevention of the DSH cuts that were supposed to go into effect last October 1st.

That extension was provided by this committee. So the body of work is considerable for the last 18 months, and all I would say to that is you're welcome.

Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record. I ask the witnesses to submit their responses within 10 business days upon receipt of those questions.

And without objection, the subcommittee is adjourned. You got five minutes to go over and vote.

[Whereupon, at 1:52 p.m., the committee was adjourned.]