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OPPORTUNITIES TO IMPROVE THE 340B DRUG PRICING PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

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CONTENTS

OPPORTUNITIES TO IMPROVE THE 340B DRUG PRICING PROGRAM

WEDNESDAY, JULY 11, 2018

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

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, Cárdenas, 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.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

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 5 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 4 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 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, 5 minutes for an opening statement, please.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Today, we convene to learn about opportunities to improve the 340B drug pricing program. This hearing builds on previous work by the Energy and Commerce Committee this Congress and last Congress. Our subcommittee and the Oversight and Investigation Subcommittee have held hearings on various aspects of the program over the last several years. The Committee also issued a comprehensive oversight report on the program earlier this year.

As we start, it is important to emphasize that members of this committee 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 as it helps many health care providers provide 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—that was around the end of the Cold War and birth of the Inter-

net. Surely, 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 in today's health care system.

In many ways, the 340B Program is certainly a success. Yet, at the same time, there are numerous ways in which the program's current operation raises valid concerns. Multiple reviews by nonpartisan auditors have identified notable challenges with the program's current operation and oversight.

- For example, we know the Health Resources and Services Administration (HRSA), the agency overseeing the 340B Program, lacks key regulatory authorities.
- Additionally, HRSA has delayed multiple program regulations repeatedly without a compelling and clear rationale.
- We learned that, in 2016, HRSA audited less than two 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 GAO 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 contracted with has increased from approximately 1,300 to almost 20,000 in 2017.

I think GAO raises a number of serious challenges with HRSA's current oversight of contract pharmacies. I am also troubled by the fact that many covered entities 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 high health care costs—drug costs, hospital costs, and other costs—is an ongoing concern. So, I am proud to have a discussion draft today which outlines one possible solution to this issue—to ensure that covered entities stretch resources through 340B while making sure some of the most vulnerable patients see the financial benefit. Overall, I found this an eye-opening report and I hope we will each review it carefully as we seek to ensure the program helps patients effectively.

I appreciate that members approach the 340B program with different backgrounds and from a variety of perspectives. But, I trust we all share the goal of ensuring this Federal program operates with integrity, and 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 might 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 members have. These bills—whether drafts to generate discussion, or introduced bills—are members' ideas from both sides of the aisle to improve the 340B Program. I support several of the policies outlined in these bills but have questions on others. We also need to hear from the wide range of stakeholders impacted by this program.

Now, I would like to welcome Debra Draper, Director of Health Care, at GAO to our hearing and thank her in advance for her willingness to testify before us and answer our many questions.

I also want to give a warm Texas welcome to Dr. Frederick Cerise, President and CEO of Parkland Hospital in Dallas, and Dr. Debra Patt, Vice President of Texas Oncology on our next panel. Both Drs. Cerise and Patt will be able to share their unique perspectives on the role the 340B Program has in providing care to their patients. We also welcome Dr. Charles Daniels from California.

Today's hearing promises to offer thought-provoking ideas and insights to inform our next steps to improve the 340B Program. Again, thank you to each of our witnesses for being here, and I look forward to a constructive dialogue today.

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

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 in 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 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 5 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 appears at the conclusion of the hearing.]

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

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Good morning and thank you, Mr. Chairman, for holding today's hearing. I also thank all of our witnesses for coming here to testify on this important issue.

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

Since its creation in 1992, stakeholders and policymakers have debated the intended purpose and appropriate scope of the 340B Program.

I hope we all agree on the importance of 340B and the need 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 has been highlight by both supporters and opponents of the program.

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

For example, Harris Health System, which primarily serves the indigent population of Harris County, Texas, saves $90 million a year through its participation in the 340B Program.

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

Harris Health System, and 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 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 the 340B Program.

The 340B Program has grown significantly in recent years and oversight is appropriate to ensure it is working properly. According to GAO, the number of 340B covered entities has nearly doubled in the past five years to over 38,000.

Similarly, the number of contract pharmacy agreements has grown dramatically since 2010, going from 1,300 to 18,700 in 2017.

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

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

I would like to have added to the record a statement from the American Hospital Association and the Association of American Medical Colleges on today's hearing.

Thank you, Mr. Chairman. I now yield the remainder of my time to my colleague, Congresswoman Matsui of 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, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. 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 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 5 years, from 3,200 participating hospitals in 2011 to 12,148 in October of 2016. So quadrupling in 5 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 2-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 appears at the conclusion of the hearing.]

Mr. 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.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Mr. Chairman, for holding this legislative hearing to examine ideas to improve the 340B Drug Pricing Program (340B Program). Since its creation by Congress more than 25 years ago, the 340B Program has helped provide life-saving medicines at reduced prices to certain safety-net health care providers.

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 (HRSA) estimates that in 2015, covered entities saved about $6 billion on 340B drugs through their participation in the program.

For some participating health care providers, known as "covered entities," this program and the savings it generates are critical not to just their mission to help patients—but it undergirds their financial viability and their ability to keep their doors open. I've met with hospitals and health including those in Bend, and Hermiston, and they've told me about how they're using 340B savings to increase access to health care for the underserved.

But it's important to note that a lot has changed since the program's creation. The number of unique hospital organizations participating in the program has nearly quadrupled in just 5 years—increasing from 3,200 participating hospitals in 2011 to 12,148 in October 2016.

While the actual number of 340B contract pharmacy arrangements is unknown because it is not tracked, GAO 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 accountability of the program. For example, both HHS' Office of the Inspector General and GAO have identified the lack of a clear definition of a 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 clearer, audits need to be more comprehensive, and enforcement needs to be more consistent.

There's also the report following the committee's 2-year investigation by our own Oversight and Investigations Subcommittee. That report detailed a lack of oversight, reporting requirements, and 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 operation 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 we can improve the 340B Program.

I fully expect that my colleagues will bring different views and ideas forward in examining these bills to strengthen 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 they need and deserve.

Finally, I would like to highlight one bill in particular, H.R. 6273, a bill I've introduced along with Representative 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 (SAFE) facility, so they can be properly examined and treated by a qualified health provider.

I'd like to thank our two panels of witnesses for being with us today and for your feedback on the bills before us. There is certainly a lot to discuss, and I look forward to working with my colleagues on both sides of the aisle to strengthen this vital program.

Mr. BURGESS. Thank you, Mr. Chairman.

The chair now recognizes the gentleman from New Jersey, Mr. Pallone, the ranking member of the full committee, 5 minutes for an opening statement, please.

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

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 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 2-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.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Twenty-five years ago, Congress passed bipartisan legislation establishing the 340B program. 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 underinsured patients in their communities. By purchasing drugs at a discounted rate, 340B providers can stretch resources to provide more comprehensive health services. After all, many of these drugs have experienced dramatic price increases over the years. 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 it is 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 absurd. 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 is simply too difficult to be appropriately substantive with this many items before us on so short a time frame.

That said let me comment briefly on some of the legislation. I want to commend Rep. Matsui for her leadership on H.R. 6071, the SERV 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 8 years ago, and includes many other provisions that would 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 example of an important area where we could have a realistic conversation about strengthening the 340B program—had this process looked a little different.

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 that 340B-providers 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 is why I do not support legislation that would curtail or restrict this program. Legislation like H.R. 4710 that includes a 2-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 would see 50 percent or more of their DSH hospitals cut from the program, with five states having all their DSH hospitals cut from the program.

These types of bills are not about improving or strengthening 340B-they are about gutting the program—which I 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.

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 5 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 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:]

United States Government Accountability Office

GAO

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

For Release on Delivery
Expected at 10:00 a.m. ET
Wednesday, July 11, 2018

DRUG DISCOUNT PROGRAM

Improvements Needed in Federal Oversight of Compliance at 340B Contract Pharmacies

Statement of Debra A. Draper
Director, Health Care

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

I am pleased to be here today to discuss our June 2018 report on contract pharmacies in the 340B Drug Pricing Program (340B Program).[1] As you know, the 340B Program, named for the statutory provision authorizing it in the Public Health Service Act, requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities in order to have their drugs covered by Medicaid.[2] Covered entities include 6 types of hospitals and 10 types of federal grantees, such as federally qualified health centers. A covered entity typically purchases and dispenses 340B drugs either through an in-house pharmacy; through the use of a contract pharmacy arrangement, in which the entity contracts with an outside pharmacy and pays it to dispense drugs on its behalf; or both.

According to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.[3] Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to do so. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to HRSA. In addition, covered entities can generate revenue when they purchase 340B drugs for eligible patients whose insurance reimbursement exceeds the 340B price paid for the drugs. The statute authorizing the 340B Program does not dictate how covered entities should use this revenue or require discounts received on the drugs to be passed along to patients. The ability to have their drugs

[1]GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480. (Washington, D.C.: June 21, 2018).

[2]42 U.S.C. § 256b. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations.

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

covered by Medicaid provides incentives for manufacturers to participate in the 340B Program.

Covered entities are required to meet certain conditions set forth both in law and interpretive agency guidance. For example, they are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.[4] They are also prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.[5] Covered entities that use contract pharmacies are responsible for overseeing those pharmacies to ensure compliance with these 340B Program requirements. Some covered entities hire and pay private companies, referred to as third-party administrators (TPA), to help determine patient eligibility and ensure compliance at contract pharmacies.

HRSA's original guidance permitting the use of contract pharmacies limited their use to entities that did not have in-house pharmacies and allowed each entity to contract with only one outside pharmacy. However, March 2010 guidance lifted these restrictions, thus allowing covered entities to have an unlimited number of contract pharmacies.[6] Since that time, the number of contract pharmacies has increased significantly, from about 1,300 to around 20,000. Given the growth in the 340B Program, there has been interest in obtaining a better understanding of program oversight, and the impact of contract pharmacies on the integrity of the program.

My testimony today summarizes the findings from our June 2018 report. Accordingly, this testimony addresses: 1) the extent to which covered entities contract with pharmacies to distribute 340B drugs, and characteristics of these pharmacies; 2) the financial arrangements selected covered entities have with contract pharmacies and TPAs related to the administration and dispensing of 340B drugs; 3) the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and

[4]42 U.S.C. § 256b(a)(5)(B).

[5]42 U.S.C. § 256b(a)(5)(A).

[6]*Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services*, 75 Fed. Reg. 10272 (Mar. 5, 2010).

4) HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies.

To conduct the work for our report, we analyzed HRSA's 340B Program database of covered entities and contract pharmacies; selected and reviewed a nongeneralizable sample of 30 contracts between covered entities and contract pharmacies; and received completed questionnaires from 55 of 60 covered entities about the discounts provided to patients on 340B drugs dispensed by contract pharmacies and how the entities reimburse TPAs. Additionally, we reviewed relevant program policies, procedures, and guidance; analyzed summaries of HRSA's audits of covered entities; and conducted an in-depth review of a nongeneralizable sample of 20 HRSA audits. We also interviewed officials from HRSA, two TPAs, and 10 of the covered entities that responded to our questionnaire. As part of our work, we assessed HRSA's guidance and oversight of covered entities against federal internal control standards related to control activities, information and communication, and monitoring.[7] Additional information on our scope and methodology is included in our report.[8] The work this statement is based on was performed in accordance with generally accepted government auditing standards.

[7]See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

[8]See GAO-18-480.

About One-Third of Covered Entities Had One or More Contract Pharmacies, and Pharmacy Characteristics Varied

We found that as of July 1, 2017, about one-third of the more than 12,000 covered entities in the 340B Program had contract pharmacies. A higher percentage of hospitals (69.3 percent) had at least one contract pharmacy compared to federal grantees (22.8 percent). Among covered entities that had at least one contract pharmacy, the number of contract pharmacies ranged from 1 to 439, with an average of 12 contract pharmacies per entity. The number of contract pharmacies varied by covered entity type, with disproportionate share hospitals having the most on average (25 contract pharmacies), and critical access hospitals having the least (4 contract pharmacies).[9]

Across all covered entities, the distance between the entities and their contract pharmacies ranged from 0 miles (meaning that the contract pharmacy and entity were co-located) to more than 5,000 miles; the median distance was 4.2 miles.[10] About half of the entities had all their contract pharmacies located within 30 miles, but this varied by entity type. Specifically, more than 60 percent of critical access hospitals and federally qualified health centers, a type of federal grantee, had all of their contract pharmacies within 30 miles. In contrast, 45 percent of disproportionate share hospitals had at least one pharmacy that was more than 1,000 miles away compared to 11 percent or less for critical access hospitals and grantees.

Selected Covered Entities Used Various Methods to Pay Contract Pharmacies and TPAs

Contracts we reviewed between selected covered entities and contract pharmacies showed that entities generally agreed to pay their contract pharmacies a flat fee per 340B prescription, with some entities also paying additional fees based on a percentage of revenue. The flat fees generally ranged from $6 to $15 per prescription, but varied by several factors, including the type of covered entity and drug, as well as the patient's insurance status. In addition to flat fees, many of the contracts

[9]Disproportionate share hospitals are general acute care hospitals that serve a disproportionate number of low-income patients. Critical access hospitals are small, rural hospitals with no more than 25 inpatient beds.

[10]When asked why contract pharmacies may be located many miles away from the covered entity, HRSA officials indicated that the pharmacies may provide prescriptions by mail (even if they are not classified as mail order pharmacies) or dispense specialty drugs. In addition, HRSA officials noted that some covered entities may serve patients who live far away from the entity and thus have contracts with pharmacies located close to where their patients reside.

we reviewed included provisions for the covered entity to pay the pharmacy a fee based on the percentage of revenue generated by each prescription. These percentage fees only applied to prescriptions provided to patients with insurance, and ranged from 12 to 20 percent of the revenue generated by the prescriptions.

Selected covered entities and TPAs included in our review indicated two main methods entities use to pay for TPA services: 1) per prescription processed, or 2) per contract pharmacy. Officials with the two TPAs we interviewed and the covered entities that responded to our questionnaire reported that agreements between the parties most frequently involved covered entities compensating their TPAs with a fee for each prescription processed on behalf of the entity, but the exact method and the amount of the fee varied. For example, some covered entities reported paying their TPAs for each prescription regardless of whether it was determined to be 340B eligible, others limited the fees to prescriptions that were 340B eligible, and some reported paying TPAs for 340B-eligible prescriptions dispensed to an insured patient.

About Half of the Covered Entities GAO Reviewed Provided Low-Income, Uninsured Patients Discounts on 340B Drugs at Some or All of Their Contract Pharmacies

Thirty of the 55 covered entities responding to our questionnaire reported providing low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies. Federal grantees were more likely than hospitals to provide patients with discounts on the price of drugs and to provide them at all contract pharmacies. Of the 30 covered entities that provided discounts, 23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs. In many cases, these covered entities indicated that patients received drugs at no cost.

The 30 covered entities providing 340B discounts to low-income, uninsured patients, reported using a variety of methods to determine whether patients were eligible for these discounts. Fourteen of the covered entities said they determined eligibility for discounts based on whether a patient's income was below certain thresholds as a percentage of the federal poverty level, 11 reported providing discounts to all patients, and 5 said they determined eligibility for discounts on a case-by-case basis.

Some covered entities that did not provide discounts on 340B drugs at their contract pharmacies reported assisting patients with drug costs through other mechanisms. For example, some covered entities reported providing charity care to low-income patients, including free or discounted

prescriptions; and some reported providing discounts on drugs dispensed by their in-house pharmacies.

Oversight Weaknesses Impede HRSA's Ability to Ensure Compliance at 340B Contract Pharmacies

We found weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies. Specifically:

- **Incomplete Data.** We found that HRSA does not have complete data on all contract pharmacy arrangements in the 340B Program to inform its oversight efforts, including its audits of covered entities—the agency's primary method for assessing entity compliance with program requirements. Although HRSA requires covered entities to register their contract pharmacies with the agency, it does not require covered entities to separately register contract pharmacies to each site of the covered entity with which a contractual relationship exists.[11] HRSA officials told us that the number of registered contract pharmacy arrangements increases a covered entity's chance of being randomly selected for a risk-based audit.[12] Our analysis of HRSA data showed that the registration of contract pharmacies for 57 percent of covered entities with multiple sites only specified relationships between contract pharmacies and each entity's main site, as opposed to all sites contracted to distribute drugs on that entity's behalf. Thus, the likelihood of an entity being selected for an audit is dependent, at least in part, on how an entity registers its pharmacies as opposed to the entity's actual number of pharmacy arrangements. We concluded that without more complete information on covered entities' contract pharmacy arrangements, HRSA cannot ensure that it is optimally targeting the limited number of risk-based audits done each year to entities that are at a higher risk for compliance issues because they have more contract pharmacy arrangements.
- **Limited Oversight of Duplicate Discounts.** We found that HRSA audits do not fully assess compliance with the 340B Program

[11]Some covered entities have multiple sites: the main site and one or more other associated sites, such as satellite clinics, off-site outpatient facilities, hospital departments, and other facilities.

[12]HRSA currently audits 200 covered entities per year; less than 2 percent of covered entities. Approximately 90 percent of the audits conducted each year are of covered entities that are randomly selected based on risk-based criteria, while the remaining 10 percent of audits are of covered entities that are targeted based on information from stakeholders such as drug manufacturers.

prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, covered entities are prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care, despite the fact that the majority of Medicaid enrollees, prescriptions and spending for drugs were in managed care. HRSA officials told us that they do not assess the potential for duplicate discounts in Medicaid managed care as part of their audits because they have yet to issue guidance as to how covered entities should prevent these duplicate discounts. We concluded that until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance, and manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

- **Lack of Information on Full Scope of Noncompliance.** We found that HRSA requires covered entities for which it identifies issues of noncompliance during audits to assess the full extent of the noncompliance, but it does not provide guidance as to how entities should make these assessments. Specifically, HRSA does not specify the time period covered entities must review to see if any related noncompliance occurred and instead, relies on each entity to make this determination. Additionally, HRSA does not require most covered entities that were audited to communicate the methodology used to assess the full scope of noncompliance, or the findings of their assessments, including how many or which manufacturers were due repayment. As a result, we concluded that HRSA does not know the scope of covered entities' assessments and whether they were effective at identifying the full extent of the noncompliance identified in the audit.
- **Lack of Evidence of Corrective Actions.** We found that prior to closing an audit, HRSA's audit procedures do not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements. Instead, HRSA relies on the 90 percent of covered entities subject to risk-based audits to self-attest that all audit findings have been addressed and that the entity has come into compliance with 340B Program requirements. We concluded that HRSA, therefore, does not have reasonable assurance that the majority of covered entities audited have corrected the issues identified in the audit, and are not continuing practices that

could lead to noncompliance, thus increasing the risk of diversions, duplicate discounts, and other violations of 340B Program requirements.

- **Limited Guidance on Contract Pharmacy Oversight.** We found that HRSA's contract pharmacy oversight guidance for covered entities lacks specificity and thus, provides entities with considerable discretion on the scope and frequency of their oversight practices. Specifically, HRSA's 2010 guidance on contract pharmacy services specifies that covered entities are responsible for overseeing their contract pharmacies to ensure that the drugs entities distribute through them comply with 340B Program requirements, but states that, "the exact method of ensuring compliance is left up to the covered entity."[13] According to HRSA officials, if a covered entity indicates that it has performed oversight in the 12 months prior to a HRSA audit, then HRSA considers the entity to have met its standards for conducting contract pharmacy oversight, regardless of what the oversight encompassed. However, due, at least in part, to a lack of specific guidance, we found that some covered entities performed minimal contract pharmacy oversight. Additionally, the identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices. For example, 66 percent of the 380 diversion findings in HRSA audits since 2012 involved drugs distributed at contract pharmacies, and 33 of the 813 audits for which results were available had findings for lack of contract pharmacy oversight.[14] We concluded that as a result of the lack of specific guidance and the numerous HRSA audit findings of noncompliance occurring at contract pharmacies, HRSA does not have assurance that covered entities' contract pharmacy oversight practices are sufficiently identifying 340B noncompliance.

Our June 2018 report contained seven recommendations to HRSA to strengthen its oversight of the 340B Program. HHS concurred with our four recommendations that HRSA should 1) issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care; 2) incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed

[13]75 Fed. Reg. 10278 (Mar. 5, 2010).

[14]These figures are based on the audits conducted by HRSA from fiscal year 2012 to fiscal year 2017 for which results were posted on HRSA's website as of Feb. 8, 2018.

care claims, into its audit process once the guidance is issued; 3) issue guidance on the length of time covered entities must look back following audits to identify the full scope of noncompliance identified during audits; and 4) provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.

HHS did not concur with our three recommendations that HRSA should 1) require covered entities to register contract pharmacies for each site of the entity for which a contract exists; 2) require all covered entities to specify their methodology for determining the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of covered entities' methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance; and 3) require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit. HHS cited concerns that implementing these recommendations would be burdensome on covered entities and HRSA. However, as explained in our report, we believe that these recommendations would only create limited additional burden on covered entities and the agency and are warranted to improve HRSA's oversight of the 340B Program.

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to answer any questions that you may have at this time.

GAO Contacts and Staff Acknowledgments

If you or your staff members have any questions concerning this testimony, please contact Debra A. Draper at (202) 512-7114 or draper@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. In addition to the contact named above, Michelle Rosenberg (Assistant Director), Amanda Cherrin (Analyst in Charge), Jennie Apter, George Bogart, and David Lichtenfeld made key contributions to this statement.

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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 5 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 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, 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 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 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. OK.

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, 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 Medicaid-managed care beneficiaries.

So this is where the bulk of the beneficiaries are enrolled and 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 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, 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.

It's anecdotal evidence but they express concern about the extent to which this is happening and how they're supposed to 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 do you allocate 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 that was why we made a recommendation. HRSA will need to work with CMS to provide guidance on how to deal with 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 5 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 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 they thought that that would be administratively burdensome. 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 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 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 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 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 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 specifically for those purposes?

Ms. DRAPER. Well, 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 that they've had in place for the last 2 years for a contractor to conduct the audits. So, they do have limited resources. So I would expect that it's probably something to do with the resource limitation around 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, 5 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 timeframe, particularly in the last couple of years?

Ms. DRAPER. This really has to do with HRSA lifting the restriction about lifting the restriction to now allow covered entities that have an unlimited number of contracts with outside pharmacies.

Mr. GUTHRIE. OK. 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 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, I think it would be something that 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 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 a wide variation. So it's really difficult to say, and we really didn't look at the impact. So we looked at the financial arrangements but not at the back end what were the most effective.

Mr. GUTHRIE. OK. Well, thank you, and that does conclude my questions. I know I have 2 ½ 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, 5 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. OK. 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. OK. 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 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—they've had no findings on those manufacturer audits.

Ms. MATSUI. So——

Ms. DRAPER. Out of 600 manufacturers, about .5 percent.

Ms. MATSUI. OK. 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. OK.

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

Ms. DRAPER. That's correct.

Ms. MATSUI. OK. 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. OK. 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. OK. 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. OK. 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 appears at the conclusion of the hearing.]

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, 5 minutes for questions.

Mr. BARTON. Thank you, Mr. Chairman, and thank you for holding this very important hearing.

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. OK. 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, 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 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—the intent was really, to me, closer to what a covered—like, a grantee.

It was to stretch scarce federal resources to 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, 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. OK.

Ms. DRAPER [continuing]. The Federal grantees are the remaining.

Mr. BARTON. So the 40 percent number——

Ms. DRAPER. It's probably 40—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. OK. 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 5 minutes for questions, please.

Ms. CASTOR. Thank you, Mr. Chairman.

Dr. Draper, I want to return to GAO's recommendations 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 the use of contract pharmacies and, as I mentioned ear-

lier, we have not done work looking at audits of manufacturers and HRSA does post that on their website and, as I said, I think they talked about 12 completed today.

Ms. CASTOR. That wasn't in your scope this time and then 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. 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.

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 ask them what's important, this is always the top of their list and 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 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 tto have this program to be of the highest integrity and I think that 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 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, 5 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 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 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 averse 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 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. 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 multiple child sites that may be 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 covered entities talked about, when there are very expensive drugs, for hepatitis C or a hemophilia drug or HIV, that what happens is even if a patient rarely needed it maybe once every 2 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 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, 5 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, 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 OK 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 conducive setting than being in a hospital by making sure people have access to these medications that we should embrace that. 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.

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.

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 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 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?

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 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 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, what percentage of the hospital—there's other entities, too.

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—there's more prevalence.

Ms. DRAPER. So 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. 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 the majority of beneficiaries in Medicaid are in managed care. So that is an important place for that——

Mr. SCHRADER. Last question. I am sorry. I am running out of time.

Ms. DRAPER. That's OK.

Mr. SCHRADER. 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 time period from 2010 until now?

Ms. DRAPER. The 25 percent increase in costs paid?

Mr. SCHRADER. Yes.

Ms. DRAPER. Well, you have to look at the proportion of the, the cost of the——

Mr. SCHRADER. If the program is costing us 25 percent more since 2010, some of that is, obviously, increased in popularity. People are realizing they can actually do that nice wraparound service.

The other piece is 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 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, 5 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, you're probably talking about tens of thousands of contracts. So it would be probably pretty burdensome.

The other issue is that HRSA doesn't have legal authority 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 reviewed, discussing that it could be potentially disruptive to the drug pricing market and 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 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, HRSA does not require those unless they do an audit of the covered fee and 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 the general public. But it seems like an administrative process—an 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 that register only one contract pharmacy, there were 1,645 of those.

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

So HRSA does not have really that information and it does go to inform 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 actually provide the drugs to that entity.

Mr. LATTA. OK.

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. 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. OK. Well, as you're looking at the GAO side, on the HRSA side, 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. That needs to be clarified because 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 timeline 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, 5 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 hospital 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 doing. 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 what the reason behind this is, OK. 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 improve the program for everyone.

So, Ms. Draper, the reach has expanded way beyond—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 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—ythe rules are ambiguous that there's always, at least a lot of interpretation and why the interpretation.

So I think, if you don't have clear roles and responsibilities and rules then, 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 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? What year do you think?

Ms. DRAPER. Yes. We made recommendations in 2011 and they still have two yet to be implemented.

Mr. BUCSHON. OK. That's roughly 7 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 a lot of it is we haven't had this discussion about HRSA—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. OK. 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 "legislative fix" so they can't improve things.

So my major push is this. In health care in general, 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, 5 minutes for questions, please.

Mr. LONG. Thank you, Mr. Chairman.

Dr. Draper, the GAO report indicates that a disproportionate share of 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 covered entity contracts with a pharmacy they are to have 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, 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 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.

Again, this is not specific guidance as to how entities are supposed to 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 that contract pharmacies are complying with program requirements?

Ms. DRAPER. Well, 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 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 register the parent site alone, which doesn't cover individual child sites. So they don't really have that information readily accessible in their records.

Mr. LONG. OK. 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 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 patients. There's not similar requirements necessarily for hospitals that participate in the program. So that's the difference between the two.

Mr. LONG. OK. 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. OK. 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, 5 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 "significant concerns regarding many of the findings in the draft report," 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 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 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 it's important for manufacturers to have that information available to them because if they don't have that that 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, 5 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 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 those drugs are much more expensive. So, 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, I think there's been some talk about making the fees the same——

Mr. LANCE. Yes.

Ms. DRAPER [continuing]. And the problem with that is that then you might end up that a patient pays more for being in the 340B program than if they weren't because—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 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 if they find that that happens, then 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. Yes, 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 whatever fee that's being charged is not creating—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 [continuing]. 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, 5 minutes for questions.

Mr. COLLINS. Thank you, Mr. Chairman.

I think, 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, 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, vary significantly different today than 25 years ago and many of these drugs are extraordinary 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, 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—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 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 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, 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 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, 5 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 I 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 like-

ly 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 are the team that did this work, we will be moving over to that work very soon.

Mrs. BROOKS. And 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, basically, duplicate discounts related to the 340B program including managed care.

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. Yes. It's hard to say. But I would say 9 to 12 months, something like that. We'll have to scope it and see how broad the scope will be. We will be happy to 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, it is I guess a risk-aversion process and if the TPA doesn't do it then someone within the covered entity needs to ensure that those patients that are getting the drugs are actually eligible patients.

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

Mrs. BROOKS. So 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. OK.

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, 5 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. 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.

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 current patient definition that dates back all the way to 1996. We've got staff members who weren't even born then.

So, 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 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 Service 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 then to be given to a movie star and then to get a 340B discount?

Ms. DRAPER. Well, outpatient drugs are covered.

Mr. CARTER. So yes or no?

Ms. DRAPER. Yes. 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.

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 I want us to do.

Let me ask you one other thing and that's 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 related to Medicaid-managed care. That's where the issue is. 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 [continuing]. 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. The resolution to all this seems to be simple. We just need to update the code.

Ms. DRAPER. Somebody mentioned this, that covered entities—they would like to have the guidance issued——

Mr. CARTER. Absolutely.

Ms. DRAPER [continuing]. 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 5 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 reporting requirements are all the same.

Do you think that something needs to change with that? Or do you think that what's in place is appropriate?

Ms. DRAPER. Well, there are no requirements for covered entities to account for 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. As I said, 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 was developed in the early '90s when the program first became operational. There's a lot that's happened in the 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 currently serving people—these entities, particularly hospitals are much more complex organizations 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 health care landscape really support the current intent of the program.

And 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 track individuals. It's for institutions that are——

Ms. DRAPER. Right. Covered entities.

Ms. ESHOO [continuing]. 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 have more rigorous oversight of the program and——

Ms. ESHOO. How? Give me something specific. I asked you about——

Ms. DRAPER. I think we made——

Ms. ESHOO [continuing]. 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. 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 have guidance for at this point.

I think that's one. Another recommendation was that the number of contract pharmacy arrangements is clear that they track each one of those because right now they're really understated.

So 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 which covered entities they select for audits because it does increase 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, 5 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. 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, even in the reaudits they find, 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?

Ms. DRAPER. Or require some kind of documentation. At GAO, 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 more rigorous information that they require 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 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 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 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 [continuing]. That as well. So——

Mr. GRIFFITH [continuing]. 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, so what we did find was some of the covered—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. It's hard to make generalizations because 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 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, 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 [continuing]. That you don't want to create negative incentives that the program doesn't work as intended and I think that, it's hard to make a blanket generalization because I think some of these things really do require a further look 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 5-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 5 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 3 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, 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. OK. Thirteen. Maybe I read it wrong.

Ms. DRAPER. So, we haven't looked at manufacturer audits. But our understanding is that 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 that they look at the drug pricing, the ceiling, and some other policies and processes and, it's also our understanding, just based on the information that we found from their website is that 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 we haven't looked at that so I don't know 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 understand. There's still some things that—they have statutory authority to do—posting the ceiling prices on a website, creating civil monetary penalties, and also dispute the resolution process.

Those things have 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 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—the fact that there's 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, as far as I know, I assume that that's one of the things that HRSA is looking at.

They did revise their guidance on that a few years ago based on a recommendation that we made. But I really can't give you details about what their audits entailed or, 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, 5 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 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 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 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 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 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 "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. 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 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 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 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 5 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 5 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 hos-

pital. She watched it progress in her chest for the next 3 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 8 to 10 weeks to get her an appointment.

Another 16 patients I am aware of sat for more than 6 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.

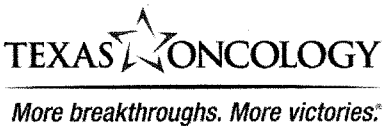
In Boulder, a patient with aggressive lymphoma who had Medicare Part A but was waiting on Medicare Part B was referred to the local 340B hospital to receive therapy. They would not see or schedule him until he got Part B and he died several weeks later without ever being seen.

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:]



Submitted Testimony of Dr. Debra Patt on
Opportunities to Improve the 340B Drug Pricing Program
Energy and Commerce Health Subcommittee Hearing
July 11, 2018

Chairman Burgess and Ranking Member Green, thank you for the opportunity to testify today on behalf of Texas Oncology and the Community Oncology Alliance (COA) before the Energy and Commerce Subcommittee on Health on proposed opportunities to improve the 340B Drug Pricing Program. The Members of the Health Subcommittee have demonstrated commitment to the nation's cancer patients and care providers over the years and many of the Members on this Committee can take credit for policies that have shaped our world-class cancer care delivery system. Thank you for your dedication and support for Americans and their families fighting cancer and for those of us who deliver that care.

I am Dr. Debra Patt and I am honored to appear before the Committee today. For the last 15 years I have spent the majority of my time taking care of cancer patients as a practicing medical oncologist in the great state of Texas. On an average day I treat around 30 patients in a 12 hour day. I also donate my free time in different capacities including serving as a leader in cancer research, informatics, health care policy, and various leadership roles in my practice, The US Oncology Network, COA and ASCO. While I am a community oncologist in a private practice, I also volunteer my time and work collaboratively with Seton, my local 340B hospital, and their

medical school affiliate. As a Professor at The University of Texas Dell Medical School I direct breast health services and co-chair the access to care working group and serve on other committees to collaboratively improve access to cancer care for the uninsured and underinsured patients in my community. These complimentary roles allow me to see care delivery concerns for vulnerable patients from multiple perspectives.

I am proud to be a part of community oncology—the most effective and successful cancer care delivery system in the world, and the highest value site of service in the United States. After nearly 100 years of increasing cancer death rates in the US, we have turned the corner in the fight against cancer. Cancer mortality has fallen by more than 20 percent from a 1991 peak and there are now nearly 15.5 million cancer survivors alive in the US alone. This number of survivors continues to increase as cancer treatment paradigms transform cancer to a chronic disease that is more akin to diabetes than a rapidly lethal entity. The reasons for this success are due in large part to earlier detection through screening programs, scientific breakthroughs such as immunotherapies and the dedication of the nation's oncology providers.

Sadly, not all Americans have had access to these improved cancer outcomes. Vulnerable patients without access to health care have almost 50 percent higher mortality for the 10 most deadly cancers, in comparison to their insured counterparts.[1] The 340B program was created to facilitate qualifying entities to stretch limited resources to improve care for vulnerable patient populations in critical access areas. Unfortunately, the lack of transparency, oversight, and accountability within the 340B program has led to unintended consequences including excessive

[1] Walker GV, Grant SR, Guadagnolo BA, Hoffman KE, Smith BD, Koshy M, Allen PK, Mahmood U. "Disparities in stage at diagnosis, treatment, and survival in nonelderly adult patients with cancer according to insurance status." J Clin Oncol. 2014 Oct 1;32(28):3118-25

growth of the program, expansion of its reach, closure of private oncology practices, and the shift to a much more expensive site of service in hospitals. When cancer care is shifted from private practices to the hospital outpatient department, the cost of care doubles. I share this committee's commitment to maintain the 340B drug discount program by re-imagining it to include meaningful enhancements to the program, including reforms to enhance program oversight, transparency, and accountability. While there may be differences between Members' approach to program reform, I think we can all agree that we want to see the program preserved with transparency, integrity, and accountability.

In my time before you today, I would like to focus on two aspects of the 340B program: The natural consequences of its excessive growth on the cost of health care, and the total lack of clarity regarding the use of the program to directly help underserved patients.

Growth of the 340B Program

When Congress established the 340B Drug Pricing Program in 1992, it was to give covered entities access to price reductions so that they could stretch scarce federal resources to reach eligible patients and provide more comprehensive services. Since then the program has grown substantially from a few hundred participating entities in 2005, to more than 12,000 qualifying entities in 2017. In 2017, 340B program drug purchases amounted to more than $19 Billion. This rapid growth of the program suggests powerful economic incentives are at work. A substantial increase in new hospital qualifying entities and 340B hospital-contract pharmacy relationships have accounted for the majority of growth of the program in recent years. This allows hospitals to contract with many pharmacies to implement the 340B discount through

additional, unaffiliated pharmacy partners in the community. The rapid growth of 340B hospital-pharmacy relationships have changed some of the dynamics of the program. Pharmacies with new margin based contracts have substantial economic benefit from program participation. In cancer care, we have many oral drugs that cost $10,000 a month that patients take for many years. A 5-15 percent margin on a $10,000 drug is a substantial economic benefit. An entire business of post-hoc split fee billers have emerged to adjudicate participating pharmacy scripts to identify potential hospital patients that qualify for the 340B discount and transfer additional funds to the qualifying hospital entity. As opposed to a community practice that pays nearly $10,000 for a $10,000 drug that they sell for $10,000 with a minor ASP increment, hospital contract pharmacies may purchase the drug for $5,000 then sell the drug for $10,000 with a small ASP increment. There were more than 16,000 contract pharmacy arrangements between covered entities and a pharmacy as of January 1, 2017. [i2]
This growth has translated into incremental revenue for all participating entities. Based on the Energy and Commerce report on the 340B program, some of these programs enjoyed more than $100 Million in drug savings in 2016. The tremendous economic opportunity the 340B program provides for hospital systems has been a contributor to hospitals seeking to grow their outpatient cancer service line. When 340B qualifying hospitals treat privately insured patients and prescribing these $10,000 drugs, each time they purchase the drug for $5,000 and keep nearly $5,000 in additional profits. Commonly 340B hospitals have acquired private oncology clinics in their market to leverage the incremental revenue opportunity they can see from the program. When this site of service shift occurs, costs double. Any CFO of any corporation in the world

[2] Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. On Energy and Commerce, 115th Cong, at footnote 19 (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, GAO)

would embrace the opportunity to purchase a drug for $5,000 and sell it for $10,000. Hospitals are no different. This arbitrage opportunity on drugs (to buy low and sell high) affords a clear market advantage and allows them to acquire community oncology practices. A recent Community Oncology Alliance report indicates that 658 private community oncology clinics have closed or aligned with hospital systems since 2008.[3] When hospitals acquire community oncology practices, the cost of care doubles and everyone in the country pays more for healthcare. A recent study published in JAMA Oncology confirmed that by disease type and by episode of care, outpatient cancer care costs at least twice as much in the hospital outpatient department in comparison to a private practice.[4]

Hospitals qualify for 340B status based on their inpatient DSH rates, though this does not guarantee that vulnerable patients will have access to their outpatient departments. In fact, qualifying hospitals sometimes refuse to see these patients. To make matters worse, it is not clear how an entity defines a qualifying patient. With the exponential growth of the post hoc vendor market, laxity in patient definition allows for expansion of the program as it becomes more likely that "hospital patients" are being identified who aren't being directly managed by the hospital entity.

Is there evidence that revenues from the 340B program are being used to enhance the care of vulnerable patients?

This is a tough question and hard to answer with limited data the lack of transparency provides us. Cleary there are hospitals that use incremental revenue to stretch their limited resources to

[3] 2018 Community Oncology Alliance, Practice Impact Report. Full Report available at: https://www.communityoncology.org/downloads/pir/COA-Practice-Impact-Report-2018-FINAL.pdf.
[4] Winn AN, Keating NL, Trogdon JG, Basch EM3, Dusetzina SB, "Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014." JAMA Oncol. 2018 Apr 1;4(4):580-581.

enhance care for vulnerable patients. Parkland Hospital in Dallas is a great example of a hospital that is using this program in alignment with its original intent. While Parkland Hospital's drug savings exceeded $100 Million, the hospital is almost at 50 percent DSH, far exceeding the required 11.75 percent. Parkland requires this funding and actually needs far more to provide the services it needs to serve its high volume of vulnerable patients, but Parkland hospital is not a typical 340B hospital. In a report by the National Academies Press there is discussion that nonprofit hospitals are increasingly displaying characteristics of for profit hospitals.[5] Many 'nonprofit' hospital executives have seven or eight figure annual salaries.[6]

The most important challenge that I would like to discuss is the lack of responsibility to care for vulnerable patients in some 340B qualifying entities. Because of the lack of transparency, oversight, and accountability, we can observe tremendous variability across the country in the philanthropic commitment of 340B hospitals in using additional revenue to enhance care for vulnerable patient populations. Because spending incremental 340B revenue on vulnerable patients is not mandated, some hospitals use these funds to build lavish new towers and enhance executive compensation.

As of 2015, there was only a 1 percent difference in the amount of uncompensated care provided by 340B qualifying hospitals in comparison to non-340B qualifying hospitals, and participating hospitals were no more likely to offer low profit services.[7] A 2016 report by Avalere Health

[5] National Acadamies Press, Making Medicines Affordabe: A National Imperative, Pre publication copy (Nov. 2017)
[6] "The Million-Dollar Club: About 2,700 individuals employed by organizations legally classified as charities earned at least $1 million during 2014" The Wall Street Journal, 2017.
[7] Nikpay, S, Buntin, M, Conti, R, "Diversity of Participants in the 340B Drug Pricing Program for US Hospitals" JAMA Intern Med. 2018 May 21

found that 24 percent of 340B hospitals provide 80 percent of all charity care, despite representing less than half of the beds in the program.

No one knows exactly how the incremental revenue of the 340B program is used without appropriate oversight and transparency, though data that we do have is troubling. As a clinician, working in close proximity to 340B hospitals in my market, across my state, and across the country there are pervasive and deep access to care issues for vulnerable patients like I see every day in clinic. I want to share with you some of my experiences and the experiences of some of my colleagues across the state and across the country.

In Texas, where we have about 9 percent of the US population and rates of poverty are higher than the national average at 15.6 percent in comparison to 12.7 percent. Across the state there are grave challenges in caring for vulnerable patients with cancer. As cancer care for vulnerable patients is complex and dependent on many factors, not just 340B funding, I limited my examples to misses and near misses that have involved 340B entities.

In Longview, Texas, about 2 hours East of Dallas, a 340B qualifying hospital declines to provide care for uninsured or underinsured patients for systemic chemotherapy. They require cash payments for this group of patients prior to administering therapy.

In Austin, I and my partners work collaboratively with our local 340B entity and with the its medical school affiliate. There are widespread deficiencies, delays, and detours in care for uninsured patients that impact care effectiveness and efficiencies across the system. There are multiple uninsured patients with cancer who are county residents who are placed on a queue for months to be seen. Last year, I saw a 50 year old Austin musician who had a clinical stage III

breast cancer found in March of 2017. She had a mammogram at the hospital outpatient unit, and was even connected to a navigator. She was referred to the 340B hospital outpatient department for oncologic evaluation but sat on a queue for 3 months while her aggressive Her 2 amplified locally advanced breast cancer progressed. In June, she presented to my private clinic with a locally advanced stage III breast cancer and scared to death. We were able to evaluate her and get some of her expensive chemotherapy drugs donated from the pharmaceutical manufacturer. The remaining services were billed to her, which ultimately resulted in bad debt. The patient received appropriate care. She ultimately was found to have a breast cancer in each breast, and a genetic predisposition to getting breast cancer as we discovered she carried the BRCA gene. After receiving chemotherapy, she was able to successfully undergo surgery and remains disease free in follow up. The same month, a 26 year old massage therapist presented to my office with a stage II aggressive breast cancer. She was uninsured and a young county resident but was refused services at our local 340B institution. We were able to see her in our private clinic, help her apply for Medicaid, and she was able to have chemotherapy and surgery and remains disease free today. We also were able to preserve her fertility by harnessing embryos so that when she is older and a many year cancer survivor, she will have the option of becoming a mother as she survives cancer. These stories are near misses, as these patients ultimately received appropriate care and we believe will have a good outcome.

Many of the stories however, don't have happy endings. My partner's patient, a 61 year old man, was seen in South Austin with a new metastatic colon cancer with brain metastasis in December 2017. He was referred to the 340B entity for treatment where they have a contract for radiation services with another cancer provider, but was told that they needed to wait for social security determination before he could qualify for treatment in the county system. He was

ultimately admitted to the hospital 5 months later with a complication and had not yet started treatment for his cancer. A few weeks after his April admission he qualified for Medicaid and ultimately was able to start chemotherapy. A partner had a 34 year old pregnant woman with stage IV colon cancer. During her pregnancy we had to start her on FOLFOX chemotherapy. We treated her for five cycles as a hospital inpatient under emergency care because the 340B hospital took 8-10 weeks to get her an appointment in clinic. Another 16 patients sat on a gynecologic oncology queue last year for more than 6 months while they waited to be given appointments in the 340B qualifying entity. Some of these patients had curable advanced cervical cancer, and many represented to the emergency room while they waited on the queue. Additionally, the lack of ability to give timely access leads to alterations in care delivery that raise the cost of care. Patients who cannot get adequate follow up have disproportionately longer hospital stays and inpatient as opposed to outpatient management.

The lack of commitment to services also extends to a near absence of cancer screening efforts. This absence removes the opportunity to cure cancer cheaply and effectively. There is minimal current availability for uninsured county residents to have screening mammography, and screening colonoscopy is only minimally available through a program run by a local private practice. More so, the 340B entity has recently decreased already limited screening services. In our community there is a pervasive lack of screening in uninsured patients that contribute to late stage diagnosis and higher mortality rate. Lack of breast and colon cancer screening rates among the uninsured are staggering. Early stage breast cancer and colon cancer is virtually undiagnosed in my community amongst the uninsured because of failure of screening. Higher stage of cancer and substantially higher mortality afflict the vulnerable population across the state.

Across the Country these are also similar recurring stories of lack of access to care for vulnerable patients with a 340B hospital in their area. In Kentucky, a patient was diagnosed with a locally advanced but still curable Non Small Cell Lung Cancer in late February 2018, and in follow up he saw a 340B hospital based oncologist in March with further work up. In follow up in April and May the patient still had not started treatment for his curable cancer as he had an application to insurance denied. The 340B hospital plan was to wait to start chemotherapy when insurance was approved. Ultimately the patient sought care outside of the hospital system to initiate definitive chemotherapy and radiation in June. For this patient, a three month delay in diagnosis is the difference between life and death. It is these misses and near misses to treat curable cancer that are so devastating. In Boulder, one of our oncologists was seeing a patient with aggressive lymphoma who had Medicare part A but was waiting on part B and was delayed in getting Medicaid. He was referred to the local 340B hospital to receive therapy or for evaluation for a clinical trial. They would not see or schedule the patient until he got part B. He died several weeks later without ever being seen by the qualifying entity or given the opportunity.

Just because qualifying entities choose not to use the profit from the 340B program to evaluate and manage uninsured cancer patients, it does not necessarily imply that they are not stretching limited resources to serve vulnerable patients in other ways. Without transparency and oversight, it remains unclear. For hospitals that choose not to spend additional funds towards the care of vulnerable patients, there is no statutory obligation that prevents hospital systems from directing these additional funds to other strategic initiatives including building physical plants or enhancing executive compensation. We see troubling examples in community oncology where vulnerable patients have no ability to even be evaluated for treatment, and executive

compensation within those systems exceeds millions of dollars. If a hospital administrator chooses to direct funds towards other priorities instead of increasing care delivery for vulnerable patients there is no way to know because there is no transparency and it is not illegal. They are simply following their fiduciary duty to their organization. If there were transparency and accountability within the 340B program, the policy would reinforce actions in alignment with the initial intent of the program.

On behalf of oncologists nationwide, I appreciate the Committee's leadership and dedication to our nation's health care system in examining the 340B program. When community cancer clinics close their doors, access to care is compromised for all cancer patients. The continued shift to hospital–based care doesn't just reduce access to care for cancer patients, especially in rural areas, but it also increases healthcare costs for all Americans.

I urge the Committee and Congress to act to protect the integrity and viability of the 340B program. Without your action, continued growth of the program will render it susceptible to abuse, vulnerable patients will not see a maximal benefit of the program and community cancer clinics will continue to close and care will continue to shift to the more expensive, less-accessible hospital outpatient setting. Americans fighting cancer will experience diminished access to care, and patients, payers, and taxpayers will pay more.

My oncology colleagues across the country and I are doing our very best to help patients fight cancer, and win. In order to do that effectively we need the 340B program to be implemented optimally. To do that, we need your help. Once again, thank you for the opportunity to address the Committee. I am happy to answer any questions the Committee has regarding my testimony.

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 5 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 atour 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 fFederal 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 1-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 year.

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:]

Statement of
Fred Cerise, MD, MPH
President and Chief Executive Officer
Parkland Health & Hospital System
Before the House Energy and Commerce Committee,
Subcommittee on Health
July 11, 2018

Chairman Burgess, 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 subcommittee meaningful feedback on policy related to the program.

My name is Fred Cerise and for the last four years I have served as the President and CEO of Parkland Health & 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 & Hospital System; my testimony reflects my views as the CEO of Parkland.

Located in Dallas County, Texas, Parkland is one of the largest safety-net health systems in the country. The system includes an 878 bed acute care hospital, twelve primary care clinics, twelve youth and family centers, ten women's health clinics, acute response clinics, homeless outreach, jail health and nursing homes. We are the primary teaching hospital for the University of Texas Southwestern Medical Center and recognized nationally for our Level I Trauma, Level III NNICU and one of the largest civilian burn units in the nation. We are also proud to claim Chairman Burgess as one of the many excellent physicians who have trained at

our facility. We appreciate his continuing support of Parkland and his understanding of our mission.

In fiscal year 2017, Parkland provided approximately $879 million in uncompensated care. Our payor mix for that year was 45% uninsured, 31% Medicaid, 16% Medicare and 8% commercial insurance. We provided more than 1.2 million outpatient visits and filled over 10.5 million prescriptions in both outpatient and inpatient settings. Our pharmacy's payor mix was over 62% charity care. Parkland's pharmacy department includes one inpatient, seven retail, one central fill and 26 Class D clinic pharmacies.

Overview of Parkland's 340B Program

Parkland has participated in the 340B Program since its inception. The program is a critical component to fulfilling our mission to serve the most vulnerable in our communities. Our Medicare DSH percentage for fiscal year 2017 was 47.52% well above the 340B eligibility threshold of 11.75%. The health system holds 101 HRSA site registrations: one parent (DSH), 83 child sites (DSH), ten family planning sites and seven FQHC sites.

In 2017, the 340B Program saved Parkland and the Dallas County taxpayers who support us $152 million. Still, 9% of Parkland's budget was spent on pharmaceuticals. The cost of pharmaceuticals to Parkland has more than doubled in the last ten years and the cost of prescription drugs is often a barrier to receiving appropriate healthcare for working low-income residents. The 340B savings allow the health system to administer free and reduced-cost medicines, often at a lower cost than 340B prices, to low-income patients, which is a benefit to both those patients and the taxpayers.

Under our Parkland Financial Assistance program, Dallas County residents who are under 100% of poverty receive drugs at no cost. Dallas County residents between 101% of the Federal Poverty Income Level and 250% of the FPIL receive significantly discounted drugs based on a sliding scale between $5 and $15. That represents the total cost to the patient regardless of our acquisition costs. Additional programs supported by 340B savings include: expansions in access to care including homeless outreach, diabetes management, pediatric asthma programs and smoking cessation education. Parkland also recently embarked on a sophisticated medication adherence program. Our healthcare providers now are able to see in a patient's electronic medical record whether that patient has filled their prescriptions and thus their level of adherence to prescribed medications. For this tool we compile pharmacy fill data from Parkland pharmacies and pharmacies outside our system. This adherence data better guides patient conversations. Instead of guessing why someone's diabetes is poorly controlled providers use this adherence score to quickly rule in or rule out medication nonadherence. The provider may then start a conversation with, "I see that you might be having some trouble filling your medications, can you tell me more about that?" Providers can better tailor medical treatments for chronic diseases with accurate information and can all upon our pharmacists and care managers to help patients overcome any barriers to obtaining their needed medications.

Parkland's Compliance and Oversight of 340B

Compliance is an incredibly important and essential piece of the program. We have one dedicated 340B manager assigned to oversee the program and he serves as the primary contact

for HRSA. We also established a multi-disciplinary team to assist with compliance which includes staff from pharmacy, legal, corporate compliance, government reimbursement, procurement and information technology. We believe self-audits are the backbone of a compliant 340B Program. We perform quarterly scheduled audits on both the inpatient and outpatient areas. We also perform other targeted audits throughout the year in order to better ensure program compliance. Our audits are based on educational materials and guidance provided by the Prime Vendor Program, Apexus. While we believe we are thorough in self-auditing, clearer guidance by HRSA would strengthen compliance adherence by covered entities.

Contract Pharmacy

Parkland does not currently have any contract pharmacy relationships. We have had companies solicit Parkland to develop a contract pharmacy relationship in order to generate savings. We are fortunate to be able to provide all of our 340B pharmacy services in-house. While contract pharmacy savings could be used to further care for our low-income patients, we share Congress' concern that some pharmacies may prioritize revenue generation over providing the lowest cost prescriptions to the consumer.

RECOMMENDATIONS

1) **Program Intent:** The original intent of the 340B Program was to "enable covered entities to stretch scarce Federal resources as far as possible." This intent is still relevant today and therefore we believe Congress should not modify the intent to narrow the eligibility of the patient or limit the uses of the savings. 340B savings are used to provide free and

reduced cost drugs. Savings are also used system-wide to benefit our patients, the majority of whom are uninsured or on Medicaid. In 2017, Parkland dispensed 1.6 million outpatient prescriptions. Tracking each of these prescriptions by site of origin or by individual patient characteristics would be very difficult to manage. All Parkland outpatient clinics are registered with HRSA and our pharmacies only fill 340B eligible prescriptions. Therefore, we only maintain a 340B drug inventory at each pharmacy. Even though an overwhelming majority of our patients are indigent, narrowing the program's scope to a certain patient qualifier (regardless of the number qualified – 1% or 99% of patients), would require the use of a wholesale acquisition cost (WAC) based virtual inventory. Limiting 340B drugs to certain patient types would require the purchase of more expensive pharmaceuticals for our other patients, more tracking software and more human resources to operate and maintain compliance.

2) **HRSA Oversight:** Parkland supports efforts to strengthen HRSA oversight to police both covered entities and drug manufacturers. The agency must be given the appropriate tools to ensure the integrity of the program. Covered entities must be given clear regulatory guidance.

3) **Reporting of Savings and Uses:** Covered entities should be transparent in how the 340B Program is being used to provide charity care to patients and we support reporting the savings to HRSA. Any reporting requirements should clearly define the method of how to calculate the savings. Congress and HRSA should continue to allow flexibility on how covered entities use the savings. Preventive care is essential to maintaining good health, lowering healthcare costs and having a better quality of life. While drug costs are a

critical piece of the puzzle, providing other medical services may be just as important. Therefore, we believe savings should be allowed to be used for more than just lowering drug costs for the indigent population.

4) **Restore Medicare Outpatient Prospective Payment Cuts:** The cuts significantly harm safety-net systems, which are providing the majority of care to those who are low-income and uninsured. The increased burden for Dallas County taxpayers for the top 21 drugs is $2.2 million. Health systems with a larger Medicare population are seeing larger decreases in payments. Additionally, the modifier reporting regulations are burdensome by requiring complex programming with quarterly updates to place specific modifiers on select drugs.

5) **Contract Pharmacies:** These pharmacies are essential for many 340B participants to extend access to low-cost drugs for many patients since not all entities are able to have in-house pharmacies. Better oversight is needed to ensure that these arrangements are appropriately targeting low-income patients and that these patients are benefitting from the 340B prices.

6) **Moratorium on new 340B entities and child-sites:** A moratorium will only limit access for persons who are low-income. As the population grows and demographics change, safety-net systems should be allowed to receive 340B discounts via new clinics or new accounting cost centers in order to serve the indigent according to the intent of the program. If this moratorium is being used to limit the number of new covered entities or child sites, do not limit those providers who are truly caring for the low- income and uninsured. Many of those safety-net systems like Parkland serve patients in medically-

underserved areas and make decisions on clinic locations based on the needs of their communities. If the intent is to limit the scope of the program a preferred approach would be to increase the DSH percentage.

Mr. BURGESS. Thank you, Dr. Cerise. We appreciate your testimony.

Dr. Daniels, you're recognized for 5 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:]

Testimony of Dr. Charles Daniels
House Energy and Commerce Committee
340B Oversight Hearing, July 11, 2018

Introduction
Good morning, Chairman Burgess and 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 want to 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 have been able to personally share with Congressman Peters and Congresswoman Matsui the value of the 340B discount to UC San Diego Health patients, as well as patients seen throughout UC Health System. My name is Dr. Charles Daniels, and I serve as 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 UC San Diego Health's administration and use of the 340B Program.

Who is UC San Diego Health?
UC San Diego Health is a public academic medical center serving the people of San Diego and surrounding communities. The medical center's service imprint extends over 100 miles into remote El Centro in Imperial County. Our mission is to deliver outstanding patient care through commitment to the community, groundbreaking research, and inspired teaching. UC San Diego Health, a premier provider of tertiary and quaternary services, is comprised of three major inpatient facilities, the Hillcrest Medical Center, the Jacobs Medical Center, and the Sulpizio Cardiovascular Center, along with the region's only National Cancer Institute (NCI)-designated Comprehensive Cancer Center. We provide the region's first Level I Trauma Center and its only Regional Burn Center, serving San Diego, Imperial, and Riverside Counties, as well as portions of Arizona. UC San Diego Health also houses two Comprehensive Stroke Centers, multi-organ transplant programs, and California's only advanced certification program for chronic kidney disease care.

UC San Diego Health includes two professional schools, the UC San Diego School of Medicine and the Skaggs School of Pharmacy and Pharmaceutical Sciences, where close to 1,694 faculty, including myself as an Associate Dean of the School of Pharmacy, educate close to 3,021 students, residents, fellows and post-docs. Our faculty advance patient care through their contributions to biomedical research. In fiscal year (FY) 2017, UC San Diego Health faculty received $659 million in faculty research awards, including $424 million from the National Institutes of Health (NIH). UC San Diego Health has been a formidable leader in innovating the use of precision medicine and initiating discoveries in brain, central nervous system, and cancer research.

UC San Diego Health's medical center is eligible for the 340B program because it is a state-owned "disproportionate share hospital" or "DSH" hospital, meaning that it serves a disproportionate share of low income Medicare and Medicaid (referred to in California as "Medi-Cal") patients, as measured using a complex statutory formula set out in the Medicare

statute.[1] While the minimum DSH adjustment percentage required for eligibility to participate in the 340B program is 11.75 percent, UCSD's DSH adjustment percentage is 34.77 percent. UC San Diego Health's Hillcrest Medical Center also qualifies as a Medi-Cal DSH hospital under federal and state law, based on the high percentages of Medi-Cal patient days that the hospital provides and Medi-Cal revenue that the hospital receives.

UC San Diego Health is deeply committed to serving patients and communities in San Diego, Riverside, Imperial counties, and beyond. In FY 2017, UC San Diego Health provided nearly $17 million in charity care and more than $155 million in uncompensated care, the vast majority of which was provided to Medi-Cal patients. As the Committee may know, the Affordable Care Act's Medicaid expansion resulted in nearly 3.7 million low-income individuals in California getting health care coverage from the Medi-Cal program. San Diego has no county hospital. That function is largely served by UC San Diego Health, which treats a significant number of Medi-Cal patients. Currently, nearly 40 percent of the patients that UC San Diego Health's medical center treats (measured in patient days) have Medi-Cal coverage. It's important to understand that California has one of the lowest Medicaid provider reimbursement rates in the country and that for many Medi-Cal patients, the costs of providing the specialty services that UCSD Medical Center offers are much higher than the Medi-Cal reimbursement that UC San Diego Health receives for those services. As a result, UC San Diego Health incurs tens of millions of dollars in uncompensated costs for providing care to Medi-Cal patients, including more than ten million in uncompensated costs for cancer care provided in the hospital inpatient setting and several million dollars more in uncompensated costs for cancer care provided in the outpatient setting. UC San Diego Health also serves a significant number of Medicare patients: 34 percent of UC San Diego Health's patient days are provided to individuals with Medicare coverage.

Intent of the 340B Program

Congress enacted the 340B Drug Pricing Program in 1992, and from the beginning, included public DSH hospitals that meet certain criteria, like UC San Diego Health's medical center, as "covered entities" that are eligible to participate in the program. UC San Diego Health has been a 340B provider, or "covered entity," since the program's inception. The program was designed to support qualifying safety net providers, such as UC San Diego Health, so they could stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. From the 340B program's birth to the present day, the 340B drug discount is furnished entirely by participating drug manufacturers.

UC San Diego Health Services to Low-Income and Uninsured Patients

UC San Diego Health fulfills the intended purpose of the 340B Drug Discount Program by using savings generated from the program to provide a variety of services for the uninsured, low-income uninsured, and other vulnerable patient populations in San Diego, Riverside, and Imperial counties. For example, UC San Diego Health pharmacies provides discounted or free outpatient drugs following a case-by-case evaluation process to patients who meet standard financial need criteria and who are not able to afford their medications. An example of such a

[1] UC San Diego Health does not purchase covered outpatient drugs through a group purchasing organization (GPO), and therefore it satisfies all three criteria to be eligible to participate as a "covered entity" in the 340B Drug Pricing Program.

patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved $750 in out-of-pocket costs because of UC San Diego Health's help supplementing the drug's cost.

UC San Diego Health also uses its 340B savings to provide other necessary medical services to the underserved. For example, presently, UC San Diego Health invests savings it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County residents lived in poverty, and Imperial County residents' median household income was $42,560.

UC San Diego Health also runs one of the most successful HIV/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 HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a "meds to beds" program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients' medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration's (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use the savings to serve the unique needs of its underserved patient populations.

Ensuring Compliance with 340B Program Rules

Because the 340B drug discount provides critical support for so many of UC San Diego Health's programs and services offered to our patients, we take very seriously our responsibility to be good stewards of the program and to comply with 340B program rules. We have put into effect numerous practices to promote compliance with the 340B program rules.

For example, at UC San Diego Health, we employ dedicated pharmacy staff to conduct internal audits each month of a random sample of 340B transactions from our hospital facilities and child sites. Audits include both in-house pharmacies and contract pharmacies, to verify that those prescriptions meet all of the HRSA requirements to be eligible for a 340B discount. The results of those internal audits are formally reported to the pharmacy department leadership on a quarterly basis and to the Executive Steering Committee for UC San Diego Health, at least twice

per year. This is done to ensure that any detected discrepancies or deficiencies are investigated and corrected in a timely way, and that any safeguards needed to prevent re-occurrence of any incident are put into place. UC San Diego Health also routinely hires an outside auditor to conduct an annual review of our 340B Program compliance. We also regularly provide continuing education on 340B rule clarifications to our 340B compliance staff and pharmacy personnel who work directly with patient prescriptions at the prescription counter.

Additionally, UC San Diego Health requires that any contract pharmacies that we work with meet the same standards for compliance. We have mapped out where our patients go to fill their prescriptions, have entered into contract pharmacy arrangements with pharmacies located within zip codes that are accessible to most of our patients. For example, Hillcrest Pharmacy, one of UC San Diego Health's contract pharmacies is located in a neighborhood accessible to many of our HIV patients. The Hillcrest Pharmacy offers services that are highly valued by our HIV patients. UC San Diego Health also does not accept "all in" contractual clauses from pharmacy chains which would require us to contract with any future pharmacy erected in the chain's San Diego area network, regardless of whether these new pharmacies are typically used by UCSD patients. This is a statement on our commitment to follow HRSA rules and protect access to the 340B program.

Qualifying A Prescription for the 340B Drug Discount

To further underscore UC San Diego Health's commitment to complying with the 340B program rules, I thought it would be helpful to explain the process for determining whether a particular drug dispensed to a UC San Diego Health patient is eligible for the 340B discount. The fact that UC San Diego's hospital meets the eligibility criteria for being a 340B covered entity is not sufficient for claiming the 340B discount on an outpatient drug; rather, it's only the first of many steps. There are multiple other requirements that must be satisfied, including all of the elements that HRSA has specified to define which patients are eligible for the 340B discount. (See the flowchart attached as Exhibit 1).

For example, HRSA requires the covered entity to have an established relationship with the patient. The treatment history for the patient must be maintained in the covered entity's medical records. It must go beyond the provider simply writing a prescription for the patient. Also, the patient must be treated by someone who is employed by or contracted with the covered entity, such that the covered entity retains responsibility for the patient's care. Further, the prescription must be written based on an encounter within the covered entity at one of its facilities or registered child sites. Additionally, to be eligible for the 340B discount, the prescription must be filled at the hospital's in-house pharmacy or contract pharmacy. Only after all of these requirements are met, does the covered entity receive the 340B drug discount on an eligible outpatient prescription.

Conclusion

The 340B Program helps safety net healthcare providers like UC San Diego Health to invest private dollars up front, in the unique needs of underserved patients, so that federal and state dollars need not later be expended for more costly care. UC San Diego Health, like the other medical centers in the UC Health system, uses the benefits from the 340B program to provide not only medications, but also a comprehensive array of high quality primary care and specialty

care services to patients in underserved communities across the state of California. I am very concerned that the financial impact of the nearly 30 percent cut in Medicare Part B reimbursement to DSH hospitals for drugs purchased under the 340B program will restrict UC San Diego Health's ability to provide some of the services we offer our underserved patient communities throughout San Diego, Imperial, and Riverside Counties. Any efforts in rulemaking or legislation to scale back the 340B Drug Pricing Program would be detrimental to our patients, and the patients of so many safety net providers across the country. I welcome this opportunity to answer your questions. Thank you.

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 5 minutes for questions.

Mr. BARTON. Well, thank you, Mr. Chairman, and I want to thank our panelists for being here, especially the two from Texas. It's good to have you 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 say the pharmaceutical suppliers of the drugs had to lower their payment so they could, in essence, subsidize the operating costs?

Dr. PATT. 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 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—require the the manufacturers to provide discounts 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, 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. Well, first of all, should we increase the DSH percentage requirement under current law?

Dr. CERISE. So from Parkland's perspective, as you said, we are going to meet that threshold whether you increase it 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 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, the reason people are coming to the program is because of high drug costs. And so it would not be the first place I went, but because it is an attempt 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 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 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 5 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 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 the specific question.

Mr. GREEN. 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 this program is?

Dr. CERISE. I can't tell you. 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. OK. 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 22.5 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 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. OK. 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 program—hospital, child sites, contract pharmacies, and our own in-house pharmacies—and that information then is provided back. We analyze it at the department level and at the hospital level to make sure that we've done that.

I guess I would also want to share with the subcommittee that over the last 3 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 1 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 8 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 5 minutes for your questions, please.

Mr. BUCSHON. Thanks for the 7 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 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 the outlay of funds and they'll cut it again and this time 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 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 mix is, including the uninsured, looking at outpatient metrics, 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 you all already have internal data that—could we require things that are too burdensome? Sure. That's what the government sometimes 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 going 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, 5 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 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 toward 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 being able to separate the payment that comes back to the organization from the payers. From the drug cost side 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 drug spend. But on an individual patient level, we don't track it that way.

Mr. PALLONE. Do you have any suggestions to change that so we can have better tracking?

Dr. CERISE. So 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, 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, 5 minutes for questions.

Mr. GUTHRIE. Thank you. Thank you, Mr. Chairman. Thank you for the opportunity and for the panelists 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 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 340B pharmacist who's dedicated to this program. So he will look at all of 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. OK. Similar, Dr. Daniels?

Mr. DANIELS. 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 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 least 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 5 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 tthat gives us, I guess, qualification as a DSH hospital and that's how we participate.

Ms. MATSUI. OK. 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 [continuing]. 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 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 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 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 5 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, 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, if you're going to do a fee 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 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, 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, 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 hospitals that are seeing such a high percentage of disproportionate share make money to extend other services to low income patients.

So 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 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, 5 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—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.

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. 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 they have these audits. They're not doing enough of them.

We've heard good bipartisan testimony we could have more complete audits. But 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 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, 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, 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 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. Some folks did not choose the Medicaid expansion. OK, you're going to have high charity care caseloads.

But 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 the 340B program for these wraparound services to provide good patient care, and I think that 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.

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, 5 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, we'll 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 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 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'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 provided 10-year authorization for Children's Health Insurance this year. This committee provided 2 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 5 minutes.

Mr. CÁRDENAS. 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. CÁRDENAS. Anybody disagree with that? Is everybody consistent with it? OK. 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 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 acquiring—and how we acquire drugs but——

Mr. CÁRDENAS. Pretty minimal out there—the application.

Mr. DANIELS. Yes. 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 has been for 25 years that it doesn't cost the citizens in the United States directly.

Mr. CÁRDENAS. That point being made, 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, 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?

Dr. PATT. Yes. So I would say that 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. 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. CÁRDENAS. OK. 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. CÁRDENAS. Exactly. So basically, Dr. Patt, you basically pointed out 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, 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. CÁRDENAS. Overall?

Dr. PATT [continuing]. We need better transparency.

Mr. CÁRDENAS. 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 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, 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 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. CÁRDENAS. OK. 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, 5 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.

Yes, he says yes, 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, what is it costing the taxpayers, you said it didn't cost the taxpayers directly, which I agree with, 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 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—like we are dealing with now—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 that's industry wide as well, isn't it?

Dr. CERISE. I can't speak for the rest of the world. Sorry.

Mr. GRIFFITH. OK. 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 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—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 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 the payer mix is predominantly private and Medicare, it allows them a tremendous economic advantage.

And so because they have such an arbitrage opportunity with purchasing power, it's really easy to say hey, community oncologist A—practice A and B, 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, 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, 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 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 5 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 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 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. OK. Well, just to note that, 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 have collaborative relationships with 340B hospitals. But I am trying to understand the nature of that collaboration.

We know that many of the uninsured patients 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 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, as you mentioned, some cancer drugs are very expensive. Actually, we've had a lot of success so we've——

Ms. SCHAKOWSKY. 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. 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, 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, 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 [continuing]. I do, too.

And I yield back. Oh, wait. I do have more money—more time.

Mr. BURGESS. No. Your time is way——

Ms. SCHAKOWSKY. Oh, it's way over. OK. I yield back.

Mr. BURGESS. You're in arrears.

[Laughter.]

We are going to the next hearing.

So I recognize the gentleman from Georgia 5 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, 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. OK. 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. OK. Dr. Cerise, do you?

Dr. CERISE. In general, 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 [continuing]. A higher percentage of uninsured.

Mr. CARTER. Well, then, and, I've gotten legislation that I am introducing that would require the outpatient be factored in as well, because I think that's very important because, obviously, one of the abuses—it's just one of what 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 are being denied care and I was just wondering 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 focuses 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 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, 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, 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 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 appears at the conclusion of the hearing.]

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. OK.

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 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. Mr. Chairman, I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Oklahoma 5 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 as 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 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 would not want to restrict ——

Mr. MULLIN. So what type of clarification would you need on that?

Dr. CERISE. Well, 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 my colleague from Georgia had alluded to, that there's unclarity that is happening right now when it's designed even—what Dr. Daniels had just said—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, 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 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 be-

half of UC San Diego is that 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 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 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 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. 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 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman. I am not a member of this subcommittee 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 the intent was to provide discounts to drugs to providers to "reach more eligible patients and provide more comprehensive services."

I think that's pretty basic. Just for the record, we have 199 cosponsors on our piece of legislation. That's more than any of the other pieces that have been debated here.

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 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 if this program isn't modified.

Now, I could go on with it—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 "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.

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.

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. Most of the other places throughout north Texas do not have an in-house pharmacy, strict formularies. There are reasons why what you do cannot be extrapolated across the entire north Texas community.

Still, 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. 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 appears at the conclusion of the hearing.]

Mr. BURGESS. One last commercial before we conclude—I ran through a litany of positive things that this committee has deliv-

ered 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 5 minutes to go over and vote.

[Whereupon, at 1:52 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement for the Record Submitted by the Association of American Medical Colleges (AAMC) to the Energy and Commerce Subcommittee on Health "Opportunities to Improve the 340B Drug Pricing Program" Submitted July 11, 2018

The Association of American Medical Colleges (AAMC) is pleased to submit this statement for the record for the House Energy and Commerce Health Subcommittee's July 11 hearing, "Opportunities to Improve the 340B Drug Pricing Program." The AAMC strongly supports the 340B Drug Pricing Program and is especially supportive of legislative efforts to improve the program and expand access to care, including the Stretching Entity Resources for Vulnerable (SERV) Communities Act (H.R. 6071) and the bill to rescind the Medicare cuts in the calendar year (CY) 2018 outpatient final rule (H.R. 4392).

The AAMC is a not-for-profit association representing all 151 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. Through these institutions and organizations, the AAMC services the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Many AAMC-member teaching hospitals are safety-net providers that rely on the savings from the 340B program to improve the health of their communities. At no cost to taxpayers, the 340B program has been successful in providing patients with access to health care services and relief from high drug prices. As the committee reviews the program, we believe that any potential changes should be measured against the goal of enhancing – not diminishing – the services made available by the 340B program.

Congress created the 340B program 25 years ago to support safety-net hospitals and other providers that serve low-income, vulnerable patients. The program allows participants, also known as covered entities, to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services."[1] In addition to providing low-income patients with free or discounted drugs, hospitals use their savings to address the needs of their local communities. Any proposal to reduce the scope of the program is counter to the intent of the program.

The 340B Program Provides Vital Support to Patients at No Cost to Taxpayers

Congress created the 340B program under the Public Health Service Act to help reduce the burden of high drug costs on safety-net hospitals. Under the rules of the program, pharmaceutical manufacturers that participate in Medicaid are required to sell outpatient drugs at discounted prices to eligible providers that care for a disproportionate share of uninsured and underinsured

[1] H.R. Rept. No. 102-384(II), at 12 (1992)

patients. There is no cost to taxpayers since the program allows safety-net hospitals and other eligible providers to leverage these discounts from pharmaceutical companies to provide patients and communities with access to care they otherwise would not receive.

Consistent with the intent of the program, safety-net hospitals invest their 340B savings in a wide variety of programs to meet the needs of their local communities and help vulnerable patients. In addition to providing low-income patients with free or substantially discounted prescription drugs, AAMC-member 340B teaching hospitals use their savings to create and sustain critical programs that otherwise might not be financially possible, including:

- Improving access to specialized care previously unavailable in underserved areas;
- Establishing and improving neighborhood clinics;
- Creating multidisciplinary clinics to treat substance use and mental health disorders;
- Providing underfunded cancer patients with access to counseling from pharmacists at their bedside; and
- Providing mobile clinics staffed by bilingual nurse practitioners, nurses, and social workers to vulnerable communities to provide free health care to children and their families.

The 340B Program Provides Enormous Benefits to Patients at Little Cost to Manufacturers

The 340B program is a relatively small program but is a lifeline for many safety-net hospitals and their patients. Without the savings from the program, hospitals may have to reduce access to these critical health care services.

According to the most recent data from the Health Resources and Services Administration (HRSA), which administers the program, 340B sales represent just 3.6 percent[2] of the total $457 billion U.S. drug sales[3]. The net reduction to drug manufacturer revenue is even less - estimated to be approximately 1.9 percent.[4] This is a negligible impact to drug manufacturers, whose worldwide estimated sales revenue increased to $775 billion in 2015 with the largest 25 drug companies reporting annual profit margins between 15-20 percent.[5]

Drug manufacturers argue that the 340B program is responsible for the increase in drug prices. There is no question that drugs have become unaffordable for millions of Americans and the providers that care for them. However, it is illogical and misleading to suggest that the solution to rising drug costs is to shrink a program that represents a de minimis percentage of the total U.S. drug market and enables safety-net providers to care for vulnerable populations. We urge policymakers to address this national problem of unaffordable drug prices directly – not by

[2] Department of Health and Human Services Fiscal Year 2019, Health Resources and Services Administration, Justification of Estimates for Appropriations Committees

[3] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. "Observations on Trends in Prescription Drug Spending." https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.

[4] Coukell, Allan and Dickson, Sean. "Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenues." JAMA Internal Medicine. Published online May 21, 2018.

[5] U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." https://www.gao.gov/assets/690/688472.pdf

undermining a program that provides drug pricing relief and valuable health care services to patients.

The Closure of Oncology Practices and Physician Consolidation are Not Related to 340B

Critics have falsely asserted that the 340B program incentivizes physician-hospital consolidation in cancer care. However, the increase in hospital ownership of physician practices is a relatively recent phenomenon compared to the 25-year history of the 340B program and is explained by other factors, including a broader trend toward integrated health care systems.[6]

For many years, the most cited driver of consolidation was payment reform under the Medicare Modernization Act of 2003 (MMA), which significantly reduced physician reimbursements for cancer drugs beginning in 2005. According to a 2007 study, drug reimbursement accounted for 77 percent of oncology practice revenue.[7] As recently as 2012, David Eagle, MD, past president of the Community Oncology Alliance (COA) noted "the key driver of consolidation in oncology is financial strain."[8]

Other factors have also contributed to the dramatic increase in the number of oncology clinics that have either closed, struggled financially, merged, or been acquired since 2008. These include rising bad debt and tightened lending standards during the recession; the evolution of cancer care to integrate services like genetic testing, specialty pharmacies, and nutritional support, which made solo practice less economically viable; and the appeal of economies of scale for activities such as billing and general technology infrastructure, which provided strong incentives to consolidate.[9]

Legislative Proposals to Strengthen the 340B Program

The AAMC strongly supports two bills that the subcommittee is considering as part of this legislative hearing – H.R. 4392 and H.R. 6071. These bills strengthen the 340B program by rescinding the drastic Medicare cuts to 340B hospitals and improving program integrity by ensuring that drug manufacturers are held to the same level of oversight as other program participants.

Congress Must Rescind the $1.6 Billion Cut to Safety-Net Hospitals

The AAMC supports **H.R. 4392**, bipartisan legislation introduced by Representatives David McKinley (R-W.Va.) and Mike Thompson (D-Calif.), which would rescind a flawed policy in the CY 2018 Medicare Outpatient Prospective Payment System (OPPS) final rule that

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[6] Alpert A, His H, and Jocobson M. "Evaluating the Role of Payment Policy in Driving Vertical Integration in the Oncology Market." Health Affairs, Vol. 36, No. 4.
[7] Akscin J, Barr TR, Towle EL. "Key practice indicators in office-based oncology practices: 2007 report on 2006 data." J Oncol Pract. 2007; 3(4): 200-203. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2793811/
[8] Ullman K. "Oncologist Practice Consolidation Continues" American Journal of Managed Care, Dec. 2012. http://www.ajmc.com/journals/evidence-based-oncology/2012/2012-2-vol18-n5/oncologist-practice-consolidation-continues
[9] Tetreault SA, Harwin WN, and Eagle D. "'Economies of Scale' Yield Multiple Benefits for a Private, Physician-run Oncology Practice." Practice and Policy, Oncology Journal. Vol. 27, Issue 7.

dramatically reduces outpatient drug reimbursement rates for hospitals participating in the 340B program by nearly 30% annually. The legislation currently has nearly 200 bipartisan cosponsors.

The Centers for Medicare and Medicaid Services (CMS) finalized this proposal despite concerns from over half the members of both houses of Congress. Previously, Medicare paid for separately payable, non-pass through drugs under Part B at the average sales price (ASP) plus 6 percent. Under this final rule, Medicare now pays for drugs purchased under the 340B program at ASP minus 22.5 percent. According to CMS, this change will result in $1.6 billion in payment cuts annually to safety-net hospitals. These reimbursement cuts further strain hospitals' ability to provide needed services to their patients and communities. A recent report from S&P Global Ratings concludes that the impact of these cuts will weaken the operating performance of safety-net hospitals at a time of already tightened margins.[10]

The OPPS final rule contravenes statutory intent by inappropriately leveraging Medicare to undermine the 340B program. CMS argues this policy will lower the cost of prescription drugs. While it is critical that policymakers take steps to make prescription drugs more accessible and affordable, reducing Medicare payment rates for prescription drugs in the 340B program is not a solution to this problem. These cuts simply impede hospitals' ability to maintain programs to provide services to vulnerable populations – including Medicare beneficiaries – while doing nothing to bring down the cost of prescription drugs.

All 340B Program Participants Should be Held to the Same Oversight Standards

In addition to rescinding the Medicare cuts in the OPPS final rule, the **SERV Communities Act (H.R. 6071)**, introduced by Rep. Doris Matsui (D-Calif.), would strengthen the 340B program by clarifying the intent of the program and enhancing program integrity.

The SERV Communities Act clarifies that the program is intended to provide safety-net providers with discounts on covered outpatient drugs so that they can use the savings to provide comprehensive services to the patients and communities they serve. It also codifies the definition of an eligible "patient" and prevents the Health and Human Services (HHS) Secretary from narrowing this definition, which would reduce the scope of the program, result in fewer services to vulnerable patients, and harm patient health.

During the June 19 Senate Health, Education, Labor, and Pensions (HELP) Committee hearing, Capt. Krista Pedley, PharmD, MS, Director, HRSA Office of Pharmacy Affairs, noted that covered entities are audited at a much higher rate than drug manufacturers.[11] H.R. 6071 would address this discrepancy by requiring parity in the percentage of audits for covered entities and manufacturers.

The SERV Communities Act also would address longstanding problems of drug manufacturers overcharging covered entities for 340B drugs by implementing the ceiling price and civil

[10] S&P Global Market Intelligence, "Cuts To The 340B Drug Pricing Program May Render U.S. Hospitals Serving Vulnerable Patient Groups Vulnerable Themselves." Published online May 29, 2018.
[11] U.S. Senate Committee on Health, Education, Labor and Pensions Hearing, Effective Administration of the 340B Drug Pricing Program. Statement of Capt. Krista Pedley, PharmD, MS.

monetary penalties final rule[12]. The rule, which has gone through several notice and comment periods, was expected to go into effect in January 2017. However, the administration has delayed the rule five times, pushing back the implementation date until at least July 2019.

The HHS Office of Inspector General (OIG) has issued several reports finding high rates of 340B overcharges by manufacturers. Yet, providers have no significant remedies available to address this problem, such as auditing manufacturers or entering into litigation. They cannot even confirm whether or not they are being charged the correct price by manufacturers. In 2010, Congress mandated that providers be given access to 340B ceiling prices, but that information remains unavailable. The SERV Communities Act would address these problems and improve program integrity by holding drug manufacturers accountable for ensuring covered entities are able to verify the ceiling price for their 340B drugs.

Several Legislative Proposals Would Harm Patients and Worsen Health

The AAMC has significant concerns about several of the legislative proposals in the bills and discussion drafts that the subcommittee is reviewing; specifically, we have concerns about provisions related to creating a moratorium on hospital participation, imposing additional reporting requirements on covered entities, changing the definition of an eligible patient, and changes to the intent of the program.

A Moratorium Would Limit Access to Care

The 340B Protecting Access for the Underserved and Safety-Net Entities Act (PAUSE Act, H.R. 4710) would create a moratorium to prevent newly eligible DSH hospitals and new outpatient clinics associated with current 340B hospitals from enrolling in the 340B program. It would also prevent these hospitals from expanding services and prohibit other hospitals that provide a high level of care to underserved populations from leveraging the program to benefit their communities. Since many of the services that hospitals provide as a result of the discounts they receive through the 340B program are preventative, this would lead to higher health care costs and less access to services for those who need them the most. Because the 340B program is not funded by taxpayers, these changes would not save the government any money – they would simply limit discounts that pharmaceutical companies would be required to provide.

Additional Reporting Requirements Would Increase Burden on Hospitals Without Helping Patients

The AAMC supports HRSA's program integrity efforts to ensure the 340B program continues to allow safety-net hospitals to strengthen care for patients and their communities. However, several of the legislative proposals, including the **PAUSE Act** and a discussion draft, **To Require Certain 340B Covered Entities to Report Charity Care Expenditures**, include additional reporting requirements for covered entities that seek to limit the scope of the program and impose excessive administrative burdens on participants and HRSA. These changes would

[12] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017)

weaken the 340B program by reducing access to health care services without saving the government money.

The AAMC does not believe that additional reporting requirements for hospitals are necessary. HRSA already has extensive reporting measures in place to maintain compliance among covered entities and has substantially enhanced its oversight of hospitals and other providers since 2011. To participate and remain in the program, covered entities must undertake an initial certification process to demonstrate that they serve a disproportionate share of underserved patients, recertify annually, and have mechanisms in place to prevent duplicate discounts and diversion to ineligible patients. HRSA also conducts random audits and posts the findings on its public website. Many hospitals go beyond these requirements and invest additional resources and staff to ensure continued compliance.

Some legislative proposals call for increased hospital reporting within the program. Any changes to program integrity and oversight of the 340B program must consider the extensive information that hospitals already publicly report. Hospitals are among the most highly regulated and transparent organizations in the country. They complete extensive Medicare cost reports each year, which include information related to levels of uncompensated care they provide. Non-profit hospitals also report information annually to the Internal Revenue Service on Schedule H regarding the community benefits they provide and every three years must complete a community health needs assessment and an implementation strategy. Moreover, efforts to link charity care to the 340B program do not take into account the magnitude of comprehensive services DSH hospitals provide for underinsured and uninsured patients, including bad debt and underpayment by public programs. This change would shift the focus of the program and reduce the amount of services hospitals are able to provide to low-income patients and communities.

As noted above, in stark contrast to existing requirements for hospitals in the 340B program and beyond, there is little transparency or accountability among the pharmaceutical manufacturers that participate in the 340B program. Any proposal to increase reporting for hospitals should also include provisions to improve transparency for manufacturers, including the implementation of the ceiling price and civil monetary penalties final rule.

Changes to the Definition of "Patient" Will Significantly Reduce the Scope of the Program

The AAMC is very concerned about the discussion draft, **Defining the Term "Patient" for Purposes of the 340B Drug Discount Program**, which would change drastically the definition of an eligible patient. This proposal is unnecessarily restrictive and would severely limit drugs eligible for 340B pricing – including limitations on discharge prescriptions and infusion services – which would undermine the original intent of the 340B program and efforts by covered entities to expand care and services to underserved populations.

Many hospitals employ discharge prescription programs to maximize the likelihood that patients will comply with medication therapy regimens after they leave the hospital. By ensuring that patients have necessary medications in hand when leaving the hospital, these programs reduce the hurdles that patients – especially low-income and high-risk patients – face in the transition from hospital to home recovery. In addition to improving patient convenience, this practice seeks

to improve patient education on adherence to the prescribed therapy and avoid deterioration of the patient's condition to the point of crisis, which would require readmission to the hospital. Excluding discharge prescriptions and orders from the program would effectively penalize hospitals that issue discharge prescriptions for their patients' benefit, substantially reducing the savings available to them to reinvest in expanding access to care.

Teaching hospitals routinely treat patients referred by community physicians, including oncologists. Often, these are complex patients with advanced disease requiring high-cost, intensive treatment and many are uninsured or underinsured. These proposed changes would limit the ability of covered entities to utilize savings from the 340B program to expand access to needed medications and services for these referred patients.

The discussion draft would also exclude infusion orders that are not written as a result of services provided by an eligible provider of the covered entity or one of its registered sites. Infusion services involve administration of medication intravenously under the careful attention of supervising physicians and other skilled health professionals. Hospitals are legally responsible for the clinical care these individuals receive. For all intents and purposes, the individual would be a considered a "patient" of the covered entity. Yet, if the order originated from outside of the covered entity or one of its child sites, it appears the individual would not be considered a "patient" under 340B. Infusions are highly complex services that require careful attention and skilled clinical care. Administration of infusion drugs should not be treated in the same manner as dispensing of a drug and should not be excluded from 340B pricing as the discussion draft proposes.

Contract Pharmacies Expand Resources to Low-Income Patients

The Government Accountability Office's (GAO) recent report on contract pharmacies highlights that these arrangements play an important role in helping uninsured and low-income patients access needed care, including prescription drugs. The report includes a series of recommendations to increase HRSA oversight of contract pharmacy arrangements, including additional reporting, registration, and auditing of 340B covered entities that have these arrangements.

The discussion draft, **To Require the Secretary of Health and Human Services to Implement the Government Accountability Office Report on 340B Contract Pharmacy Arrangements**, would implement all of the GAO's recommendations, including those that HRSA has characterized as impractical. The AAMC shares HRSA's concern, as expressed in the report, that many of the recommendations are overly burdensome for both the agency and covered entities, including the recommendation for all covered entities to register contract pharmacies for each site of the entity for which a contract exists. Additionally, HRSA already reviews contract pharmacy arrangements for child sites as part of its standard auditing protocol.

Additional Concerns:

The discussion draft, **Protect Safety-Net 340B Hospital Act**, would increase the Medicare DSH adjustment percentage from 11.75 percent to 18 percent for program participation[13]. The current eligibility threshold already ensures that covered entities are safety-net hospitals. 340B DSH hospitals treat significantly more Medicaid and low-income Medicare patients, provide more uncompensated care, and are more likely to provide specialized health care services that are critical for low-income patients compared to non-340B DSH hospitals. While 340B DSH hospitals represent just 34 percent of short term general hospitals, they bear 70 percent of charity care costs, 57 percent of bad debt costs, and 61 percent of Medicaid shortfalls.[14] They also treat more low-income patients than non-340B hospitals.[15] Increasing the Medicare DSH threshold for program eligibility would reduce the number of hospitals in the program and threaten access for patients.

The **User Fees Under the 340B Drug Discount Program** (H.R. 6240), would impose user fees on 340B hospitals. These hospitals already invest resources and staff to ensure rigorous compliance with the program's extensive requirements for participation. Any funding for program administration and oversight should come through the appropriations process, not from user fees paid by covered entities. In fact, the draft report to accompany the fiscal year (FY) 2019 Labor, Health and Human Services, Education appropriations bill currently under consideration by the House Appropriations Committee provides a $5 million increase for HRSA's Office of Pharmacy Affairs to implement recommendations from the Energy and Commerce Committee's 340B report. Specifically, the draft spending bill directs HRSA to use the additional funding to conduct additional audits of covered entities, finalize guidance to clarify parameters of the 340B program, and complete the rulemaking process for areas where HRSA has regulatory authority.

The discussion draft, **To Require Certain Covered Entities Under the 340B Drug Discount Program to Establish Certain Fee Amounts Charged to Certain Low-Income Patients for 340B Drugs,** is counter to the intent of the program. The 340B program provides hospitals and other covered entities the ability to identify the needs of their community and to provide low-income patients and communities with access to the broad array of health care services that address these needs. While we appreciate the interest in ensuring that low-income patients have access to affordable drugs, many safety-net hospitals already have programs in place to ensure this access. We are concerned that by reducing the scope of the 340B program, the discussion draft likely would be counterproductive in making medications more affordable.

The discussion draft, **Granting HRSA Regulatory Authority**, would give HRSA additional regulatory authority. However, the AAMC is concerned that HRSA is not currently using its existing regulatory authority to improve transparency around drug manufacturers that participate in the program. By once again delaying implementation of the ceiling price final rule, the administration is neglecting to provide sufficient oversight over drug manufacturers.

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[13] Note that a DSH adjustment percentage of 11.75% equates to low-income DSH patient percentage of 27.3%
[14] AAMC analysis of 2015 Medicare cost report data
[15] Tomai, Lisa. Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients. L&M Policy Research, March 2018.

Conclusion

The AAMC appreciates the opportunity to submit this statement in support of the 340B Drug Pricing Program and looks forward to working with the committee to strengthen the program so that it continues to provide vital support to safety-net hospitals and other health care providers as they work to improve the health of their communities.

Ronald A. Paulus, MD
President and CEO

MISSION HEALTH

July 10, 2018

The Honorable Mimi Walters
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

RE: Mission Hospital's SANE Program

Dear Congresswoman Walters:

Thank you for the opportunity to provide additional information regarding Mission Hospital's Sexual Assault Nurse Examiners (SANE) program, funded in part by the 340B Drug Pricing Program. A more detailed description of this program is attached.

We appreciate your allowing Mission Health to provide the Committee with additional information and to share our thoughts on key policy issues both now, and in the future.

Sincerely,

Ronald A. Paulus, MD
President and Chief Executive Officer
Mission Health

cc: The Honorable Greg Walden, Chairman
Committee on Energy and Commerce

STATEMENT OF

RONALD A. PAULUS, MD

PRESIDENT AND CEO

MSSION HEALTH

FOR THE

HOUSE ENERGY AND COMMERCE COMMITTEE

SUBCOMMITTEE ON HEALTH

OPPORTUNITIES TO IMPROVE THE 340B DRUG PRICING PROGRAM

JULY 11, 2018

Mission Health truly appreciates the opportunity to provide a statement as part of the House Energy and Commerce Committee, Subcommittee on Health's hearing entitled *Opportunities to Improve the 340B Drug Pricing Program*. As the House Energy and Commerce Committee continues to discuss the importance of the 340B Drug Pricing Program, we are pleased to provide additional information on Mission Hospital's SANE program.

It is important that I note that while Mission Health uses 340B savings to fund its SANE program, each community is understandably different and each hospital must make its own decision on whether this program is where those resources are best utilized taking into account current service availability from providers in the local community. However, at Mission Health we have found this program to be of vital importance to our community and a terrific use for 340B funds.

As brief background, Mission Health is a not-for-profit, integrated health system with six hospitals, numerous ambulatory sites, an employed Clinic of over 800 providers, one of the largest ACOs in the nation, and a $100M+ post-acute provider. We provide services to 18 mostly rural, mountainous counties in western North Carolina, and our region's residents are older, poorer, sicker and less likely to be insured than state and national averages.

Through our 132 years of service to the region, we have had the same mission: *to improve the health of the citizens of western North Carolina and the surrounding region.* Mission Health lives this focus by providing, maintaining, and investing in access to high quality health, wellness and medical care services for all citizens of our region without regard to their ability to pay. We have established a national reputation for providing high quality, safe, effective and low cost care. As just one example, Mission has been named one of America's Top 15 Health Systems by IBM Watson Health in six of the past seven years (2012-2018). Mission Health is the only health system in the country to receive this recognition for four consecutive years, and the only health system in North Carolina to ever receive this recognition.

Understandably, questions have arisen about how covered entities use the savings generated from the 340B program. Mission Health, and likely most other health systems, share these savings to address our mission of serving low-income, underinsured and uninsured patients. Specifically, Mission Health uses its resources – even beyond those resources made available from 340B savings – to offer multiple Community Health Improvement programs and services, totaling approximately $630 million from 2012-2017.

In 2017, Mission Health saved $39.8 million through the 340B program - savings that have gone directly into critical programs that our community needs such as the Sexual Assault Nurse Examiners (SANE) program. Program detail, including training requirements and costs, about the SANE program follows.

Sexual Assault Nurse Examiners (SANE)

Mission Hospital employs 10 forensic nurse examiners that are specially trained, registered nurses who provide comprehensive care for victims of sexual assault, domestic violence, and child, elder, and dependent-adult abuse and neglect, and other violent crimes. Forensic nurses are also involved in community outreach and educational programs designed to raise public awareness of sexual assault, safe relationships, and recognizing and dealing with intimate partner violence. These nurses are on duty 24/7/365, with a presence at the Mission Hospital Emergency Department and the Buncombe County Family Justice Center. They are also available as a resource for each Emergency Department in the Mission Health system. In 2017, operational costs of the SANE program totaled just over $854,000.

A forensic nurse examiner encompasses not only sexual assault examinations, but also examinations for domestic violence and abuse victims. To function as a forensic nurse examiner, a registered nurse must attend a 40-hour didactic training course provided by an authorized program. In addition to the didactic training, there are 40-60 required hours of clinical training that must be completed. Once these requirements are met, the RN is authorized by the state of North Carolina to practice as a Sexual Assault Nurse Examiner (SANE). This training is above and beyond what is provided in a nursing program or in an emergency nursing orientation/residency. Not all of our

forensic nurses have an emergency nursing background, but many of our patients are first connected with our services via the emergency department. Additionally, these highly specialized nurses are able to obtain voluntary SANE-A or SANE-P (adult or pediatric, respectively) certification through the International Association of Forensic Nurses. Ongoing education and annual competencies are also required to maintain this specialty recognition.

On average, the 40-hour didactic training costs approximately $450 per nurse. Clinical training is often not provided by the training institution and falls instead upon the responsibility of the nurse. At Mission, we've found that it takes approximately six months following the completion of the didactic training in a mentoring model in order for a new SANE to be ready to function independently as a forensic nurse examiner.

These nurses play a crucial role in serving victims in our community. Comprehensive care provided by forensic nurse examiners for our patients includes, when appropriate, forensic evidence collection, forensic photography, referral for ongoing care, and integration into community resources such as victim advocacy, law enforcement, and legal assistance. Our collaborative relationship with the Buncombe County Family Justice Center allows victims to seek care following an assault or domestic violence abuse with all of needed services available under one roof in a comfortable, safe, and non-threatening environment. Additionally, our SANEs can be called to testify for these cases as their expertise helps validate the evidence collected during the course of an exam.

Victims of sexual assault, domestic violence, and abuse are a particularly vulnerable population, and at times, social stigma associated with these situations remains. It takes courage

for any victim to request assistance for these situations, and even more so to pursue justice. By providing these specially trained RNs, victims can be assured that all components of evidence collection are performed accurately, that they are receiving appropriate care, and that they have an advocate in their corner. Sexual assault, domestic violence, and abuse do not discriminate; they affect all races, genders, and age. Our forensic nurses provide care to any victim, regardless of their status or ability to pay. Our forensic nurses also believe in the importance of public education in the hopes of prevention, and they provide education to local schools, colleges, and other organizations.

Simply put, the ability to fund these forensic examiner nurses through our 340B savings is of great value to our patients and community.

May 14, 2018

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Democratic Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Chuck Schumer
Democratic Leader
United States Senate
Washington, DC 20510

Dear Speaker Ryan, Leader Pelosi, Leader McConnell, and Leader Schumer:

For more than 25 years, the 340B drug discount program has allowed safety net providers to purchase discounted drugs, allowing them to enhance their services to millions of low income and vulnerable patients. The statutory intent of the program is to allow 340B providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The undersigned patient and consumer advocacy organizations are compelled to speak out in strong support of the 340B drug pricing program. **We stand together to oppose any efforts to diminish the 340B program's proven ability to help serve vulnerable patients and communities.**

340B is vital to the health care safety net as it enables trusted community providers to fulfill their missions. In many communities – particularly low-income rural and urban areas – safety net providers are the sole pathways to affordable health care. Safety net providers use 340B savings for direct health care services, drug adherence and management programs, and education and prevention programs, among many others, to benefit their patients and the communities they serve. These services are often geared towards mental health programs, HIV adherence programs, education and prevention programs, substance abuse treatment, holistic care for the disabled, integrated cancer care, care for those with serious chronic illness like kidney disease, and medication management, among others.

We are troubled by assertions that the program has grown too large, suggestions that safety net providers are "profiting" from the 340B program, and allegations that safety net providers are not truly serving underserved patients. As advocates for patients and consumers, we support transparency in the program to ensure that 340B is meeting the needs of patients. However, we cannot support any proposals branded as enhancing "transparency and oversight" that would have the effect of reducing the number of safety net providers in the program and, in turn, the number of patients served.

As policymakers prepare to consider changes to the 340B program, we urge Congress to reject any proposals that would have the effect of:

- Limiting access to affordable, clinically appropriate, pharmaceuticals for low-income, uninsured, underinsured, and other vulnerable patients
- Reducing access to care by cutting safety net providers out of the program
- Curtailing the ability of providers to use 340B savings to reach more eligible patients and provide more comprehensive services

We are committed to patients and recognize the fragile nature of our nation's safety net. We ask that you join us in supporting, not weakening, the 340B program. To discuss further, please contact Shawn Gremminger at sgremminger@familiesusa.org.

Sincerely,

Families USA
ACCSES
ADAP Advocacy Association
Alliance for Retired Americans
American Academy of Nursing
American Association on Health and Disability
American Foundation for the Blind
American Muslim Health Professionals
American Psychological Association
American Public Health Association
Association for Ambulatory Behavioral Healthcare
Association of Asian Pacific Community Health Organizations
Being Alive San Diego
Big Cities Health Coalition
Black AIDS Institute
Black Women's Health Imperative
Center for Law and Social Policy (CLASP)
Center for Public Policy Priorities
Clinical Social Work Association
Community Access National Network (CANN)
Congregation of Our Lady of Charity of the Good Shepherd, US Provinces
Disability Policy Consortium of Massachusetts
Disability Rights Education and Defense Fund (DREDF)
Doctors for America
Entre Hermanos
Epilepsy Foundation
Farmworker Justice
First Focus
Gay Men of African Descent, Inc.
GRIOT Circle
Hemophilia Federation of America
Hep B United
Hepatitis B Foundation
Lakeshore Foundation
Lupus Foundation of America
Mendocino County AIDS/Viral Hepatitis Network
NAACP
National Advocacy Center of the Sisters of the Good Shepherd
National Association for Children's Behavioral Health
National Association of County and City Health Officials
National Association of Social Workers
National Association of State Mental Health Program Director (NASMHPD)

National Black Justice Coalition
National Dental Association
National Hemophilia Foundation
National Indian Health Board
National Latina Institute for Reproductive Health
National Organization for Women
National Partnership for Women & Families
National Viral Hepatitis Roundtable
National WIC Association
National Women's Health Network
NC Community AIDS Fund
NETWORK Lobby for Catholic Social Justice
New Jersey Association of Mental Health and Addiction Agencies, Inc.
Not Dead Yet
POCAAN
Project Kindle
Public Citizen
Religious Institute
Service Employees International Union (SEIU)

cc: The Honorable Greg Walden, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee
The Honorable Lamar Alexander, Chairman, Senate HELP Committee
The Honorable Patty Murray, Ranking Member, Senate HELP Committee
The Honorable Orrin Hatch, Chairman, Senate Finance Committee
The Honorable Ron Wyden, Ranking Member, Senate Finance Committee

Statement of 340B Health

United States House of Representatives Energy and Commerce Committee
Subcommittee on Health

Hearing: *Opportunities to Improve the 340B Drug Pricing Program*
July 11, 2018

340B Health appreciates the opportunity to provide these comments as the Committee seeks to gather additional perspectives on the 340B program and to consider proposals that would alter the program. 340B Health represents more than 1,300 nonprofit and public hospitals that participate in the 340B program. Our membership consists of a broad spectrum of hospitals, including academic medical centers, community hospitals, children's hospitals, and rural facilities.

The 340B program was enacted in 1992 with broad bipartisan support and Congress clearly stated that the program is intended to provide additional resources to safety net providers so they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] This goal is still of critical importance today.

The 340B Program Helps Preserve the Health Care Safety Net in the United States

The 340B program is a critically important program that allows participating entities to serve the needs of low-income and/or rural patients in their communities. Some hospitals use their 340B savings to provide free community clinics or discounted drugs while others may rely on the program to offset the provision of high levels of uncompensated care or a high volume of

[1] H.R. Rep. 102-384, Pt. 2 (1992).

Medicaid patients. A recent report found that 340B hospitals provide significantly more care to low-income patients than other hospitals, including uncompensated care and unreimbursed care.[2] They also provide more specialized and community-based health services that are critical for low-income patients but are often underpaid (i.e., labor and delivery and trauma services).[3] Researchers from the Pew Charitable Trusts recently noted that curtailing or scaling back the 340B program would simply transfer money from 340B safety net providers to pharmaceutical manufacturers.[4]

Hospitals Providing Data and Information About 340B

There have been a number of questions raised by policymakers about how hospitals are using savings realized through the 340B program to assist low-income patients. 340B Health encourages hospital members to share information about the benefits that the hospital realizes through participation in the program as well as details about the myriad of services that those savings then allow the hospital to provide in support of low-income patients. 340B Health has created a resource document for hospitals to use as a template to prepare and share this information.[5]

Conversations about data review and disclosure should take into account the wide array of services that 340B hospitals provide to support low-income and rural patients as well as the reporting requirements with which these hospitals currently comply that gather information related to services provided to low-income patients through Medicare Cost Reports and IRS filings (Form 990). Discussions on the topic should also consider the extensive services that hospitals provide over and above those specifically captured in these reporting structures.

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[2] L&M Policy Research, Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients (March 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf.

[3] *Id.*

[4] Coukell AJ, Dickson S. Reforming the 340B Drug Pricing Program Tradeoffs Between Hospital and Manufacturer Revenues. *JAMA Intern Med.* Published online May 21, 2018. Doi:10.1001/jamainternmed.2018.2007

[5] 340B Health, *Impact Profile Guide*, available at https://www.340bhealth.org/files/340B_ImpactProfileGuidebook_.pdf

Discussion on this issue must also consider manufacturer data disclosure obligations. Congress required that manufacturer 340B prices be disclosed to covered entities after receiving reports of widespread manufacturer overcharging. After eight years, these provisions have yet to be implemented. HHS should proceed immediately with publishing the government-verified pricing list.

340B Health believes there should be balanced oversight, including proper oversight of manufacturers. H.R. 6071, The Stretching Entity Resources and Vulnerable (SERV) Communities Act, would ensure balanced oversight of both 340B covered entities and manufacturers. In particular, the bill highlights evidence of manufacturers overcharging providers and recognizes that HHS has not implemented civil monetary penalties (CMPs) to address these overcharges as required by law. The bill would also require HHS to share 340B prices with providers, which will help them verify that manufacturers are charging the correct prices.

340B Health also supports legislative efforts to reverse the Medicare payment reduction affecting certain 340B hospitals. H.R. 4392 and H.R. 6071 would provide relief to 340B hospitals subject to a nearly 30 percent reduction in Medicare Part B drug payments that went into effect January 1, 2018, as part of the FY2018 Outpatient Prospective Payment System (OPPS) payment rule. Reversing the cuts is critical to ensuring safety net hospitals have the resources needed to serve their low-income and rural patients.

Several Legislative Proposals Seek to Significantly Scale Back the Program or Require Data from Hospitals That Goes Beyond Evaluating Whether the Program Meets its Purpose

A number of the legislative proposals go well beyond promoting transparency and reporting requirements and would significantly scale back the program, resulting in fewer low-income and rural patients having access to care in their communities. The discussion draft offered by Representative Barton would raise the minimum disproportionate share (DSH) adjustment percentage for certain hospitals to qualify for the 340B program and would significantly scale

back the number of hospitals in the program. Based on an analysis by 340B Health, this proposal would eliminate 573 safety-net providers that treat high volumes of low-income patients from the program.

The discussion draft put forward by Representative Collins to re-define the term "patient" would limit the number of eligible patients and H.R. 4710, The 340B Protecting Access for the Underserved and Safety-Net Entities (PAUSE) Act would freeze enrollment of disproportionate share/safety-net hospitals and their "child sites" into the 340B program and seek to obtain information solely about charity care levels alone—which comprise only a portion of the services that hospitals provide to low-income patients. 340B Health strongly opposes these provisions.

It is important to recognize that any attempt to evaluate the amount of care that hospitals provide to low-income patients must look at a variety of factors; not just charity care. Charity care refers only to the costs of covering the care provided to patients who apply to participate in a hospital's financial assistance program prior to care being provided and complete the necessary paperwork. Safety net hospitals are also responsible for bad debt costs and under-reimbursed care. Bad debt refers to care provided by the hospital for which the hospital expects to be paid but is ultimately not reimbursed. This typically occurs when a patient's insurance does not cover certain services and the patient is unable to pay for these services themselves. Hospitals also incur significant shortfalls due to chronic under-reimbursement from Medicaid and other state and local indigent care programs that do not cover hospital costs.

In creating the 340B program, Congress intentionally targeted hospitals for the program that treat a high volume of Medicaid and low-income Medicare patients or are located in rural areas—specifically recognizing that these entities treat patients with complex medical conditions or face other unique challenges ensuring access to care, and yet are under-reimbursed for these services. Hospitals participating in the 340B program are also

distinguished by the types of specialized services they provide that are critical to low-income patients—such as labor and delivery, trauma care and substance abuse/addiction treatment – for which they are frequently underpaid.

Legislative Proposals that Seek to Require Reporting on a Hospital's 340B Savings Target Extraneous Data Points

We also have concerns with several legislative proposals that seek to gather information on the benefit or savings that participating hospitals obtain through the 340B program but miss the mark in terms of the specific data points they target. Hospitals accrue a financial benefit through participation in the 340B program by acquiring outpatient drugs at discounted prices, resulting in savings as compared to what hospitals would have paid for those drugs outside the 340B program. 340B transparency or disclosure of savings should not focus on reimbursement that hospitals receive from payers for 340B drugs, as that information is not applicable to how much hospitals save through participation in the program. Focusing on payer reimbursement information may in fact present an inflated and misleading picture of a hospital's savings obtained through 340B participation.

Physician-Hospital Consolidation In Oncology Is Part of a Larger Trend—Not Specifically Attributable to the 340B Program

Critics of the 340B program have claimed that 340B hospitals are consolidating with oncology practices in wealthy areas. If this were true, one would expect those hospitals to be treating fewer low-income people with oncology drugs. However, Medicare data shows that the share of low-income Medicare Part B cancer drug recipients in 340B hospitals (those dually eligible for Medicaid) increased from 2013 to 2014, and in both years was significantly higher than the share of low-income Medicare cancer drug recipients treated at non-340B hospitals and private physician clinics. In fact, 340B hospitals treat over 60 percent more low-income Medicare cancer patients than non-340B providers.[6] This Medicare data is consistent with other data

[6] http://www.340bhealth.org/files/LowIncomeOncology.pdf

indicating that community oncologists do not serve commensurate levels of low-income patients as 340B hospitals. Only 4 percent of patients treated by community oncologists were uninsured, and only 4 percent were Medicaid, according to information reported by insurers related to community oncology practices.[7]

It is important to realize that consolidation and mergers in the area of health care are an industry-wide occurrence due to a variety of market forces. A recent article published in Health Affairs noted that hospital integration with specialty practices is slower than has been reported in the media, with hospitals acquiring "only one or two more specialty practices, such as oncology practices, over the decade."[8] The authors specifically noted that their data calls into question immediate legislation to slow vertical integration around the 340B program and recommended that more research be conducted.[9] Another Health Affairs article noted that "the health care industry has experienced massive consolidation over the past decade."[10] Other recent studies link increased consolidation in the market for cancer care as part of a broader trend toward integrated health care systems and a shift to value-based care.[11]

The 340B Program is Intended to Provide Safety Net Providers With Additional Resources to be Used in a Variety of Ways and was Never Intended to be Limited to Specific Purpose or Prescription Drug Program.

The 340B program was intended to provide hospitals with additional resources to increase access to care in the safety net, which may include making medicines more affordable or providing preventative care services or specific programs to meet the unique needs of the low-income or underserved community. The program was never intended to be limited to offering discounts on medications. Providing discounts on drugs to low-income patients is one way entities can use 340B savings to support their low-income populations, but it is not the only

[7] https://pdfs.semanticscholar.org/5935/93e63b3a8322a3485e63815c707caf5255c1.pdf
[8] https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1520
[9] *Id.*
[10] https://doi.org/10.1377/hlthaff.2016.0830
[11] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.0830

way. The discussion draft put forward by Representative Burgess would require covered entities to establish certain fee amounts charged to certain low-income patients for 340B drugs. In response to a recent 340B Health survey of members, hospitals unanimously reported using their program savings to support low-income and rural patients, consistent with the program's purpose. Both disproportionate share (DSH) and rural hospitals reported using those savings to maintain or increase uncompensated care (95%) and increase the type of services provided (89%). DSH hospitals were particularly likely to report using their savings to provide direct services and support for low-income patients, with 80 percent of DSH hospitals reporting they used 340B discount savings to offset low Medicaid reimbursement rates in their state. Rural hospitals, however, were more likely to report using program savings to ensure access to care in remote areas, with three-quarters of rural hospitals (74%) reporting they used 340B savings to keep their doors open and preserve access to care for their patients and communities. As such, it may be premature for Congress to limit the mechanisms by which hospitals may use program savings to support care for low-income patients and there may be value in further exploring data on the services hospitals are currently providing to low-income populations.

The 340B Program Does Not Contribute to Manufacturers' Decision to Set High List Prices

Researchers have concluded that 340B discounts are such a small share of the overall drug market that they cannot plausibly be causing manufacturers to increase drug prices.[12] In a report released in May 2018, the Pew Charitable Trusts also noted that in 2015, 340B discounts amounted to a net reduction in total manufacturer revenue of approximately 1.9%.[13]

In addition, there is no evidence that reducing the level of discounts that manufacturers provide to hospitals would result in manufacturers voluntarily lowering list prices rather than simply returning those amounts to their respective companies and shareholders. We believe that the program as a whole is such a small share of the drug market, that any proposed

[12] Dobson DaVanzo, Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers (July 2017), https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf

[13] Coukell AJ, Dickson S. Reforming the 340B Drug Pricing Program Tradeoffs Between Hospital and Manufacturer Revenues. *JAMA Intern Med*. Published online May 21, 2018. Doi:10.1001/jamainternmed.2018.2007

changes to shrink the program would not reduce list prices for drugs but may limit the extent to which 340B hospitals are currently able to provide care to underserved patients. It is clear, however, that drug prices are at an all-time high, and it is drug manufacturers that set list prices.

Conclusion

340B Health appreciates this opportunity to provide our viewpoint and suggestions regarding the 340B program. If there are any questions about the information presented in this statement please contact Maureen Testoni, Interim CEO, at maureen.testoni@340health.org or 202-552-5860.

Energy and Commerce Subcommittee on Health

Hearing on: "Opportunities to Improve the 340B Drug Pricing Program"

July 11, 2018

Statement for the Record
Submitted by ASHP

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ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Energy and Commerce Subcommittee on Health Hearing on: "Opportunities to Improve the 340B Drug Pricing Program."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP has a longstanding history of support for the federal 340B , as many of our members serve as patient care providers in hospitals and health systems that are 340B-eligible and have seen, firsthand, the benefits of the program to the patients they serve.[1] At a time when federal budgets are stretched thin, the 340B program helps maximize federal resources while providing access to lifesaving medications.

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[1] ASHP's full policy on the sustainability of the 340B Drug Pricing Program is as follows: (1) To affirm the intent of the federal drug pricing program (the "340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; (2) further, to advocate legislation or regulation that would optimize access to the 340B program in accordance with the intent of the program; (3) further, to advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; (4) further, to encourage pharmacy leaders to provide appropriate stewardship of the 340B program by documenting the expanded services and access created by the program; (5) further, to educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; (6) further, to educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; (7) further, to encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

Today, the federal 340B program continues to meet Congress' original intent "of enabling these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Access to primary care, behavioral health services, pharmacist-led substance abuse treatment, expanded pharmacy services, provision of naloxone to law enforcement, discounted or free prescription medications, pediatrics, and other services for many uninsured and underinsured are made possible only by the savings realized through the 340B program. In some communities, without the financial savings garnered through the 340B program there would be limited or no access to healthcare services.

ASHP also recognizes the great importance of program compliance. The provision of healthcare has evolved considerably since the program was enacted over 25 years ago. Should Congress determine that the Health Resources and Services Administration (HRSA) needs additional regulatory authority, ASHP recommends that this authority extend to the proper oversight of manufacturers to ensure that covered entities are being charged appropriately.

ASHP remains supportive of the 340B program; we believe it is a critical component for safety-net providers to provide care to uninsured and underinsured patients. Safety net providers are especially critical in our nation's rural areas, where access and ability to pay for care are often compromised. We remain committed to working with HRSA and other 340B program stakeholders to ensure that the requirements of the program are being met and that the program functions as intended.

As we have worked with the Committee in the past on a number of important public health issues, including drug shortages and compounding, ASHP welcomes the opportunity to be a resource for the Committee on this issue, as well as other issues pertaining to the practice of pharmacy or healthcare in general. Again, we thank the Committee for the opportunity to provide input.

# # #

September 2017

The 340B Drug Discount Program in Review:

How Abuse of the 340B Program is Hurting Patients

Over 15 Years of Making a Difference in Cancer Care

The 340B Drug Discount program exemplifies how good ideas, no matter how well-intended, can easily go bad if they fall into the wrong hands and are abused. Ultimately, abuse of the 340B program has begun to harm the very poor, uninsured, and underinsured patients it was meant to serve.

340B is a critically important program for Federal grantees, community and disease-specific health clinics, and the true safety-net hospitals that rely on the drug discounts it provides to treat America's most vulnerable patients. However, in recent years, the 340B program has been co-opted and grossly abused by some large hospital corporations. Today, nearly half the hospitals in the United States are in the 340B program, even though research has shown that most provide very little charity care.

Bad actors in the 340B program have realized that they can make substantial profits by buying deeply discounted cancer drugs, which are then reimbursed by Medicare and private insurers at full cost — providing hospitals with up to 100% profit margins on these expensive drugs. However, hospitals are under no obligation to use 340B savings to directly help patients or lower the cost of care for them. 340B hospitals don't even have to disclose how 340B profits are being used. 340B profits can be used to finance new hospital construction, fund CEO bonuses, and a host of other hospital interests that do not directly, or even indirectly, benefit the very needy patients that the 340B program was designed to serve.

Today, patients whom 340B was intended to help are often paradoxically harmed by the program, cut off from timely and high-quality care by hospitals seeking to make profits from it. This has been particularly acute for cancer patients who face quotas, wait lists, and significantly higher costs at 340B hospitals that prioritize fully-insured patients and the profits they bring.

Community oncology practices provide substantial amounts of charity care to poor, uninsured, and vulnerable patients despite not receiving the benefits of discounts, subsidies, tax exemptions, or non-profit statuses enjoyed by 340B hospitals. They are, however, unable to write off the costs of chemotherapy drugs purchased at full price. Referring eligible patients to 340B hospitals to receive discounted drugs is the very purpose of this program. Yet, as the stories in this compilation show, some 340B hospitals have introduced barriers that actually prevent patients from accessing the care they so desperately need.

Today, patients whom 340B was intended to help are often paradoxically harmed by the program, cut off from timely and high-quality care by hospitals seeking to make profits from it.

Oncologists and administrators at community oncology practices provided the Community Oncology Alliance (COA) with the real stories in this compilation as firsthand examples of the negative impact that bad actors in the 340B program are having on patients. The real stories in these pages provide just a small glimpse into how the program has gone off the rails, and is just a sampling of the problems being created by some greedy 340B hospitals. The stories are presented anonymously because some local physicians and practices have been punished for speaking out against 340B program abuses by hospitals.

Favoring the Rich Over the Poor

In March, a singer in her early 50s felt a mass in her breast. Uninsured, she went to get a mammogram on a mobile bus that travels the city offering free breast screenings to women. The mammography technicians noticed signs of abnormality and sent her to have a biopsy, which confirmed she had HER2 amplified breast cancer. However, when she went to the local hospital that receives 340B drug discounts for treating uninsured patients, she was turned away. And she was not the first.

Like many other cancer patients before and after, the singer was placed on a waiting list at the hospital and denied care. This was not because of an actual capacity issue, but because

the hospital has placed a cap on the number of uninsured patients it is willing to see each month — despite the fact that this particular hospital participates in 340B and receives millions of dollars in funding. In fact, $12 million alone of this money has been earmarked for treating breast and gynecological cancer patients like her.

After three months of waiting for the hospital to accept her, and the cancer meanwhile growing unchallenged, an acquaintance got her an appointment at the local community oncology clinic. She met with the head doctor there and finally began treatment, with the clinic advocating on her behalf to access free and low-cost chemo meds. "She was one of three similar pro-bono cases we took on last month alone," says her doctor. "However, what of those women out there who don't know we're here? Who just curl up in a corner and don't receive care, while there's the ticking time bomb of cancer working away inside them?"

Like many other cancer patients before and after, the singer was placed on a waiting list at the hospital and denied care. This was not because of an actual capacity issue, but because the hospital has placed a cap on the number of uninsured patients it is willing to see each month — despite the fact that this particular hospital participates in 340B and receives millions of dollars in funding.

Another patient, a 26-year-old, felt a mass in her breast one morning. Despite the patient having insurance and being unable to afford the cost of a mammogram, the 340B hospital turned her away. She managed to find a local clinic that charges patients on a sliding scale and had a mammogram and an ultrasound performed. Finding an abnormality, the technicians there referred her to the community oncology clinic, where the oncologist confirmed that she had a risky and rapidly growing, but highly curable form of cancer, as well as the inheritable BRCA mutation. Time was of the essence. The clinic started her on chemotherapy, scheduled her for surgery, and ensured that she had fertility preservation. They also helped her complete the necessary paperwork to get on Medicaid. She had always qualified for the insurance; simply no one at the hospital had ever taken the time to escort her through the process.

Despite all this, these two patients were actually the fortunate cases.

According to the community oncology clinic, these women are a drop in the bucket; in fact, doctors there know of at least sixteen additional women currently waiting for treatment of their gynecological cancers at the local 340B hospital. Many of these patients have curable yet rapidly growing cancer, and the delay in their diagnosis and treatment, even by a few months, is easily handing each one a death sentence.

"Despite their tax-exempt status, and despite the fact that there is physician time and clinic space available, this 340B hospital has decided internally on a specific budget limit for treating indigent patients, which translates to a certain quota of patients for the month. Once they exceed that quota, they start turning patients away at the door. So instead of using their resources on the patients who actually need 340B drug discounts, the hospital can enjoy all the profits coming from 340B by treating more affluent patients," explains the doctor.

340B hospitals receive drug discounts that are meant to benefit indigent patients, but without any real requirements or oversight to ensure that this actually happens. Thus, we see situations in which a tax-exempt facility that has received 340B discounts, in addition to millions of dollars in funding — even targeted funding for breast and other specialized cancers — refuses to see patients because of their inability to pay.

You Need Chemo? Sorry — We Treat Only the Rich

A 50-year-old mother on Medicaid came to a community oncology clinic suffering from angiosarcoma of the gallbladder. This is a highly aggressive cancer with a very poor prognosis and the patient was badly in need of treatment, which included tests, a port, chemotherapy, and more.

The doctor said, "Let's admit you to the hospital and get you started on your treatment while your Medicaid goes through." The patient was admitted to the non-profit, 340B hospital on a Friday, yet on Monday, it discharged her, saying they could not provide treatment. Why? Because she needed chemotherapy, and the hospital only treated indigent patients with chemotherapy in the outpatient setting.

Recognizing the urgency of starting treatment, the doctor referred his patient to a for-profit hospital, knowing it would take her. "This patient got her insurance worked out over the next few months, and that 340B hospital would have ultimately been paid. However, they didn't want to take any chances, despite being one of the region's most profitable hospitals."

340B hospitals often argue that savings from the program are being used to support all operations across the hospital to offer patients increased access. That is one of the many reasons why they do not need to demonstrate that patients are directly benefiting from the program. However, stories of hospitals restricting or avoiding treating patients in need because of

the profit they can make from more affluent, insured patients abound — particularly in the inpatient setting, where space can be saved for more lucrative patients.

Our Way or the Highway

One community oncology clinic covers a large regional geographical area, in which there are two competing hospitals, both with 340B, with one serving a fairly rich and well-insured patient community. The community clinic was originally renting space from the hospital located in the affluent neighborhood. That hospital then acquired 340B status by becoming a child site of a separate location in their system.

One day, the hospital informed the community oncology clinic that there were so many cancer patients, they needed to provide additional care and would be hiring their own oncologist. The manager of the community clinic responded that they felt confident they could handle the entire cancer population and such changes were unnecessary. Nevertheless, the hospital opened its own infusion center and started providing chemotherapy, literally next door to the existing community oncology clinic.

This community oncology clinic never turns a patient away; they treat everyone regardless of their insurance situation. However, without the benefit of programs like 340B, they cannot afford to give away cancer drugs for free, so they will often start treatment while trying to get the patient financial assistance — from patient assistance foundations, pharmaceutical companies, etc.

Realizing a situation that could benefit patients in need, the community oncology clinic proposed an arrangement with the hospital: "We have patients with no insurance and in need of chemotherapy; you have 340B — designed exactly for this purpose — so we'll send our indigent patients to you for their outpatient chemotherapy." But when they tried to put this into practice, the hospital refused.

The community oncologists met with them, arguing, "But you are supposed to use this charity for indigent patients! How can a patient, in a community with a 340B hospital, not benefit from it?" The hospital answered that they would help the patient, but only if they took over all of their care. This happened time after time, until finally the community clinic stopped asking. Today, they send their indigent patients to the other 340B hospital. "It's a 45-60 minute drive for them, and while it compromises their care, the patients deal with it to stay with us as their oncologists," they explain.

One example of a patient affected by the hospital's policy was an elderly man with multiple disabilities who was diagnosed with a blood clot in his lung. He was prescribed an oral anticoagulant in combination with a series of daily injections that must be given until the oral drug begins to work. In effect, he needed a few small shots along with a simple blood test, to be done over the weekend to determine if the medicine was working. The local 340B hospital nevertheless refused to take him. The patient was reduced to tears. He would now need to find a family member or neighbor to give up the better part of their day and drive him each day to the other hospital — a 2-hour round trip plus waiting time. This, as opposed to the 20-minute outpatient procedure he would have had, and the ability to handle it without feeling he was inconveniencing someone else.

> **"This patient got her insurance worked out over the next few months, and that 340B hospital would have ultimately been paid. However, they didn't want to take any chances, despite being one of the region's most profitable hospitals.**

Another patient with Stage III breast cancer had no insurance and no money, yet desperately needed chemotherapy to shrink the tumor before surgery. Her doctor tried to get her 340B drugs at the local hospital, explaining that she needed daily shots and blood work, and it would be very taxing for her to drive daily an hour and a half each way to the alternate hospital. As always, the hospital refused. So, the patient had to get in her car and drive 3 hours round trip every day for a 5 minute shot to boost her white blood count.

When hospitals begin making profit-centered policies rather than patient-centered ones, the situation becomes dire. Quite simply, the potential for profiting from 340B drugs has caused a shift in many hospitals' priorities, and poor patients are the ones to suffer.

We Don't Get Paid for Ambulance Transport

A 58-year-old indigent woman with Stage IV non-small cell lung cancer was admitted into the local 340B hospital, suffering from superior vena cava syndrome (obstruction of the vessels that carry circulating blood into the heart). The hospital refused treatment, immediately discharging her and referring her to the private oncology clinic down the street.

Despite the patient's critical condition, the 340B hospital even refused to transfer her by ambulance, citing the cost they would incur. Thus, an uninsured patient, in urgent need of radiation and chemotherapy, had no alternative but to walk out of the hospital, get in her car and drive to the community

oncology clinic, in danger at every moment of becoming hypoxic and coding. Upon reaching the community oncology clinic, the patient received immediate radiation, upon which her condition stabilized, breathing improved, and there was a decrease in her symptoms.

Since the 340B hospital came under new ownership, it has been unwilling to accept indigent and uninsured patients.

According to a doctor at the community oncology clinic, this has been a familiar scenario over the last few years. Since the 340B hospital came under new ownership, it has been unwilling to accept indigent and uninsured patients. While the community oncology clinic provides free radiation treatments, they cannot afford to provide free chemotherapy drugs. The result is that, despite having a 340B hospital in their community, indigent patients have nowhere to turn for the medication they need. "340B pricing exists to help just such patients," says the clinic doctor, "but with the hospital so concerned about utilizing this program to increase its margins on privately insured patients, they fail to use the program as it was intended — to help the patients who truly need it."

When 340B hospitals start discharging patients in critical condition, refusing to treat or even transport them to another facility, it is clear that there is something very wrong with the system.

If You've Got the (Insurance) Money, We've Got the Time

A young woman went to the local 340B hospital one day to follow up on a suspicious lump she had found. Sure enough, they diagnosed her with breast cancer. As if that wasn't bad news enough, the hospital then told her that they did not take her insurance, and since they could not figure out her co-pay and co-insurance, she would have to leave the hospital — despite the fact that they have seven oncologists practicing there. They didn't even bother to refer her to a place that would treat her.

Fortunately, the woman learned of, and went to, the nearby community oncology clinic. There she was welcomed with open arms, and the staff patiently helped her to figure out all of the insurance paperwork to begin treatment. Today, she is in her third course of chemotherapy and doing great, but she's one of the lucky ones. According to the clinic's office manager, there are multiple stories, just like hers, many of whom never make it through the clinic's doors.

"The real damage is the blatant abuse of the 340B program," says the office manager. "What happens is the hospital system buys up a variety of medical practices, and then refers their best patients to those practices. In the case of this patient, she was not seen as worthy enough from an economic standpoint, so they simply turned her away. They don't want anyone on Medicaid or who is uninsured. But they love those who are fully insured."

Again and again, practices across the country are reporting that hospital systems with 340B discounts shut out the very patients the program was meant for — often without even trying to help. One of the most frustrating parts is that if they would simply dedicate some time to helping these patients, they would find that there is insurance money available to them, and thus to the hospital. But these hospitals don't feel it's worth the effort.

Send Us Your Profitable Patients

One community oncology clinic has been desperately fighting for its existence against a local 340B hospital system. This hospital is one of several oncology units located in wealthy, well-insured neighborhoods — all of which serve as satellite cancer centers of a single downtown hospital that has 340B certification due to the inner city's indigent population.

The 340B hospital located near the community oncology clinic decided to go aggressively after what it saw as profitable cancer patients. First, the hospital set up its own oncology department, and then went after the clinic's doctors, offering salaries well beyond market prices and successfully wooing three of them over. Next, the 340B hospital established a new policy that refused privileges to any of the clinic's doctors. Thus, whenever a clinic patient ends up in the hospital, their treating doctor is unable to see them. In the meantime, the hospital tries to convince the patient to switch over to the hospital's own oncology unit for their cancer care.

According to the clinic, the hospital system's original 340B downtown location doesn't even have its own outpatient infusion center. After diagnosing indigent patients with cancer, they are referred to one of the satellite centers in the suburbs. These patients must then either take a bus or find a ride out to the suburbs; or, as perhaps the hospital hopes they'll do, find themselves a different hospital system altogether.

This hospital is one of several oncology units located in wealthy, well-insured neighborhoods — all of which serve as satellite cancer centers of a single downtown hospital that has 340B certification due to the inner city's indigent population.

Oftentimes, multiple hospital locations gain access to 340B discounts thanks to a single eligible site that treats a high number of eligible patients. At that point, the 340B hospitals in affluent areas build up oncology wings for the rich, with little to no money being pumped back into the original location with patients that truly need it — and that it was meant to help in the first place.

Charging More Than Double for the Same Care

A retiree with neuroendocrine carcinoma has been under the care for several years of an oncologist at a community oncology clinic. As part of her treatment, she receives monthly injections.

A few years into her treatment, the patient received notice from her insurance provider that she would now have to go to the local hospital to receive the injections. Thus, now she must go first to the clinic to get the prescription, and then go to the hospital for the injections.

According to the insurance company, the change was meant to reduce expenses; however, the bills the patient has received tell a different story. Previously, the community oncology clinic was charging some $4,000 a month for the medication, $3,000 of which was paid for by Medicare. Now, for the same injections, the hospital is billing $9,500, out of which Medicare is paying $3,800.

Despite the fact that the hospital is 340B certified and gets a substantial discount on its outpatient drugs, it is charging an exorbitantly higher price for them — nearly two and half times!

Despite the fact that the hospital is 340B certified and gets a substantial discount on its outpatient drugs, it is charging an exorbitantly higher price for them — nearly two and half times! It seems everyone is losing… except the hospital.

Another side effect of shifting patient care into 340B hospitals is the significant difference in costs that patients, payers, and taxpayers must bear. It is a well-documented fact that cancer care delivered in a hospital setting is much more expensive than the same exact care delivered in the community oncology setting.

About the Community Oncology Alliance

The Community Oncology Alliance (COA) is the only non-profit organization dedicated solely to preserving and protecting access to community cancer care, where the majority of Americans with cancer are treated. COA helps the nation's community cancer clinics navigate a challenging practice environment, improve the quality and value of cancer care, lead patient advocacy, and offer proactive solutions to policymakers. To learn more, visit www.CommunityOncology.org.

Statement for the Record
Committee on Energy and Commerce
Subcommittee on Health

Opportunities to Improve the 340B Drug Pricing Program
July 11, 2018

America's Essential Hospitals appreciates the opportunity to submit a statement for today's hearing on the recent Government Accountability Office (GAO) report on the 340B Drug Pricing Program and 340B-related legislation under the committee's consideration. The 340B program is among our association's top legislative priorities because our hospitals depend on the savings it provides. This program not only helps essential hospitals across the country keep their doors open, it also helps them meet their mission of caring for the nation's most vulnerable patients and underserved communities.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care to all. While our membership represents 325 hospitals out of more than 5,500 nationally, they provide 20 percent of all charity care nationwide and 14.4 percent of all uncompensated care, or about $5.5 billion. In the communities our hospitals serve, three out of four patients have no insurance or rely on Medicaid or Medicare, 10.1 million people face food insecurity, 25.3 million live below the federal poverty line, and 350,000 are homeless. Essential hospitals account for more than a third of the nation's level I trauma centers and nearly 40 percent of burn care beds. Our members train nearly three times as many physician residents as other U.S. teaching hospitals.

Essential hospitals anchor health care and economic activity in their communities. To meet this commitment, they operate with margins about half that of other U.S. hospitals, on average. Many essential hospitals operate at even lower margins. It is because of their commitment to providing high-quality care for all that our hospitals rely on the 340B program and other sources of support. Since its inception, this program has helped ease the burden of high drug prices so hospitals can direct more resources to patient care and service to the community, helping those who have nowhere else to turn.

Below, America's Essential Hospitals provides feedback on the GAO report and on legislative proposals the committee will discuss at today's hearing.

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GAO Report: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

America's Essential Hospitals strongly supports continuing to allow contract pharmacy arrangements, which are vital to ensuring access to affordable drugs for vulnerable patients. Essential hospitals are known for establishing accessible clinics in neighborhoods across their service areas to make it easier for individuals to obtain care. To that end, they have leveraged the ability to dispense 340B drugs through contract pharmacies to ensure patients can readily fill and refill prescriptions vital to maintaining health and holding down the cost of care. Any limitation on the flexibility to use contract pharmacies in this way would reduce patient access to drugs and, in turn, jeopardize patient health.

Covered entities' use of contract pharmacies allows patients to more easily access medications within their communities. The ability to enter into arrangements with contract pharmacies enables patients to fill their prescriptions closer to home and without having to return to an in-house pharmacy at the main hospital. This is particularly critical for rural patients, for whom it would be time-consuming and difficult to return to the hospital to fill a prescription. The usefulness of contract pharmacies in fulfilling the original intent of the 340B program has been fully endorsed by the Health Resources and Services Administration (HRSA), which first allowed covered entities to enter into contract pharmacy arrangements in 1996 guidance.[1] Since then, HRSA has expanded the use of contract pharmacies through a demonstration project in 2001. HRSA then formally allowed for the use of multiple contract pharmacy arrangements in 2010 guidance, recognizing that these arrangements "allow covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served."[2] Rolling back contract pharmacy arrangements would run counter to the program's original intent and severely limit patient access to lifesaving, affordable drugs in their communities.

In its June 2018 report, the GAO published its findings on covered entity contract pharmacy arrangements and made seven recommendations to HRSA. Two of these recommendations are limited to the contract pharmacy context, including recommending that HRSA require covered entities to register contract pharmacy arrangements for each child site of the covered entity and directing HRSA to provide more guidance on contract pharmacy oversight. The remaining recommendations focus on preventing duplicate discounts in Medicaid managed care and, more generally, on covered entity audits. HRSA disagreed with three of the seven recommendations, noting that some would be administratively burdensome or unnecessary, given existing audit practices and procedures. We agree there are certain areas in which HRSA can provide additional direction to covered entities in complying with program requirements. For example, it is important HRSA work with the Centers for Medicare & Medicaid Services (CMS) on developing guidance for states and covered entities on identifying 340B drugs in the managed care context.

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[1] 61 Fed. Reg. 43,549 (August 23, 1996).
[2] 75 Fed. Reg. 10,272 (March 5, 2010).

But we disagree with GAO's assessment that HRSA should go beyond clarifying guidance to impose additional compliance requirements on hospitals related to audits. Hospitals readily comply with audits and respond to adverse audit findings. In fact, hospitals and other 340B covered entities have complied with nearly 900 federal audits since fiscal year (FY) 2012, while drug companies have faced only 11 audits since FY 2015, when manufacturer audits began.

As some of the 340B program's original participants, essential hospitals have a vested interest in ensuring program integrity. They invest substantial time and resources into internal processes to verify compliance with program requirements, including with prohibitions against diversion and duplicate discounts. Participation in the 340B program creates significant administrative and compliance-related costs, including to hire appropriate staff, such as a program manager, pharmacists, and pharmacy technicians to ensure the hospital follows the program's highly technical and evolving requirements. Also, 340B hospitals must invest in appropriate billing software and allocate resources to comply with the program and respond to audits. Additional requirements, such as mandating that covered entities register contract pharmacies at the child site level, would be extremely burdensome for hospitals already navigating complex regulatory and compliance requirements.

Legislative Proposals

Legislative proposals we believe would ensure appropriate program oversight and preserve the 340B program's value to essential hospitals and vulnerable patients include these:

H.R. 4392, TO PROVIDE THAT THE PROVISION OF THE MEDICARE PROGRAM: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS FINAL REGULATION RELATING TO CHANGES IN THE PAYMENT AMOUNT FOR CERTAIN DRUGS AND BIOLOGICALS PURCHASED UNDER THE 340B DRUG DISCOUNT PROGRAM SHALL HAVE NO FORCE OR EFFECT, AND FOR OTHER PURPOSES.
H.R. 4392 would impose a permanent moratorium on the 2018 Outpatient Prospective Payment System (OPPS) rule provision that cut by more than 27 percent reimbursement for Medicare Part B drugs prescribed at 340B hospitals. This damaging cut hits essential hospitals hard, given their high levels of uncompensated care and narrow margins. Some will be forced to scale back services made possible by 340B and others might consider leaving the program entirely. H.R. 4392 would put a permanent stop to this harmful policy.

H.R. 6071, STRETCHING ENTITY RESOURCES FOR VULNERABLE (SERV) COMMUNITIES ACT
This legislation would affirm Congress' intent for the 340B program, increase manufacturer transparency and accountability, and stop the deeply damaging OPPS payment cuts. H.R. 6071 is a step in the right direction to create parity between 340B covered entities and drugmakers.

H.R. 2889, CLOSING LOOPHOLES FOR ORPHAN DRUGS ACT
Under current law, orphan drugs are excluded from 340B discounts. In 2013, HRSA issued a rule to limit the orphan drug exclusion to apply only when a drug is used for the rare condition or disease for which it was designated. However, a court ruling stated that HRSA did not have the authority to issue the rule, and it was rescinded. H.R. 2889 would put the intent of HRSA's 2013 rule into statute. This legislation would expand access to 340B discounts for more patients,

particularly those who need covered drugs to treat more common or chronic conditions for which the medication was approved, while maintaining the higher cost of the drug when used for rare orphan indications.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REQUIRE THE SECRETARY OF HEALTH AND HUMAN SERVICES TO CONDUCT AUDITS

Although HRSA is not required to comply with the standards proposed under this legislation, we believe that using accepted government auditing standards issued by the comptroller general would provide a more streamlined audit process. Additionally, it would apply to both covered entities and manufacturers, ensuring parity in auditing standards.

Proposals of Concern

H.R. 4710, 340B PROTECTING ACCESS FOR THE UNDERSERVED AND SAFETY-NET ENTITIES (340B PAUSE) ACT

H.R. 4710 would impose an excessive administrative burden on 340B hospitals through unneeded new reporting requirements. Further, the proposed moratorium on enrollment of new child sites and new covered entities will jeopardize patient access to care in our most underserved communities.

H.R. 5598, 340B OPTIMIZATION ACT

H.R. 5598 would burden hospitals with new administrative requirements by requiring reporting at the child site level under a metric not currently collected. This requirement yields nothing relevant to HRSA's oversight role and would not usefully increase program transparency. The bill also would widen the disparity in 340B program accountability for hospitals versus that for drug companies, putting hospitals and their vulnerable patients at a disadvantage and undermining the program's value as a hedge against high drug prices.

H.R. 6240, DRUG DISCOUNT ACCOUNTABILITY ACT

This legislation would require hospitals to pay a 0.1 percent user fee to the program and report their total 340B purchases. An industry user fee program is not necessary, as HRSA has the authority to oversee the program and Congress has the authority, should it choose, to fund stronger program oversight.

H.R. 6273, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ENSURE APPROPRIATE CARE BY CERTAIN 340B COVERED ENTITIES FOR VICTIMS OF SEXUAL ASSAULT, AND FOR OTHER PURPOSES.

This legislation could limit access to 340B program participation and impose additional financial burden on essential hospitals to comply with the bill's requirements. H.R. 6273 is inconsistent with Congress' intent for the 340B program and conflates unrelated—albeit, important—issues.

H.R. ____, PROTECTING SAFETY-NET 340B HOSPITALS ACT

This legislation would exclude a significant group of essential hospitals currently participating in the 340B program by increasing the Medicare disproportionate share hospital (DSH) threshold from 11.75 to 18 percent. There should be thoughtful consideration and review of the potential impact when considering any change in threshold.

H.R. ____, BETTERING OPERATIONS AND OVERSIGHT THROUGH SENATE PROCESS TRANSPARENCY (BOOST) IN 340B ACT
This legislation would impose an additional layer of regulatory burden on the 340B program, putting it at odds with the administration's goal of reducing regulatory complexity and burden.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO DEFINE THE TERM PATIENT FOR PURPOSES OF THE 340B DRUG DISCOUNT PROGRAM
This bill significantly restricts the definition of a patient under the 340B program in a way that would drastically reduce access to discounted drugs and services made possible by 340B savings. It also fails to recognize the way hospitals, particularly DSH hospitals, deliver care.

H.R. ____, TO REQUIRE THE SECRETARY OF HEALTH AND HUMAN SERVICES TO IMPLEMENT THE GOVERNMENT ACCOUNTABILITY OFFICE RECOMMENDATIONS
This legislation would require HHS to implement all seven recommendations in the GAO's June report. But HRSA disagreed with three of the seven recommendations, noting they were burdensome or unnecessary given current safeguards in place. Further, the analysis used a nongeneralizable sample, and broad conclusions about all covered entities cannot be made from a small, non-representative sample.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REQUIRE UNDER THE 340B DRUG DISCOUNT PROGRAM REPORTS BY COVERED ENTITIES
This legislation does not demonstrate a benefit to 340B program oversight or administration that would justify the additional burden it would place on providers. This proposal overlooks how 340B covered entities use their savings. It also imposes burdensome administrative and reporting requirements, based on patient payer mix and charity care, which do not accurately determine hospitals' care for low-income patients.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REQUIRE CERTAIN COVERED ENTITIES UNDER THE 340B DRUG DISCOUNT PROGRAM
This legislation would prohibit hospitals from charging low-income patients more than the ceiling price for 340B drugs. While we support the intent of the proposal, essential hospitals already have financial assistance and charity care policies in place to ensure low-income patients are not overcharged. Additionally, there is a public reporting process in place under IRS 501(r) rules for nonprofit institutions requiring that these policies be publicly available.

H.R. ____, TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ALLOW THE SECRETARY OF HEATH AND HUMAN SERVICES TO PRESCRIBE REGULATION
We support granting HRSA authority to oversee the 340B program within its original statutory intent: to help covered entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." But we have concerns with HRSA having discretion to regulate the program's scope beyond this original congressional intent.

Again, America's Essential Hospitals thanks the committee for the opportunity to provide feedback on the recent 340B program-related GAO report and legislative proposals under consideration. Our association looks forward to working with the committee and its leadership to strengthen the 340B program and to ensure it continues to help covered entities stretch their scarce resources to meet their mission of caring for the nation's most vulnerable people.

Ascension | Seton

Statement for the Record
Submitted to the United States Committee on Energy & Commerce
For the hearing "Opportunities to Improve the 340B Drug Pricing Program"
July 11, 2018

Craig Cordola
President and Chief Executive Officer, Ascension Texas

On behalf of Ascension Texas, we appreciate the opportunity to submit for the record our comments on the 340B Drug Pricing Program. Thank you for holding this hearing to discuss opportunities to improve the 340B program, which benefits the communities we are privileged to serve throughout Central Texas.

340B Program Helps Seton Serve the Most Vulnerable

Seton is the largest charity care provider in Central Texas. We provide $250 million a year in charity care, and over the past 10 years, we have provided more than $2 billion to those who need it most in our community. In Fiscal Year 2017, the 340B program allowed Ascension Texas to save approximately $10 million on the cost of medications. In total, Ascension Texas had drug costs of $73 million in FY2017. Seton has participated in the 340B program for 12 years, and it has enabled us to extend our resources so that we can provide additional services for those most vulnerable. In addition to charity care, these services include charity pharmacies, prescription drug assistance, charity clinics and community programs for low-income, uninsured patients.

Accessing lower cost medications through the 340B program has enabled us to expand our primary and specialty care clinics that serve the poor and vulnerable in our urban and rural communities. In addition, these savings help us provide clinical and ambulatory pharmacy services, financial assistance to patients who are unable to afford their prescriptions, oncology services, and it helps offset the cost of providing free medical care for the ever-increasing number of uninsured and underinsured patients in our community. Of people who seek care from Seton, 30 to 35 percent are uninsured, underinsured or have Medicaid.

Last year, our patient assistance program served and provided free drugs to 4,702 indigent and underinsured patients. In addition, using the Dispensary of Hope program at our retail pharmacy, 2,261 discharged indigent and underinsured patients received free drugs.

In Texas, Ascension operates Providence Healthcare Network and Seton Healthcare Family, which includes Dell Children's Medical Center of Central Texas, the region's only comprehensive children's hospital and pediatric Level I trauma center, and Dell Seton Medical Center at The University of Texas, the region's only Level I trauma center for adults. Seton partners with Dell Medical School at The University of Texas at Austin, and shares a common vision of transforming healthcare through a focus on quality and value. Serving Texas for 115 years, Ascension is a faith-based healthcare organization committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable.

Across our national health system in 22 states and the District of Columbia, 46 of Ascension's hospitals participate in the 340B program. Of these, 24 are critical access hospitals (CAHs), 16 are disproportionate share hospitals (DSHs) and the remaining six fall into a variety of other categories, including sole community hospitals, children's hospitals and rural referral centers. Across Ascension, the 340B program provides about $190 million in assistance with drug costs that is devoted to supporting care for the poor and vulnerable. In total, we provided more than $1.8 billion in charity care and investments in community benefit programs in FY2017. Even including the savings resulting from our participation in the 340B program, the annual impact that the cost of pharmaceuticals has on the cost of delivering healthcare services within Ascension is $1.1 billion and growing rapidly. The cost of pharmaceuticals has added more than $560 million in additional cost just over the last four years to our cost of care.

The purpose of the 340B Drug Discount Program is to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The program is working as intended to provide care for the poor and vulnerable.

Providing High-Quality Oncology Care

Patients who come to receive care at Seton often have no alternatives for care. This is particularly true of those in need of oncology services to treat cancer. Many oncology patients have sought care from Seton when they need to begin a second line of treatment after receiving their first line of treatment at an outside location. Because the second line of treatment can be very expensive and patients may not be able to afford to pay full price for medications, Seton is able to help through our patient assistance programs.

For example, the 340B program allowed Seton to help a patient who had been diagnosed with Juvenile Xanthogranuloma, a disease that attacks the central nervous system. The patient completed her second round of chemotherapy at the Children's Blood & Cancer Center of Dell Children's. Though hospitalized several times, most of her care was provided on an outpatient basis at the Blood & Cancer Center. She also took 30 pills a day, which included an anti-seizure medication and steroids. Due to the high cost of her therapy and drug treatments her family would have incurred a crippling amount of debt in the absence of assistance from Seton.

Seton had close to 1,000 oncology inpatient encounters in FY2017. Of those, 150 were charity care cases. In FY2017, Seton had about 4,500 outpatient oncology encounters, 32 percent of which were charity care, or about 1,440 charity encounters for outpatient oncology treatment.

The Seton Infusion Center (SIC), formerly Shivers Cancer Center, has been providing care for a variety of outpatient services for adult patient-centered care in Austin since 1996 when Seton assumed management of the University Medical Center Brackenridge, now Dell Seton Medical Center at The University of Texas, from the City of Austin. The patient experience at the SIC includes chemotherapy, rehabilitative services, blood product transfusions and biotherapy. The SIC has expanded its services and population served throughout its history, most notably over the last five fiscal years, 2013 through 2017. Total SIC infusion visits related to the uninsured population have risen 17 percent in the last five years, from 3,889 in 2013 to 4,550 in 2017.

The 340B program is especially important for helping to lower the very high cost of oncology treatment. In fact, the savings we receive on oncology and hermatology drugs through the 340B program alone represents 60 percent of our total 340B savings. The savings on cancer drugs are critically important for the services we offer.

We are humbled by the service we are able to provide to the Austin community. However, there is more work to be done. The possibility of the 340B program being curtailed or eliminated is of great concern and would have a devastating impact on our community. In addition, the uncertainty about the future of the program makes it difficult to manage the growing need for care for the those who rely on services that are dependent upon these savings to be viable.

Rising Drug Costs Are Impacting Healthcare

In addition to the growing needs in the community for providing care for the uninsured, rising drug costs are compounding the issue. In addition to fewer people being able to afford their medications, increasing drug costs are creating significant barriers in the move to improve the quality and value of healthcare in our country. Even including the savings resulting from our participation in the 340B program, the annual impact that the cost of pharmaceuticals has on the cost of delivering healthcare services within Ascension is $1.1 billion and growing rapidly. The cost of pharmaceuticals has added more than $560 million in additional healthcare costs over the last four years.

The 340B program is helping many organizations, including ours, meet the health needs of low-income and rural patients in Central Texas and nationwide. Under the program, pharmaceutical manufacturers provide outpatient drugs at significantly reduced prices to eligible safety-net providers that treat large numbers of uninsured, vulnerable patients. In turn, the savings from the program allow the entities to stretch resources to further their missions of serving those most in need. When prices on age-old brand name and generic drugs increase with often little explanation, these high costs cascade to patients in higher out-of-pocket costs and higher insurance premiums. These skyrocketing drug costs are making the 340B program as important as ever, and it is working as intended to hold down those costs.

Conclusion

Thank you for the opportunity to weigh in on this important program helping many people throughout Central Texas. To help fund crucial healthcare services to serve more community members, we urge you to preserve the 340B program to provide important drug discounts to charity hospitals and other safety net providers that serve the most vulnerable in our community.

We appreciate the Committee's attention to this critical issue and look forward to working with all stakeholders to ensure the 340B Drug Pricing Program continues to help the communities who need it most.

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July 11, 2018

The Honorable Greg Walden
Chairman
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The Honorable Frank Pallone
Ranking Member
Energy & Commerce Committee
U.S House of Representatives
Washington, DC 20515

The Honorable Michael Burgess, MD
Chairman
Energy & Commerce Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Energy & Commerce Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone, Chairman Burgess and Ranking Member Green,

The American Society of Clinical Oncology (ASCO) applauds the Committee's examination of the 340B Drug Pricing Program (340B program) in today's hearing, "Opportunities to Improve the 340B Drug Pricing Program." As the 340B Drug Pricing program (340B program) continues to grow in size so does its impact on health care accessibility and quality. We appreciate the Committee's continued efforts to ensure the program addresses the needs of underserved patients, particularly their ability to access cancer therapy. In January, ASCO responded to this Committee's thoughtful report reviewing the program.

ASCO represents nearly 45,000 physicians and other health care professionals specializing in cancer prevention, diagnosis, and treatment who provide cancer care both within and outside 340B-covered entities. In 2014, ASCO published its "Policy Statement on the 340B Drug Pricing Program" in the *Journal of Oncology Practice*, which includes recommendation for reforming the 340B Program.

ASCO supports increased transparency, including an accounting of covered entities' 340B savings and the percentage of 340B savings used directly to care for underinsured patients and patients living on low-incomes.

In past letters to the Centers for Medicare and Medicaid Services (CMS) and to the Committee, ASCO recommended the Health Resources and Services Administration (HRSA) collect an annual comprehensive accounting of the amount of 340B savings covered entities receive under the 340B program and the percentage of those savings that are reinvested into caring for the uninsured, underinsured, and Medicaid patients. Such transparency is necessary to ensure the program remains true to its original intent. ASCO supports the transparency elements of several of the proposals under consideration by the subcommittee today, including provisions of *H.R. 4710*, the *340B Pause Act*, and *H.R. 5598, the 340B Optimization Act,* and the discussion draft to amend the Public Health Service Act (PHSA) which would require reports by covered entities to further the goal of transparency.

ASCO supports greater authority, resources, and staff for HRSA to conduct the increased oversight and enforcement needed for the 340B program.

While HRSA currently conducts audits of 340B covered entities, these audits are limited in scope. HRSA maintains a limited regulatory and enforcement authority to address compliance in the 340B program, however the scope and depth of that authority is not sufficient. ASCO applauds the Committee for considering measures to strengthen the oversight authority and resources of the agency.

ASCO urges Congress to discontinue the use of the Disproportionate Share Hospital (DSH) adjustment as a determining measure for program eligibility and urges Congress to create a metric that appropriately measures levels of charity care for program eligibility.

While ASCO recognizes the intent of legislation such as the *Protecting Safety-Net 340B Hospitals Act* to ensure the program focuses on providing care in those systems where need is the greatest, we do not believe DSH is the appropriate formula to calculate that need. ASCO calls on the Committee to work with ASCO and other stakeholders to identify a formula that would more appropriately recognize levels of charity care across the entire cancer care delivery system. DSH determinations do not capture all services to outpatient populations that are underserved or medically indigent.

New 340B hospital eligibility measures are needed to better link program eligibility with the program's intent. Policymakers should focus on metrics that align program eligibility with the care provided by the institution to indigent and underserved individuals. Doing so will better position the program to serve the patient populations originally intended to benefit. Alternative eligibility measures may be calculated by analyzing the amount of charity care provided by a hospital in the outpatient setting or another appropriate metric. However, any potential metrics must be designed to promote participation by hospitals of all sizes, standardized across all hospitals to ensure that eligibility is based on a single set of parameters applied in uniform fashion, and verifiable to ensure that program integrity is protected. ASCO is prepared and ready to assist Congress and the Administration in developing and implementing policies to better reflect the original intent of the 340B program in this area.

ASCO urges Congress to keep the impact of the 340B program on cancer patients and access to cancer care at the forefront moving forward with reform.

ASCO agrees that the 340B program needs reform. However, significant payment reductions like the one most recently implemented by HHS do not address the fundamental flaws in the program. If enacted in

conjunction with other program reforms, we support H.R. 4392 to nullify the 22 percent reduction in 340B reimbursement that took effect earlier this year.

ASCO is concerned that the cut could harm the very facilities that are truly satisfying the spirit and intent of the program. ASCO urges policymakers to focus on meeting the original intent of 340B to provide resources and incentives for the delivery of high-quality care for uninsured, underinsured, and low-income patients.

Because drug therapies are a fundamental part of cancer treatment, the 340B program has had a strong influence on the cancer care delivery system by encouraging consolidation. Practice closures and acquisitions have had a major impact on access to cancer care in communities across the country. For the same reasons, we urge the Committee to consider the challenges physician-owned oncology practices face when providing care to vulnerable populations in rural, frontier, and other small communities experiencing access issues.

We further call on Congress to consider the impact the 340B Drug Pricing program puts on physician oncology practices and to work with HRSA to establish 340B eligibility for all oncology practices demonstrating a commitment to serving low-income and underserved patients.

Community oncology practices are vital outlets for patient access to high-quality and cost-efficient oncology services for cancer patients from all walks of life. These practices regularly engage in the provision of care to indigent, underserved and uninsured individuals at a financial loss, yet do so without the benefit of 340B discounts enjoyed by oncology providers in other settings of care. Community based oncology practices form the backbone of cancer care in many rural and underserved areas by serving as the sole point of access for oncology services.

ASCO supports expanding eligibility to the 340B program for community oncology practices with a demonstrated commitment to serving uninsured, underinsured and indigent patients to promote increased access for these individuals. ASCO's working group is developing a mechanism to provide a pathway to eligibility for community oncology practices that is based on the portion of care a practice provides to uninsured, underinsured and indigent individuals relative to the levels of other community practices. Minimizing regulatory burdens for clinical oncology practices of all sizes to demonstrate 340B eligibility is crucial to meeting the program's original intent. Any eligibility criteria for community-based practice eligibility should be designed to facilitate participation by practices of all sizes, defined based on standardized data that are unique to community practice, and verifiable to promote program integrity.

ASCO thanks the Committee for its commitment to improving the 340B program. If you have questions about this or any issue affecting cancer care, feel free to reach out to Amanda Schwartz at amanda.schwartz@asco.org or 571-483-1647.

Sincerely,

Monica M. Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology

A Passionate Voice for Compassionate Care

Catholic Health Association of the United States

Statement for the
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives

Hearing on "Opportunities to Improve the 340B Drug Pricing Program"

July 11, 2018

The Catholic Health Association of the United States (CHA), the national leadership organization of the Catholic health ministry, representing more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities and related organization across the continuum of care, is pleased to submit a statement for the record on the 340B drug discount program. We appreciate the Subcommittee's interest in this important program.

As health care facilities guided by the teaching of the Catholic church, CHA and its members are committed to respecting the human dignity of each person, promoting the common good, having special concern for low-income and other vulnerable persons, and being responsible stewards of resources. These foundational beliefs drive our long-standing commitment to ensure that every patient has access to quality care regardless of ability to pay, and that all persons in our communities reach their highest potential for health possible. The 340B program plays an important role in enabling Catholic safety net hospitals to meet these commitments in serving their communities.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers that participate in the Medicaid program to provide covered outpatient drugs at a discounted rate to safety net and other health care facilities serving low-income, vulnerable communities or remote rural areas. Congress created the program as a response to the high pharmaceutical costs faced by safety net hospitals. The intent was "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The significant pharmacy discounts available under the program allow hospitals to continue to provide and expand community services that otherwise would not be available to these populations.

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A Passionate Voice for Compassionate Care

To participate in the 340B program, hospitals must provide a significant level of care to low-income patients or serve rural communities. In 2015 340B hospitals of all types provided $23.8 billion in uncompensated care[1] and $51.7 billion in total benefits to their communities.[2] 340B DSH hospitals account for only 38 percent of all Medicare acute care hospitals but they provide nearly 60 percent of all uncompensated care, and are much more likely than non-340B hospitals to offer vital health care services that are often under-reimbursed, including trauma centers, HIV/AIDS services, outpatient alcohol/drug abuse services and immunizations.[3]

We support measures to strengthen the 340B program consistent with its original intent: to allow safety net and rural hospitals to serve more people and provide more comprehensive services by giving these hospitals access to lower cost outpatient drugs. CHA supports improvements such as:

- Adequate funding for the Health Resources and Services Administration (HRSA) to ensure compliance with 340B program requirements
- Steps to make sure that drug manufacturers are not overcharging covered entities, including completion by HRSA of a secure web-based pricing system to allow hospitals to confirm they are being charged the right price
- Rescission of the steep cuts to reimbursement for 340B drugs in the Medicare Outpatient Prospective Payment System (OPPS)
- Immediate implementation of rules allowing HRSA to assess civil monetary penalties (CMPs) against manufacturers that knowingly or intentionally overcharge

We are pleased to support two of the bills under discussion by the Subcommittee. H.R. 4392, a bipartisan bill introduced by Rep. David McKinley (R-WV), would stop the implementation of a 28%, or $1.6 billion, reduction in Medicare reimbursement for 340B drugs in the OPPS. The Stretching Entity Resources for Vulnerable (SERV) Communities Act, H.R. 6071, introduced by Rep. Doris Matsui (D-CA) would also stop the OPPS 340B cuts. Among its other provisions, H.R. 6071would codify the current definition of patient, require implementation of the of the HRSA ceiling price website,

[1] AHA 2015 Annual Survey Data
[2] AHA 340B Community Benefit Analysis, March 2018, accessed at https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf
[3] L&M Policy Research, Analysis of 340B Disproportionate Share Hospital Services to Low-income Patients (March 12, 2018)

the manufacturer CMP rule and establish parity in auditing of covered entities and manufacturers.

Several other bills are under consideration by the Subcommittee, many of which would have negative effects on the program and the communities who benefit from services supported by 340B. CHA has deep concerns with proposals that would:

- Change the intent of the program
- Take services away from communities by reducing the number of safety net providers who are eligible for 340B, for example by increasing Medicare DSH adjustment percentage eligibility thresholds for disproportionate share hospitals
- Narrow the definition of an eligible individual or restrict patient access to services
- Impose reporting requirements that are unduly burdensome or do not provide information relevant to the program's intent or operation
- Limit the ability of providers to use 340B savings to provide a range of comprehensive services based on community need

It is of utmost importance that the 340B program be maintained and improved. The savings from the 340B program allow safety net and rural hospitals to serve their patients and communities in many ways, according to local need. Many Catholic hospitals rely on 340B savings to, for example, run free and low-cost clinics; to provide infusion and other services in remote or low-income areas; to offer generous financial aid policies as well as programs that provide low-cost or free prescriptions; to maintain critical services that operate at a loss; and to support community benefit programs meeting the identified needs of their service areas. The 340B program plays a crucial role in providing access to health care in the communities served by the ministry.

Thank you again for the Subcommittee's attention to this essential program. As you move forward, please always bear in mind the communities and individuals that rely on 340B for continued access to the health care they need.

The US Oncology Network

July 11, 2018

The Honorable Greg Walden
Chairman
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The Honorable Frank Pallone
Ranking Member
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The Honorable Michael Burgess, MD
Chairman
Energy and Commerce Subcommittee on Health
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The Honorable Gene Green
Ranking Member
Energy and Commerce Subcommittee on Health
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone, Chairman Burgess and Ranking Member Green,

On behalf of The US Oncology Network, thank you for your continued efforts to protect the viability of the federal 340B drug discount program by exploring meaningful reforms to enhance program oversight, transparency and accountability. We strongly support this committee's approach to having a thoughtful and collaborative discussion aimed at improving the fundamentals of this program. We are hopeful that commonsense reforms will emerge from this dialogue that preserve the program while assessing the impact on community oncology practices across the country.

The US Oncology Network (The Network) is one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 850,000 cancer patients annually in more than 400 locations across more than 25 states. The Network unites over 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, most cost-effective integrated cancer care to help patients fight cancer, and win.

Our dedication to providing high-quality, integrated cancer care is demonstrated by the sixteen oncology practices within The Network, encompassing roughly 900 providers, that have been selected to participate in the Centers for Medicare & Medicaid Services' Oncology Care Model (OCM). These practices have accepted the challenge of participating in the pilot with the shared goal of improved patient outcomes and cost savings for the Medicare program. We embrace innovation in both treatment options and care delivery, and we are committed to working with you and your colleagues toward policies that enable physicians to practice medicine so that patient outcomes are improved, rather than compromised.

The Network supports the underlying goal of the 340B drug discount program which is largely aimed at stretching scarce federal resources to benefit indigent patients in critical access areas. However, we believe the program's recent growth may be contributing to the consolidation of community oncology practices. Based on an internal study from the Community Oncology Alliance[1], it is estimated that roughly 658 community

[1] 2018 Community Oncology Alliance, Practice Impact Report. Full Report available at: https://www.communityoncology.org/downloads/pir/COA-Practice-Impact-Report-2018-FINAL.pdf

The US Oncology Network

cancer practices have been acquired by or affiliated with hospitals since 2008, with a significant portion of those transactions believed to be leveraged with 340B benefits. This has resulted in a shift in the site of service for chemotherapy administration from the physician-office setting to other, more-costly outpatient settings.

In fact, 10 years ago over 80% of cancer care was delivered in the community-based setting – today that number is closer to 50%[2]. This trend not only creates patient access issues, but often results in higher healthcare and patient out-of-pocket costs. The Network is committed to ensuring all cancer patients receive high quality, clinically appropriate care. We firmly believe in the value of community-based providers, who are at the front line of care delivery, providing local solutions to meet the needs of their patients.

For policymakers and regulators to properly assess the scope and value of the 340B program, The Network supports increased transparency through public reporting on meaningful data that provides additional clarity on a covered entity's patient mix, savings associated with enrollment, revenue associated with 340B-eligible outpatient drugs/services and charity care or patient services underwritten by 340B proceeds. We also encourage the committee to consider separate detailed reporting of these transparency measures for off-campus outpatient facilities to ensure accurate savings and revenue data is understood for child sites that may have a different patient profile than that of the covered entity.

This data is an essential component for informed oversight and will provide an opportunity for eligible entities to demonstrate how they are using funds derived from the program to benefit patient care. To ensure overall program integrity, operability and proper analysis of the data submitted, Congress should further equip the Health Resources and Services Administration (HRSA) with the tools needed to sufficiently administer and refine the program.

On behalf of the nation's leading community cancer care providers, we appreciate your leadership on this issue and look forward to working with you to address the growth of the 340B drug discount program in an effort to lower out-of-pocket costs for patients and preserve patient access to community-based cancer care.

Sincerely,

Lucy R. Langer, MD, MSHS
Chair, National Policy Board
The US Oncology Network

[2] Milliman Report, April 2016: Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014

CHILDREN'S HOSPITAL ASSOCIATION

Champions for Children's Health

Statement for the Record

In support of the 340B Drug Pricing Program

Submitted to the House Committee on Energy and Commerce
Subcommittee on Health

Opportunities to Improve the 340B Drug Pricing Program

July 11, 2018

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www.childrenshospitals.org | © Children's Hospital Association

The Children's Hospital Association (CHA) represents 220 hospitals nationwide dedicated to the health and well-being of our nation's children. On behalf of our nation's children's hospitals and the patients and families we serve, we urge the committee to protect the 340B Drug Pricing Program (340B) and to retain the original intent of the program to stretch scarce federal resources as far as possible.

340B supports safety-net providers, such as children's hospitals, in their mission to serve low-income, uninsured, and under-insured patients. To date, 52 freestanding children's hospitals have enrolled in the program. Children's hospitals depend on support from programs like 340B to provide the necessary care our patients need and to expand vital services to the communities we serve. On average, more than half of all patients treated at children's hospitals are covered by Medicaid, which pays approximately 30 percent less compared to Medicare for the same procedures and significantly less than private insurance.

Children's hospitals support H.R. 6017, the Stretching Entity Resources for Vulnerable (SERV) Communities Act. Oversight of pharmaceutical manufacturers needs to be strengthened and aligned with covered entity standards. In addition, we support efforts that allow covered entities to access ceiling prices through a designated Health Resources and Services Administration (HRSA) website

We encourage the committee to reconsider efforts that put a freeze on new entities or require hospitals to report on additional reporting measures that do not result in improved program integrity. In addition to the annual recertification and ongoing audits by HRSA Health Resources and Services Administration necessary for 340B, children's hospitals annually submit cost reports to Medicaid agencies and report financial assistance and community benefits to the Internal Revenue Service. Further reporting that does not improve program integrity would only mean increased administrative burden for little to no value.

We also request that the committee re-evaluate proposals that indiscriminately impose Medicare requirements on 340B providers. As explained above, the majority of patients treated at children's hospitals are covered by Medicaid. Proposals should not subject 340B hospital entities to Medicare requirements without considering their applicability to children's hospitals.

We also ask the committee to weigh the impact of proposals that look to change current program definitions, specifically the patient definition. Proposals aimed at changing the patient definition will limit an entity's ability to administer infusions and to provide prescriptions upon discharge under 340B. These potential changes are troubling for children's hospitals. The infusion of a drug — especially in a pediatric patient — is very complex and requires the administration of medication intravenously, under the management of a trained health care professional. These infusions play a vital role in treating neonatal and pediatric patients with different types of health conditions, including blood diseases, cancer, immune disorders and genetic abnormalities. As a result, some pediatric patients are referred to children's hospitals' infusion clinics because they require specialized care, including having a trained nurse or health care provider that understands the unique physiology of children and can closely monitor, observe and provide additional health care services as necessary. Since children's hospitals are regional providers, patients and their families often travel from all over the state, or possibly from a neighboring state, to receive infusion treatment. While it is important that these children receive this treatment at a children's hospital, it may not be necessary for the patient to receive their overall care from a children's hospital. This is important since we believe children should receive the care they need in the most appropriate and cost effective setting as possible.

Additionally, we are concerned with proposals that prevent hospitals from receiving 340B pricing for drugs billed as outpatient drugs if the prescription order was written in connection with a discharge from an inpatient stay. We worry that this may adversely affect patient care. For example, in an effort to improve patient outcomes and reduce hospital readmissions, discharge prescription programs have been implemented by many institutions to facilitate the transition of care and increase compliance with medication therapy. These types of programs help educate patients' families and remove some of the challenges related to medication compliance. Finalizing this policy could jeopardize the important progress made in this area and negatively affect pediatric health.

We thank the Chairman, Ranking Member, and committee members for the opportunity to provide comments. We look forward to working with the committee to ensure 340B remains strong.