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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., ir
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).
23	Also present: Representative Sarbanes.
24	Staff present: Jennifer Barblan, Chief Counsel, Oversight
25	& 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,
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

196 didn't have 340B, they couldn't provide these services. 197 We heard this consistent message from all types of providers 198 and, from what this committee has seen, they don't seem to be 199 lining their pockets. They are using this savings to provide 200 critical care for the community and vulnerable populations. 201 Now I think we can discuss the definitions regarding what 202 is what or what is not charity care but, in the end, what should 203 not be lost is these organizations are using this compensation 204 for important community work. 205 I look forward to hearing from the witnesses about this work. 206 I think we can make improvements on transparency to the program but, in doing so, we should not reduce the providers' abilities 207 to fulfill their missions and to continue their important work. 208 209 I yield back. 210 Mr. Griffith. I thank the gentlelady and now recognize the chairman of the full committee, Mr. Walden. 211 212 The Chairman. And I thank you, Vice Chairman. Thank you 213 for leading this hearing today. The committee has been examining the 340B Drug Pricing 214 Program for about 2 years now, as I think you all know, and the 215 216 Oversight Subcommittee has been particularly focused on it since 217 last spring. The 340B Drug Pricing Program allows covered entities to 218 219 purchase certain outpatient drugs at reduced prices, in order to 220 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 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

371 also ask unanimous consent that members not on the Subcommittee 372 on Oversight and Investigations be permitted to participate in 373 today's hearing. 374 Without objection, I would now like to introduce our panel 375 of witnesses for today's hearing. 376 First, we have Ms. Sue Veer, who is the President and CEO 377 of Carolina Health Centers in South Carolina. Thank you for being 378 here today. Next is Mr. Mike Gifford, who serves as the President and 379 380 CEO of the AIDS Resource Center of Wisconsin. Thank you, sir. Then we have Dr. Ronald Paulus, who is the President and CEO 381 of Mission Health Systems in North Carolina. 382 Fourth is Mr. Charles Reuland, the Executive Vice President 383 384 and COO of Johns Hopkins Hospital in Baltimore. Thank you, sir. 385 And finally, we have Ms. Shannon Banna, who serves as the Director of Finance and System Controller at Northside Hospital 386 387 in Georgia. 388 I thank each of you for being here today and providing We look forward to the opportunity to discuss how 389 entities across the country utilize the 340B Program. 390 As you are aware, this committee is holding an investigative 391 392

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

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the rules of the committee, you are entitled to be advised by counsel. Do any of you desire to be advised by counsel during your testimony today?

In that case, if you would please rise and raise your right hand, and I will swear you in.

[Witnesses sworn.]

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Mr. Griffith. Having heard all respond in the affirmative, you all can sit. Thanks.

You are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now 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 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

483 patients who would either not qualify or have incredibly long 484 delays in accessing care from the local mental health agency. 485 In addition the 340B savings contribute to my health center's 486 ability to ensure continued access to primary care and preventive 487 care at certain of our primary care delivery sites in communities, 488 which due to their particularly rural location would not likely 489 be sustainable otherwise. 490 The health center statute requires FQHCs to use all their 491 340B savings for purposes that advance their HRSA-approved scope 492 In other words, for activities that increase access 493 to high-quality affordable care for medically-underserved 494 populations. 495 As my testimony demonstrates, the 340B Program is vital to 496 my health center and to our ability to provide patients with access to affordable prescriptions, as well as needed services for our 497 low-income and underserved patients. 498 499 Thank you for the opportunity to testify before you today 500 and for recognizing the importance of this program for the health centers and all the patients we serve. 501 502 [The prepared statement of Ms. Veer follows:]

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Mr. Griffith. Thank you.

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

506 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. She 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.

582 She is no longer being beaten. Sadly, she was no longer 583 undetectable. 584 Today, she is accessing many of our services and is back on 585 the way to that gold standard. Throughout it all, our services 586 were always there for Kathy, even if she couldn't pay, each one 587 of them supported by 340B savings -- savings that saved her life. 588 Thank you for this opportunity to testify before the 589 committee. I look forward to responding to any questions you may 590 have. 591 [The prepared statement of Mr. Gifford follows:] 592 593 *********INSERT 2******

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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. 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. 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 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.

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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.

These programs, like many others that we work so hard to support are the heart of what safety providers do. So we appreciate this opportunity to participate in the dialogue, share how the 340B Program impacts our patients and we are eager to help you make this important program even better.

[The prepared statement of Dr. Paulus follows:]

*********COMMITTEE INSERT 3*******

693 Mr. Griffith. Thank you very much.

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.

770 The 340B Program has been a success in our community, 771 allowing JHH to operate a variety of programs and provide services 772 for vulnerable patients that improve their health and well-being 773 that otherwise would not be possible. These efforts help avoid 774 other, more expensive medical interventions, the cost of which 775 would be borne in large part by Federal and State governments if 776 funds were not -- funds, if not for the 340B Program. Now is the time for the Federal Government to recommit to 777 778 the 340B Program. The program is as relevant and vital today as 779 it was when first enacted. The legacy of the 340B program is that today JHH, along with the national network of other 780 Disproportionate Share Hospitals and other 340B-covered entities 781 782 are the bedrock of the national safety net dedicated to saving 783 lives and improving the health of our most vulnerable neighbors. 784 Thank you for the opportunity to provide these comments and I look forward to your questions. 785 786 [The prepared statement of Mr. Reuland follows:] 787 ***********************************

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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

865 services such as financial assistance, wellness counseling, 866 nutrition, navigation, clinical research, and much more. 867 Northside Atlanta qualifies for participation in the 340B 868 Program because of our disproportionate share of indigent and 869 low-income inpatient days, currently running at approximately 16 870 percent of total inpatient days. 871 Northside started our 340B Program in 2013 under the guidance 872 and oversight of our 340B Steering Committee and then independent third-party consultant. In addition to constant oversight by the 873 874 Steering Committee, which encompasses individuals from several 875 departments of the hospital, our 340B Program undergoes frequent and rigorous internal and external auditing and monitoring. 876 877 In 2016, Northside underwent an audit by HRSA, which 878 confirmed Northside's compliance with 340B Program requirements. Following a thorough review of the 340B Program, HRSA found a 879 single instance of inadvertent diversion, representing less than 880 881 \$7. 882 Northside is proud of our commitment to charity and the 883 services we provide to our community, the extent of which is made possible through 340B savings. We appreciate the opportunity to 884 885 provide this information and we look forward to answering your 886 questions. 887 [The prepared statement of Shannon Banna follows:] 888

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

899 Mr. Griffith. And with that, we will go to questions. Ι 900 recognize myself for 5 minutes. 901 And I would ask each of the witnesses how did you calculate 902 your 340B savings. Is it an estimate or a precise amount? And 903 if it is an estimate, what information do you need that you do 904 not have in order to accurately calculate your savings? 905 And as position has it, we will start of this end of the table with Ms. Veer. 906 907 Thank you, Mr. Chair, for the question. Ms. Veer. 908 Our savings for 2016 were \$561,620 and if my CFO were here, 909 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 910 center it has been that margin remaining after the sale of the 911 912 We manage all of our programs using profit and loss druq. 913 statement specific to that program or to that site. And so it 914 is an exact number based on the net margin after the sale of all 915 drugs. 916 Mr. Griffith. All right, thank you very much. Mr. Gifford. 917 Thank you, Mr. Chairman. 918 Mr. Gifford. 919 We calculate our 340B savings in a very direct and simple 920 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 921 922 costs that we use.

Thank you, sir.

Mr. Griffith.

924	Dr. Paulus.
925	Dr. Paulus. Thank you.
926	We calculate our savings in two ways. One, with respect to
927	drugs that we get through our wholesaler, we calculate those based
928	upon the difference between the discounted price and what our GPO
929	price is. And for contract pharmacies, our 340B vendor
930	calculates them based upon the discount.
931	Mr. Griffith. All right.
932	Mr. Reuland.
933	Mr. Reuland. Thank you, Mr. Chairman.
934	Yes, we calculate the GPO price versus the 340B price and
935	use that differential as our savings.
936	Mr. Griffith. All right.
937	Ms. Banna.
938	Ms. Banna. We also calculate the 340B price per unit of drug
939	and compare that to the price in the non-340B locations.
940	Mr. Griffith. Are those savings earmarked for specific
941	programs or are they channeled to a general fund?
942	And we will start on this end this time so that we try to
943	be more fair. Ms. Banna.
944	Ms. Banna. We monitor our savings first and foremost and
945	then, separately, we focus on growth and expansion of charity and
946	indigent care, and additionally expansion of oncology services,
947	and other services that our community is looking for.

Mr. Griffith. But I guess the question is is it earmarked

949 for those programs or does it go into a general fund and then those 950 are the things that, as a part of your institutional mission you 951 go forward with? 952 They aren't earmarked. They are tracked and 953 monitored and then our growth is tracked and monitored. And we 954 do ensure that our growth far exceeds the savings. 955 Mr. Griffith. Thank you. 956 Mr. Reuland. 957 Mr. Reuland. We invest in a variety of different programs that are for community benefit using our savings. And they vary 958 959 in size and range and for different kinds of patient types. 960 Mr. Griffith. But are they earmarked or does it go into a 961 general fund and then that is part of your general mission? 962 is what I am trying to sort out. 963 Mr. Reuland. One way maybe to think about it, perhaps, is that there is not really a check that comes back, if you will. 964 965 This is a lower price paid. So there isn't a check that comes 966 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 967 968 pay. 969 So there is not really a budgeted amount that you could say 970 that is what you are going to put in each of these buckets. 971 Mr. Griffith. All right. 972 Dr. Paulus. 973 Dr. Paulus. To directly answer the question, there is not 975 earmark for a tax dollar that I might pay in income tax. 976 But on the other hand, we track very closely our savings. 977 We know those savings and when we are preparing our budget for 978 each year, we include those dollars in the charity care 979 allocations in all of these programs. 980 So I would say that yes, they are targeted but not literally 981 dollar-for-dollar. 982 Mr. Griffith. Okay and when you say that, so when you are 983 doing your budget, you actually have a line in your budget that 984 says 340B savings and then they go out in these different 985 directions. 986 Dr. Paulus. Yes, we do. 987 Mr. Griffith. All right, thank you. 988 Mr. Gifford. In our budgeting process, we identify the 989 Mr. Gifford. 990 savings that we anticipate in the coming year and we direct it 991 to the pharmacy, health, and social services that I discussed in my testimony. 992 993 Mr. Griffith. Thank you. 994 And Ms. Veer. 995 I would have to echo my colleagues to some degree. 996 It is not an exact line item transfer dollar-for-dollar from one 997 cost center to another cost center, but at the beginning of the 998 year, as part of both the budgeting and the strategic planning

a dollar-for-dollar tracking no more than there would be an

999	process, we estimate what we anticipate those savings to be and
1000	then look at what programs they can fund, what otherwise unfunded
1001	programs they can fund.
1002	Then at the end of the year, we do an annual report to our
1003	Board of Directors linking those two together.
1004	Mr. Griffith. I appreciate that. I like the concepts that
1005	both Dr. Paulus and Ms. Veer that doesn't mean the others are
1006	not doing it right but I kind of like those because then somebody
1007	can actually take a look at it and see what you are doing with
1008	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
1046	
1047	Ms. DeGette. If you could just briefly
1048	Ms. Veer. Sure.
l	

1049 Ms. DeGette. -- describe some of those services. 1050 unfortunately, only have 5 minutes and I would like to hear from 1051 everybody. 1052 Absolutely. The delivery service that I Ms. Veer. 1053 mentioned that is delivering over 20,000 prescriptions to 1054 outlying rural areas would have to be eliminated because those 1055 costs are directly covered by the 340B savings, as would our 1056 in-house behavioral health counseling for people who don't 1057 receive care, or would not qualify for care, or experience delays 1058 in the mental health agency. 1059 Ms. DeGette. Thank you. 1060 Mr. Gifford, can you give me some examples? Mr. Gifford. Elimination of the 340B Program would 1061 1062 substantially undermine the fight against AIDS. It would mean 1063 fewer resources, fewer services. Our patients would become more 1064 They would not have an undetectable viral load. 1065 would be new and more HIV infections and, sadly, far bigger health 1066 care costs. 1067 Ms. DeGette. All right, let me ask you why that is. 1068 are the services that you provide that you would not be able to 1069 provide without this savings? 1070 Mr. Gifford. Certainly, we would not be able to provide as 1071 much medical care for uninsured patients, dental care, mental 1072 health therapy and drug treatment. 1073 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 --

1099 that is a half a million dollars plus for us that we would have 1100 to take out that is an investment we make. 1101 Ms. DeGette. And Ms. Banna. 1102 Ms. Banna. You know immediately our organization's 1103 resources would be directed to offsetting the substantial drug 1104 price increases that we all experience annually. In doing so, 1105 the reduction of resources would slow our ability to provide 1106 additional services. So in our case, the 250 positions that we 1107 put in our oncology clinics that were not there before, either 1108 social workers, nurses, supervisors, research staff, care 1109 navigators, nutrition, genetic counselors, that pace would slow 1110 Those positions might not be funded, in addition to down. 1111 financial assistance directed directly to patients. 1112 Ms. DeGette. Thank you so much, Mr. Chairman. 1113 The gentlelady yields back. Mr. Griffith. 1114 I now recognize the chairman of the full committee, Mr. 1115 Walden of Oregon. 1116 I appreciate it. The Chairman. 1117 I served on a hospital board for 4 and 1/2, 5 years. 1118 first of all, if talking about eliminating 340B Program. So, 1119 everybody breathe. 1120 Second, I have got to tell you I think when the average 1121 American hears what you would cut, not a one of you said any 1122 overhead, capital construction, salary bonus. It was infants 1123 trying to recover from opioids is the first thing.

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

1174 cell disease is a disease that you may know disproportionately 1175 affects African Americans. And we have set up a very 1176 comprehensive program, the only one in the region to manage those 1177 kinds of patients. 1178 We can't really set it up with different sort of swim lanes 1179 for payer capability. People move in and out of insured status 1180 throughout their life, as you might imagine. And so what we set 1181 up is a clinical program to care for them in whatever state of 1182 care they need and then try to support around that whatever the 1183 insurance needs are. 1184 Dr. Paulus. First with respect to your comment, which I 1185 respect you have perspective on that, I did not say that we would 1186 not detox babies. What I said was we developed a program that 1187 saved the Medicaid program \$3 million by detoxing them at home 1188 and we would probably have to revert back to inpatient care. 1189 Second, we do every single day, or we would already be closed, 1190 the overhead, capital projects, et cetera. So, that is a routine 1191 part of our business. 1192 I would point you, perhaps, to the idea behind Schedule H 1193 for the IRS filing and the community benefit. I think there might 1194 be opportunities there to define and identify a specific 1195 I would think about total unreimbursed care because reporting. 1196 that is really what we are talking about here. 1197 And those are my thoughts.

Mr. Gifford.

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Ryan White grantees may have a slightly less

1199 complex financial world that we operate in. We welcome the 1200 opportunity to report the savings and how they are directed to 1201 specific costs for the delivery of care. 1202 I think the term or concept of charity care is 1203 one that is not terribly familiar for community health centers 1204 or in the community health center world, not because we don't 1205 understand that concept but because we operate under a set of 1206 statutory requirements that essentially mean we are on the hook 1207 for taking care of everyone, regardless of their ability to pay, 1208 and for providing a full range of services, regardless of their 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 So, thank you. on. 1222 Mr. Griffith. Thank you very much for yielding back, Mr. 1223 Chairman.

1224 I now recognize the ranking member, Mr. Pallone of New 1225 Jersey. 1226 Thank you, Mr. Chairman. Mr. Pallone. 1227 I have been impressed with the responses the committee has 1228 received with its inquiries about how covered entities use the 1229 340B Program and it appears that recipients rely on program 1230 savings to provide important services to vulnerable patient 1231 populations. 1232 But I just want to briefly go with each of you, if I could, 1233 if you can just answer my question in 30 seconds. 1234 Mr. Gifford, your testimony states that the AIDS Resource 1235 Center of Wisconsin received \$7.4 million in 340B discounts last 1236 year and that these savings played a crucial role in providing 1237 service to your patients. Can you explain in 30 seconds how the 1238 340B Program helps you provide services? 1239 Mr. Gifford. Certainly. They support the cost that Ms. 1240 Veer was discussing in terms of the professional time providing 1241 medical care, the laboratory costs, the medications that 1242 uninsured patients receive. 1243 And then for our physicians, they often talk about health 1244 care needed is overcoming the social barriers to care. So, making 1245 sure that mental health illnesses and drug addictions are 1246 addressed before they can get into the medical exam room. 1247 Mr. Pallone. Thank you. 1248 Now to Mission Health. Dr. Paulus, you reported that

1249 Mission Health provided \$105 million in charity and unreimbursed 1250 You also reported that Mission Health's community benefits 1251 were worth \$183 million that year. 1252 In 30 seconds or less, how does the 340B Program help you 1253 provide services? 1254 Well, we are faced with a tsunami of illness Dr. Paulus. 1255 and of need in our community. And as I described, we take our 1256 anticipated savings on 340B and specifically look to allocate 1257 those to funds to programs that we could otherwise not afford to 1258 provide. 1259 So there is a great amount of detail in our testimony in the 1260 written document about each of those program. 1261 Mr. Pallone. All right, next, Johns Hopkins. Dr. Reuland, 1262 you reported that Johns Hopkins provided \$28 million in charity 1263 care and community benefits worth \$191 million. Briefly, how 1264 does the 340B Program help Johns Hopkins provide services to the 1265 community? 1266 So I will give you just two very guick Mr. Reuland. 1267 examples, one that is in our community benefit report and one that 1268 isn't. 1269 In the community benefit report, the Health Leads Program 1270 is an opportunity for us to prescribe basic things like food, 1271 shelter, clothing, utility support for patients who need it. 1272 that can be for any disease state. That is a general concept that

we use in a lot of our outpatient areas.

58 1274 More broadly, we have done a development exercise in the 1275 region right north of our campus that is a partnership with the 1276 city and some developers to basically take an old burned out part 1277 of the city and redevelop it in a way that we would be happy to 1278 tell you more about. But it is those kinds of city building and 1279 infrastructure-building activity that are on the broader scale. 1280 Mr. Pallone. Well, thank you. 1281 And then moving on to Carolina Health Centers, Ms. Veer, you 1282 state in your testimony the 340B savings enable Carolina Health 1283 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?

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1299 Absolutely. I think in its most simplest form, Ms. Banna. 1300 340B reduces our costs. And as a nonprofit hospital, that is what 1301 we strive for each and every day. Reducing our costs fuels our 1302 ability to expand our mission into our communities. And you are 1303 hearing from each of us that our missions are different but we 1304 use that savings to empower growth out into the communities that 1305 we serve. 1306 Mr. Pallone. All right, thanks. 1307 I wanted to ask anyone how you make sure the savings actually 1308 go to help patients. I know 30 seconds, maybe I will go back to 1309 Mr. Reuland. Well, there are plenty of very direct 1310 Mr. Reuland. assistance programs, including a Pharmacy Assistance Program, for 1311 1312 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 1313 1314 for them, we have the discretion through a Pharmacy Assistance 1315 Program on the spot to make sure that the patient can leave with 1316 the medications that they needed. And then we can help them after 1317 that to perhaps connect them to some other form of payment going 1318 on over time or, sometimes, we continue supporting that right 1319 through these dollars. 1320 Mr. Pallone. That is a good example. 1321 Thank you, Mr. Chairman. Thank you all. 1322 Mr. Griffith. The gentleman yields back. 1323 I now recognize Mr. Walberg of Michigan.

1324	Mr. Walberg. Thank you, Mr. Chairman and thanks to the
1325	witnesses for taking the time to be here with us today.
1326	I want to get to the concerns about the savings that you have
1327	had that you have talked about today. I also want to ask some
1328	questions relative to how you train and evaluate the success of
1329	the program, the costs, et cetera, how you administer it. But
1330	I think our chairman brought up some points I would like to go
1331	into first and meddle a little bit, I guess, at this point, kind
1332	of get personal.
1333	I pulled the 990s of each of your organizations for the most
1334	recent years that we are able to get to, 2015. So let me ask you
1335	just to respond yes or no, correct or false to these questions.
1336	Ms. Veer, Carolina Health Centers indicated that the salary
1337	for the CEO was \$198,000. Is that correct?
1338	Ms. Veer. That is correct.
1330	
1339	Mr. Walberg. Mr. Gifford, for the AIDS Resource Center, it
	Mr. Walberg. Mr. Gifford, for the AIDS Resource Center, it was indicated that the salary for the CEO was \$350,000. Is that
1339	
1339 1340	was indicated that the salary for the CEO was \$350,000. Is that
1339 1340 1341	was indicated that the salary for the CEO was \$350,000. Is that correct?
1339 1340 1341 1342	was indicated that the salary for the CEO was \$350,000. Is that correct? Mr. Gifford. That is cash compensation, yes.
1339 1340 1341 1342 1343	was indicated that the salary for the CEO was \$350,000. Is that correct? Mr. Gifford. That is cash compensation, yes. Mr. Walberg. Okay, cash compensation. Okay.
1339 1340 1341 1342 1343 1344	was indicated that the salary for the CEO was \$350,000. Is that correct? Mr. Gifford. That is cash compensation, yes. Mr. Walberg. Okay, cash compensation. Okay. Let me ask Mr. Paulus, Mission listed at \$1.6 million,
1339 1340 1341 1342 1343 1344 1345	<pre>was indicated that the salary for the CEO was \$350,000. Is that correct? Mr. Gifford. That is cash compensation, yes. Mr. Walberg. Okay, cash compensation. Okay. Let me ask Mr. Paulus, Mission listed at \$1.6 million, approximately.</pre>
1339 1340 1341 1342 1343 1344 1345 1346	was indicated that the salary for the CEO was \$350,000. Is that correct? Mr. Gifford. That is cash compensation, yes. Mr. Walberg. Okay, cash compensation. Okay. Let me ask Mr. Paulus, Mission listed at \$1.6 million, approximately. Dr. Paulus. I assume that is correct.

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
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.
1383	The program has grown rapidly in the last decade and it seems
1384	it will continue to grow. So, those figures are important.
1385	In the area of education, let me ask you each to respond.
1386	First of all for the sake of context, how many full-time employees
1387	do you have total? And secondly, how many employees of those
1388	full-time employees do you have devoted fully to 340B
1389	administration and compliance?
1390	Ms. Veer?
1391	Ms. Veer. In our most recent Universal Data System report
1392	to HRSA, we reported 231.20 full-time employee equivalent. Of
1393	that, 45.40 are pharmacy employees. And since approximately 50
1394	percent of our business in the pharmacy is 340B, I would estimate
1395	that our pharmacy staff devoted to 340B is approximately 25.
1396	Mr. Walberg. Twenty-five, okay.
1397	Mr. Gifford?
1398	Mr. Gifford. ARCW has 240 employees, about 25 of them who

1399	work in our pharmacy. 340B is the largest part of our pharmacy
1400	operations so, they are all devoted to it. Additionally, we have
1401	a compliance department that includes two full-time employees and
1402	parts of six other employees.
1403	Mr. Walberg. Mr. Paulus?
1404	Dr. Paulus. We have two dedicated full-time people who do
1405	nothing but 340B and 76 others that have 340B as part of their
1406	job description, including five people who have gone through a
1407	complete 340B university training.
1408	Mr. Walberg. Total employees how many?
1409	Dr. Paulus. Twelve thousand.
1410	Mr. Walberg. Twelve thousand total employees.
1411	Mr. Reuland?
1412	Mr. Reuland. Johns Hopkins Hospital employs about 10,000
1413	FTEs directly, not counting our physicians. And we have about
1414	nine to ten whose effort is primarily dedicated toward the
1415	program, significantly toward the compliance of the program.
1416	Mr. Walberg. Okay and Ms. Banna?
1417	Ms. Banna. We have over 14,000 employees. We have an
1418	integrated approach. There are people in multiple departments
1419	across our hospital that have been educated and we consider
1420	content experts. Fifty to seventy-five people are educated in
1421	content experts. I would say the pharmacists are most directly
1422	full-time 340B-responsible. So that is probably 25 to 25.
1423	Mr. Walberg. Thank you. I yield back.

1424 Mr. Griffith. The gentleman yields back. I now recognize 1425 Ms. Castro of Florida for 5 minutes for questions. 1426 Ms. Castor. Thank you, Mr. Chairman. Based upon what I 1427 have seen from my hospitals, and providers back home, and the 1428 testimony today, I think it is clear that the 340B Program is 1429 critical to America's healthcare safety net. And according to 1430 HRSA, 340B savings represent less than two percent of total drug 1431 spending in this country but the benefits here under 340B are so 1432 broad where you are able to expand health services, you are able 1433 to see more patients, offset losses from uncompensated care. 1434 And at a time when drug prices are skyrocketing across the 1435 board for consumers, here is one bright light for our neighbors 1436 And I have seen it at Saint Joseph's Hospital. 1437 is part of the BayCare Health System. They provide over \$100 million in charity care per year, about, and 340B has helped them 1438 1439 save about \$17 million. 1440 They run the Children's Hospital there, a complex clinic for 1441 the medically fragile. And what they are able to do with 1442 wraparound services, as has been mentioned, is remarkable. 1443 They have had to expand substantially behavioral health and substance abuse services and that is where part of the savings 1444 1445 And we are all grappling with that. go. 1446 And they have a care clinic that stretches the federal Ryan 1447 White funding to support a continuum of care to maintain a higher 1448 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

1474 between eight to ten percent a year over the past 5 years, 1475 oncologics, new therapies, immunotherapies, and in some cases 1476 just explained drug inflation that we can't explain. We had seven 1477 very common drugs, the price of which went up 312 percent with 1478 volume going up 12 percent. And one of those drugs is commonly 1479 found on a crash cart, a cart that we use to resuscitate patients. 1480 So the drug spend growth is what leads the savings growth 1481 for us and that is a big part of it. 1482 Ms. Castor. And there is an important qualifier. Ιf 1483 someone just tuned into this hearing, they would say wow, what 1484 is happening here but HRSA and the parameters that the Congress 1485 has put into law over time says these covered entities are a real 1486 subset of providers across the country. Can you explain that a 1487 little further? What is the covered entity gateway to qualify 1488 for 340B? 1489 Mr. Reuland. If I understand the question, we qualify by virtue of being a DSH hospital. Our percentage DSH is about 19 1490 1491 percent. 1492 DSH hospital for someone that is tuning in --Ms. Castor. 1493 Disproportionate share of our patients come Mr. Reuland. 1494 from an underserved and have a social security disability 1495 eligibility. 1496 You are saying a disproportionate share of our Ms. Castor. 1497 neighbors back home who don't have health insurance coverage or 1498 they are underinsured.

1499 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

1524	respond to only the indigent and charity care that we provide,
1525	simply because
1526	Ms. Castor. You didn't include bad debt?
1527	Ms. Banna. We didn't include bad debt and we didn't include
1528	other elements of uncompensated care, which includes the care that
1529	is not covered that is provided to Medicare and Medicaid
1530	beneficiaries.
1531	There are entire other populations of care that is provided
1532	effectively free to the community.
1533	Ms. Castor. Thank you very much.
1534	Mr. Griffith. The gentlelady yields back.
1535	I now recognize Mr. Costello of Pennsylvania for 5 minutes
1 5 2 6	for guartiens
1536	for questions.
1536	Mr. Costello. Thank you, Mr. Chairman.
1537	Mr. Costello. Thank you, Mr. Chairman.
1537 1538	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities
1537 1538 1539	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide
1537 1538 1539 1540	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide all 340B patients with discounted prices on prescription drugs?
1537 1538 1539 1540 1541	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide all 340B patients with discounted prices on prescription drugs? Ms. Veer. Starting on this end, I am assuming. Yes, we do,
1537 1538 1539 1540 1541 1542	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide all 340B patients with discounted prices on prescription drugs? Ms. Veer. Starting on this end, I am assuming. Yes, we do, according to the rules, HRSA rules, around our sliding fee scale.
1537 1538 1539 1540 1541 1542 1543	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide all 340B patients with discounted prices on prescription drugs? Ms. Veer. Starting on this end, I am assuming. Yes, we do, according to the rules, HRSA rules, around our sliding fee scale. Sliding fee is required. A sliding fee program is required for
1537 1538 1539 1540 1541 1542 1543	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide all 340B patients with discounted prices on prescription drugs? Ms. Veer. Starting on this end, I am assuming. Yes, we do, according to the rules, HRSA rules, around our sliding fee scale. Sliding fee is required. A sliding fee program is required for all services that we provide.
1537 1538 1539 1540 1541 1542 1543 1544	Mr. Costello. Thank you, Mr. Chairman. To each witness, the 340B Program provides covered entities with discounts on prescription drugs. Does your entity provide all 340B patients with discounted prices on prescription drugs? Ms. Veer. Starting on this end, I am assuming. Yes, we do, according to the rules, HRSA rules, around our sliding fee scale. Sliding fee is required. A sliding fee program is required for all services that we provide. So in my organization, the price to a patient under 200

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
1559	at the time of service but we provide, as I said, free care up
1560	to 200 percent of the federal poverty guidelines. And we have
1561	the Medication Assistance Program that provides free or
1562	discounted drugs to all of those patients.
1563	Mr. Costello. Okay, Mr. Reuland.
1564	Mr. Reuland. Yes, our Pharmacy Assistance Program applies
1565	to any patient, whether uninsured, underinsured. If they can't
1566	afford their coinsurance and their copayments, we use our Pharmacy
1567	Assistance and Charity Care policies to help cover them.
1568	Mr. Costello. Yes to both questions?
1569	Mr. Gifford. Yes.
1570	Mr. Costello. Ms. Banna?
1571	Ms. Banna. Yes to both questions. If you qualify for
1572	indigent or charity care, then we are looking for opportunities
1573	to provide that.

1574	Mr. Costello. Okay, back to Ms. Veer. Does your
1575	organization use patient assistance programs offered by
1576	biopharmaceutical companies or other entities to help lower the
1577	cost of prescription medicines for patients?
1578	Ms. Veer. Yes, we do.
1579	Mr. Costello. What percentage of your patients have free
1580	receive free medicine from a patient assistance program that
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

not-for-profits.

Mr. Costello. Ms. Banna?

Ms. Banna. We do have an Oncology Patient Assistance 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

1624 the money is being spent in those programs and in the ways with 1625 which it was intended. And so when we read that while we weren't 1626 able to unearth through an audit whether compliance was in fact 1627 successful or not as a consequence of us not being able to audit, 1628 it causes a great deal of frustration and we want to fix that. 1629 Mr. Gifford, as I understand it, you have -- let me make sure 1630 I have this right, have you developed software to monitor 1631 compliance? 1632 Mr. Gifford. Yes, we have. 1633 Mr. Costello. Okay. Are all of you familiar with the software that he has developed to monitor compliance? 1634 1635 Do any of you object to creating an accounting mechanism so 1636 that as you get this funding, it is able to be audited in a way 1637 which comports with us being able to ensure that you have 340B I think that that is the gist of it, as I --1638 compliance? 1639 Do you have concerns? Ms. Veer. 1640 Ms. Veer. Yes, I was just going to say I do think, at least 1641 for -- I can only speak from the perspective of a HRSA grantee 1642 but from that perspective, one of our grant conditions is that 1643 we are required to use all program income, including what is 1644 generated outside of the grant, for the purposes of advancing our 1645 HRSA scope of projects. So we do have a reporting mechanism for 1646 accountability. And in terms of our pharmacy, from the compliance standpoint, 1647

we audit daily to ensure that the program is being used

1650 Yes, I would add it sounds like there may be Mr. Reuland. 1651 two issues, is the compliance with meeting the requirements and 1652 I think the software program. I am not sure which one you are 1653 referring to there but we use one as well to assure that we only 1654 avail ourselves of a discount for the appropriate patients. 1655 that is an important part of the program. 1656 Anything that would curtail the flexibility, as you said, 1657 of our ability to invest in that entire patient would be a 1658 challenge I think. So we would look at a policy proposal but the 1659 flexibility remains the most important thing, as you pointed out. 1660 I yield back. Thank you, Mr. Chairman. Mr. Costello. 1661 Mr. Griffith. I thank the gentleman. The gentleman yields 1662 back. 1663 I know recognize Ms. Schakowsky -- Ms. Clarke has just walked 1664 Are you ready to go, Ms. Clarke? in. 1665 Ms. Clarke. Yes, I am. 1666 Mr. Griffith. All right, then Ms. Clarke of New York. 1667 Ms. Clarke. Thank you very much, Mr. Chairman and I thank 1668 our Ranking Member DeGette. I thank our expert panelists for 1669 their testimony here today. I understand that a lot of the questions my colleagues about 1670 this program relate to whether providers are using their 340B 1671 benefit to stretch scarce federal resources as far as possible 1672 1673 to help low-income patients.

specifically for 340B 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

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,

these populations.

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|| 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,

1725 Lastly, you can't look at this without also looking at bad 1726 As high deductible plans have gotten ever higher, the 1727 patients have no ability to pay those amounts. They then become 1728 part of the charity care, which is one of the reasons why our 1729 charity care is up 20 percent in 2017 over 2016 because those 1730 people have no capacity to pay those deductibles. 1731 Mr. Reuland. Thank you for the question. And I think an 1732 example, I will build on that sickle cell disease program I 1733 mentioned earlier. One of the things that Dr. Lanzkron and her team do is 1734 1735 actually reach out to patients to make sure -- because high and 1736 low temperature exposure can actually bring on a sickle cell 1737 crisis, they work hard to make sure that they in fact have appropriate air conditioning option or heating option so that they 1738 can avoid having a crisis in the first place. Those are the kind 1739 of things that you could imagine would suffer. 1740 1741 On a larger scale, we have invested in a program, a bundle 1742 of case management services that has been shown to reduce 1743 readmissions and inappropriate use of our hospitals and EDs on 1744 a broad scale. If we can't fund those kind of interventions, we 1745 could drive utilization back up in an unintended way. 1746 Ms. Clarke. I thank all of you for your response and I yield 1747 back, Mr. Chairman. Thank you. 1748 Mr. Griffith. Thank you for yielding back.

the entire benefit for 340B is less than just our charity care.

1749	I now recognize the gentleman, Mr. Carter of Georgia.
1750	Mr. Carter. Thank you, Mr. Chairman and thank all of you
1751	for being here today.
1752	As the only pharmacist currently serving in Congress, I am
1753	very familiar with the 340B Program. I have seen the benefits.
1754	I have also seen where it can be abused.
1755	As the chairman said earlier, the chairman of the full
1756	committee, the reason we are here is because one of the initiatives
1757	of this committee, hence, Oversight and Investigations, is to look
1758	into programs and see how we can improve those programs.
1759	I will remind you that we had a hearing in July. And for
1760	my colleagues, I want to remind them, if you can play the clip
1761	now, of what we heard in that hearing.
1762	Well, it looks like we are not going to get it. But what
1763	we heard over and over was the statute is silent. The statute
1764	is silent. It was irresponsible, as Members of Congress, that
1765	we did not specify exactly what we heard.
1766	Have you got it now?
1767	[Video shown.]
1768	Mr. Carter. That is what we heard. That is why we are here
1769	today. That is why we need your help because it is irresponsible
1770	of us. That is our responsibility in Congress.
1771	You know I take offense and I am resentful of my colleagues
1772	on the other side of the dais to insinuate that we have somehow
1773	said we wanted to cut out this program. I have never heard anyone

1774 say we wanted to cut out this program but we have a responsibility, 1775 as Members of Congress, to make sure this program is running 1776 correctly and it is not being abused. 1777 I want to ask some very quick questions here. Ms. Vanna, I am very familiar with Northside Hospital and I have worked with 1778 1779 you in the State Legislature. You enjoy a great reputation in 1780 the State of Georgia. I am sure it is hard-earned. 1781 it is well-deserved. 1782 However, I need to ask you some questions, particularly as 1783 it relates to consolidation. One of the things that I have 1784 discovered as a Member of Congress is just what an impact our 1785 actions here in Congress can have on the private sector and have 1786 on the free market. Have you, in recent years since you have 1787 started this program, has there been an increase in the number of clinics that Northside Hospital has acquired, specifically 1788 1789 oncology clinics? 1790 I think that we are, as a hospital system, are Ms. Banna. 1791 being encouraged to expand our clinically-integrated outpatient 1792 care model, yes. 1793 That is not what I asked and you are under oath. Mr. Carter. 1794 Have you increased the number of oncology 1795 clinics that you have bought since the 340B Program has come into 1796 effect? 1797 Well in our case, we did acquire oncology clinics 1798 in 2011 and 2012, yes.

1799	Mr. Carter. Does the 340B Program have anything to do with
1800	that or are you acquiring the oncology clinics because you have
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.
1822	Mr. Reuland. But we would be happy to work with you.
1823	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 --

1849	Mr. Carter. So your answer to me is that this is actually
1850	restricting you. You could actually, if we were to loosen it up
1851	instead of tightening it up, that you could actually do more as
1852	these other hospitals have done.
1853	Mr. Gifford. If we could loosen this up for Ryan White
1854	Mr. Carter. But my question to you was since you have got
1855	more stringent requirements, you still benefitted from the
1856	program. You spoke very highly of the program.
1857	Mr. Gifford. The program does support the fight against
1858	AIDS in many ways and we would hope that the committee would expand
1859	our ability to offer life savings
1860	Mr. Carter. Again, let me explain to all of you that no one
1861	has said they want to do away with this program. All we have said
1862	is that we understand we have a responsibility to tighten this
1863	up, to make sure it is being used like it was.
1864	And Ms. Veer, you have made some very good points and I want
1865	to thank you for what you are doing over there.
1866	Thank you very much, Mr. Chairman.
1867	Mr. Griffith. The gentleman yields back.
1868	I now recognize Mr. Tonko of New York for 5 minutes for
1869	questioning.
1870	Mr. Tonko. Thank you, Mr. Chair.
1871	Before I begin my questioning, I will echo my colleagues'
1872	expressions of strong support for the 340B Program. While it is
1873	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,

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

1899 Northside reported to the committee that most of its 340B child 1900 site were sites already associated with Northside prior to 2012 1901 but were registered between 2012 and 2017 because of changes to 1902 the HRSA guidance. 1903 Northside did, however, acquire two oncology practices in 1904 2013, did it not? 1905 Those discussions began in 2011 and completed Ms. Banna. in 2012. 1906 1907 Mr. Tonko. Okay. So Ms. Banna, can you explain why 1908 Northside acquired these sites? 1909 Ms. Banna. Absolutely. We were approached by a large 1910 oncology practice that was seeking integration with the hospital 1911 system, as were several other hospital systems in the Atlanta 1912 We worked with them throughout 2011 and 2012 to determine area. 1913 the model that would provide the right kind of 1914 clinically-integrated care that both parties were looking for and 1915 completed that transaction in 2012. 1916 And Ms. Banna, to your knowledge, has any patient 1917 been denied service at these oncology sites due to inability to 1918 pay since you acquired them? 1919 Since we acquired them, no. As a nonprofit 1920 hospital, that is a service that we extend to meet the need no 1921 matter the ability to pay. 1922 And typically, that is a service that is not in place prior 1923 to a nonprofit hospital's entrance.

1924 Thank you, Ms. Banna. And would it be accurate Mr. Tonko. 1925 then to say that since Northside does not deny services to 1926 Medicare-eligible, Medicaid-eligible, or uninsured patients, it 1927 is likely that these oncology sites now provide services to more 1928 patients than when the sites were privately owned? 1929 Ms. Banna. Absolutely. 1930 Mr. Tonko. And one last question, Ms. Banna. 1931 Northside place oncology patients into any type of queue through 1932 which commercially-insured patients are treated before Medicaid 1933 and Medicare patients? 1934 Ms. Banna. No. 1935 Mr. Tonko. Thank you. 1936 I would like to also go over to address the Mission Health 1937 So, Dr. Paulus, I understand that the 340B savings program. 1938 cannot be directly attributed to individual services. However, 1939 generally speaking, if Mission Health could not rely on savings 1940 from the 340B program, how would that affect your ability to 1941 provide these community benefits? 1942 Well, as I mentioned, it would have a major Dr. Paulus. 1943 We had about \$37.4 million worth of 340B savings last impact. 1944 year and our entire operating margin was \$53 million. So, that 1945 is 70 percent of the total. We need that operating margin to be 1946 able to maintain services, replace outdated buildings and 1947 equipment and so forth. And so we would have to go through and 1948 figure out how to cut our budget. And by definition, some of the 1949 outreach and charity that we do today would have to be curtailed. 1950 Thank you. And Dr. Reuland, Johns Hopkins Mr. Tonko. 1951 reported \$109 million, I believe, in 340B savings in 2016. Ιf 1952 you could not rely on those savings, what impact would that have on your ability to provide services in your given community? 1953 1954 Well thank you for the question. Mr. Reuland. 1955 certainly, as I think we have been elaborating on, the wraparound 1956 services and the preventive services that we try to put in place 1957 in addition to the standard services is really what it is to serve 1958 an underserved community. And our inability, if we had to 1959 increase our drug prices by \$109 million, that would cause a 1960 significant amount of cost pressure and cause us to have to cut 1961 back on some other programs, just like the ones we have mentioned. 1962 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 1963 1964 therapist, and a handyman or handywoman to a person's house. 1965 they will typically install a second bannister for somebody who 1966 can get up and down the stairs now and get to a doctor's appointment 1967 It is that kind of hands-on community work that we more easily. 1968 would simply not be able to support. Thank you. And Ms. Veer, how would losing 340B 1969 Mr. Tonko. 1970 savings impact Carolina Health's ability to provide services in 1971 your given community? 1972 Well I have spoken to two or three specific 1973 programs that are funded by the 340B savings. Our delivery of 1974 prescriptions into very rural outlying areas that would be very 1975 We also provide behavioral health difficult to sustain. 1976 counseling in our sites for people who would experience long 1977 delays in accessing the local mental health agency. Both of those areas would be significantly impacted. 1978 1979 Beyond that, we have sites in -- we have medical sites in 1980 rural areas that, because of the nature of the population there 1981 and how rural the area is, they operate at a loss. And so total 1982 out of our 13 sites, those operating losses are around \$1.8 1983 We would definitely need to look at how we redistributed 1984 care to those areas, possibly combining some of those sites or 1985 reducing hours at those sites. 1986 Mr. Tonko. Thank you. I appreciate the quality services 1987 you all provide with these savings. 1988 And with that, Mr. Chair, I yield back. 1989 Mr. Griffith. The gentleman yields back. 1990 I now recognize the gentleman from New York, Mr. Collins. 1991 Mr. Collins. Thank you. And I want to thank the panelists 1992 for being here and maybe reset the stage just a bit. 1993 All of us stipulate the great benefits the 340B -- the 1994 pharmaceutical companies stipulate that. I mean it has been 1995 around a long time. I think what we are starting to look into, 1996 though, and I won't use the word abuse because if something is 1997 legal, it is not an abuse, but I will use the word loophole. 1998 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.

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

2074 declining in the past couple of years down to --2075 Yes, my time has expired. I was going to get Mr. Collins. 2076 into, though, with Johns Hopkins the last 2 years of your diversion 2077 of pricing through the contract pharmacies but that will have to 2078 wait for another hearing. 2079 The gentleman yields back. Mr. Griffith. 2080 I now recognize Ms. Schakowsky of Illinois for 5 minutes for 2081 questioning. Ms. Schakowsky. 2082 Thank you. First of all, I want to thank 2083 the witnesses for their testimony. 2084 I know 340B is essential to people in my district with 2085 skyrocketing drug prices or, as the President would say, price 340B is literally a lifesaver and not one of us 2086 gouging prices. 2087 opposes transparency. I am certainly not for waste, or fraud, 2088 I am for transparency. But it does raise questions or abuse. 2089 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

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91 2099 is going to develop new drugs and for research and development, 2100 what that is really about. We know about your CEO, how much they 2101 We don't know about theirs. And we need to concentrate 2102 more on that. 2103 And I think it is really a dereliction of duty that we allow 2104 these prices to get so out of control that they do imperil the 2105 health of people across this country. 2106 In my district, Advocate Health has used its 340B savings 2107 to provide support for low-income patients through child

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.

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2124 Two, our distribution entities and there is no revenue 2125 associated with those; two we own. 2126 And the total value of Mission Health's contracted 2127 pharmacies is \$7.6 million but the value of that is that, for 2128 example, at Angel Medical Center, which is one of our rural 2129 Critical Access Hospitals, patients are provided with vouchers 2130 to go to those contract pharmacies and receive free medication. 2131 So the contract pharmacies we view as an extension of our 2132 Our goal is, either through our own medication 2133 assistance program or through those contracted pharmacies, that 2134 no patient goes without free or discounted medications, if they 2135 need that medication. 2136 Ms. Schakowsky. Thank you. I am just wondering if any of 2137 you have witnessed dramatic increases in the cost of a particular 2138 drug that your patients need that you might want to tell us about. 2139 I have heard those horror stories from a number of doctors in the 2140 Chicago area. 2141 Yes, Dr. Reuland. 2142 Mr. Reuland. Thank you for the question. I mentioned 2143 earlier that we have seen a couple of -- seven very common 2144 medications. We noticed that our spend on them increased 312 2145 percent with a volume growth of 12 percent. 2146 So it was clearly a price increase that we could not explain and these were not medications that were easily substitutable with 2147 2148 something else.

2149	Dr. Paulus. If I could just add, you know there is a variety
2150	of reasons for the quote growth in the programs, one of which is
2151	prices. And I think the data are a third of the savings is due
2152	to price changes alone.
2153	But let me bring up another issue, which is a thank you to
2154	the pharmaceutical manufacturers. When we compare our 2014 to
2155	2017 data, there are six drugs that are new that didn't exist that
2156	comprised over \$5 million of spend in 2017.
2157	So the growth of the program is a multifactorial attribute
2158	and it is important to look into the detail.
2159	Ms. Schakowsky. Thank you and I yield back.
2160	Mr. Griffith. Thank for yielding back.
2161	I now recognize Mrs. Brooks of Indiana for 5 minutes for
2162	questioning.
2163	Mrs. Brooks. Thank you, Mr. Chairman.
2164	Ms. Banna, we heard about the acquisition by Northside of
2165	the oncology practices in 2012. Are those two practices 340B
2166	child sites?
2167	Ms. Banna. The locations operating as hospital outpatient
2168	departments are.
2169	Mrs. Brooks. And when did you register those oncology
2170	practices for the 340B Program?
2171	Ms. Banna. I believe it was spring of 2014.
2172	Mrs. Brooks. And can you talk about the registration
2173	process? So that is the date that the registration process

2174	concluded, is that correct, in 2014?
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
2197	maybe those patients didn't pay prior to them becoming hospital
2198	sites? Are there other fees that patients are charged once they

2199 become hospital sites that they weren't charged previously, 2200 oncology patients, for example? 2201 Ms. Banna. I think you know I can't speak to charges that 2202 are not hospital-based. They are charged commensurate with any 2203 hospital service area. 2204 So are you aware as to whether or not patients Mrs. Brooks. 2205 -- what a patient's bill might have looked like prior to them being 2206 acquired by the hospital versus what they are after the 2207 acquisition, a comparison of the costs? 2208 I mean I understand what hospital charges are, 2209 I think it is important, though, to state that charges are yes. 2210 not directly related really to what people pay. People pay based 2211 on what kind of insurance coverage they have or don't have. 2212 Mrs. Brooks. And so on the hospital fees and whether there 2213 are any other fees, are they all included in the one bill or might 2214 there be an additional separate bill to the patient? 2215 Patients may receive bills for non-hospital Ms. Banna. 2216 services. 2217 I want to ask each of the panelists what is 2218 the DSH percentage of your entities and is that for the parent 2219 entity or the DSH percentage compared to the child sites? 2220 What is your DSH And I will just start with you, Ms. Banna. 2221 percentage for your parent entity and how does that compare to 2222 your child sites? 2223 The DSH percentage is a representation of Ms. Banna.

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
2241	percentages, has that percentage fluctuated over the years? And
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.
2263	Our oncology, as I mentioned, is not a growth based on
2264	acquisition of any practices. It is as a comprehensive cancer
2265	center. As new therapies come along, as Dr. Paulus pointed out,
2266	they often bring some very nice promise but they certainly bring
2267	a heavy cost with them and that is part of our reality.
2268	Mrs. Brooks. Thank you. My time is up. I yield back.
2269	Mr. Griffith. Thank you. I appreciate that very much.
2270	I now recognize Dr. Ruiz from California for 5 minutes for
2271	questioning.
2272	Mr. Ruiz. Thank you very much, Mr. Chairman.
2273	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

2324 struggling working families also get cancer. They also need the 2325 They also need care. medications. 2326 And I think it is misleading to insinuate that you decided 2327 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 2328 2329 leadership. 2330 So let me just ask you point blank. Did you do that? What 2331 was the reason for you purchasing some of these oncology clinics, 2332 Dr. Paulus? 2333 Dr. Paulus. Yes, as I mentioned just a bit ago, for us it 2334 was a matter of maintaining oncology services in the region and 2335 getting those clinics available in the 18 diverse and mountainous 2336 counties. 2337 So keeping oncology services for the patients in Mr. Ruiz. 2338 your catchment area that you want to serve. 2339 Ms. Veer? We don't operate oncology services. 2340 Ms. Veer. However, I 2341 will say the next to the last site that we opened was opened at 2342 the request of a local hospital that 75 percent of their emergency 2343 visits were ambulatory care-sensitive. And since we have -- I 2344 can give the example of one patient who had 11 visits down to none. 2345 Well, yes, I mean how do you measure the ability Mr. Ruiz. 2346 to use some of the cost savings to go into the community to provide 2347 nutrition classes, exercise classes, prevention, education for 2348 diabetics knowing, that by them participating in these programs,

101 2349 they will prevent going blind, they will prevent leg amputations, 2350 they will prevent costly renal insufficiency and hemodialysis? 2351 So how do we measure the true value of these cost-saving programs 2352 that allow you to do more outreach into underserved communities? 2353 And that is where the real problem lies. If we are just narrowly 2354 focused on uncompensated care, then we are missing the big picture 2355 here. 2356 So you know I think we need to expand services. We need to 2357 empower the clinics and hospitals to do more outreach into more 2358 underserved areas to provide more lifesaving care that will help 2359 prevent rising costs for the emergency care that they are going 2360 to need if they don't get those services to begin with. 2361

Thank you very much.

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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. 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

2424 this opioid crisis. Baltimore has very special challenges with 2425 respect to heroin and opioid addiction crisis. And maybe you 2426 could speak on behalf of hospitals across the country of who 2427 benefit from the 340B Program in terms of their ability to respond 2428 to that crisis in those communities, which is absolutely critical 2429 right now. 2430 Mr. Reuland. And I am happy to respond and others may want 2431 to contribute. But we are absolutely seeing an increase in opioid 2432 It is an estimate of about 45,000 residents in 2433 Baltimore have a dependence. And in an emergency department, as 2434 Dr. Ruiz knows, patients will present often having overdosed and 2435 will be reversing that with naloxone and trying to bring them back. 2436 And as more powerful substances are available on the streets, we 2437 are doing more and more of that. 2438 The aftercare, the recovery and management of addiction, I 2439 mentioned earlier some of the wraparound services we provide, so 2440 that not only can we treat the patient with standard therapies 2441 but provide them with supportive housing on the outside so they 2442 don't go back quite to that same neighborhood. It is that kind 2443 of thing that I suspect all of us do at some level. 2444 Mr. Sarbanes. I appreciate your testimony. I thank all of 2445 you for what you are doing in your various communities. 2446 I yield back.

if you all can bear with us a few more minutes, I have a couple

Mr. Griffith. I thank the gentleman for yielding back and

2447

2449 of additional questions. 2450 So I am going to recognize myself for an additional 5 minutes. 2451 And Ms. DeGette may wish to but she is going to play that by ear. 2452 So I am going to feed off of what Mr. Sarbanes was just asking 2453 about and this committee has important bipartisan work underway 2454 to see how we can leverage federal resources and authorities to 2455 better combat the opioid crisis. 2456 As part of our work, it is important to understand how all 2457 federal programs intersect and what their interest is with the 2458 crisis that has left virtually no American family or community 2459 That being said, can each of you identify what untouched. 2460 percentage of the 340B prescription opioids represents as a 2461 percentage of your program and can you detail for us what steps 2462 might be in place to prevent diversion or misuse of these drugs, once they are dispensed to the patients? 2463 2464 I will start with you again, Ms. Veer. And if we could be 2465 quick. 2466 I don't have the exact percentage but I Sure. Ms. Veer. 2467 could provide that in writing. 2468 Mr. Griffith. Okay. 2469 Ms. Veer. I can tell you that we use medication management 2470 contracts with our patients. We do standard drug testing to make 2471 sure that it is not being diverted. 2472 Mr. Griffith. I appreciate it. 2473 Mr. Gifford.

2474 Mr. Gifford. I also can provide the data on the percentage 2475 We do provide medication management therapy of prescriptions. 2476 and we do a lot of counseling with our patients and clients about 2477 it. But on this issue of opioids and fighting the opioid 2478 2479 epidemic, this is one of the problems with the Ryan White 2480 constricting language. We cannot use 340B savings to provide 2481 Narcan to somebody to save them from an overdose and a clear death. 2482 And that is one of the examples that I would hope this committee 2483 would look to expanding our ability to fight both the HIV epidemic 2484 and the opioid epidemic. It is a federal regulation that is 2485 inhibiting our ability to fight the opioid epidemic. 2486 Mr. Griffith. That is interesting information. 2487 Ms. DeGette and she didn't know that either. I was not aware of 2488 So thank you for bringing that to our attention. 2489 Dr. Paulus? 2490 Dr. Paulus. I don't know the exact numbers. I know that 2491 it is less than one percent of our revenue. 2492 What we have done is we have done academic detailing for each 2493 of our practices to reeducate them about the prescription 2494 evidence-based best practices for opioids. We have supported 2495 providing free Narcan for our community. And on any given day, 2496 we have between 37 and 60 behavioral health patients being brought 2497 into our emergency department that are uncompensated that relate 2498 to the tragedy that is occurring.

2499 If I could ask one other thing like that, we also provide 2500 support to a free clinic that provides medication assistance and 2501 education but free clinics don't qualify for 340B either. So that 2502 is a parallel. 2503 Mr. Griffith. I appreciate that. 2504 I also don't know our precise percentage but Mr. Reuland. 2505 we certainly have plenty of programs in place to prevent 2506 diversion. 2507 Mr. Griffith. And if you all could just get us that 2508 information, as some others have offered, that would be great. 2509 Ms. Banna. Agreed and I would argue or articulate for us 2510 the opioid epidemic is striking all patient populations. 2511 case, you see it affecting the extension of behavioral health 2512 services dramatically and, certainly, our babies. I mentioned 2513 we have a really high amount -- a high population of special care 2514 babies in our nursery. The opioid epidemic has increased their 2515 length of stay. Many of those babies are Medicaid babies. That 2516 is part of what contributes to our DSH percentage. 2517 Mr. Griffith. And another subject that we will probably 2518 have to touch on another day because, in my area, Bristol, 2519 Virginia-Tennessee -- think of the GEICO gecko -- the newspaper 2520 ran a series of articles on the problems that we are having in 2521 our region with those infants born already addicted. 2522 As a follow-up to my first round of questions, I want to 2523 discuss again how each of you calculate your savings.

2524 and Mr. Gifford, I believe I understand the answers you gave. 2525 understand Mission and Johns Hopkins use of the GPO price to 2526 calculate their savings, which you get by comparing a wholesale 2527 manufacturer price. You get that GPO from them. 2528 Following up on Northside, it appears, from what I have been 2529 able to read and discern, that you all have chosen not to use the 2530 GPO price or you use some other mechanism. Can you explain it 2531 to me and then explain why? 2532 We are actually comparing the GPO price. 2533 comparing the average unit paid on drugs in 340B oncology clinics to those paid in non-340B clinics where GPO is applicable. 2534 2535 So it is, effectively, 340B pricing to GPO pricing. 2536 Mr. Griffith. But you all are taking an average. 2537 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. 2538 2539 all are doing an average across the board. Is that correct? 2540 Ms. Banna. That is correct. What we do is monitor the 2541 program's effect in totality. Each individual drug, there are 2542 some that see bigger savings than others on a per unit but the 2543 units that you purchase move day by day, depending on the patients 2544 that appear and the drug sizing and such that are sold. 2545 Mr. Griffith. I am just curious why you all think that is 2546 a better method. 2547 Right. Oh, so I guess we consider it to be less 2548 We are monitoring the total program impact across the noisy.

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	
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2570	Mr. Griffith. And with that being said, any additional
2571	okay. That being said, this committee is adjourned.
2572	[Whereupon, at 12:24 p.m., the subcommittee was adjourned.]