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6	EXAMINING HOW COVERED ENTITIES UTILIZE THE
7	340B DRUG PRICING PROGRAM
8	WEDNESDAY, OCTOBER 11, 2017
9	House of Representatives
10	Subcommittee on Oversight and Investigations
11	Committee on Energy and Commerce
12	Washington, D.C.
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16	The subcommittee met, pursuant to call, at 10:00 a.m., in
17	Room 2123 Rayburn House Office Building, Hon. Morgan Griffith
18	[vice chairman of the subcommittee] presiding.
19	Members present: Representatives Griffith, Burgess, Brooks,
20	Collins, Walberg, Walters, Costello, Carter, Walden (ex officio),
21	DeGette, Schakowsky, Castor, Tonko, Clarke, Ruiz, Peters, and
22	Pallone (ex officio).

Also present: Representative Sarbanes.

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Staff present: Jennifer Barblan, Chief Counsel, Oversight & Investigations; Adam Buckalew, Professional Staff Member, Health; Kelly Collins, Staff Assistant; Zachary Dareshori, Staff Assistant; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, Oversight & Investigations, Digital Commerce and Consumer Protection; Theresa Gambo, Human Resources/Office Administrator; Brighton Haslett, Counsel, Oversight & Investigations; Brittany Havens, Professional Staff, Oversight & Investigations; Katie McKeogh, Press Assistant; Alex Miller, Video Production Aide and Press Assistant; Jennifer Sherman, Press Secretary; Sam Spector, Policy Coordinator, Oversight & Investigations; Josh Trent, Deputy Chief Health Counsel, Health; Natalie Turner, Counsel, Oversight & Investigations; Hamlin Wade, Special Advisor, External Affairs; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Rachel Pryor, Minority Senior Health Policy Advisor; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; and C.J. Young,

45 Minority Press Secretary.

Mr. Griffith. Welcome. Today the subcommittee is holding a hearing entitled Examining How Covered Entities Utilize the 340B Drug Pricing Program. The 340B Program was created by Congress in 1992 and mandates that drug manufacturers provide outpatient drugs to eligible entities at reduced prices in order for the manufacturers to remain eligible for reimbursements through entitle programs such as Medicaid and Medicare.

The 340B Program helps covered entities stretch scarce federal resources in order to reach more eligible patients and provide more comprehensive services to those patients. This is, undoubtedly, and important program. The dramatic growth of the program, however, couple with a dearth of information about how it is used, has led to questions about whether the program has grown beyond Congress' original intent.

The Subcommittee on Oversight and Investigations has been looking into the 340B program for several months now. Our work began with an examination of the Health Resources and Services Administration's, HRSA, role in overseeing the 340B Program. The committee requested a sample of HRSA's audits in order to understand the interactions between HRSA and covered entities and the thoroughness of HRSA's audits.

In July, the subcommittee held a hearing in which we heard

from HRSA, GAO, and OIG on the challenges they face in overseeing the program. As we heard in July, the number of unique participating entities nearly quadrupled between 2011 and 2016 without a proportional growth in oversight and HRSA has struggled to keep up. However, our last hearing left many questions unanswered.

Because of the lack of reporting requirements in the 340B statute, HRSA is simply unable to collect data on exactly how covered entities use the program. Because HRSA is not able to report how covered entities use the program, the committee wrote to a diverse group of entities in September about their use of the program. We asked the entities to report a wide range of information, including the amount saved on drug purchases through participation in the 340B program, the level and type of charity of care provided by the entities, and how patients benefit from 340B discounts.

Over the past few months, we have heard from these entities and many others. Some entities reached out to the committee on their own, very eager to share with us the great work they are doing with the program dollars. We have heard from rural entities that started delivery services to ensure that patients in remote areas are able to receive their medications, entities that pass

savings directly to their patients using a cash card program, and entities that are using their savings to combat the opioid crisis, including by examining prescribing practices and providing behavioral health services to their communities. However, I am concerned by reports that not all participating entities have devoted the program dollars to improving patient care, providing access to vital services, or lowering prescription drug costs for the patients. I have seen news accounts indicating that some covered entities spend millions on salaries and bonuses for their CEOs and hundreds of millions on building expansions, even as charity care at those entities is on the decline. Perhaps even more concerning are some reports showing that patient costs are actually on the rise at some 340B entities.

In 2015, GAO found the 340B disproportionate share hospitals were either prescribing more drugs or more expensive drugs to Medicare Part B beneficiaries than their non-340B counterparts. Similarly, we have concerns that 340B hospitals are acquiring physician-owned oncology practices which can result in higher treatment costs to patients within that practice.

The 340B drug pricing program is vital to many covered entities and, by extension, to the patients that those entities serve. As such, it is crucial that Congress ensure that the

program dollars used in accordance with the intent of the program to stretch scarce federal resources as far as possible to better serve uninsured and underinsured patients. We must ensure there is accountability and transparency in the program.

I am pleased that the panel we have assembled today includes three disproportionate share hospitals that serve both urban and rural populations, one Federally-Qualified Health Center, and one Ryan White Center. Each of these entities serve a different patient population and offer services that are of particular importance to their communities.

I thank these witnesses for their cooperation in producing data, to this committee about their use of the 340B program, and their willingness to appear before us today.

I look forward to hearing more about the ways in which they benefit and, more importantly, how their patients benefit from their participation in the 340B program.

I do appreciate it very much. And with that, I will yield to Ms. DeGette for 5 minutes.

Ms. DeGette. Thank you. Chairman, it is nice to see you sitting there in the chair. Welcome. We are glad to have you.

I think that investigation like this, of programs like this, really are the core job of this committee and I am pleased that

we are looking into the viability of the 340B Program. This program, I think we will all agree on both sides of the aisle, has been a lifeline for providers who care for low-income and vulnerable patients. Eligible entities like DSH hospitals, Federally-Qualified Health Centers and AIDS Drug Assistance Program are a critical part of the communities that they serve. The 340B Program helps them to make the best of their limited resources.

When we talk about the 340B Program, we often hear about the drug discounts but the program provides so much more than that. When Congress established this program, we made clear that the purpose was to quote stretch scarce federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services.

Mr. Chairman, it seems like the providers are doing just that. 340B recipients include large hospitals that serve urban settings and rural hospitals that often provide the only care available in their communities. They include Ryan White Clinics and Federally-Qualified Health Centers. All of these centers provide extraordinary amounts of uncompensated care and services to those in need.

Now this investigation was initiated to see whether

recipients were properly using their savings and that is certainly appropriate. So we received responses from most of the people who received a letter from the Majority Council. As part of that process, my committee staff has also conducted interviews with most of them as well. While most of the recipients have reported that the 340B Program is a vital source of funding that makes possible to reach vulnerable populations, many have also explained that these savings only cover a fraction of the care that they provide.

For example, as a covered entity, the University of Washington saved \$24 million through the 340B Program. Well, that is impressive but the institution spent more than \$270 million covering uncompensated care costs for Medicaid and Medicare recipients, as well as people who show up at the emergency room with no insurance at all.

Mission Health, which has a witness which will testify today, saved \$38 million in 2016 by participating in the 340B program but that same year, it provided \$69 million in uncompensated care, as well as \$183 million in community benefits. This includes services like mobile children's dental care units, a medical airlift service for surrounding states.

In an interview with committee staff, Mission Health

reported that if its 340B revenues were cut, it would be forced to significantly limit programs and services.

Parkland Hospital in Dallas provided \$431 million in charity care in 2016, which was over three times the amount of their 340B discounts. Parkland explained to my committee staff that when all uncompensated care is taken into account, it actually provided \$870 million in critical community benefits.

Northside Hospital in Atlanta, which also has a witness here today, reported in 2016 that it generated nearly \$53 million in 340B savings, which does cover a lot of care, but there was nearly \$370 million in charity care.

And UCSF saved about \$83 million but, again, that savings only covered a portion of the \$331 million in charity care.

Last but certainly not least, the AIDS Research Center of Wisconsin, which recently merged with Rocky Mountain CARES in my home district. These clinics provide critical services to people affected by HIV-AIDS -- medical, dental, mental health care, food services, housing services, and pharmacy services. If they didn't have 340B, they couldn't provide these services.

We heard this consistent message from all types of providers and, from what this committee has seen, they don't seem to be lining their pockets. They are using this savings to provide

critical care for the community and vulnerable populations.

Now I think we can discuss the definitions regarding what is what or what is not charity care but, in the end, what should not be lost is these organizations are using this compensation for important community work.

I look forward to hearing from the witnesses about this work.

I think we can make improvements on transparency to the program but, in doing so, we should not reduce the providers' abilities to fulfill their missions and to continue their important work.

I yield back.

Mr. Griffith. I thank the gentlelady and now recognize the chairman of the full committee, Mr. Walden.

The Chairman. And I thank you, Vice Chairman. Thank you for leading this hearing today.

The committee has been examining the 340B Drug Pricing

Program for about 2 years now, as I think you all know, and the

Oversight Subcommittee has been particularly focused on it since

last spring.

The 340B Drug Pricing Program allows covered entities to purchase certain outpatient drugs at reduced prices, in order to allow those entities to stretch scarce federal resources as far as possible to better serve their patients.

As you all know, the subcommittee held a hearing in July. We invited Government witnesses here to testify about the program. They were unable to answer many of our questions on how covered entities use the 340B program, due to the lack of reporting requirements in the statute. This lack of transparency and coherent reporting requirements is concerning. Frankly, without the data it is hard to know if this program is working as Congress intended when it was created.

So today, we are going to hear directly from five covered entities, all top-notch medical organizations that provide important services to their communities. They range from of smallest to some of the largest participants in the program.

The 340B Program enables covered entities to do some real good in our communities, to extend care to underserved populations, to create programs that serve specific community needs, and to provide life-saving drugs at discounted prices to the populations that need them the most. For some entities, this program is the difference in keeping their doors open or in closing shop, which could result in a loss of care to vulnerable populations. So this is a very important program.

I have met with several hospitals in rural Oregon that are using the 340B Program to improve care and reduce costs for

low-income patients and I have heard how vital this program is to maintain their high levels of charity care. I, myself, served on a nonprofit small community hospital board for about 4 years before coming to the Congress. So, I understand the importance of these programs. I am troubled, however, by the response of some stakeholders and entities who see our oversight efforts as a threat to the 340B Program and to their charity work. It is the job of this committee to ensure that the programs that Congress creates serve their intended purpose and operate with integrity and that participating entities are held accountable for how they spend the program dollars. That is our job.

Our goal in our oversight work is always to take a deliberate and fair look at all sides of the issues. We know that each entity provides unique services, serves a unique population and faces unique challenges in their communities. Because of that diversity, we want to allow entities to tell their own stories and highlight the successes they have experienced through participation in this important program. However, the lack of transparency requirements has resulted in inconsistent data and dueling reports from every side of this issue. And believe me, we hear from every side.

Much of the data that we do have is self-reported by entities

that measure charity care and program savings but they do so in various ways. While I believe it is important that entities be able to share their work in a way that takes into account the specific needs of their communities, the inconsistencies here only further demonstrate that we need better data on this program.

The 340B Program has grown rapidly over the years. The increase in program participation has led to a dramatic increase in 340B drug purchasing and savings. According to HRSA, covered entities' drug savings grew from \$3.8 billion in fiscal year 2013 to \$6 billion dollars in fiscal year 2015. I am concerned that, as the program continues to grow, participating entities are not investing the necessary resources and time to oversee the program, ensure accountability and transparency, and, above all, ensure that they are using the program savings to improve patient care.

For example, some entities that we spoke with reported they do not have policies to help ensure that uninsured and underinsured patients directly benefit from the program by receiving discounts on out-patient drugs. Most surprisingly, many entities did not track their 340B savings at all and, until they received our request, didn't seem to have any idea how much they saved through participation in the 340B Program.

On the other hand, some participating entities tracked their

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340B savings on a regular basis and provide regular training to staff on federal program requirements.

With a program this large, it is essential that Congress understands how it is being used and I hope that that is what we will accomplish in this hearing. Our goal today is to develop a better understanding of how much money different entities saved through participation in the 340B program, how covered entities tracked their savings, and how those savings are used to actually improve patient care in various ways.

So I want to thank each of the witnesses for being here today and I look forward to hearing more about how each of your organizations provides vital care to your communities. And know that I have said from day one, Mr. Chairman, we are going to look from one end of the cost curve of healthcare delivery to the other. It is our job and responsibility. It just happened 340B and hospitals were first up but this is just the start. If we are ever going to tackle high cost of health care in America, it is our responsibility.

With that, I yield back, Mr. Chairman.

Mr. Griffith. Thank you, Mr. Chairman. I appreciate it very much.

I now recognize the ranking member of the full committee,

Mr. Pallone.

Mr. Pallone. Thank you, Mr. Chairman.

Twenty-five years ago, Congress passed bipartisan legislation establishing the 340B Program to help healthcare providers expand their capacity to serve their patients. And since that time, the 340B Program has played a critical role ensuring that low-income Americans and most vulnerable populations have access to essential healthcare services and helping safety net providers expand innovative care to these communities.

This summer, the Republican majority initiated an investigation to determine how entities are using the program. From what we have heard over the last couple of weeks, it appears that 340B recipients are using their savings to reach vulnerable populations and without that money, these programs would be reduced or cut altogether.

The committee has reviewed responses from most of the healthcare facilities that the Republicans contacted. Committee staff have also interviewed representatives from most of the letters' recipients. Many entities have explained that the 340B savings often cover only a portion of the cost of their uncompensated care and services to vulnerable populations. And

through these interviews and responses, we have found that covered entities rely on 340B funds to provide a diverse range of essential services to the community. Today, we will hear firsthand from our witnesses about the type of care and treatment that might be impossible to provide without the help of 340B.

For instance, 340B recipients have told the committee that they use their savings to support mobile clinics for low-income patients, or to provide free prescriptions to uninsured and underinsured patients. One provider reported that 340B savings made it possible for them to treat low-income patients with substance abuse disorders. Another said that thanks to the 340B savings, it is able to serve more vulnerable children in its neonatal intensive care unit. And this provider reported that without 340B, it might have had to cut the number of children it can help by nearly half.

It is beyond question that the resources provided through the 340B program directly augment patient care throughout the country. We have consistently heard this message from all types and sizes of 340B providers from small AIDS clinics to large urban hospitals. And the 340B Program plays an integral role in supporting the mission of safety net providers serving low-income, uninsured, and underinsured patients.

Now some have suggested that we can improve the program by increasing transparency and program integrity. And I certainly agree good program integrity strengthens our programs not only for today but for the future. But I want to be clear, however, that while I am always happy to have a conversation about strengthening the 340B program, it is plain from the responses we have received that 340B-covered entities are using their savings to serve the community and Congress should commend and support those efforts.

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

And I yield back if someone else wants time but I don't think so. I yield back, Mr. Chairman.

Mr. Griffith. Thank you.

And now I ask for unanimous consent that the members' written opening statements be introduced into the record. Without objection, the documents will be entered into the record. I also ask unanimous consent that members not on the Subcommittee on Oversight and Investigations be permitted to participate in today's hearing.

Without objection, I would now like to introduce our panel of witnesses for today's hearing.

First, we have Ms. Sue Veer, who is the President and CEO of Carolina Health Centers in South Carolina. Thank you for being here today.

Next is Mr. Mike Gifford, who serves as the President and CEO of the AIDS Resource Center of Wisconsin. Thank you, sir.

Then we have Dr. Ronald Paulus, who is the President and CEO of Mission Health Systems in North Carolina.

Fourth is Mr. Charles Reuland, the Executive Vice President and COO of Johns Hopkins Hospital in Baltimore. Thank you, sir.

And finally, we have Ms. Shannon Banna, who serves as the Director of Finance and System Controller at Northside Hospital in Georgia.

I thank each of you for being here today and providing testimony. We look forward to the opportunity to discuss how entities across the country utilize the 340B Program.

As you are aware, this committee is holding an investigative hearing and, when doing so, as has been the practice of this subcommittee, we take testimony under oath. Do any of you have an objection to testifying under oath?

The Chair then advises that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during

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398	your testimony today?
399	In that case, if you would please rise and raise your right
400	hand, and I will swear you in.
401	[Witnesses sworn.]
402	Mr. Griffith. Having heard all respond in the affirmative,
403	you all can sit. Thanks.
404	You are now under oath and subject to the penalties set forth
405	in Title 18, Section 1001 of the United States Code. You may now
406	give a 5-minute summary of your written statement and, of course,

we will begin with Ms. Veer.

STATEMENT OF SUE VEER, PRESIDENT AND CHIEF EXECUTIVE OFFICER,
CAROLINA HEALTH CENTERS, INC.; MICHAEL GIFFORD, PRESIDENT AND
CHIEF EXECUTIVE OFFICER, AIDS RESOURCE CENTER OF WISCONSIN;
RONALD A. PAULUS, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER,
MISSION HEALTH; CHARLES REULAND, EXECUTIVE VICE PRESIDENT AND
CHIEF OPERATING OFFICER, THE JOHNS HOPKINS HOSPITAL; AND SHANNON
BANNA, DIRECTOR OF FINANCE AND SYSTEM CONTROLLER, NORTHSIDE
HOSPITAL, INC.

STATEMENT OF SUE VEER

Ms. Veer. Thank you, Chairman Griffith, Ranking Member DeGette, and members of the subcommittee.

My name is Sue Veer and I am the President and CEO of Carolina Health Centers, a Federally-Qualified Health Center that serves as the primary care medical home for 26,952 patients in the west central portion of South Carolina known as the Lakelands. We operate 13 primary care sites and two community pharmacies serving patients within an HHS-designated medically underserved area of over 3,700 square miles.

I appreciate the opportunity to serve as a witness before the subcommittee today and to speak to the importance of the 340B Program for Carolina Health Centers. If there are two key things

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that I hope you will take away from my testimony they are, first, that the 340B Program is a critically important tool for FQHCs as we work to provide the highest quality of care to underserved patients and the communities in which our sites are located.

Second, each category of 340B-covered entity has unique aspects that must be considered in any potential reforms. In the case of FQHCs, we are already subject to HRSA oversight and specific health center requirements that guide many aspects of our participation in the 340B Drug Pricing Program. Consistent with these specific FQHC requirements, we never turn a patient away due to inability to pay or due to demographic, geographic, and socioeconomic barriers. Patients with incomes before the poverty level pay no more than a nominal fee for the full range of services that we provide. And patients whose incomes are between 101 and 200 percent of the poverty level pay a discounted rate according to a sliding fee scale that's based on their ability to pay.

We are also governed by a community-based Board of Directors, a majority of whose members are patients of the health center. This structure ensures that we remain directly responsive to the unique needs of our patients and the community.

And finally, all health centers are subject to intensive and

ongoing oversight from the Department of Health and Human Services
Health Resources and Services Administration. The HRSA
requirements with which we must comply are spelled out in a 92-page
manual and grouped into 18 major categories, which include but
are not limited to, clinical quality, financial management,
ensuring access, and our collaboration with other local
healthcare providers.

At Carolina Health Centers, we make every effort to ensure that uninsured and low-income patients are able to afford their prescriptions. While every health center may use their 340B savings differently, these savings enable my health center to provide deeply discounted pharmacy services to those patients eligible for the income-based sliding fee program. Those pharmacy services include clinical programs, such as medication therapy management, which promote clinical outcomes and cost-effective care. We are also about to launch a new multi-disciplinary program for the reduction of the use of controlled substances.

We also use our 340B savings to support the following services that are designed to expand access to essential primary care services for patients throughout our rural service area.

Daily delivery of health center patient prescriptions to Carolina

Health Centers' medical practices that in our outlying rural communities, communities where patients have little or no access to affordable pharmacy services. That delivery service makes over 20,000 affordable prescriptions accessible to low-income and uninsured patients every year.

Oral health service, both preventive and restorative provided through uninsured -- provided to uninsured and sliding fee-eligible patients through a network of contract dentists and behavioral health counseling, which is provided on-site for patients who would either not qualify or have incredibly long delays in accessing care from the local mental health agency.

In addition the 340B savings contribute to my health center's ability to ensure continued access to primary care and preventive care at certain of our primary care delivery sites in communities, which due to their particularly rural location would not likely be sustainable otherwise.

The health center statute requires FQHCs to use all their 340B savings for purposes that advance their HRSA-approved scope of project. In other words, for activities that increase access to high-quality affordable care for medically-underserved populations.

As my testimony demonstrates, the 340B Program is vital to

my health center and to our ability to provide patients with access to affordable prescriptions, as well as needed services for our low-income and underserved patients.

Thank you for the opportunity to testify before you today and for recognizing the importance of this program for the health centers and all the patients we serve.

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Mr. Griffith. Thank you.

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I now recognize Mr. Gifford for 5 minutes for an opening statement.

STATEMENT OF MICHAEL GIFFORD

Mr. Gifford. Good morning, Chairman Griffith, Ranking
Member DeGette, and members of the subcommittee. Thank you for
inviting me to provide testimony today.

As we gather here today, we can talk credibly about the end of the HIV epidemic in our lifetime. The 340B Program is vital to attaining that goal.

My name is Mike Gifford. I serve as the President and Chief Executive Officer of the AIDS Resource Center of Wisconsin.

Earlier this year, ARCW expanded our services into Denver,

Colorado and the unique model of care that we offer. In total,

we serve more than 4,000 people with HIV.

The 340B Program costs the Federal Government nothing, yet generates hundreds of millions of dollars in care for HIV patients. For HIV patients, the purpose of the 340B program, to stretch scarce federal resources, to serve more patients, and to provide more comprehensive services, is met every single day. We assure unfettered access to medical care, dental care, mental health therapy, drug treatment, and pharmacy services tightly integrated with social services like case management, food assistance, and housing.

More than 90 percent of our patients are low-income and one-third of all of our medical visits care for uninsured patients.

Our patients achieve some of the finest clinical outcomes in the country, 89 percent of whom achieve the gold standard in HIV health care and undetectable viral load. That is a rate far above the national average. Governor Scott Walker's administration has found that our patients are so healthy they cost of the State of Wisconsin 30 percent less than HIV patients cared for elsewhere.

Further, DHHS data shows HIV patients in Wisconsin have the lowest HIV mortality rate in the country. Our HIV medical home buoyed by 340B savings result in people with HIV living in Wisconsin longer than anywhere else in the country.

At ARCW, 340B savings are used consistent with legal and regulatory requirements. Savings have supported opening an opioid treatment program in Green Bay, expanding mental health services throughout Wisconsin, launching clinical pharmacy care in Denver, and increasing the number of patients we care for throughout all of our services by more than one-third.

Last year, ARCW generated \$7,429,666 in savings, the exact use of which is included in my written testimony. To track 340B

medications and savings, we have developed specialized software that monitors compliance related to patient eligibility, diversion, and duplicate discount. We audit ourselves on a monthly basis and have an annual third-party external audit.

Last year, it showed 99.57 percent compliance. This year our compliance rate is at 99.9996 percent.

As the subcommittee reviews the 340B program, there are critically important policies necessary to achieve that goal I mentioned earlier, a world without AIDS. The current patient definition used for Ryan White grantees must be maintained to support the integrated care necessary in achieving substantially better clinical outcomes. Without it, there will be fewer resources, worse outcomes, and increased healthcare costs, not to mention the substantial difficulties for the people we serve.

Separately, the use of 340B savings for Ryan White grantees has been limited, prohibiting their use to extend access to: 1) lifesaving prep services; 2) expand the number of locations we can offer our care; and 3) assure the financial sustainability of our providers. These regulations create significant barriers to ending AIDS.

Statistics and advocacy tell only part of the story.

Briefly, let me tell you about one of our patients, Kathy. Sh

came to us newly diagnosed with HIV 20 years ago, struggling with substance abuse. Through our drug treatment program, she entered a life of sobriety. Kathy then accessed medical care, housing, food services, and mental health therapy to achieve that gold standard in care in undetectable viral load.

She proceeded to meet her boyfriend and relocate to another town. Just weeks later, we received a call from Ms. Kathy. Her boyfriend turned out to be a domestic abuser. We rushed to her aid, removed her from harm's way, and provided her a safe home. She is no longer being beaten. Sadly, she was no longer undetectable.

Today, she is accessing many of our services and is back on the way to that gold standard. Throughout it all, our services were always there for Kathy, even if she couldn't pay, each one of them supported by 340B savings -- savings that saved her life.

Thank you for this opportunity to testify before the committee. I look forward to responding to any questions you may have.

[The prepared statement of Mr. Gifford follows:]

Mr. Griffith. Thank you.

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Now, I yield to Dr. Paulus for 5 minutes for an opening statement.

STATEMENT OF RONALD PAULUS, M.D.

Dr. Paulus. Vice Chair Griffith, Ranking Member DeGette, and members of the subcommittee, on behalf of the nearly one million patients and 12,000 Mission Health Care Givers in western North Carolina, I would like to thank you for inviting me to discuss our participation in the 340B Drug Program.

I simply cannot overstate the importance of this program in enabling what we do. Mission Health is an independent community-governed integrated health system providing services to the 18 mostly rural and mountainous counties of western North Carolina. We've earned numerous awards and achieve national recognition, including being named one of the nation's top 15 health systems in the 5 of the past 6 years by IBM Watson. Mission Health is a significant provider of medical education and training, serving as a branch campus of the UNC Chapel Hill School of Medicine and as a clinical training site for the numerous primary care residencies like family practice, OB/GYN, general surgery, and psychiatry.

Our community board members, clinicians, and staff focus each and every day on the delivery of compassionate high-quality care to everyone, without regard to their ability to pay. The

weight of our safety net responsibility is sometimes heavy but it is always real. Our patients are disproportionately older, poorer, sicker, and less likely to be insured than state and national averages, with nearly 70 percent covered by Medicare, Medicaid, or having no insurance at all.

Communities in our southern Appalachian Mountains are beautiful but they have real challenges. Globalization of manufacturing, particularly for furniture, decimated many communities. Opioid abuse is an absolute epidemic. Our infrastructure is stretched and the rugged terrain of our mountainous region adds complexity for patients in getting the care that they need. We make difficult decisions every single day to keep our regional safety net system viable. The 340B Program directly enables those crucial efforts by providing savings that we use, yes, to stretch scarce federal resources as far as we possibly can. Six Mission Health hospitals qualified for the 340B Program, based on either DSH or Critical Access Hospital status. Our use of 340B Program savings directly reflects the intent of the program. We operate the region's only tertiary-quaternary referral center. Mission is the sole provider of numerous essential services, including being the only Level II trauma center, the only Level III NICU, the only open

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heart program, the only children's hospital, the only medevac helicopters, and the list goes on.

For un- and underinsured patients, Mission Health provides robust financial assistance, including completely free care for those earning up to twice the federal poverty guidelines on a sliding scale up to 300 percent of the federal poverty guidelines.

We have also implemented a novel community investment program that identifies and funds external programs that are not Mission Health to address the most urgent, underserved health needs that serve the uninsured or are either not covered by insurance or are not reimbursed at a financially viable level. We require for those investments a real business plan, metrics, and forecasts as if it were a real investment and we are seeing real results.

In 2016, Mission Health's total value of charity and unreimbursed care was nearly \$105 million and our total community investments exceeded \$180 million. In that same year, Mission Health generated \$37.4 million in 340B savings and this year we expect to generate a little more than \$38 million. Our total charity care, up 20 percent this year over last, and bad debt alone is more than double the value of our 340B savings and those savings only represent one-fifth of our total community benefit provided

in the most recent year.

Now what are some examples? C3@356. This is a walk-in urgent care center for those with behavioral health needs that we helped fund and create on behalf of the community.

The Mountain Child Advocacy Center, which supports and treats child abuse victims and their families.

The Dale Fell Health Center, a Federally-Qualified Health Center that provides primary care to the most vulnerable in our community with a particular focus on homeless families and individuals.

The Family Justice Center, which provides wraparound services for victims of domestic and sexual violence in a trauma-informed setting.

Other services include our Children's Hospital ToothBus Program, 40-foot-long buses that go to schools to provide dental care for children and our Medication Assistance Program, which is a centralized service for all system hospitals, offering patients help with both short- and long-term, and discounted medications, one-on-one pharmacist education, and help with chronic medical conditions. That program is not limited to 340B discounted outpatient drugs and includes a Meds-to-Beds Program so people go home with their medications.

Mr. Griffith. Thank you very much.

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Mr. Reuland now for a 5-minute opening.

STATEMENT OF CHARLES REAULAND

Mr. Reuland. Chairman Griffith, Ranking Member DeGette, and members of the subcommittee, my name is Charlie Reuland and I am the Executive Vice President and Chief Operating Officer of The Johns Hopkins Hospital.

I began my career at Johns Hopkins in 1990 and have served in a variety of roles over the past 3 decades. I have the privilege to be the hospital's representative on the panel here today to share with you JHH's proud legacy of care and service to the vulnerable individuals and families made possible, in part, by its participation in the 340B Drug Pricing Program.

For many, the Johns Hopkins Hospital is synonymous with world-class research and care for patients from around the nation and world but what sometimes gets lost behind the headlines is that we were founded as and continue to be first and foremost the local community hospital for the people of East Baltimore. For 127 years, the hospital has been rooted in Baltimore, still occupying the same square block as the original historic hospital which opened in 1889.

Our history as a participant in the 340B Program is much more recent, only since 2002 but the value of the program is just as

inherent, just as vital to our mission.

Dr. William Osler, one of the four founding physicians of The Johns Hopkins Hospital once said it is much important to know what sort of a person has a disease than it is to know what sort of a disease a person has. To us, that means that the care can be provided best when we understand the life circumstances of a patient and adjust our care to optimize the results in that overall context. The great strength of the 340B Program is the discretion it affords eligible hospitals in tailoring the use of program savings to address the unique needs of our communities.

Our ability to invest in interventions both at the patient level, as well as the community level is critical to our success and improving the health of our patients in our community. And here is why: In Baltimore, nearly one in four residents live at or below the poverty level and the unemployment rate is above the national average. Jobs that pay a family's sustaining wage are scarce and one in four residents in Baltimore City lives in a food desert. JHH tailors the use of its 340B savings with these grim realities in mind.

As a safety-net hospital, we respond to emerging crises, provide ongoing care, and disease prevention for the most vulnerable patients in Baltimore and invest in improvements in

our city, all made possible in no small part by the savings afforded to us by the 340B program. We have many examples of those programs, which I will be glad to tell you more about but, in general, they fall into two basic categories of action.

The first category is providing wraparound support for patients when the normal processes of diagnosis and treatment may not be enough. Patients returning to homes without running water may have greater difficulty following through on instructions to keep wound dressings clean and sterile. Children with asthma may not be able to avoid secondhand smoke that exacerbates their breathing challenges. And a senior will have difficulty taking the correct dosage of medication, if they can't read the label because of the tiny print.

Providing wraparound services, such as in-house pharmacy visits to assure safe and appropriate use of medications means the patient has a greater likelihood of adhering to the treatment plan and having a better outcome.

The second is designing and implementing prevention strategy. Picture that proverbial cliff with people sometimes falling off. There are ambulances picking up the patients at the bottom but people continue to fall. The 340B Program allows a hospital to help install a fence at the top of the cliff to prevent

further falls and, importantly, to tackle the causes of disease and disability in our community.

With 340B savings, Johns Hopkins developed programs for expectant mothers in surrounding community, for instance, to increase the likelihood of healthy on-time deliveries, rather than wait for a low birth weight baby to require a NICU stay.

These activities are not reimbursed under the traditional hospital payment structure, yet they are inherent to our mission and are all made possible with the savings of the 340B Program.

The 340B Program has been a success in our community, allowing JHH to operate a variety of programs and provide services for vulnerable patients that improve their health and well-being that otherwise would not be possible. These efforts help avoid other, more expensive medical interventions, the cost of which would be borne in large part by Federal and State governments if funds were not -- funds, if not for the 340B Program.

Now is the time for the Federal Government to recommit to the 340B Program. The program is as relevant and vital today as it was when first enacted. The legacy of the 340B program is that today JHH, along with the national network of other

Disproportionate Share Hospitals and other 340B-covered entities are the bedrock of the national safety net dedicated to saving

788 Mr. Griffith. Thank you, very much.

789 And now for a 5-minute opening, Ms. Banna.

STATEMENT OF SHANNON BANNA

Ms. Banna. Good morning, Chairman Griffith, Ranking Member DeGette, and members of the subcommittee. My name is Shannon Banna and I am here in my capacity as Director of Finance and Systems Controller for Northside Hospital. We thank you for the opportunity to demonstrate to the subcommittee how Northside utilizes the 340B Drug Pricing Program to serve Georgia communities.

The 340B Program is critical in assisting Northside with its mission of providing high-quality health care for the entire community, regardless of anyone's ability to pay. As background, Northside is a nonprofit corporation that owns and operates and extensive network of healthcare facilities in Georgia. This includes three acute care hospitals, more than 150 ancillary and physician service site, and supportive services and facilities located throughout Georgia. As one of the State's largest and most respected healthcare delivery systems, Northside offers a full range of services through over 2.5 million patient encounters each year.

As the undisputed national leader in maternity services,
Northside Hospital Atlanta delivers more babies than any other

single hospital in the nation. Our neonatal intensive care unit treats as many 100 premature and high-level special care babies each day.

Northside Center for Perinatal Medicine offers
nationally-recognized expertise and innovation in maternal fetal
medicine and diagnostic radiology.

We are also one of the largest and most respected providers of cancer care in Georgia, diagnosing and treating more gynecologic and prostate cancer cases than any hospital in Georgia and more breast cancer cases than any hospital in the southeast.

The Northside Blood and Marrow Transplant Program has among the highest survival rates in the nation and is recognized as a premiere program throughout the southeast.

The Northside Hospital Cancer Institute is one of only 21 community cancer programs nationwide selected by the National Cancer Institute for participation in the National Cancer Institute's Community Oncology Research Program. Selection criteria included scope of patient reach and overall comprehensive delivery of high-quality patient care.

Northside treats all patients the same, regardless of insurance and regardless of their ability to pay. No patient is ever turned away due to the inability to pay for their healthcare.

In the past 5 years, we have provided almost \$1.4 billion in free or discounted care. In 2016 alone, the system provided \$370 million in free or discounted care into our patient community.

From 2012 'til 2016, Northside Atlanta's provision of charity and indigent care grew at a rate 63 percent greater than our increase in hospital adjusted gross revenue. During the same period, the number of distinct patients receiving charity care at Northside Atlanta increased 350 percent.

This free and discounted care encompasses a wide range of service for those in need and makes comprehensive care available to a greater number of patients. For example, Northside offers free and low-cost educational courses on topics related to maternal and infant health, with over 700 available classes. In 2016, 18,500 individuals accessed Northside's free breastfeeding eLearning program. More than 31,000 women used our free Lactation Support telephone hotline.

In addition to providing audiology screening for all newborns and hearing screenings for many school children, we provide numerous free preventative health screenings to adults as well, including prostate cancer screening, skin cancer screening, and stroke screening.

Northside also operates a Financial Access Surgery Program

to provide radiology, cancer, and related surgical services to the uninsured and underinsured who are not otherwise able to afford medically-necessary outpatient care.

In recent years, Northside has worked hard to make state-of-the-art cancer care accessible to more patients in more locations. We offer cutting edge oncology drugs to all patients, regardless of their ability to pay. We have expanded and enhanced oncology care by adding more than 250 full-time positions in and in support of our oncology clinics. These positions provide services such as financial assistance, wellness counseling, nutrition, navigation, clinical research, and much more.

Northside Atlanta qualifies for participation in the 340B Program because of our disproportionate share of indigent and low-income inpatient days, currently running at approximately 16 percent of total inpatient days.

Northside started our 340B Program in 2013 under the guidance and oversight of our 340B Steering Committee and then independent third-party consultant. In addition to constant oversight by the Steering Committee, which encompasses individuals from several departments of the hospital, our 340B Program undergoes frequent and rigorous internal and external auditing and monitoring.

In 2016, Northside underwent an audit by HRSA, which

confirmed Northside's compliance with 340B Program requirements. Following a thorough review of the 340B Program, HRSA found a single instance of inadvertent diversion, representing less than \$7.

Northside is proud of our commitment to charity and the services we provide to our community, the extent of which is made possible through 340B savings. We appreciate the opportunity to provide this information and we look forward to answering your questions.

[The prepared statement of Shannon Banna follows:]

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890 Thank you very much to all of our witnesses. Mr. Griffith. At this point, I ask unanimous consent that the contents of the 891 document binder be introduced into the record and to authorize 892 893 staff to make any appropriate redactions. Without objection, the documents will be entered into the 894 895 record with any redactions that staff determines are appropriate. 896 [The information follows:] 897 898 *********COMMITTEE INSERT 6******

Mr. Griffith. And with that, we will go to questions. I recognize myself for 5 minutes.

And I would ask each of the witnesses how did you calculate your 340B savings. Is it an estimate or a precise amount? And if it is an estimate, what information do you need that you do not have in order to accurately calculate your savings?

And as position has it, we will start of this end of the table with Ms. Veer.

Ms. Veer. Thank you, Mr. Chair, for the question.

Our savings for 2016 were \$561,620 and if my CFO were here, he would probably give you the change. But I will say that there may be other ways to calculate 340B savings but for my health center it has been that margin remaining after the sale of the drug. We manage all of our programs using profit and loss statement specific to that program or to that site. And so it is an exact number based on the net margin after the sale of all drugs.

Mr. Griffith. All right, thank you very much.

Mr. Gifford.

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Mr. Gifford. Thank you, Mr. Chairman.

We calculate our 340B savings in a very direct and simple way, the cost of the medication at a non-340B rate less the cost

-	of the 340B medications. It is the difference between the two
2	costs that we use.
3	Mr. Griffith. Thank you, sir.

Dr. Paulus.

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Dr. Paulus. Thank you.

We calculate our savings in two ways. One, with respect to drugs that we get through our wholesaler, we calculate those based upon the difference between the discounted price and what our GPO price is. And for contract pharmacies, our 340B vendor calculates them based upon the discount.

Mr. Griffith. All right.

Mr. Reuland.

Mr. Reuland. Thank you, Mr. Chairman.

Yes, we calculate the GPO price versus the 340B price and use that differential as our savings.

Mr. Griffith. All right.

Ms. Banna.

Ms. Banna. We also calculate the 340B price per unit of drug and compare that to the price in the non-340B locations.

Mr. Griffith. Are those savings earmarked for specific programs or are they channeled to a general fund?

And we will start on this end this time so that we try to

943 be more fair. Ms. Banna.

Ms. Banna. We monitor our savings first and foremost and then, separately, we focus on growth and expansion of charity and indigent care, and additionally expansion of oncology services, and other services that our community is looking for.

Mr. Griffith. But I guess the question is is it earmarked for those programs or does it go into a general fund and then those are the things that, as a part of your institutional mission you go forward with?

Ms. Banna. They aren't earmarked. They are tracked and monitored and then our growth is tracked and monitored. And we do ensure that our growth far exceeds the savings.

Mr. Griffith. Thank you.

Mr. Reuland.

Mr. Reuland. We invest in a variety of different programs that are for community benefit using our savings. And they vary in size and range and for different kinds of patient types.

Mr. Griffith. But are they earmarked or does it go into a general fund and then that is part of your general mission? That is what I am trying to sort out.

Mr. Reuland. One way maybe to think about it, perhaps, is that there is not really a check that comes back, if you will.

This is a lower price paid. So there isn't a check that comes back that then you have the opportunity to say where it goes. This is a reflection of paying less for a drug than you otherwise would pay.

So there is not really a budgeted amount that you could say that is what you are going to put in each of these buckets.

Mr. Griffith. All right.

Dr. Paulus.

Dr. Paulus. To directly answer the question, there is not a dollar-for-dollar tracking no more than there would be an earmark for a tax dollar that I might pay in income tax.

But on the other hand, we track very closely our savings. We know those savings and when we are preparing our budget for each year, we include those dollars in the charity care allocations in all of these programs.

So I would say that yes, they are targeted but not literally dollar-for-dollar.

Mr. Griffith. Okay and when you say that, so when you are doing your budget, you actually have a line in your budget that says 340B savings and then they go out in these different directions.

Dr. Paulus. Yes, we do.

Mr. Griffith. All right, thank you.

Mr. Gifford.

Mr. Gifford. In our budgeting process, we identify the savings that we anticipate in the coming year and we direct it to the pharmacy, health, and social services that I discussed in my testimony.

Mr. Griffith. Thank you.

And Ms. Veer.

Ms. Veer. I would have to echo my colleagues to some degree. It is not an exact line item transfer dollar-for-dollar from one cost center to another cost center, but at the beginning of the year, as part of both the budgeting and the strategic planning process, we estimate what we anticipate those savings to be and then look at what programs they can fund, what otherwise unfunded programs they can fund.

Then at the end of the year, we do an annual report to our Board of Directors linking those two together.

Mr. Griffith. I appreciate that. I like the concepts that both Dr. Paulus and Ms. Veer -- that doesn't mean the others are not doing it right -- but I kind of like those because then somebody can actually take a look at it and see what you are doing with it directly.

1009	But I appreciate that and now I yield 5 minutes to Ms. DeGette
1010	for her questions.
1011	Ms. DeGette. Thank you very much, Mr. Chairman.
1012	I will just skip around. Dr. Paulus, I would like to ask
1013	you, yes or no, Mission Health reported to the committee that it
1014	saved about \$37 million through 340B in 2016. Is that correct?
1015	Dr. Paulus. I believe that is correct.
1016	Ms. DeGette. Thank you. And Mission Health spent more than
1017	\$183 million providing community benefits, including \$105 million
1018	in uncompensated care. Is that correct?
1019	Dr. Paulus. That is correct.
1020	Ms. DeGette. Now, Dr. Reuland, a similar question. In
1021	2016, Johns Hopkins generated about \$109 million in 340B savings.
1022	Is that correct?
1023	Mr. Reuland. Yes.
1024	Ms. DeGette. And Johns Hopkins provided nearly \$220 million
1025	in charitable care for vulnerable populations and other vital
1026	community benefits. Is that correct?
1027	Mr. Reuland. Yes.
1028	Ms. DeGette. No, Ms. Banna, your hospital, Northside,
1029	reported that it generated nearly \$53 million in 340B savings.
1030	Is that correct?

1031	Ms. Banna. That is correct.
1032	Ms. DeGette. And yet Northside reported to the committee
1033	that it spent nearly \$370 million in charity care. Is that right?
1034	Ms. Banna. That is right.
1035	Ms. DeGette. Now, let me just say the 340B Program doesn't
1036	seem to be some windfall that subsidizes bonuses for senior
1037	management but, as you all testified both in your written
1038	testimony and in your verbal testimony today, you are using this
1039	money to help provide essential benefits that the community needs.
1040	So I want to ask each of you if you can briefly describe what
1041	would happen if Congress eliminated the 340B money. I will start
1042	with you, Ms. Veer.
1043	Ms. Veer. Thank you because that is a wonderful question.
1044	It really gets to the heart of what we are all concerned about
1045	and our need for Congress to have confidence in the integrity and
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1047	Ms. DeGette. If you could just briefly
1048	Ms. Veer. Sure.
1049	Ms. DeGette describe some of those services. We,
1050	unfortunately, only have 5 minutes and I would like to hear from
1051	everybody.
1052	Ms. Veer. Absolutely. The delivery service that I

mentioned that is delivering over 20,000 prescriptions to outlying rural areas would have to be eliminated because those costs are directly covered by the 340B savings, as would our in-house behavioral health counseling for people who don't receive care, or would not qualify for care, or experience delays in the mental health agency.

Ms. DeGette. Thank you.

Mr. Gifford, can you give me some examples?

Mr. Gifford. Elimination of the 340B Program would substantially undermine the fight against AIDS. It would mean fewer resources, fewer services. Our patients would become more ill. They would not have an undetectable viral load. There would be new and more HIV infections and, sadly, far bigger health care costs.

Ms. DeGette. All right, let me ask you why that is. What are the services that you provide that you would not be able to provide without this savings?

Mr. Gifford. Certainly, we would not be able to provide as much medical care for uninsured patients, dental care, mental health therapy and drug treatment.

Ms. DeGette. Dr. Paulus?

Dr. Paulus. Yes, I would go back to Vice Chair Griffith's

question, which is how we approach our budgeting. So we are going to expect to earn about \$38 million this year. As we look out into next year, we would have to cut \$38 million worth of programs. Those programs would be prioritized but might include -- for example, 10 to 12 percent of our NICU babies are opioid addicted. We developed a novel detox program so that those babies can be detoxed at home. That costs us over \$3 million a year to detox them at home and that might be something but we would sure as heck be cutting some very needed programs.

Ms. DeGette. Mr. Reuland?

Mr. Reuland. Thank you. An example of a program that we might not be able to offer would be something our Broadway Center, we call it, provides. It is substance abuse recovery treatment. And we provide supportive housing for patients who are enrolled in that program because if you send patients back to the same environment from which they came, even really great daily care isn't going to help them escape --

Ms. DeGette. What do they do in this Broadway program?

Mr. Reuland. So there is counseling. There is medication treatment, typical kinds of treatment for substance abuse treatment and recovery. And the supporting housing is a good example of the wraparound project that we provide so that we don't

send folks back to the environment from which they came initially while they are trying to recover. That is the kind of thing — that is a half a million dollars plus for us that we would have to take out that is an investment we make.

Ms. DeGette. And Ms. Banna.

Ms. Banna. You know immediately our organization's resources would be directed to offsetting the substantial drug price increases that we all experience annually. In doing so, the reduction of resources would slow our ability to provide additional services. So in our case, the 250 positions that we put in our oncology clinics that were not there before, either social workers, nurses, supervisors, research staff, care navigators, nutrition, genetic counselors, that pace would slow down. Those positions might not be funded, in addition to financial assistance directed directly to patients.

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

Mr. Griffith. The gentlelady yields back.

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

The Chairman. I appreciate it.

I served on a hospital board for 4 and 1/2, 5 years. Nobody, first of all, if talking about eliminating 340B Program. So,

everybody breathe.

Second, I have got to tell you I think when the average

American hears what you would cut, not a one of you said any

overhead, capital construction, salary bonus. It was infants

trying to recover from opioids is the first thing. Really?

I mean I have owned and operated a business -- I will leave it.

We have had a lot of different ways we have heard about how the money you get out of this program is tracked to do charity care. Carolina Health Centers reported spending \$4.8 million in charity care in 2016. That represented 21 percent of the total patient revenue. Johns Hopkins Hospital reported \$28 million in charity care and nearly \$200 million on community benefit activities in 2016.

Northside Hospital reported that from 2015 to 2016,
September to August, it served over 32,000 distinct indigent and charity care patients, and reported spending \$350 million on charity care in 2016, putting its charity care at about seven percent. Yet, a 2017 Atlanta Journal Constitution article estimated Northside's charity care at 1.7 percent of total expenses for 2016, based on Northside's cost reports filed with the Federal Government. This makes it a little hard to do apples

to apples comparison of whether covered entities are truly using 340B savings to improve patient care.

So to each of you, what do you think is the best measure to estimate an entity's commitment to serving low-income and uninsured individuals? Do community benefit programs serve only low-income and uninsured patients or the entire community, including those with commercial insurance? Would a patient receive one element of care for free, at a reduced cost, be counted as one of those patients? I mean how do we track this? That is what we are trying to figure out here.

The Government Accountability Office I think or the IG told us there is no clear definition what a patient is. There is no requirement to track. This program has expanded dramatically around the country.

We are trying to figure out are the people who are supposed to get the help actually getting the help. So can you help us understand what the best measure is to estimate an entity's commitment to serving low-income and uninsured individuals?

Ms. Banna, we will just start with you.

Ms. Banna. Absolutely. I do think industry standard is not to reflect the provision of care to the vulnerable population of the percent of just operating expenses, which is what was done

in the AJC article. I would say that is inaccurate or at least incomplete. When comparing to expenses, you are including things like overhead, and telephone, and depreciation on your buildings.

So we would emphasize other more commonly quoted mechanisms, which would be the provision of charity and indigent in terms of total patient revenues or distinct patient served and those are the ways that we quoted in our submissions.

Mr. Reuland. Mr. Walden, one of the things I might mention is when we set up programs, we tend to set them up from a clinical perspective to manage a disease state or a population with a disease. And so an example might be sickle cell anemia and sickle cell disease is a disease that you may know disproportionately affects African Americans. And we have set up a very comprehensive program, the only one in the region to manage those kinds of patients.

We can't really set it up with different sort of swim lanes for payer capability. People move in and out of insured status throughout their life, as you might imagine. And so what we set up is a clinical program to care for them in whatever state of care they need and then try to support around that whatever the insurance needs are.

Dr. Paulus. First with respect to your comment, which I

respect you have perspective on that, I did not say that we would not detox babies. What I said was we developed a program that saved the Medicaid program \$3 million by detoxing them at home and we would probably have to revert back to inpatient care.

Second, we do every single day, or we would already be closed, the overhead, capital projects, et cetera. So, that is a routine part of our business.

I would point you, perhaps, to the idea behind Schedule H for the IRS filing and the community benefit. I think there might be opportunities there to define and identify a specific reporting. I would think about total unreimbursed care because that is really what we are talking about here.

And those are my thoughts.

Mr. Gifford. Ryan White grantees may have a slightly less complex financial world that we operate in. We welcome the opportunity to report the savings and how they are directed to specific costs for the delivery of care.

Ms. Veer. I think the term or concept of charity care is one that is not terribly familiar for community health centers or in the community health center world, not because we don't understand that concept but because we operate under a set of statutory requirements that essentially mean we are on the hook

for taking care of everyone, regardless of their ability to pay, 1207 and for providing a full range of services, regardless of their 1208 1209 ability to pay, and have been for decades. 1210 So my health center, the \$4.2 million that is listed as 1211 charity care really represents the cost of all care provided to 1212 patients for which we receive no compensation. 1213 And I will give you an example. If a patient qualifies for 1214 our nominal fee, it is \$10 for a visit, which might encompass a 1215 99205 visit, so a complex visit, plus radiology, plus lab work. 1216 And for that, we are receiving \$10. 1217 So the health centers do have a very concrete way of measuring 1218 that. 1219 The Chairman. I appreciate that and I thought your initial 1220 answer in the beginning about how much you account for was spot 1221 on. So, thank you. 1222 Mr. Griffith. Thank you very much for yielding back, Mr.

Mr. Griffith. Thank you very much for yielding back, Mr. Chairman.

I now recognize the ranking member, $\operatorname{Mr.}$ Pallone of New Jersey.

Mr. Pallone. Thank you, Mr. Chairman.

I have been impressed with the responses the committee has received with its inquiries about how covered entities use the

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340B Program and it appears that recipients rely on program savings to provide important services to vulnerable patient populations.

But I just want to briefly go with each of you, if I could, if you can just answer my question in 30 seconds.

Mr. Gifford, your testimony states that the AIDS Resource Center of Wisconsin received \$7.4 million in 340B discounts last year and that these savings played a crucial role in providing service to your patients. Can you explain in 30 seconds how the 340B Program helps you provide services?

Mr. Gifford. Certainly. They support the cost that Ms. Veer was discussing in terms of the professional time providing medical care, the laboratory costs, the medications that uninsured patients receive.

And then for our physicians, they often talk about health care needed is overcoming the social barriers to care. So, making sure that mental health illnesses and drug addictions are addressed before they can get into the medical exam room.

Mr. Pallone. Thank you.

Now to Mission Health. Dr. Paulus, you reported that Mission Health provided \$105 million in charity and unreimbursed care. You also reported that Mission Health's community benefits

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were worth \$183 million that year.

In 30 seconds or less, how does the 340B Program help you provide services?

Dr. Paulus. Well, we are faced with a tsunami of illness and of need in our community. And as I described, we take our anticipated savings on 340B and specifically look to allocate those to funds to programs that we could otherwise not afford to provide.

So there is a great amount of detail in our testimony in the written document about each of those program.

Mr. Pallone. All right, next, Johns Hopkins. Dr. Reuland, you reported that Johns Hopkins provided \$28 million in charity care and community benefits worth \$191 million. Briefly, how does the 340B Program help Johns Hopkins provide services to the community?

Mr. Reuland. So I will give you just two very quick examples, one that is in our community benefit report and one that isn't.

In the community benefit report, the Health Leads Program is an opportunity for us to prescribe basic things like food, shelter, clothing, utility support for patients who need it. And that can be for any disease state. That is a general concept that

we use in a lot of our outpatient areas.

More broadly, we have done a development exercise in the region right north of our campus that is a partnership with the city and some developers to basically take an old burned out part of the city and redevelop it in a way that we would be happy to tell you more about. But it is those kinds of city building and infrastructure-building activity that are on the broader scale.

Mr. Pallone. Well, thank you.

And then moving on to Carolina Health Centers, Ms. Veer, you state in your testimony the 340B savings enable Carolina Health to provide services that would otherwise go unfunded.

In a minute or less, how does that work?

Ms. Veer. Well first and foremost, I will read a quote out of my written statement that was from one of my most senior medical providers. To diagnose when the patient has not access to affordable medication is always an exercise in futility and, in some cases, it is an announcement of a death sentence.

So first and foremost, it allows us to make essential prescription medications available to low-income patients who otherwise would not have any access to their medication.

Mr. Pallone. All right, thank you.

And then last, Ms. Banna, Northside Hospital reported that

it provided nearly \$370 million in charity care, as well as community benefits such as oncology, patient assistance, maternity education, surgical services for the uninsured. Do you want to explain to us how 340B helps you provide those services?

Ms. Banna. Absolutely. I think in its most simplest form, 340B reduces our costs. And as a nonprofit hospital, that is what we strive for each and every day. Reducing our costs fuels our

ability to expand our mission into our communities. And you are hearing from each of us that our missions are different but we

use that savings to empower growth out into the communities that

1306 Mr. Pallone. All right, thanks.

we serve.

I wanted to ask anyone how you make sure the savings actually go to help patients. I know 30 seconds, maybe I will go back to Mr. Reuland.

Mr. Reuland. Well, there are plenty of very direct assistance programs, including a Pharmacy Assistance Program, for example. Patients who show up and if you walk to one of our clinics and they say I cannot pay for my medications or a copayment for them, we have the discretion through a Pharmacy Assistance Program on the spot to make sure that the patient can leave with the medications that they needed. And then we can help them after

that to perhaps connect them to some other form of payment going on over time or, sometimes, we continue supporting that right through these dollars.

Mr. Pallone. That is a good example.

Thank you, Mr. Chairman. Thank you all.

Mr. Griffith. The gentleman yields back.

I now recognize Mr. Walberg of Michigan.

Mr. Walberg. Thank you, Mr. Chairman and thanks to the witnesses for taking the time to be here with us today.

I want to get to the concerns about the savings that you have had that you have talked about today. I also want to ask some questions relative to how you train and evaluate the success of the program, the costs, et cetera, how you administer it. But I think our chairman brought up some points I would like to go into first and meddle a little bit, I guess, at this point, kind of get personal.

I pulled the 990s of each of your organizations for the most recent years that we are able to get to, 2015. So let me ask you just to respond yes or no, correct or false to these questions.

Ms. Veer, Carolina Health Centers indicated that the salary for the CEO was \$198,000. Is that correct?

Ms. Veer. That is correct.

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1339	Mr. Walberg. Mr. Gifford, for the AIDS Resource Center, it
1340	was indicated that the salary for the CEO was \$350,000. Is that
1341	correct?
1342	Mr. Gifford. That is cash compensation, yes.
1343	Mr. Walberg. Okay, cash compensation. Okay.
1344	Let me ask Mr. Paulus, Mission listed at \$1.6 million,
1345	approximately.
1346	Dr. Paulus. I assume that is correct.
1347	Mr. Walberg. Okay. Mr. Reuland, Johns Hopkins lists for
1348	that year \$2.6 million.
1349	Mr. Reuland. I also have to assume that is correct.
1350	Mr. Walberg. Okay and then Ms. Banna, it is listed for
1351	Northside at \$2.8 million that year.
1352	Ms. Banna. That is correct.
1353	Mr. Walberg. Okay. Let me plumb a little bit more here.
1354	Going back to the net assets for each of your organizations at
1355	the end of 2015.
1356	Northside, Ms. Banna, \$1 billion net asset; net income \$157
1357	million.
1358	Ms. Banna. That is correct.
1359	Mr. Walberg. Is that correct?
1360	Mr. Reuland, Johns Hopkins listed at \$1.3 billion; net income

	Committee's website as soon as it is available.
1361	\$80 million, almost \$81 million.
1362	Mr. Reuland. That is correct, about a 3.6 percent operating
1363	margin.
1364	Mr. Walberg. Okay. Mr. Paulus, Mission is listed at \$1.4
1365	billion; net income \$101-102 million.
1366	Dr. Paulus. Sounds right.
1367	Mr. Walberg. Okay. Mr. Gifford, your AIDS Resource Center
1368	\$12.7 million.
1369	Mr. Gifford. That sounds correct and it is just a fraction
1370	of what our financial advisors are suggesting necessary to assure
1371	longevity.
1372	Mr. Walberg. The net assets of \$12.7 million.
1373	Mr. Gifford. Correct.
1374	Mr. Walberg. Ms. Veer, Carolina Health Centers, \$7.7
1375	million net assets?
1376	Ms. Veer. That sounds correct, yes.
1377	Mr. Walberg. Okay. I just wanted that for the record.
1378	Again, there are certainly explanations, and extenuating
1379	circumstances, and other things that I am sure you can share with
1380	us on those issues but it is good to have those factors in,
1381	especially when we are talking about entities listing saving over
1382	\$100 million annually through the program.

The program has grown rapidly in the last decade and it seems it will continue to grow. So, those figures are important.

In the area of education, let me ask you each to respond. First of all for the sake of context, how many full-time employees do you have total? And secondly, how many employees of those full-time employees do you have devoted fully to 340B administration and compliance?

Ms. Veer?

Ms. Veer. In our most recent Universal Data System report to HRSA, we reported 231.20 full-time employee equivalent. Of that, 45.40 are pharmacy employees. And since approximately 50 percent of our business in the pharmacy is 340B, I would estimate that our pharmacy staff devoted to 340B is approximately 25.

Mr. Walberg. Twenty-five, okay.

Mr. Gifford?

Mr. Gifford. ARCW has 240 employees, about 25 of them who work in our pharmacy. 340B is the largest part of our pharmacy operations so, they are all devoted to it. Additionally, we have a compliance department that includes two full-time employees and parts of six other employees.

Mr. Walberg. Mr. Paulus?

Dr. Paulus. We have two dedicated full-time people who do

noth	ing	but	340B	and	76	oth	iers	that	hav	7e 3	840B	as	part	of	thei	Lr
job	desc	cript	cion,	incl	udi	ing	five	e peop	ole	who	hav	7e <u>c</u>	gone	thro	ugh	а
comp	lete	e 340	OB uni	ivers	sity	y tr	aini	ng.								

- Mr. Walberg. Total employees how many?
- Dr. Paulus. Twelve thousand.
- Mr. Walberg. Twelve thousand total employees.
- Mr. Reuland?

Mr. Reuland. Johns Hopkins Hospital employs about 10,000 FTEs directly, not counting our physicians. And we have about nine to ten whose effort is primarily dedicated toward the program, significantly toward the compliance of the program.

Mr. Walberg. Okay and Ms. Banna?

Ms. Banna. We have over 14,000 employees. We have an integrated approach. There are people in multiple departments across our hospital that have been educated and we consider content experts. Fifty to seventy-five people are educated in content experts. I would say the pharmacists are most directly full-time 340B-responsible. So that is probably 25 to 25.

Mr. Walberg. Thank you. I yield back.

Mr. Griffith. The gentleman yields back. I now recognize Ms. Castro of Florida for 5 minutes for questions.

Ms. Castor. Thank you, Mr. Chairman. Based upon what I

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have seen from my hospitals, and providers back home, and the testimony today, I think it is clear that the 340B Program is critical to America's healthcare safety net. And according to HRSA, 340B savings represent less than two percent of total drug spending in this country but the benefits here under 340B are so broad where you are able to expand health services, you are able to see more patients, offset losses from uncompensated care.

And at a time when drug prices are skyrocketing across the board for consumers, here is one bright light for our neighbors back home. And I have seen it at Saint Joseph's Hospital. It is part of the BayCare Health System. They provide over \$100 million in charity care per year, about, and 340B has helped them save about \$17 million.

They run the Children's Hospital there, a complex clinic for the medically fragile. And what they are able to do with wraparound services, as has been mentioned, is remarkable.

They have had to expand substantially behavioral health and substance abuse services and that is where part of the savings go. And we are all grappling with that.

And they have a care clinic that stretches the federal Ryan White funding to support a continuum of care to maintain a higher retention rate for HIV patients achieving viral suppression,

which is vital for the future.

And Tampa General Hospital is our teaching hospital for the University of South Florida. It is our Level I trauma center. They provide about \$78 million in uncompensated care. 340B has helped them save about \$35 million. And I have seen what they have been able to do as the Congress has said we are going penalize the hospital if patients are readmitted after discharge. I have seen what they have been able to do on an innovative basis to really make sure patients at discharge have the prescriptions they need and it has largely been through the 340B savings that they have been able to achieve that.

So, Dr. Reuland, Johns Hopkins recently expanded to the All Children's Hospital in the Tampa Bay area. We are grateful for that, as you raise the standard of care there.

In your written response to the committee's letter, you suggest that the total amount of free and discounted care provided you can't just look at pure charity care but also at the services provided to the community to help vulnerable populations. I have seen this working. I have seen providers become more innovative. Is that a fair understanding of how Johns Hopkins measures its commitment to the community?

Mr. Reuland. Yes, I appreciate you pointing that out. And

I also appreciate you pointing out that the growth in savings is really a reflection of the growth in our spend of drugs.

And so to give you our experience, our drug spend grows between eight to ten percent a year over the past 5 years, oncologics, new therapies, immunotherapies, and in some cases just explained drug inflation that we can't explain. We had seven very common drugs, the price of which went up 312 percent with volume going up 12 percent. And one of those drugs is commonly found on a crash cart, a cart that we use to resuscitate patients.

So the drug spend growth is what leads the savings growth for us and that is a big part of it.

Ms. Castor. And there is an important qualifier. If someone just tuned into this hearing, they would say wow, what is happening here but HRSA and the parameters that the Congress has put into law over time says these covered entities are a real subset of providers across the country. Can you explain that a little further? What is the covered entity gateway to qualify for 340B?

Mr. Reuland. If I understand the question, we qualify by virtue of being a DSH hospital. Our percentage DSH is about 19 percent.

Ms. Castor. DSH hospital for someone that is tuning in --

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Mr. Reuland. Disproportionate share of our patients come from an underserved and have a social security disability eligibility.

Ms. Castor. You are saying a disproportionate share of our neighbors back home who don't have health insurance coverage or they are underinsured.

Mr. Reuland. Yes.

Ms. Castor. And Ms. Banna, in Georgia, you are kind of in the same boat as the State of Florida. Georgia did not expand Medicaid coverage, like Florida. Our uninsured rate is about 13 percent. I think it is about that in Georgia. Is that right?

Ms. Banna. I believe it was nine percent most recently.

Ms. Castor. Most recently nine percent. So you know these disproportionate share providers and our community health centers are seeing so many folks who just do not have the ability to pay. And what you are able to do with these savings is pretty remarkable.

But let me ask you this, Ms. Banna. There are all sorts of -- this goes back to what Dr. Paulus said, the tsunami of need. Should we be looking at purely charity care provided to uninsured individuals or the total uncompensated care borne by hospitals, including bad debt and losses on Medicaid? In Florida we are

looking at a governor that wants to slash the reimbursement rate yet again. That is going to make it even more difficult to provide the care that our neighbors need.

Ms. Banna. I agree. Dr. Paulus brought this up earlier. Uncompensated care is measured on the IRS 990, which is the Schedule H is used as a reliable method for quoting the complete view of the uncompensated care that a healthcare entity is providing to its community.

In responding today, Northside chose conservatively to respond to only the indigent and charity care that we provide, simply because --

Ms. Castor. You didn't include bad debt?

Ms. Banna. We didn't include bad debt and we didn't include other elements of uncompensated care, which includes the care that is not covered that is provided to Medicare and Medicaid beneficiaries.

There are entire other populations of care that is provided effectively free to the community.

Ms. Castor. Thank you very much.

Mr. Griffith. The gentlelady yields back.

I now recognize Mr. Costello of Pennsylvania for 5 minutes for questions.

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1537	Mr. Costello. Thank you, Mr. Chairman.
1538	To each witness, the 340B Program provides covered entities
1539	with discounts on prescription drugs. Does your entity provide
1540	all 340B patients with discounted prices on prescription drugs?
1541	Ms. Veer. Starting on this end, I am assuming. Yes, we do,
1542	according to the rules, HRSA rules, around our sliding fee scale.
1543	Sliding fee is required. A sliding fee program is required for
1544	all services that we provide.
1545	So in my organization, the price to a patient under 200
1546	percent of poverty is based on the 340B discount price plus a
1547	deeply discounted dispensing fee.
1548	Mr. Costello. Does your entity provide uninsured or
1549	self-pay 340B patients with discounted prices on prescription
1550	drugs?
1551	Ms. Veer. Yes.
1552	Mr. Costello. Mr. Gifford.
1553	Mr. Gifford. Yes, we do. We operate under a comparable
1554	sliding fee scale that FQHCs
1555	Mr. Costello. Yes to both those questions?
1556	Mr. Gifford. Yes.
1557	Mr. Costello. Dr. Paulus?
1558	Dr. Paulus. Yes, we don't always know who is 340B-eligible

at the time of service but we provide, as I said, free care up					
to 200 percent of the federal poverty guidelines. And we have					
the Medication Assistance Program that provides free or					
discounted drugs to all of those patients.					

Mr. Costello. Okay, Mr. Reuland.

Mr. Reuland. Yes, our Pharmacy Assistance Program applies to any patient, whether uninsured, underinsured. If they can't afford their coinsurance and their copayments, we use our Pharmacy Assistance and Charity Care policies to help cover them.

Mr. Costello. Yes to both questions?

Mr. Gifford. Yes.

Mr. Costello. Ms. Banna?

Ms. Banna. Yes to both questions. If you qualify for indigent or charity care, then we are looking for opportunities to provide that.

Mr. Costello. Okay, back to Ms. Veer. Does your organization use patient assistance programs offered by biopharmaceutical companies or other entities to help lower the cost of prescription medicines for patients?

Ms. Veer. Yes, we do.

Mr. Costello. What percentage of your patients have free -- receive free medicine from a patient assistance program that

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1581	is offered by a biopharmaceutical company or other entity? What
1582	percentage?
1583	Ms. Veer. I don't have that exact percentage at my
1584	fingertips.
1585	Mr. Costello. Do you have that, though, the answer to that,
1586	in terms of the percentage?
1587	Ms. Veer. I could obtain that but I don't have it in my
1588	documents.
1589	Mr. Costello. Mr. Gifford?
1590	Mr. Gifford. Yes, we use financial pharmacy assistance
1591	programs and I could obtain the percentage of patients that
1592	utilize them for you also.
1593	Mr. Costello. Dr. Paulus?
1594	Dr. Paulus. We do, from time to time, use that. I do not
1595	know what the percentage is. I could try to find out.
1596	Mr. Costello. Mr. Reuland?
1597	Mr. Reuland. Yes, we do use those programs. I don't have
1598	that percentage here. And we also use foundations and other
1599	not-for-profits.
1600	Mr. Costello. Ms. Banna?
1601	Ms. Banna. We do have an Oncology Patient Assistance
1602	Program. Forty-nine million of care was identified specifically

to oncology patients that is completely separate from charity and indigent care. So needs beyond say means tested, \$31 million of that represented free drugs that were supplied by vendors. So some of the full-time equivalent of people that I mentioned that we have hired work to contact vendors directly and identify programs to supply drugs free to these patients.

Mr. Costello. Okay. So another line of inquiry here.

I served on the hospital board for a little while. I also served as a county commissioner. The best thing was flexible funding. When you had a funding stream that you were able to sort of figure out where to fill in the gaps that didn't have a lot of reporting requirements, that wasn't subject to an audit that sort of froze where or when you could use the money, that was always preferable to a funding stream that had attachments to it that required an audit.

And I think the concern here, everybody supports 340B.

Okay? I look at all of you. You are in it for the right reasons.

You want to do good. You are helping people. Totally onboard.

I think the concern, as I read through the materials is that with the 340B funding does not necessarily come the type of accounting accountability that enables us to audit, to ensure that the money is being spent in those programs and in the ways with

which it was intended. And so when we read that while we weren't able to unearth through an audit whether compliance was in fact successful or not as a consequence of us not being able to audit, it causes a great deal of frustration and we want to fix that.

Mr. Gifford, as I understand it, you have -- let me make sure I have this right, have you developed software to monitor compliance?

Mr. Gifford. Yes, we have.

Mr. Costello. Okay. Are all of you familiar with the software that he has developed to monitor compliance?

Do any of you object to creating an accounting mechanism so that as you get this funding, it is able to be audited in a way which comports with us being able to ensure that you have 340B compliance? I think that that is the gist of it, as I --

Do you have concerns? Ms. Veer.

Ms. Veer. Yes, I was just going to say I do think, at least for -- I can only speak from the perspective of a HRSA grantee but from that perspective, one of our grant conditions is that we are required to use all program income, including what is generated outside of the grant, for the purposes of advancing our HRSA scope of projects. So we do have a reporting mechanism for accountability.

And in terms of our pharmacy, from the compliance standpoint,
we audit daily to ensure that the program is being used
specifically for 340B patients.

Mr. Reuland. Yes, I would add it sounds like there may be two issues, is the compliance with meeting the requirements and I think the software program. I am not sure which one you are referring to there but we use one as well to assure that we only avail ourselves of a discount for the appropriate patients. And that is an important part of the program.

Anything that would curtail the flexibility, as you said, of our ability to invest in that entire patient would be a challenge I think. So we would look at a policy proposal but the flexibility remains the most important thing, as you pointed out.

Mr. Costello. I yield back. Thank you, Mr. Chairman.

Mr. Griffith. I thank the gentleman. The gentleman yields back.

I know recognize Ms. Schakowsky -- Ms. Clarke has just walked in. Are you ready to go, Ms. Clarke?

Ms. Clarke. Yes, I am.

Mr. Griffith. All right, then Ms. Clarke of New York.

Ms. Clarke. Thank you very much, Mr. Chairman and I thank our Ranking Member DeGette. I thank our expert panelists for

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their testimony here today.

I understand that a lot of the questions my colleagues about this program relate to whether providers are using their 340B benefit to stretch scarce federal resources as far as possible to help low-income patients.

As I understand the purpose of the 340B Program, Congress intended to provide a financial benefit to qualifying providers who treat high volume of low-income, Medicaid, uninsured, and underinsured patients so they are able to provide services to these populations.

I hear frequently from hospitals in my district about how they are able to provide services to low-income patients in my district because of the 340B Program. For example, NYU Langone Health has invested 340B funds in several areas in my district, in particular, at the Family Health Center and four school-based health centers. 340B funds were used to implement at the Family Health Center and the school-based health centers the same electronic health system that is used at NYU Langone Health for all its hospitals' and physicians' offices so that when one of their patients goes to the NYU Langone Hospital-Brooklyn, after being seen at the Family Health Center, there is a full record of the treatment that patient received at the Family Health Center

or school-based health center, avoiding duplication of tests and giving the treating physician a full view of the patient's history prior to care.

I also hear frequently from hospitals that there would be an impact on their ability to treat low-income and rural patients if access to 340B savings was limited.

So my question to you is can you tell me about that. Without 340B, what would be the impact on patient care? And feel free, whoever.

Ms. Veer. I think the most immediate impact on patient care is without the 340B Drug Pricing Program, the prescriptions themselves would be unaffordable for many of our patients.

On the medical side of our health center, we serve approximately 22 percent of uninsured patients of our 26,000. So for that 22 percent of our patients, I am not sure that they would have access to affordable medication. Affordable medication drives — it is the greatest driver of improved clinical outcomes. So it would have a dramatic impact on our clinical outcomes.

Dr. Paulus. I would just add to that. For us, if you look back to 2016, we had about \$37 million in 340B savings and we had a \$53 million operating margin. So 70 percent of our entire operating margin, which is not for largess but for maintaining

programs, and replacing buildings that are deteriorated, and so forth, and so on, that would be gone.

In addition to that, as Ms. Veer just noted, when you look at the long-term impact of appropriate pharmaceuticals, it is one of the few places where we can make secondary prevention. By that, I mean we can treat a disease like hypercholesterolemia or other kinds of things and avoid much more expensive, much more debilitating programs downstream.

So unless people perceive that there is free money laying around or we are sort of just grossly inefficient and incompetent, you can't remove that kind of benefit. And again, in our case, the entire benefit for 340B is less than just our charity care.

Lastly, you can't look at this without also looking at bad debt. As high deductible plans have gotten ever higher, the patients have no ability to pay those amounts. They then become part of the charity care, which is one of the reasons why our charity care is up 20 percent in 2017 over 2016 because those people have no capacity to pay those deductibles.

Mr. Reuland. Thank you for the question. And I think an example, I will build on that sickle cell disease program I mentioned earlier.

One of the things that Dr. Lanzkron and her team do is

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actually reach out to patients to make sure -- because high and low temperature exposure can actually bring on a sickle cell crisis, they work hard to make sure that they in fact have appropriate air conditioning option or heating option so that they can avoid having a crisis in the first place. Those are the kind of things that you could imagine would suffer.

On a larger scale, we have invested in a program, a bundle of case management services that has been shown to reduce readmissions and inappropriate use of our hospitals and EDs on a broad scale. If we can't fund those kind of interventions, we could drive utilization back up in an unintended way.

Ms. Clarke. I thank all of you for your response and I yield back, Mr. Chairman. Thank you.

Mr. Griffith. Thank you for yielding back.

I now recognize the gentleman, Mr. Carter of Georgia.

Mr. Carter. Thank you, Mr. Chairman and thank all of you for being here today.

As the only pharmacist currently serving in Congress, I am very familiar with the 340B Program. I have seen the benefits. I have also seen where it can be abused.

As the chairman said earlier, the chairman of the full committee, the reason we are here is because one of the initiatives

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of this committee, hence, Oversight and Investigations, is to look into programs and see how we can improve those programs.

I will remind you that we had a hearing in July. And for my colleagues, I want to remind them, if you can play the clip now, of what we heard in that hearing.

Well, it looks like we are not going to get it. But what we heard over and over was the statute is silent. The statute is silent. It was irresponsible, as Members of Congress, that we did not specify exactly what we heard.

Have you got it now?

[Video shown.]

Mr. Carter. That is what we heard. That is why we are here today. That is why we need your help because it is irresponsible of us. That is our responsibility in Congress.

You know I take offense and I am resentful of my colleagues on the other side of the dais to insinuate that we have somehow said we wanted to cut out this program. I have never heard anyone say we wanted to cut out this program but we have a responsibility, as Members of Congress, to make sure this program is running correctly and it is not being abused.

I want to ask some very quick questions here. Ms. Vanna,
I am very familiar with Northside Hospital and I have worked with

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you in the State Legislature. You enjoy a great reputation in the State of Georgia. I am sure it is hard-earned. I am sure it is well-deserved.

However, I need to ask you some questions, particularly as it relates to consolidation. One of the things that I have discovered as a Member of Congress is just what an impact our actions here in Congress can have on the private sector and have on the free market. Have you, in recent years since you have started this program, has there been an increase in the number of clinics that Northside Hospital has acquired, specifically oncology clinics?

Ms. Banna. I think that we are, as a hospital system, are being encouraged to expand our clinically-integrated outpatient care model, yes.

Mr. Carter. That is not what I asked and you are under oath.

Okay, Ms. Banna? Have you increased the number of oncology clinics that you have bought since the 340B Program has come into effect?

Ms. Banna. Well in our case, we did acquire oncology clinics in 2011 and 2012, yes.

Mr. Carter. Does the 340B Program have anything to do with that or are you acquiring the oncology clinics because you have

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1801	a chance to make more money through the 340B Program, hence, what
1802	we have done in Congress is leading to a consolidation in health
1803	care inadvertently on our part?
1804	Ms. Banna. No and forgive me, that goes back to my prior
1805	answer. We are being encouraged to expand our
1806	clinically-integrated model past the hospital
1807	Mr. Carter. Ms. Banna, can you get me in writing how many
1808	oncology clinics Northside Hospital has acquired since 1992?
1809	Will you do that for me? I would appreciate that very much.
1810	I want to go now to Mr. Reuland and Johns Hopkins and I want
1811	to ask you how many 340B drugs were distributed to Part B
1812	beneficiaries last year. Do you know that?
1813	Mr. Reuland. I don't know that.
1814	Mr. Carter. Can you get me that in writing?
1815	Mr. Reuland. I think so. So what is the question?
1816	Mr. Carter. The question is how many 340B drugs were
1817	distributed to Part B recipients last year through Johns Hopkins?
1818	Mr. Reuland. It might be good to work offline to make sure
1819	we know what you mean by how many drugs.
1820	Mr. Carter. How many drugs, obviously 340B drugs that you
1821	got through that.

Mr. Reuland. But we would be happy to work with you.

Mr. Carter. Okay you all are familiar with CMS and their recent proposal to cut the reimbursement for Part B reimbursement on these drugs from APS plus six to APS minus 22 and a half. Are all of you familiar with that proposal?

Mr. Gifford, you said earlier in your testimony, in your opening testimony that it doesn't cost the government any money whatsoever. And I would refute that point. In fact, I would tell you that the CMS has said that by changing this formula that it could save over \$900 million. So it does cost taxpayers money and it costs taxpayers money not only in the Part B program but also in the programs with Part D, when it pushes people out of the donut hole into the catastrophic. Then, the Federal Government has to pay more and that is something that costs us as well.

One question for you, Mr. Gifford, and that is as I understand it the requirements for the Ryan White patients for the AIDS patients are actually more stringent than they are for anywhere else. You seem to be a strong advocate of the program and very supportive of the program.

If we were to tighten it up for the other areas, do you think that it would impact them that much?

Mr. Gifford. I would hope that the community would look at

expanding the use of the dollars that we save through 340B and I included that in the written testimony. The current constriction on Ryan White programs are actually inhibiting our ability to --

Mr. Carter. So your answer to me is that this is actually restricting you. You could actually, if we were to loosen it up instead of tightening it up, that you could actually do more as these other hospitals have done.

Mr. Gifford. If we could loosen this up for Ryan White -Mr. Carter. But my question to you was since you have got
more stringent requirements, you still benefitted from the
program. You spoke very highly of the program.

Mr. Gifford. The program does support the fight against AIDS in many ways and we would hope that the committee would expand our ability to offer life savings --

Mr. Carter. Again, let me explain to all of you that no one has said they want to do away with this program. All we have said is that we understand we have a responsibility to tighten this up, to make sure it is being used like it was.

And Ms. Veer, you have made some very good points and I want to thank you for what you are doing over there.

Thank you very much, Mr. Chairman.

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Mr. Griffith. The gentleman yields back.

I now recognize Mr. Tonko of New York for 5 minutes for questioning.

Mr. Tonko. Thank you, Mr. Chair.

Before I begin my questioning, I will echo my colleagues' expressions of strong support for the 340B Program. While it is always appropriate to conduct oversight and review that the implementation of a 25-year-old law, the testimony we have heard from our witnesses today about the ways in which they are using 340B savings to reinvest in their communities and serve needy populations shows us that the program is working well across our country.

In my district, the 340B program is also paying dividends, benefiting community health centers, Ryan White clinics, and safety net hospitals.

Ellis Hospital in Schenectady used 340B savings to treat a patient suffering from an acute porphyria attack. As you know, porphyria is a very rare disease that causes cycles of extreme abdominal pain, vomiting, high blood pressure, increased heart rate and anxiety. The patient had previously been unable to obtain treatment, which costs upwards of \$50,000, due to the cost. As a direct result of the 340B Program, Ellis was able to provide

the initial treatment and also to develop a procurement and administration plan for future attacks.

These types of human success stories help to illuminate the value that the 340B Program provides and should also serve as a note of caution to policy makers as we evaluate the program.

As with other efforts to address health care in this body, our goal when considering changes to 340B must always be first do no harm.

I want to go back to the questioning of our witness from Northside Hospital. To you, Ms. Banna, I am understanding that Northside reported to the committee that most of its 340B child site were sites already associated with Northside prior to 2012 but were registered between 2012 and 2017 because of changes to the HRSA guidance.

Northside did, however, acquire two oncology practices in 2013, did it not?

Ms. Banna. Those discussions began in 2011 and completed in 2012.

Mr. Tonko. Okay. So Ms. Banna, can you explain why Northside acquired these sites?

Ms. Banna. Absolutely. We were approached by a large oncology practice that was seeking integration with the hospital

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system, as were several other hospital systems in the Atlanta area. We worked with them throughout 2011 and 2012 to determine the model that would provide the right kind of clinically-integrated care that both parties were looking for and completed that transaction in 2012.

Mr. Tonko. And Ms. Banna, to your knowledge, has any patient been denied service at these oncology sites due to inability to pay since you acquired them?

Ms. Banna. Since we acquired them, no. As a nonprofit hospital, that is a service that we extend to meet the need no matter the ability to pay.

And typically, that is a service that is not in place prior to a nonprofit hospital's entrance.

Mr. Tonko. Thank you, Ms. Banna. And would it be accurate then to say that since Northside does not deny services to Medicare-eligible, Medicaid-eligible, or uninsured patients, it is likely that these oncology sites now provide services to more patients than when the sites were privately owned?

Ms. Banna. Absolutely.

Mr. Tonko. And one last question, Ms. Banna. Does

Northside place oncology patients into any type of queue through
which commercially-insured patients are treated before Medicaid

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and Medicare patients?

Ms. Banna. No.

Mr. Tonko. Thank you.

I would like to also go over to address the Mission Health program. So, Dr. Paulus, I understand that the 340B savings cannot be directly attributed to individual services. However, generally speaking, if Mission Health could not rely on savings from the 340B program, how would that affect your ability to provide these community benefits?

Dr. Paulus. Well, as I mentioned, it would have a major impact. We had about \$37.4 million worth of 340B savings last year and our entire operating margin was \$53 million. So, that is 70 percent of the total. We need that operating margin to be able to maintain services, replace outdated buildings and equipment and so forth. And so we would have to go through and figure out how to cut our budget. And by definition, some of the outreach and charity that we do today would have to be curtailed.

Mr. Tonko. Thank you. And Dr. Reuland, Johns Hopkins reported \$109 million, I believe, in 340B savings in 2016. If you could not rely on those savings, what impact would that have on your ability to provide services in your given community?

Mr. Reuland. Well thank you for the question. And

certainly, as I think we have been elaborating on, the wraparound services and the preventive services that we try to put in place in addition to the standard services is really what it is to serve an underserved community. And our inability, if we had to increase our drug prices by \$109 million, that would cause a significant amount of cost pressure and cause us to have to cut back on some other programs, just like the ones we have mentioned.

So I think, I will give you an example that there is a program called the CAPABLE Program, where we send a nurse, an occupational therapist, and a handyman or handywoman to a person's house. And they will typically install a second bannister for somebody who can get up and down the stairs now and get to a doctor's appointment more easily. It is that kind of hands-on community work that we would simply not be able to support.

Mr. Tonko. Thank you. And Ms. Veer, how would losing 340B savings impact Carolina Health's ability to provide services in your given community?

Ms. Veer. Well I have spoken to two or three specific programs that are funded by the 340B savings. Our delivery of prescriptions into very rural outlying areas that would be very difficult to sustain. We also provide behavioral health counseling in our sites for people who would experience long

delays in accessing the local mental health agency. Both of those areas would be significantly impacted.

Beyond that, we have sites in -- we have medical sites in rural areas that, because of the nature of the population there and how rural the area is, they operate at a loss. And so total out of our 13 sites, those operating losses are around \$1.8 million. We would definitely need to look at how we redistributed care to those areas, possibly combining some of those sites or reducing hours at those sites.

Mr. Tonko. Thank you. I appreciate the quality services you all provide with these savings.

And with that, Mr. Chair, I yield back.

Mr. Griffith. The gentleman yields back.

I now recognize the gentleman from New York, Mr. Collins.

Mr. Collins. Thank you. And I want to thank the panelists for being here and maybe reset the stage just a bit.

All of us stipulate the great benefits the 340B -- the pharmaceutical companies stipulate that. I mean it has been around a long time. I think what we are starting to look into, though, and I won't use the word abuse because if something is legal, it is not an abuse, but I will use the word loophole. We have seen a huge increase in the number of oncology practices which

deliver the most expensive drugs to America being bought up by hospitals, whether it is Johns Hopkins or others. Right in my area, the largest oncology practice was recently purchased by a DSH hospital and, I would say, for only one reason and that is the 340B profit.

You know they are buying up oncology practices where basically, when you are out in the suburbs, the vast majority of those patients are fully insured. Those practices have never gotten 340B discounts on the \$100,000 kind of drugs. The minute a DSH hospital acquires that practice, all of a sudden these 25 to 50 percent discounts flow to the bottom line of the hospital, plain and simple. A business decision. I can't blame you for it. It is legal.

But I call that a loophole and here is why. If I look at the requirements to be a DSH hospital, you have to have a certain percent of Medicare and Medicaid patients -- inpatients not outpatients. It is defined and calculated by inpatient stays in the hospital. But yet when you get to a clinic in the suburbs, those are outpatient.

So these DSH hospitals which qualify based on inpatient hospital stays are able to acquire outpatient oncology practices, without that impacting that calculation. That is a loophole.

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Number two, the whole idea that what you call a child site is one of these oncology practices, nothing changes. The patients go to, in many cases, like a shopping center. They park there. They see their same doctors except the doctors now work for the hospital. And the monies, the discount paid by the pharmaceutical company now goes to the bottom line of the hospital and we have no idea what it is going for. You tell us you are using it for outpatient work.

The Ryan White clinics, they tell us exactly where they go.

The hospitals tell us that is too much administrative overhead
to tell us but, trust us, we are providing more services. Maybe
you are. And if you are, you should be held accountable for it.

Because here is the bottom line. I know this isn't government money and this is the problem. The discount the pharmaceutical companies are giving and people go whoa, the big pharmaceutical companies, they make too much money, yadda, yadda, yadda but let us face it, that is where the new discoveries are coming from that is improving health care in the United States.

And here is my worry. The business model used to be let's call it a 25-30 percent discount over a certain number of groups, including your hospitals but you didn't own these oncology practices. And I would put forth you are buying them for only

one reason and that is the bottom line of the discount.

At some point, the prices for these pharmaceuticals are going to go up for everyone. Pharmaceutical companies that used to have to discount, I don't know, half my drugs, now I am discounting 90 percent of my drugs. Guess what? The list price goes up. There is no free lunch. And that is my problem.

It is not that we don't understand the importance of 340B. It is that the definition of the DSH hospital doesn't even take into account the outpatient work in these clinics. These are people that were fully reimbursed.

The other thing I am a little troubled by and you can tell me if I am right or wrong but many cases, \$100,000 procedure might be discounted to \$40,000. Is that reasonable? For a fully insured patient you see it. \$100,000, oops, discount down to \$40,000. But when you write it off as charity care or bad debt, don't you put it in as \$100,000 and not \$40,000?

Mr. Reuland?

Mr. Reuland. Well, what I was going to say is a couple of comments. The State of Maryland is a little bit different in that regard. And the State of Maryland's hospital rates are regulated by the entity called the Health Services Cost Review Commission. And the charges are actually governed to a level that is very close

to the cost and so there is no opportunity that you are describing there.

I would also point out that as a comprehensive cancer center, our growth has not been because of the purchase of any practices.

Johns Hopkins Hospital has purchased no oncology practices. We grow because there is sort of a limitless demand based on demographics for the treatments that we offer. And so our growth in oncology is a growth in our drug spend that outpaces our revenue growth. And that is why our operating margin has actually been declining in the past couple of years down to --

Mr. Collins. Yes, my time has expired. I was going to get into, though, with Johns Hopkins the last 2 years of your diversion of pricing through the contract pharmacies but that will have to wait for another hearing.

Mr. Griffith. The gentleman yields back.

I now recognize Ms. Schakowsky of Illinois for 5 minutes for questioning.

Ms. Schakowsky. Thank you. First of all, I want to thank the witnesses for their testimony.

I know 340B is essential to people in my district with skyrocketing drug prices or, as the President would say, price gouging prices. 340B is literally a lifesaver and not one of us

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opposes transparency. I am certainly not for waste, or fraud, or abuse. I am for transparency. But it does raise questions when it is the pharmaceutical companies that are the loudest complainers about the 340B Program.

And it is interesting to me that while the pharmaceutical companies have argued for transparency for the 340B Program, PhRMA has spent millions of dollars to prevent laws that require transparency in their own drug pricing. And this leaves us blind as we work to lift the burden of crushing drug prices and it is well past time that this committee talk about how we are going to lower drug prices.

You know we have no clue when they tell us that all this money is going to develop new drugs and for research and development, what that is really about. We know about your CEO, how much they make. We don't know about theirs. And we need to concentrate more on that.

And I think it is really a dereliction of duty that we allow these prices to get so out of control that they do imperil the health of people across this country.

In my district, Advocate Health has used its 340B savings to provide support for low-income patients through child vaccination programs and the Medication Assistance Program that

helps people who are uninsured and underinsured, as some of you do as well.

So let me just ask a couple of questions. Each of you mentioned very -- oh, no, no. I wanted to go to these questions.

Dr. Paulus, I see that Mission Health used a large number of contract pharmacies to dispense 340B drugs. Can you explain the benefits of using these pharmacies?

Dr. Paulus. Yes. So first I think with respect to contract pharmacies, we only have arrangements that include dispensing fees. That is an important part of our criteria. Mission Health, as an entity, has 62 contract pharmacies but that is for six separate covered entities. Mission Hospital, which is the largest hospital, by far, has 31 but of those, 16 are mail order or specialty pharmacies that haven't had a dollar's worth of revenue. So it is an inflated number.

Two, our distribution entities and there is no revenue associated with those; two we own.

And the total value of Mission Health's contracted pharmacies is \$7.6 million but the value of that is that, for example, at Angel Medical Center, which is one of our rural Critical Access Hospitals, patients are provided with vouchers to go to those contract pharmacies and receive free medication.

So the contract pharmacies we view as an extension of our own work. Our goal is, either through our own medication assistance program or through those contracted pharmacies, that no patient goes without free or discounted medications, if they need that medication.

Ms. Schakowsky. Thank you. I am just wondering if any of you have witnessed dramatic increases in the cost of a particular drug that your patients need that you might want to tell us about. I have heard those horror stories from a number of doctors in the Chicago area.

Yes, Dr. Reuland.

Mr. Reuland. Thank you for the question. I mentioned earlier that we have seen a couple of -- seven very common medications. We noticed that our spend on them increased 312 percent with a volume growth of 12 percent.

So it was clearly a price increase that we could not explain and these were not medications that were easily substitutable with something else.

Dr. Paulus. If I could just add, you know there is a variety of reasons for the quote growth in the programs, one of which is prices. And I think the data are a third of the savings is due to price changes alone.

But let me bring up another issue, which is a thank you to the pharmaceutical manufacturers. When we compare our 2014 to 2017 data, there are six drugs that are new that didn't exist that comprised over \$5 million of spend in 2017.

So the growth of the program is a multifactorial attribute and it is important to look into the detail.

Ms. Schakowsky. Thank you and I yield back.

Mr. Griffith. Thank for yielding back.

I now recognize Mrs. Brooks of Indiana for 5 minutes for questioning.

Mrs. Brooks. Thank you, Mr. Chairman.

Ms. Banna, we heard about the acquisition by Northside of the oncology practices in 2012. Are those two practices 340B child sites?

Ms. Banna. The locations operating as hospital outpatient departments are.

Mrs. Brooks. And when did you register those oncology practices for the 340B Program?

Ms. Banna. I believe it was spring of 2014.

Mrs. Brooks. And can you talk about the registration process? So that is the date that the registration process concluded, is that correct, in 2014?

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2175	Ms. Banna. It was April 2014.
2176	Mrs. Brooks. And about how long does that process take?
2177	Ms. Banna. To register them?
2178	Mrs. Brooks. Uh-huh.
2179	Ms. Banna. You must demonstrate that you are operating them
2180	as a hospital outpatient department. So if you own a location
2181	and it appears on your hospital cost report as a hospital
2182	department, then you request. You bring it in as a child site
2183	and about a quarter later, you can begin operating it as a 340B.
2184	Mrs. Brooks. And are patients that are treated at these
2185	centers, oncology centers, charged a facility fee?
2186	Ms. Banna. If it is a hospital location, they are billed
2187	in accordance with hospital standards.
2188	Mrs. Brooks. And those are billed as hospital sites, then?
2189	Ms. Banna. Correct.
2190	Mrs. Brooks. So they would be charged a facility fee.
2191	Ms. Banna. Correct.
2192	Mrs. Brooks. And how much is that fee?
2193	Ms. Banna. I can't quote that.
2194	Mrs. Brooks. Can you get that for us?
2195	Ms. Banna. I can, sure.
2196	Mrs. Brooks. And what other fees are patients charged that

maybe those patients didn't pay prior to them becoming hospital sites? Are there other fees that patients are charged once they become hospital sites that they weren't charged previously, oncology patients, for example? Ms. Banna. I think you know I can't speak to charges that are not hospital-based. They are charged commensurate with any hospital service area. Mrs. Brooks. So are you aware as to whether or not patients -- what a patient's bill might have looked like prior to them being acquired by the hospital versus what they are after the acquisition, a comparison of the costs? Ms. Banna. I mean I understand what hospital charges are, I think it is important, though, to state that charges are not directly related really to what people pay. People pay based on what kind of insurance coverage they have or don't have. Mrs. Brooks. And so on the hospital fees and whether there are any other fees, are they all included in the one bill or might there be an additional separate bill to the patient? Ms. Banna. Patients may receive bills for non-hospital services.

the DSH percentage of your entities and is that for the parent

Mrs. Brooks.

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I want to ask each of the panelists what is

2219	entity or the DSH percentage compared to the child sites?
2220	And I will just start with you, Ms. Banna. What is your DSH
2221	percentage for your parent entity and how does that compare to
2222	your child sites?
2223	Ms. Banna. The DSH percentage is a representation of
2224	inpatient days, as was mentioned a moment ago. So the child sites
2225	don't have that percentage but our parent has a 16 percent ratio.
2226	Mrs. Brooks. And how about you, Mr. Reuland?
2227	Mr. Reuland. Johns Hopkins Hospital is 18.97 percent.
2228	Mrs. Brooks. Okay, Dr. Paulus.
2229	Dr. Paulus. We are between 15 and 16 percent across all
2230	sites.
2231	Mrs. Brooks. Mr. Gifford.
2232	Mr. Gifford. That is a requirement that we are not required
2233	to adhere to.
2234	Mrs. Brooks. Okay.
2235	Mr. Gifford. That is not a part of the Ryan White
2236	Mrs. Brooks. Okay, thank you.
2237	Ms. Veer.
2238	Ms. Veer. Similar to Mr. Gifford, our eligibility is based
2239	on our approved scope of project under HRSA.
2240	Mrs. Brooks. And so for those of you that maintain the

percentages, has that percentage fluctuated over the years?

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2242	if so, what kind of fluctuation have you seen?
2243	Dr. Paulus.
2244	Dr. Paulus. I couldn't quote that off the top of my head.
2245	It has been relatively consistent.
2246	If I might add two comments about the oncology practices,
2247	our integration in our market has largely been driven by two
2248	things. You know one is physicians who, because of the same
2249	demographic challenges that we face, find it hard to exist in that
2250	marketplace. And by becoming part of a system and being able to
2251	be paid a salary, as an example, are able to do that.
2252	One of the additional benefits you raised fair points,
2253	but one of the additional benefits is all of those patients in
2254	that new setting are eligible for all of our charity policies,
2255	which did not exist in those practices previously.
2256	The other point is you know we are being pressured by
2257	everyone, including the Federal Government and others, to form
2258	integrated systems to coordinate care across that network.
2259	Mrs. Brooks. Right, of course.
2260	Mr. Reuland?
2261	Mr. Reuland. I don't know the history of our roughly 19
2262	percent number. We could, I am sure, provide that.

Our oncology, as I mentioned, is not a growth based on acquisition of any practices. It is as a comprehensive cancer center. As new therapies come along, as Dr. Paulus pointed out, they often bring some very nice promise but they certainly bring a heavy cost with them and that is part of our reality.

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

Mr. Griffith. Thank you. I appreciate that very much.

I now recognize Dr. Ruiz from California for 5 minutes for questioning.

Mr. Ruiz. Thank you very much, Mr. Chairman.

As you know, I have spent a lifetime trying to figure out how to provide care for underserved communities and I just want to remind everybody of the big picture. It is easy to get lost in the details but let's just keep the big picture in mind. We are talking about populations with severe barriers to accessing the healthcare services they need to live healthy and fulfilling lives.

We are talking about communities that exist with one doctor per 9,000 residents, like in certain areas in my district. We are talking about catchment areas, where even though you may be in a big tertiary care academic institution, they are still hard to read for whatever reason. So just the mere existence of these

clinics or programs in these communities is a benefit, a very vital important benefit. And on top of their existence, whether they have to pay the electricity bill or whether they pay their multiple salaries to keep their doors open, they also do outreach, and public health education, and programs, and prevention programs, and education, and all these benefits that the underserved communities exist.

There is a community clinic Desert AIDS Project in my district, you might be familiar with them, Mr. Gifford, who do amazing work but they provide critical wraparound services and lifesaving treatment programs. They exist in narrow margins and the money they have been able to save with 340B Programs allows them to provide hepatitis C medications, which we know is very expensive.

But in addition to that, the cost savings allows them to provide the nutrition that augments the support that the patients need, allows them to providing housing that we know is a critical factor in a patient's ability to recover from the AIDS or having the HIV infection.

So these are very important that oftentimes gets missed in these conversations. So I think the real question here is how do we measure value of the cost savings of the 340B system. And

it has been very misleading to hear that the only way that we measure this is charity care. And since you know that charity care is going down, meaning that that was an active choice by hospitals to make, while their profits is going up is very misleading because we know that uncompensated care has gone down because the number of insured has gone up by 20 million in this country thanks to the Affordable Care Act.

But that doesn't mean that families are still struggling. That doesn't mean that there is more uncompensated -- residual uncompensated care out there that we need to hassle -- I mean we need to handle.

So the fact that clinics and hospitals are expanding to more communities is a good thing. The fact that you are bringing in patients that otherwise, or oncology clinics, for example, that otherwise would be inaccessible through other healthcare systems into your mission-driven hospital is a good thing. So now your patients have access to oncology care. For example, the poor and struggling working families also get cancer. They also need the medications. They also need care.

And I think it is misleading to insinuate that you decided to purchase a clinic so that you can dive into the 340B Programs to acquire more money to then line the pockets of CEOs and

leadership.

So let me just ask you point blank. Did you do that? What was the reason for you purchasing some of these oncology clinics, Dr. Paulus?

Dr. Paulus. Yes, as I mentioned just a bit ago, for us it was a matter of maintaining oncology services in the region and getting those clinics available in the 18 diverse and mountainous counties.

Mr. Ruiz. So keeping oncology services for the patients in your catchment area that you want to serve.

Ms. Veer?

Ms. Veer. We don't operate oncology services. However, I will say the next to the last site that we opened was opened at the request of a local hospital that 75 percent of their emergency visits were ambulatory care-sensitive. And since we have -- I can give the example of one patient who had 11 visits down to none.

Mr. Ruiz. Well, yes, I mean how do you measure the ability to use some of the cost savings to go into the community to provide nutrition classes, exercise classes, prevention, education for diabetics knowing, that by them participating in these programs, they will prevent going blind, they will prevent leg amputations, they will prevent costly renal insufficiency and hemodialysis?

So how do we measure the true value of these cost-saving programs that allow you to do more outreach into underserved communities? And that is where the real problem lies. If we are just narrowly focused on uncompensated care, then we are missing the big picture here.

So you know I think we need to expand services. We need to empower the clinics and hospitals to do more outreach into more underserved areas to provide more lifesaving care that will help prevent rising costs for the emergency care that they are going to need if they don't get those services to begin with.

Thank you very much.

Mr. Griffith. The gentleman yields back. I appreciate.
I now recognize Mr. Sarbanes of Maryland.

Mr. Sarbanes. Thank you, Mr. Chairman, and thank you for allowing me to participate in the hearing today.

I want to thank the panel. Your testimony is, obviously, very critical and you have, I think, seen that there is broad and deep support for the 340B Program on both sides of the aisle. And I want to thank all of your institutions for the contributions you are making at the community level to address the situation of vulnerable populations and sort of change the underserved vulnerable populations and to serve vulnerable populations.

I come with a very biased, in the positive direction, view of Johns Hopkins and the role that it has played in Baltimore City, having watched that my whole life.

Dr. Reuland, I think you said you started in 1990 at Johns Hopkins. So in 1989, when I returned to Baltimore from school, I became involved in a program in East Baltimore, a community-based education and health initiative. And one of the reasons the health component was so critical to that -- and we were working with Dunbar High School and Lombard and Dunbar Middle Schools and other schools that you are familiar with -- one of the reasons the health piece was so critical is the impact on education of children in that community from asthma, from lead paint poisoning was significant. And we didn't think we could bring a kind of holistic response in needs of those children without having the health piece right in the center of it. Hopkins has always stood up and was a full partner in that effort.

So I am going to ask you to maybe go over again in a little more detail some of the services that the 340B Program savings have allowed Hopkins to provide in the community. Why don't you start by talking about what you have been able to do to address the issues of asthma and lead paint poisoning? I know you have the Johns Hopkins Children's Center. There has been a lot of

innovation there. If you could speak to that, I would appreciate it.

Mr. Reuland. Thank you for joining us and thank you for the question, Mr. Sarbanes.

The presence in the schools is something that is, as you have pointed out, very important. I was talking with Dr. Connor the other day, one of our pediatricians who works in one of the schools in Baltimore. And about 1500 elementary and middle school kids in the school and she estimates that 30 percent of them may have asthma. And so the steady presence there is immediate diagnostics, sometimes nebulizer treatments right there on the spot to treat them, rather than sending them to an emergency department. She thinks in the first year she prevented 75 emergency visits just with that program alone. And so that is an example of a kind of thing that we are very proud of.

And you are right, pairing the health with the education, she thinks we prevented 167 absences from school as a result of asthmatic complications. So, a very strong contribution.

The other school I will mention is -- you are familiar, but others may not be, with the development work to the immediate north of our campus a very troubled area that has been rebuilt. The Henderson-Hopkins School is something we helped establish as a

part of that redevelopment initiative. And it has been an extraordinary success so far. If you were to see that area back in 1989, when you referred to, and look at it today, it is a startlingly better story.

Mr. Sarbanes. Let me ask you to speak as well -- I have got about a minute left but, obviously, every community across the country and certainly every congressional district is experience this opioid crisis. Baltimore has very special challenges with respect to heroin and opioid addiction crisis. And maybe you could speak on behalf of hospitals across the country of who benefit from the 340B Program in terms of their ability to respond to that crisis in those communities, which is absolutely critical right now.

Mr. Reuland. And I am happy to respond and others may want to contribute. But we are absolutely seeing an increase in opioid dependence. It is an estimate of about 45,000 residents in Baltimore have a dependence. And in an emergency department, as Dr. Ruiz knows, patients will present often having overdosed and will be reversing that with naloxone and trying to bring them back. And as more powerful substances are available on the streets, we are doing more and more of that.

The aftercare, the recovery and management of addiction, I

mentioned earlier some of the wraparound services we provide, so that not only can we treat the patient with standard therapies but provide them with supportive housing on the outside so they don't go back quite to that same neighborhood. It is that kind of thing that I suspect all of us do at some level.

Mr. Sarbanes. I appreciate your testimony. I thank all of you for what you are doing in your various communities.

I yield back.

Mr. Griffith. I thank the gentleman for yielding back and if you all can bear with us a few more minutes, I have a couple of additional questions.

So I am going to recognize myself for an additional 5 minutes. And Ms. DeGette may wish to but she is going to play that by ear.

So I am going to feed off of what Mr. Sarbanes was just asking about and this committee has important bipartisan work underway to see how we can leverage federal resources and authorities to better combat the opioid crisis.

As part of our work, it is important to understand how all federal programs intersect and what their interest is with the crisis that has left virtually no American family or community untouched. That being said, can each of you identify what percentage of the 340B prescription opioids represents as a

percentage of your program and can you detail for us what steps might be in place to prevent diversion or misuse of these drugs, once they are dispensed to the patients?

I will start with you again, Ms. Veer. And if we could be quick.

Ms. Veer. Sure. I don't have the exact percentage but I could provide that in writing.

Mr. Griffith. Okay.

Ms. Veer. I can tell you that we use medication management contracts with our patients. We do standard drug testing to make sure that it is not being diverted.

Mr. Griffith. I appreciate it.

Mr. Gifford.

Mr. Gifford. I also can provide the data on the percentage of prescriptions. We do provide medication management therapy and we do a lot of counseling with our patients and clients about it.

But on this issue of opioids and fighting the opioid epidemic, this is one of the problems with the Ryan White constricting language. We cannot use 340B savings to provide Narcan to somebody to save them from an overdose and a clear death. And that is one of the examples that I would hope this committee

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would look to expanding our ability to fight both the HIV epidemic and the opioid epidemic. It is a federal regulation that is inhibiting our ability to fight the opioid epidemic.

Mr. Griffith. That is interesting information. I asked Ms. DeGette and she didn't know that either. I was not aware of that. So thank you for bringing that to our attention.

Dr. Paulus?

Dr. Paulus. I don't know the exact numbers. I know that it is less than one percent of our revenue.

What we have done is we have done academic detailing for each of our practices to reeducate them about the prescription evidence-based best practices for opioids. We have supported providing free Narcan for our community. And on any given day, we have between 37 and 60 behavioral health patients being brought into our emergency department that are uncompensated that relate to the tragedy that is occurring.

If I could ask one other thing like that, we also provide support to a free clinic that provides medication assistance and education but free clinics don't qualify for 340B either. So that is a parallel.

Mr. Griffith. I appreciate that.

Mr. Reuland. I also don't know our precise percentage but

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we certainly have plenty of programs in place to prevent diversion.

Mr. Griffith. And if you all could just get us that information, as some others have offered, that would be great.

Ms. Banna. Agreed and I would argue or articulate for us the opioid epidemic is striking all patient populations. In our case, you see it affecting the extension of behavioral health services dramatically and, certainly, our babies. I mentioned we have a really high amount — a high population of special care babies in our nursery. The opioid epidemic has increased their length of stay. Many of those babies are Medicaid babies. That is part of what contributes to our DSH percentage.

Mr. Griffith. And another subject that we will probably have to touch on another day because, in my area, Bristol, Virginia-Tennessee -- think of the GEICO gecko -- the newspaper ran a series of articles on the problems that we are having in our region with those infants born already addicted.

As a follow-up to my first round of questions, I want to discuss again how each of you calculate your savings. Ms. Veer and Mr. Gifford, I believe I understand the answers you gave. I understand Mission and Johns Hopkins use of the GPO price to calculate their savings, which you get by comparing a wholesale

manufacturer price. You get that GPO from them.

Following up on Northside, it appears, from what I have been able to read and discern, that you all have chosen not to use the GPO price or you use some other mechanism. Can you explain it to me and then explain why?

Ms. Banna. We are actually comparing the GPO price. We are comparing the average unit paid on drugs in 340B oncology clinics to those paid in non-340B clinics where GPO is applicable.

So it is, effectively, 340B pricing to GPO pricing.

Mr. Griffith. But you all are taking an average. I think what everybody else is doing is they are saying we are buying Drug A and Drug A costs \$10 and under 340B we save that \$10. And you all are doing an average across the board. Is that correct?

Ms. Banna. That is correct. What we do is monitor the program's effect in totality. Each individual drug, there are some that see bigger savings than others on a per unit but the units that you purchase move day by day, depending on the patients that appear and the drug sizing and such that are sold.

Mr. Griffith. I am just curious why you all think that is a better method.

Ms. Banna. Right. Oh, so I guess we consider it to be less noisy. We are monitoring the total program impact across the

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2549	board.
2550	Mr. Griffith. My additional 5 minutes is up.
2551	Ms. DeGette, I am happy to yield to you. Did you have any
2552	additional questions?
2553	Ms. DeGette. No.
2554	Mr. Griffith. All right. Oh, okay. Apparently Dr.
2555	Burgess is attempting to come down. Do we know how close he is?
2556	You don't. Okay.
2557	Well my follow-up material is here that I have to do.
2558	I do appreciate all of you all being here today. If Dr.
2559	Burgess walks in, I will yield some time to him but I do appreciate
2560	you all being here today. I know it takes a lot of time both to
2561	get here, get back, and to spend your time answering questions
2562	of a lot of different folks with slightly different opinions.
2563	Okay, in conclusion, having thanked you all, I do remind the
2564	members that they have 10 business days to submit questions for
2565	the record and then I would ask all the witnesses to agree to
2566	respond promptly to the questions that members ask.
2567	[The information follows:]
2568	
2569	**************************************

2570 Mr. Griffith. And with that being said, any additional -2571 okay. That being said, this committee is adjourned.

[Whereupon, at 12:24 p.m., the subcommittee was adjourned.]