

EXAMINING HOW COVERED ENTITIES UTILIZE THE 340B DRUG PRICING PROGRAM

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS

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EXAMINING HOW COVERED ENTITIES UTILIZE THE 340B DRUG PRICING PROGRAM

WEDNESDAY, OCTOBER 11, 2017

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

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 Rayburn House Office Building, Hon. Morgan Griffith (vice chairman of the subcommittee) presiding.

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

Also present: Representative Sarbanes.

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

OPENING STATEMENT OF HON. H. MORGAN GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

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 entitlement 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, an important program. The dramatic growth of the program, however, coupled 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.

[The prepared statement of Mr. Griffith follows:]

PREPARED STATEMENT OF HON. H. MORGAN GRIFFITH

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 entitlement 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 an important program. The dramatic growth of the program, however, coupled 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 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’ve 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 patients. I've 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 that 340B Disproportionate Share Hospitals "were either prescribing more drugs, or more expensive drugs" to Medicare Part B beneficiaries than their non-340B counterparts prescribed. Similarly, we have heard 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 are 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'm pleased that the panel we've 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.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

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 investigations 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 extraor-

dinary amounts of uncompensated care and services to those in need.

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

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

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

In an interview with committee staff, Mission Health reported that if its 340B revenues were cut, it would be forced to significantly limit programs and services.

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

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

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

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

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

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

I look forward to hearing from the witnesses about this work. I think we can make improvements on transparency to the program

but, in doing so, we should not reduce the providers' abilities to fulfill their missions and to continue their important work.

I yield back.

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

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

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

The committee has been examining the 340B Drug Pricing Program for about 2 years now, as I think you all know, and the Oversight Subcommittee has been particularly focused on it since last spring.

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

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

So today, we are going to hear directly from five covered entities, all top-notch medical organizations that provide important services to their communities. They range from 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.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

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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 heard how vital this program is to maintaining their high levels of charity care.

However, I am troubled 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 we create serve their intended purpose and operate with integrity, and that participating entities are held accountable for how they spend program dollars.

Our goal in our oversight work is always to take a deliberate and fair look at all sides of an issue. 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've 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 the issue. Much of the data that we do have is self-reported by entities that measure charity care and program savings 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.

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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 outpatient 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 track their 340B savings on a regular basis and provide regular training to staff on program requirements.

With a program this large, it's essential that Congress understand how it's being used, and I hope that is what we will accomplish in this hearing.

Our goal today is to develop a better understanding of how much money different entities save through participation in the 340B program, how covered entities track their savings, and how those savings are used to improve patient care in various ways.

I want to thank each of the witnesses for appearing before us today, and I look forward to hearing more about how each of your organizations provides vital care to your communities.

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

I now recognize the ranking member of the full committee, Mr. Pallone.

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

Mr. PALLONE. Thank you, Mr. Chairman.

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

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

The committee has reviewed responses from most of the healthcare facilities that the Republicans contacted. Committee staff have also interviewed representatives from most of the letters' recipients. Many entities have explained that the 340B savings often cover only a portion of the cost of their uncompensated care and services to vulnerable populations. And through these interviews and responses, we have found that covered entities rely on 340B funds to provide a diverse range of essential services to the community. Today, we will hear firsthand from our witnesses about the type of care and treatment that might be impossible to provide without the help of 340B.

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

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

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

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

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

Mr. GRIFFITH. Thank you.

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

Without objection, I would now like to introduce our panel of witnesses for today's hearing. First, we have Ms. Sue Veer, who is the President and CEO of Carolina Health Centers in South Carolina. Thank you for being here today. Next is Mr. Mike Gifford, who serves as the President and CEO of the AIDS Resource Center of Wisconsin. Thank you, sir. Then we have Dr. Ronald Paulus, who is the President and CEO of Mission Health Systems in North Carolina. Fourth is Mr. Charles Reuland, the Executive Vice President and COO of Johns Hopkins Hospital in Baltimore. Thank you, sir. And finally, we have Ms. Shannon Banna, who serves as the Director of Finance and System Controller at Northside Hospital in Georgia.

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

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

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

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

[Witnesses sworn.]

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

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

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

As my testimony demonstrates, the 340B Program is vital to my health center and to our ability to provide patients with access to affordable prescriptions, as well as needed services for our low-income and underserved patients.

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

[The prepared statement of Ms. Veer follows:]

Carolina Health Centers, Inc.

Written Statement

Sue Veer MBA, President and CEO

Testimony of Sue Veer

President and Chief Executive Officer, Carolina Health Centers, Inc.
House Energy and Commerce, Subcommittee on Oversight and Investigations
Hearing on “Examining How Covered Entities Utilize the 340B Drug Pricing Program”
October 11, 2017

Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee.

My name is Sue Veer. I am the President and CEO of Carolina Health Centers, Inc. (CHC) a Federally Qualified Health Center (FQHC) that serves as the primary care medical home for 26,952 patients in the west central area of South Carolina known as the Lakelands.

At the request of Subcommittee staff, I am providing the following executive summary. My testimony continues with an overview of Carolina Health Centers and specifically our 340B program. Thank you for the invitation to serve as a witness at this hearing and to highlight the vital importance of the 340B program to CHC and to health centers nationwide.

Executive Summary

Carolina Health Centers, Inc. (CHC) is a non-profit primary care corporation established in 1977, now comprised of 13 primary care medical practices, a program focused on serving migrant farmworkers, and two community pharmacies. CHC serves as the primary care medical home for 26,952 distinct and unduplicated patients in the west central area of South Carolina known as the Lakelands – an area which encompasses 7 counties and over 3,700 square miles, and which the U.S. Department of Health and Human Services has determined to be medically underserved.

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As a Federally-Qualified Health Center (FQHC) – also known as a community health center - CHC is committed to ensuring all members of our community have access to a high-quality, comprehensive primary care medical home regardless of demographic, geographic, or socio-economic barriers. Like all FQHCs, by law and by mission, we never turn a patient away due to inability to pay. Patients with incomes below the poverty level pay no more than a nominal fee for the full range of services we provide, and those between 101-200 FPL pay discounted rates based on a sliding fee scale.

In addition to providing comprehensive primary and preventive health care services, community health centers such as CHC provide a wide array of care management, patient education and support, and assistive services that support access to care, promote enhanced clinical outcomes, and reduce total costs across the health care delivery system. And like all community health centers, we are 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.

Like the roughly 1,400 HRSA-funded community health centers, CHC is subject to intensive and on-going oversight from the United States Department of Health and Human Services Health Resource and Services Administration (HRSA). The HRSA requirements with which we must comply are spelled out in a 92-page manual and are grouped into 18 major categories, including – but not limited to – clinical quality, governance structure, financial management and accountability, ensuring access, and collaboration with other local providers¹. HRSA consistently oversees and enforces compliance with all these requirements through a variety of mechanisms including on-site compliance reviews, frequent interactions with project officers,

¹ A summary of HRSA's program requirements for Community Health Centers is included in Appendix A. For a complete listing of all requirements, see the 92-page Compliance Manual available at: <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>

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and regularly-scheduled reporting obligations. HRSA also approves what is called our "Scope of Project", meaning those primary care delivery sites, services, and providers that are considered part of the health center's program operations, and therefore are subject all the requirements I've just described.

Carolina Health Centers is registered with the Office of Pharmacy Affairs Information System (OPAIS) as a 340B entity with one main site (referred to as "parent sites" in OPAIS nomenclature) and 15 satellite medical practice sites (referred to as "child sites" in OPAIS nomenclature), 2 of which have been terminated, leaving 13 active child sites. **These child sites represent primary care medical practices from which 340B eligible prescriptions may be generated.** Each child site was added to our health center's Scope of Project before becoming eligible for the 340B program. As previously mentioned, adding a site to our Scope of Project requires proving to HRSA that the new site can meet all their requirements. This includes demonstrating that CHC can provide all patients at the new site – and their family members – with access to the full range of services and discounts provided at all other CHC sites, without reducing access or raising costs at any existing sites. Thus, when determining whether to add a child site, we must, and do, consider costs and commitments that go far beyond access to 340B priced drugs.

The 340B profile for CHC in the OPAIS also lists multiple contract pharmacy arrangements; however, those contracts were terminated before implementation and are so noted in the OPAIS.

CHC's pharmacy program is exclusively "in-house" - defined as owned and operated by the health center regardless of location. As such, CHC operates 2 community pharmacy sites that serve both health center patients non-health center patients. Eligible prescriptions for health center patients only are filled with 340B purchased inventory and all non-health center patient

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prescriptions are filled with non-340B purchased inventory. Using calendar year 2016 as a sample, 142,045 or 43.1% of the 329,679 prescriptions dispensed at CHC's two pharmacies were filled with 340B purchased inventory for eligible patients. Of those prescriptions filled with 340B, 68% were not covered by a third-party payer and classified as uninsured.

The health center statute requires all FQHCs to use all 340B savings for purposes that advance their HRSA approved Scope of Project – in other words, for activities that increase access to high-quality, affordable care for medically underserved populations. While every health center may use their 340B savings differently, these funds are commonly used to support sliding fee discounts, clinical pharmacy programs, and provider salaries. In the case of CHC, our total 340B savings for 2016 – calculated as the net margin after the sale of the drug - \$561,620. These savings enable the health center to provide deeply discounted pharmacy services to those patients eligible for the income-based sliding fee program, offer medication therapy management to promote clinical and cost effective care, and assist patients with qualifying for manufacturer Patient Assistance Programs. 340B savings also directly support the following otherwise unfunded services designed to expand access to essential primary care services:

- Daily delivery of health center patient prescriptions to CHC medical practices in outlying rural communities with limited or no access to affordable pharmacy services. This service makes over 20,000 affordable prescriptions accessible to low-income and underserved persons each year. 2016 cost of this service = \$163,124.
- Oral health services – both preventive and restorative - provided to uninsured and sliding fee eligible through a network of contract dentists. 2016 cost of this service = \$57,737.
- Behavioral health counseling provided on-site to CHC patients who would either not qualify for, or have long delays in receiving care from the local mental health agency. 2016 cost of this service = \$35,000.

In addition, the 340B savings contribute to our ability at CHC to ensure continued access to primary care and preventive care at certain of our medical practice sites in rural communities

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that are operating with a negative margin and would otherwise be at risk of closing. The total cost of maintaining primary care access at those sites in 2016 was \$1,812,581.

CHC defines “charity care” as the value of services provided for which all or part of the charges are uncompensated. Organization-wide in 2016, CHC provided \$4,753,211 in charity care which represents 21% of total patient revenue.

Overview of Carolina Health Centers, Inc.²

Carolina Health Centers, Inc. (CHC) is a non-profit primary care corporation established in 1977, now comprised of 13 primary care medical practices, a program focused on serving migrant farmworkers, and two community pharmacies. CHC serves as the primary care medical home for 26,952 distinct and unduplicated patients in the west central area of South Carolina known as the Lakelands – an area which encompasses 7 counties and over 3,700 square miles, and which the U.S. Department of Health and Human Services has determined to be medically underserved.

As a Federally-Qualified Health Center– also known as a community health center - CHC is committed to ensuring everyone has access to a high-quality, comprehensive primary care medical home regardless of demographic, geographic, and socio-economic barriers. By law and by mission, we never turn a patient away due to inability to pay; patients with incomes below the poverty level pay no more than a nominal fee for the full range of services we provide, and those between 101-200 FPL pay discounted rates based on a sliding fee scale.

In addition to providing comprehensive primary and preventive health care services, community health centers such as CHC provide a wide array of care management, patient education and support, and assistive services that support access to care, promote enhanced clinical outcomes, and reduce total costs across the health care system. And like all community

² Data source: 2016 HRSA Uniform Data System Report (required of all FQHC and FQHC Look-Alikes)

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health centers, we are 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.

Community health centers are subject to intensive and on-going oversight from the United States Department of Health and Human Services Health Resource and Services Administration (HRSA). The HRSA requirements with which we must comply are spelled out in a 92-page manual and are grouped into 18 major categories, including – but not limited to – clinical quality, financial management, ensuring access, and collaboration with other local providers. HRSA consistently oversees and enforces compliance with all these requirements through a variety of mechanisms including on-site compliance reviews, frequent interactions with project officers, and regularly-scheduled reporting obligations. HRSA also approves what is called our “Scope of Project”, meaning those primary care delivery sites, services, and providers that are considered part of the health center program – and therefore, to which all the requirements I just mentioned apply.

CHC directly provides primary and preventive health care services at 10 family medicine practice sites, 2 pediatric practices, 1 school-based clinic, a farmworker health program, and 2 community pharmacy locations³. In addition, CHC’s comprehensive pediatric medical home model includes 3 evidence-based home visitation programs.

All of CHC’s service delivery sites are located in Medically Underserved Areas and/or in communities designated as having Medically Underserved Populations. The percentage of patients served at each site that are uninsured, under-insured, and low income varies dramatically among the practice locations based upon the socio-economic demographics of the community.

In addition to those services provided directly, CHC provides other statutorily-required services through contracts and affiliation agreements with community partners. When our

³ A list of service delivery sites is included as Appendix B.

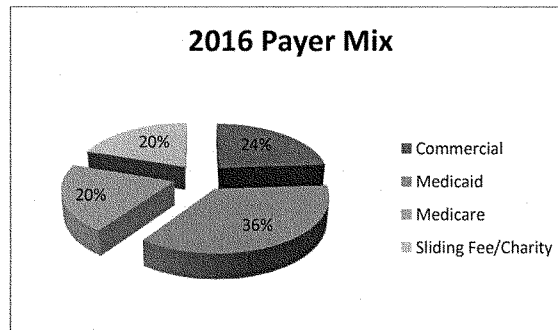
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patients are hospitalized, rounding services are provided through the hospitalist service at local hospitals; behavioral health and substance abuse services are provided through affiliation with the local mental health and substance abuse agencies; and oral health services are provided through contracts with private practice dentists with CHC providing a subsidy for the care provided to sliding-fee discount eligible patients with incomes below 200% FPL

At its direct delivery sites, CHC provided 105,433 medical visits for 26,952 unduplicated patients during calendar year 2016. Following is a breakdown of the payer-mix for 91,610 encounters that represent billable visits:



Carolina Health Centers, Inc. (CHC) staff totals 231.20 full time equivalent (FTE) employees.

The direct patient care staff includes:

- Medical providers = 25.8 FTEs
- Clinical support staff = 63 FTEs
- Enabling staff (case managers, care coordinators, outreach workers, etc.) = 18.2 FTEs
- Patient Service representatives = 48.5 FTEs
- Pharmacy personnel = 45.40 FTEs

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In 2016, CHC had an operating budget of \$28,292,993 and received \$4,291,355 in Bureau of Primary Health Care Section 330 grant funding. Other grant funding includes: \$1,879,656 in state funding provided through the Maternal and Infant Early Childhood Home Visiting (MIECHV) program, which supports the three evidence-based home visitation programs integrated into CHC's pediatric medical home model; \$110,717 in state funds allocated to FQHCs for participation in the state's Healthy Outcomes Program; \$102,650 in EHR Incentive payments; and \$176,823 in private grants and contracts restricted to support of the home visitation programs.

Carolina Health Centers Pharmacy Program

Carolina Health Centers, Inc. (CHC) opened its first in-house pharmacy, Carolina Community Pharmacy (CCP), in 2005. The pharmacy was initially located in CHC's largest pediatric practice site and was opened as a "closed" pharmacy meaning prescriptions could only be filled for health center patients and the pharmacy had only 340B purchased inventory. Within a few months CHC leadership made the decision to convert to an "open" pharmacy meaning that prescriptions could be filled for both health center patients and the general public, thereby requiring that the pharmacy maintain separate inventories for 340B eligible and non-340B eligible prescriptions. This decision was driven in large part by family members of health center patients requesting to fill their prescriptions at CCP as a matter of convenience. Many of the prescriptions filled for non-health center patients were noted as being generated in emergency departments and urgent care centers, indicating the potential lack of access to a primary care medical home. As a result, **an additional benefit CHC's "open" pharmacy model has brought to the community is that it serves as a gateway to engaging people in a primary care medical home, reducing the use of urgent and emergency care, and promoting chronic disease management.**

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CHC is registered with the Office of Pharmacy Affairs Information System (OPAIS) as a 340B entity with one main site (referred to as “parent sites” in OPAIS nomenclature) and 15 satellite medical practice sites (referred to as “child sites” in OPAIS nomenclature), 2 of which have been terminated, leaving 13 active child sites. **These child sites represent primary care medical practices from which 340B eligible prescriptions may be generated.** Each child site was added to CHC’s Scope of Project before becoming eligible for 340B. As previously mentioned, adding a site to our Scope of Project requires proving to HRSA that the new site can meet all their requirements. This includes demonstrating that CHC can provide all patients at the new site – and their family members – with access to the full range of services and discounts provided at all other CHC sites, without reducing access or raising costs at any existing sites. Thus, when determining whether to add a child site, CHC must consider costs and commitments that go far beyond access to 340B priced drugs.

As previously noted, CHC serves 7 rural counties with primary care medical sites widely dispersed over 3,708 square miles. In 2006 leadership recognized that only health center patients in close proximity to CCP were able to access affordable prescription medication through CHC’s 340B pharmacy program. In order to ensure that CHC patients in these rural communities had access to affordable prescription medication, CHC initiated a daily delivery service to its outlying medical practices. In compliance with provisions in the South Carolina Pharmacy Practice Act, and under strict quality control procedures, prescriptions for health center patients received (via fax, telephone, or e-scribed) from medical providers at CHC’s outlying practice sites are dispensed from CCP and delivered to the practice site where they are distributed to the patient by licensed personnel. Today, that **delivery service provides over 20,000 prescriptions each year to health center patients in rural communities - patients who in many cases would otherwise have no access to affordable prescription medication⁴.** In

⁴ Appendix C: Prescriptions Dispensed provides the number of prescriptions delivered to patients in the outlying rural communities for a 5-year period.

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the words of one of CHC most senior medical providers: *“To diagnose when the patient has no access to affordable medication is always an exercise in futility ... and in some cases just the announcement of a death sentence.”*

CHC opened a second pharmacy location in 2009 as a stand-alone community pharmacy doing business as Carolina Community Pharmacy Northwest. In 2012 CHC moved the original pharmacy from The Children’s Center into a second stand-alone site doing business as Carolina Community Pharmacy at The Village. Both of these pharmacies are in close proximity to the CHC medical practices in the Greenwood community and in 2016 CHC opened a co-located medical practice in CCP at The Village.

CHC entered into a contract pharmacy arrangement in 2013; however, that agreement was terminated in 2015 without being implemented. Abandoning the idea of expanding access through contract arrangements was based on CHC’s capacity to operate in-house pharmacies, and a **strategic decision made in collaboration with CHC’s medical staff leadership to focus on greater integration of the clinical pharmacy into the primary care medical home model.** CHC pharmacists at both pharmacy locations have direct access to the health center patient’s electronic medical record and the ability to send messages to the medical providers through the EHR system. The Director of Pharmacy is considered a member of the Medical Leadership Team, along with the Chief Medical Officer, Director of Family Medicine, and Director of Pediatrics, which enables a high level of collaboration between the prescribing providers and dispensing pharmacies. Beginning in 2016 CHC is focusing on increased clinical integration including rotation of clinical pharmacists at medical practice sites and participation of clinical pharmacists on interdisciplinary treatment teams.

Currently, CHC’s pharmacy program includes two community pharmacies, both of which operate as “open” pharmacies, meaning that they provide pharmacy services to both health center patients and the general retail public. However, only health center patients are eligible to have prescriptions filled with 340B purchased inventory, and CHC performs daily audits to protect against diversion of 340B drugs to non-eligible patients. In 2016, the 2 pharmacy sites

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dispensed a total of 329,679 prescriptions inclusive of those delivered to the outlying medical practices. Of the total dispensed 142,045 prescriptions were filled for health center patients using 340B purchased inventory, which represents 43.09% of total dispensed. Of the prescriptions dispensed using 340B purchased inventory, 95,590 or 67.3% were not covered by a third-party payer and 23,823 or 16.77% were delivered to outlying practice sites.⁵

Every effort is made to ensure that uninsured and low-income patients are able afford their prescriptions. As mentioned earlier, one of HRSA's expectations of community health centers is that they have a sliding fee discount policy that applies to all patients with incomes at or below 200% of the federal poverty guidelines (FPL). HRSA requires that the sliding fee discount policy be applicable to all services included in the health center's HSRA approved Scope of Project, including pharmacy services. As a component of CHC's sliding fee policy, the benefit of the 340B discount price is passed on to patients with incomes below 200% of FPL. There are times when, even at these discounted rates, patients are not able to afford much needed prescriptions. In these cases, CHC will assist the patient in securing their medication through a manufacturer Prescription Assistance Program whenever possible. When no other options are available, CHC has a Benevolence Fund, supported by employee donations that may be accessed to assist patients with payment for

CHC does not participate in a pharmaceutical group purchasing organization (GPO) but purchases all drugs from Smith Drug Company, a wholesaler headquartered in Spartanburg, SC. CHC purchases under separate 340B and non-340B accounts for each pharmacy in order to effectively maintain separate inventories. CHC operates with an open formulary – i.e. stock not limited to a predetermined list of approved drugs and devices – purchases include a large number of NDCs (National Drug Codes)⁶. When categorized by therapeutic class 85% of

⁵ Appendix C: Prescriptions Dispensed provides detailed information on the prescriptions dispensed over the five year period of 2012-2016.

⁶ Appendix D1 provides a list of all NDCs purchased in 2016.

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purchases are related to the management of chronic disease including co-existing behavioral health issues prevalent among the patients served by the community health center⁷

According to the previously referenced 2016 Uniform Data System Report, CHC's pharmacy program employs 45.40 FTEs. Because CHC operates an open pharmacy serving both 340B and non-340B patients, only a proportional amount of the personnel resources is specifically attributable to the 340B program. The staff is comprised of:

- 1 FTE Director of Pharmacy
- 1 FTE Pharmacy Operations Manager
- 1 FTE Clinical Coordinator
- 7 FTEs Staff Pharmacists
- 16 FTEs Registered Pharmacy Technicians
- 25.40 Patient Service Representatives

All pharmacy staff attend CHC New Employee Orientation, which includes a training segment on the history, purpose, and compliance framework for the 340B Drug Pricing Program. CHC encourages and supports all registered and licensed staff to complete the Apexus 340B University (either online or in person) and requires each member of the 3-person pharmacy leadership team to attend a live 340B University at least every three years. CHC's President and CEO, as well as Director of Pharmacy regularly attend 340B specific training offered by the National Association of Community Health Centers. Licensure and certification of all professional staff is maintained by CHC's Credentialing and Contract Management Specialist.

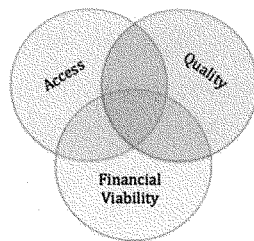
⁷ Appendix D: Drugs Purchased provides detailed information on drugs purchased over the five year period of 2012-2016 with a breakdown by therapeutic class for drugs purchased in 2016.

Carolina Health Centers, Inc.

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Sue Veer MBA, President and CEO

Participation in the 340B Drug Pricing Program is strategically important to Carolina Health Centers (CHC) and the patients it serves. The graphic below illustrates what CHC leadership has adopted as their strategic imperative to protect and optimize that benefit:



Access to affordable prescription medication and integration of the clinical pharmacy with the primary care medical home is one of the greatest drivers of improved individual and population health outcomes; and Improved individual and population health outcomes position CHC favorably in a value based reimbursement environment and positively bend the cost curve for the health care delivery system.

Participation in the 340B Drug Pricing Program is also critically important in achieving CHC's mission to remove barriers that limit access to primary and preventive care.

CHC is grateful for the resources that have been made available through HRSA's Office of Pharmacy Affairs and the HRSA Prime Vendor Program currently administered by Apexus. The availability and continued evolution of these resources has enabled CHC and pharmacy leadership to develop a solid framework for an effective and compliant 340B pharmacy program.

Conclusion

As my testimony demonstrates, the 340B program is vital to CHC and our ability to provide our patients with access to affordable prescriptions, as well as to support needed services for our low income and underserved patients. Thank you for the opportunity to testify before you today and for recognizing the importance of the 340B program for health centers and the patients we serve.

Mr. GRIFFITH. Thank you.

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

STATEMENT OF MICHAEL GIFFORD

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

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

My name is Mike Gifford. I serve as the President and Chief Executive Officer of the AIDS Resource Center of Wisconsin. Earlier this year, ARCW expanded our services into Denver, Colorado and the unique model of care that we offer. In total, we serve more than 4,000 people with HIV.

The 340B Program costs the Federal Government nothing, yet generates hundreds of millions of dollars in care for HIV patients. For HIV patients, the purpose of the 340B program, to stretch scarce federal resources, to serve more patients, and to provide more comprehensive services, is met every single day. We assure unfettered access to medical care, dental care, mental health therapy, drug treatment, and pharmacy services tightly integrated with social services like case management, food assistance, and housing. More than 90 percent of our patients are low-income and one-third of all of our medical visits care for uninsured patients.

Our patients achieve some of the finest clinical outcomes in the country, 89 percent of whom achieve the gold standard in HIV health care and undetectable viral load. That is a rate far above the national average. Governor Scott Walker's administration has found that our patients are so healthy they cost of the State of Wisconsin 30 percent less than HIV patients cared for elsewhere. Further, DHHS data shows HIV patients in Wisconsin have the lowest HIV mortality rate in the country. Our HIV medical home buoyed by 340B savings result in people with HIV living in Wisconsin longer than anywhere else in the country.

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

Last year, ARCW generated \$7,429,666 in savings, the exact use of which is included in my written testimony. To track 340B medications and savings, we have developed specialized software that monitors compliance related to patient eligibility, diversion, and duplicate discount. We audit ourselves on a monthly basis and have an annual third-party external audit. Last year, it showed 99.57 percent compliance. This year our compliance rate is at 99.9996 percent.

As the subcommittee reviews the 340B program, there are critically important policies necessary to achieve that goal I mentioned earlier, a world without AIDS. The current patient definition used for Ryan White grantees must be maintained to support the inte-

grated 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. She is no longer being beaten. Sadly, she was no longer undetectable.

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

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

[The prepared statement of Mr. Gifford follows:]



Testimony Before the United States House of Representatives

Committee on Energy and Commerce:

Subcommittee on Oversight and Investigations

*Examining How Covered Entities Utilize the
340B Drug Pricing Program*

Testimony of:

Michael Gifford

President and Chief Executive Officer

AIDS Resource Center of Wisconsin

October 11, 2017; 10am

Location: 2123 Rayburn House Office Building



Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee. I am Michael Gifford and I am the President and Chief Executive Officer of the AIDS Resource Center of Wisconsin, also known as ARCW. I appreciate the opportunity to provide written testimony in conjunction with appearing before you today to discuss the critically important role the 340B Drug Pricing Program plays in contributing to the success of ARCW and many other Ryan White funded organizations in meeting the evolving demands of the AIDS epidemic in the United States.

The AIDS Resource Center of Wisconsin (ARCW):

ARCW is a nationally recognized leader in delivering high quality, patient centered health care and social services that are driving some of the best patient outcomes in the United States. As founding member of the National Center for Innovation in HIV Care along with our partners at Fenway Health and AIDS United, our success has resulted in leaders from 26 states and organizations contacting ARCW about replicating program delivery models in their communities as a way to enhance patient and community health.

ARCW envisions a world without AIDS and strives to assure that everyone with HIV disease will live a long and healthy life. Our mission is to be at the forefront of HIV prevention, care and treatment and ARCW is dedicated to providing quality medical, dental, mental health and social services for all people with HIV.

ARCW is a not-for-profit, 501(c)3 designated organization governed by a volunteer national board of directors. ARCW has thirteen (13) locations in Wisconsin and has recently merged with, and is doing business as, Rocky Mountain CARES in Denver, Colorado to expand access to care and improve clinical outcomes. In all of these settings we are truly the safety net provider for people with HIV and AIDS.



Through the past 34 years, ARCW has grown to become the largest provider of health care to people living with HIV in the state of Wisconsin. Because of our integrated, coordinated and co-located services, more than 3,500 people living with HIV in Wisconsin are receiving the health care and support needed to live healthy with HIV. We are also one of the state's leading HIV prevention providers, reaching tens of thousands of people every year who are at-risk for contracting HIV.

The ARCW HIV Medical Home is intentionally designed to ensure our patients receive the right care, at the right time, in the right setting and from the right provider. In doing so, we are able to ensure optimal patient outcomes and reduce inefficiencies in care delivery that would otherwise result in higher costs and poorer patient outcomes.

Following the merger of ARCW with Rocky Mountain CARES, ARCW is now developing Denver's first community-based safety net HIV Medical Home and is currently providing care and treatment to more than 500 people.

The HIV continuum of care:

The importance of 340B program generated savings to support patients served by organizations that are providing HIV prevention, care and treatment services cannot be overstated, and must be examined using the backdrop of the continuum of care.

The HIV care continuum is the series of steps that a person with HIV would take in order to achieve optimal health with HIV, clinically indicated as achieving viral suppression.

Viral suppression is critically important to ending the HIV epidemic for two reasons. First, people with HIV who are achieving viral suppression experience less adverse health episodes related to their HIV disease. Second, people with HIV who achieve viral suppression have a negligible risk of transmitting HIV

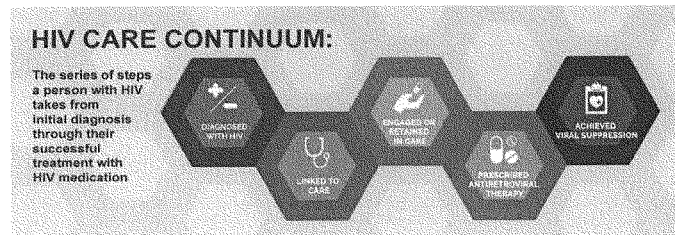


to someone else. The CDC announced Sept. 27, 2017 in a Dear Colleague letter that “people who take ART [anti-retroviral therapy for HIV] daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.”¹ Conversely, research conducted by the CDC and published in the *Journal of the American Medical Association* (JAMA) has demonstrated that more than 91% of HIV transmissions in the United States are attributed to people with HIV who were not regularly in medical care, inclusive of individuals who had HIV but were unaware of their status.² When individuals fall out of care, they can lose the ability to achieve or maintain viral suppression, making retention to care a critical component of HIV care. Not only is viral suppression an important individual health metric, it is public health imperative as well.

Within each step there are several opportunities for people living with HIV to confront barriers that prevent their successful movement along the continuum. Additionally, it is important to recognize that once a person is aware of their diagnosis, it is possible for them to move backwards along the continuum and that viral suppression must be maintained even though patients continue to face significant barriers.

¹ US Centers for Disease Control and Prevention website; <https://www.cdc.gov/hiv/library/dcl/dcl/092717.html>; accessed Oct. 2, 2017

² JAMA Intern Med. 2015;175(4):588-596. doi:10.1001/jamainternmed.2014.8180

Fig. 1. The HIV Care Continuum³

At each step in the continuum individuals face a multitude of challenges that prevent them from achieving and maintaining the ultimate goal of viral suppression. The HIV epidemic in the United States is firmly entwined with both individual and community barriers to health. Regarding personal health, many patients today confront comorbidities including mental health concerns such as anxiety, depression, neuropsychological impairments and substance abuse as well as chronic diseases including hypertension, hyperlipidemia, hepatitis and other liver impairments, and issues related to aging. Socioeconomic and/or community barriers to health – also known as social determinants of health – can include combinations of any other following such as hunger, homelessness, high rates of poverty, stigma and discrimination, lack of health insurance coverage, inadequate numbers of health care providers (both urban and rural), inadequate educational opportunities, lack of access to employment, and lack of community support in achieving health.

Overcoming these barriers often times takes precedence over managing their HIV. A person newly diagnosed with HIV who is confronting homelessness may seek housing before they seek health care. A

³ Health Resources Services Administration HIV AIDS Bureau; <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/hiv-care-continuum>; accessed Sept. 21, 2017.



person living with HIV who is living in poverty may use their limited financial resources to purchase food instead of medicine. A person without access to transportation may not be able to make several different appointments at multiple organizations or health care providers. Someone struggling with mental health issues may be challenged to take their medications on a daily basis.

Addressing these barriers is made more difficult for people living with HIV when they are receiving their care in a system of fragmented health and social service providers. Health care providers in these environments often cannot readily communicate and patients often find them to be confusing and difficult to navigate.

Helping patients overcome these barriers usually requires the provision of services that are not reimbursable under public or private insurance. Given limited and uncertain grant resources, many organizations are cannot rely solely on grants when building service delivery models. Furthermore, many Ryan White funded grantees have identified the following challenges to expanding and providing the kinds of services patients need to be successful⁴:

- 75% of HIV/AIDS-serving community based organizations reported an operating loss in one of the last three years;
- 38% of the above agencies reported an operating loss in two of the last three years;
- 15% reported an operating loss in three of the last three years;
- >90% identified a lack of financial resources as the most significant barrier to providing and/or linking to medical services; and

⁴ Capacity for Health Project at the Asian & Pacific Islander American Health Forum; HIV/AIDS ASO and CBO Stability and Sustainability Assessment Report; <http://www.apiahf.org/resources/resources-database/hiv-aids-aso-and-cbo-stability-and-sustainability-assessment-report>; Accessed October 5, 2017



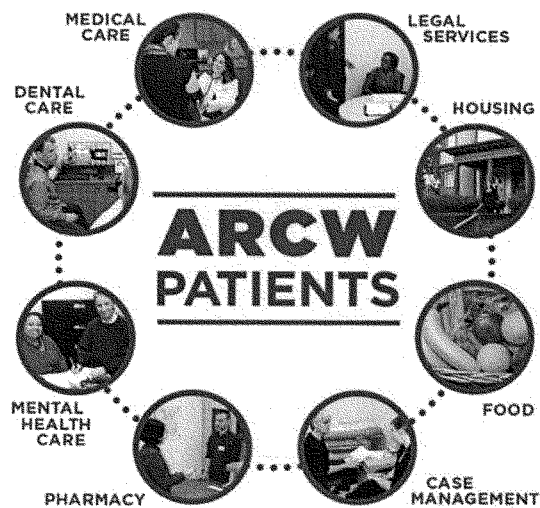
- 37.5% identified concerns about sustainability.

The financial challenges of providing care to people with HIV must be addressed to assure they have access to health and social services. 340B savings play a crucial role in assuring services for HIV patients are available and sustainable so they can achieve and maintain an undetectable viral load.

In order to help patients overcome these challenges and achieve health 340B savings have been critical as ARCW has developed one of the nation's most innovative care delivery systems for our patients and clients. The ARCW HIV Medical Home ensures patients have access to coordinated, co-located and fully integrated health and social services including: medical and dental care, mental health therapy and drug treatment, housing services including rent and utility assistance, food pantries, and nutrition services, legal services, and medical and social work case management.

The goal of the ARCW HIV Medical Home is to ensure patients receive the right care, at the right time, in the right setting, from the right provider, at the right cost – that being the lowest one possible. To accomplish this goal, it is imperative that all health care and social service professionals work together as a team to address all the challenges our patients face. To this end, every patient at ARCW receives an in-depth annual assessment by a care coordinator who then works with the patient to identify a care and treatment plan. The patient's care team including their doctor, dentist, clinical pharmacist, mental health professional, nurse and case manager then work together with the patient to achieve the patient's goals. Documentation of the patient's care plan, needs and challenges as well as their medical records are all housed within the ARCW electronic health record making for easy access of the information across disciplines within ARCW.

ARCW
AIDS RESOURCE CENTER OF WISCONSIN
Excellence in HIV Health Care
 Figure 2. ARCW HIV Medical Home



ARCW Patient Demographic Data:

Much like people living with HIV in other parts of the United States, the overwhelming majority of people we provide care and treatment to are living in poverty, are people of color and experience high rates of uninsurance, underinsurance or enrollment in public insurance programs. More than 90% of people served by ARCW programs and services are living below 200% of the FPL.



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Table 1 - ARCW Patient and Client Demographics

Race and Ethnicity		Age	
African American/Black	42.6%	24 and under	4.1%
White	39.8%	25-44	36.3%
Hispanic	11.2%	45-54	54.2%
Other	6.4%	55 and older	5.3%
Gender		Insurance Status	
Men	75.6%	Private Insurance	13.5%
Women	23.1%	Public Insurance	67.2%
Transgender	1.3%	Uninsured	19.2%

ARCW patient outcomes:

The primary goal at ARCW is for every patient to achieve optimal health. For people living with HIV, this is most commonly associated with achieving viral suppression. Viral suppression is critically important to both individual patient health and ending the HIV epidemic for two reasons. First, people with HIV who are achieving viral suppression experience less adverse health episodes related to their HIV disease, such as opportunistic infections. Second, people with HIV who achieve viral suppression have a negligible risk of transmitting HIV to someone else.

The ARCW patient-centered, team-based approach is ensuring some of the best clinical outcomes for HIV patients in the country. These outcomes are being achieved among patients who are some of the most vulnerable and who face significant challenges in succeeding in their treatment, such as poverty, mental health and substance abuse disorders, hunger, homelessness, discrimination and other social determinants of health. While not a cure for HIV, viral suppression means that the individual is managing their HIV disease as well as possible and copies of the virus in their body are undetectable.



Table 2 – ARCW patient outcomes and quality of care indicators

Patients	National Standard amongst Ryan White Program Clinics	ARCW
With an Undetectable Viral Load	81%	89%
Prescribed Anti-HIV Medications	91%	95%
Prescribed preventative PCP treatment	86%	95%
With diabetes that is well managed	56%	83%
With controlled hypertension	56%	59%

Unfortunately, the patient outcomes achieved at ARCW are not being achieved for all people with HIV in the United States. In fact, according to the US Centers for Disease Control and Prevention (CDC), only 49% of people living with HIV in the United States are achieving viral suppression.⁵ Moreover, only 48% of people living with HIV are regularly engaged in care, only 62% are receiving any care and only 85% of people living with HIV are aware they have HIV⁶.

Research and the experience of ARCW both indicate that the biggest barriers to treatment success for people living with HIV in the United States are not solely access to medical care. In fact, untreated or undiagnosed mental health issues, lack of stable housing, food insecurity, lack of transportation, lack

⁵ US Centers for Disease Control and Prevention: <https://www.cdc.gov/hiv/images/library/infographics/continuum-infographic.png>; accessed Sept. 22, 2017.

⁶ Ibid.



Excellence in HIV Health Care

of insurance coverage, and inability to pay for medications are all barriers that prevent HIV patients from staying adherent to their treatment regimens and achieving viral suppression.

The 340B program allows ARCW and other Ryan White funded organizations to make strategic investments in services for people with HIV that address these barriers to care. These services are often not covered or reimbursed by public or private insurance programs.

Financial Impact of the ARCW HIV Medical Home:

In 2010, the Wisconsin Legislature adopted legislation directing the Wisconsin Department of Health Services to develop a proposal to the US Centers for Medicare and Medicaid Services (CMS) to increase Medicaid reimbursement to ARCW to support care coordination services to people with HIV. CMS approved Wisconsin's Medicaid State Plan Amendment, submitted by Wisconsin Governor Scott Walker's administration, effective October 1, 2012.

Two significant aspects of the approval and implementation of the SPA are requirements that enhanced patient outcomes are coupled with cost savings. The ARCW HIV Medical Home is accomplishing both goals. According to independent analysis of the ARCW HIV Medical Home by the University of Wisconsin Center for Health Systems Research and Analysis (CHSRA), "[i]t is an important study revelation that an ongoing primary care relationship with the ARCW is the most influential factor in reducing costs, hospital stays / admits and the diagnostic incidence of chronic disease."⁷

In fact, the CHSRA report goes on to detail additional financial and health benefits of the ARCW HIV Medical Home.

⁷ Newsom, R., Exploration of Evaluative Analyses & Methods: Claims-Based Options for the AIDS/HIV – Medicaid Health Home SPA, Center for Health Systems Research and Analysis, UW-Madison. *Not a published document*



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Table 3. ARCW Medical Home Delivers Results⁸

Indicators	Non ARCW Patients	ARCW Patients
Average annual cost per patient	\$22,993	\$16,192
Average number of days in hospital	2.22 days	2.01 days

In addition, patients receiving care at ARCW had an overall 52% lower hospitalization rate and had 48% lower utilization of emergency department care than did patients who were not engaged in care at ARCW.⁹

In total, the ARCW HIV Medical Home is resulting in savings to the Wisconsin Medicaid program of more \$3.9 million per year.¹⁰

340B Drug Pricing Program and the Fight Against AIDS:

When Congress established the 340B Program in 1992, it intended to create a way to strengthen the health care safety net without increasing taxpayer costs and “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹¹ The clearly stated legislative intent with bipartisan support that created the 340B program never intended to ensure patients received drug discounts from manufacturers, nor was it intended to be a way to address

⁸ Newsom, R., Exploration of Evaluative Analyses & Methods: Claims-Based Options for the AIDS/HIV – Medicaid Health Home SPA, Center for Health Systems Research and Analysis, UW-Madison. *Not a published document.*

⁹ Ibid.

¹⁰ Ibid.

¹¹ US Department of Health and Human Services; 340B Drug Pricing Program & Pharmacy Affairs Office of Pharmacy Affairs <http://hrsa.gov/opa/>; Accessed October 4, 2017



concerns related to drug prices overall. As the legislative history of the law makes clear, the explicitly stated purpose of the 340B program is to help stretch scarce federal resources for safety net providers

It is within this context that the implementation and successful use of the 340B program by ARCW and other Ryan White safety net providers should be considered in responding to the AIDS epidemic.

Ryan White funded organizations that are eligible to participate in the 340B program are able to purchase certain medications at a price lower than what these medications are normally purchased for. Savings that are generated off the reimbursement for the medication purchased using 340B pricing are then reinvested into programs and services that directly benefit the individuals the covered entity serves.

At ARCW, these savings are directed into programs and services that directly and positively impact the ability of our patients to achieve the single most important factor in their health – achieving viral suppression.

340B at ARCW:

ARCW is eligible for participation in the 340B Drug Pricing Program as a Health Resources Services Administration (HRSA) grantee via the Parts B (sub recipient) and C (direct recipient) of the Ryan White Program. ARCW is also a recipient, via subcontract, of US Centers for Disease Control and Prevention sexually transmitted disease prevention grant funding. This subcontract makes ARCW eligible for the 340B program as an STD clinic.

At ARCW, Ryan White grant funding is directed into discreet service areas based on HRSA's implementation of the Ryan White Program statutes and contracts between ARCW and HRSA (Part C) or



ARCW and the State of Wisconsin Department of Health Services (Part B) once ARCW grant applications have been approved.

Our innovative HIV Medical Home model of care builds upon critical investments made in our organization through Parts B and C of the Ryan White Program. This funding, combined with our ability to leverage other private and public resources, allows us to ensure access to health care, medications and wrap around programs that address the socioeconomic barriers to health our patients face such as hunger, homelessness, and discrimination. We also support patients in navigating a complex health care system that often struggles to fully address the holistic needs of individuals who are living in poverty, have limited education and are living with a complex, expensive and communicable chronic disease.

While bipartisan Congressional support for the Ryan White program remains strong, funding for this critical program has lagged behind need, especially considering the United States still experiences more than 35,000 new cases of HIV every year and people with HIV disease are living longer. It is the ability of ARCW to leverage additional resources through the 340B program, pursue reimbursement for services, access state and local grants and engage in private fundraising that together allow us to serve a growing number of patients who face a tremendous amount of health and socioeconomic challenges.

ARCW utilizes 340B savings to fill-in the programmatic area deficits incurred in the delivery of our services to people living with HIV. This is carrying out the original intent of Congress when the 340B program was created – namely to stretch scarce federal resources as far as possible. It is also consistent with mandates from HRSA regarding how 340B savings must be utilized.

In addition to filling-in the programmatic area deficits at ARCW, 340B savings have been critical to ensuring patients have access to life-saving programs for which funding has ended. Three critical



examples of this illustrate the power of 340B savings in fulfilling the intent of the 340B program to stretch scarce federal resources:

1.) Dental Services in Green Bay, Wisconsin:

ARCW offers its entire cadre of services – medical, dental, and mental health care with integrated social services including medical and social work case management, legal services, rent and utility assistance and a food pantry – in Green Bay. While Green Bay is Wisconsin's third largest city, the city and its surrounding areas suffer from a dearth of dental providers. The ARCW dental clinic in Green Bay provides dental care to people living with HIV from more than 40 Wisconsin counties, almost all of which are rural. Estimates from the State of Wisconsin Department of Health Services Primary Care Program indicate that the area served by the ARCW dental clinic in Green Bay needs between 34 and 112 Dentist FTE to reduce shortages in access to dental care for Medicaid Members.¹²

In order to address this shortage in access to dental care for HIV patients, ARCW applied for and received funding from HRSA through the Special Projects of National Significance (SPNS) program. This funding helped ARCW establish the only HIV dental clinic in Wisconsin outside of Milwaukee and eliminated the need for many HIV patients residing in the rural northern half of Wisconsin to travel up to eight hours in one direction to receive oral health care. Today, hundreds of HIV patients receive oral health care through the ARCW dental clinic in Green Bay.

In August 2011, the HRSA grant ARCW received to establish this clinic ended, putting patients at risk of losing access to dental care that had a direct role in improving their overall health. In

¹² Wisconsin Department of Health Services Primary Care Program, <https://www.dhs.wisconsin.gov/primarycare/maps.htm>; Accessed October 3, 2017



order to ensure the sustainability of the dental clinic, ARCW has invested the savings it is realizing from participation in the 340B program into its Green Bay dental clinic.

2.) Expansion of Access to Mental Health Services Statewide

The National Institutes of Mental Health estimate that approximately 18% of adults have had a mental illness, and that the rates of mental health conditions among people living with HIV are higher.¹³ At ARCW, as many as 50% of our patients at any given time are experiencing a mental health condition such as anxiety, depression, substance abuse, post-traumatic stress disorder, insomnia or thoughts of suicide.

ARCW has long recognized the important role of good mental health in achieving overall health. People living with HIV who are experiencing poor mental health are not as likely to stay adherent to their HIV treatment regimens, making viral suppression significantly harder for them to attain.

As with the dental provider shortage in Wisconsin, there is a significant shortage of psychiatrists in the state as well. The State of Wisconsin Department of Health Services Primary Care Program indicates that more than 260 Psychiatrist FTE are needed to reduce significant shortage of this professional statewide.¹⁴ This shortage directly impacts the ability of people living with HIV who are also experiencing mental health illness to get the care they need.

¹³ US Department of Health and Human Services, National Institutes of Health, <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/27/92/hiv-and-mental-health>, Accessed October 3, 2017

¹⁴ Wisconsin Department of Health Services Primary Care Program, <https://www.dhs.wisconsin.gov/primarycare/maps.htm>; Accessed October 3, 2017x



In response, ARCW has dedicated 340B program savings into hiring additional mental health professionals, including a full time psychiatrist, and is in the process of initiating telepsychiatry. Combined, these two critical approaches will help make sure that ARCW can carry out more than 7,000 mental health appointments in the coming year.

3.) Addressing Food Security Throughout Wisconsin

More than 90% of the people ARCW serves annually are living below 200% of the federal poverty limit. With limited income, people living with HIV are often forced to choose between purchasing medications, paying for doctors' visits, making rent and utility payments or purchasing food.

For people living with HIV, studies have shown that food is medicine.¹⁵ Researchers at the University of California – San Francisco found that people with HIV who regularly eat and receive healthy meals are more likely to adhere to their medication regimens, which translates into better health outcomes.

To ensure the nutritional health needs of people living with HIV are met, ARCW operates a network of food pantries that span the entire state of Wisconsin in each of the 10 cities in which we operate. Using savings from the 340B program, ARCW is able to ensure that each of these pantries is always fully stocked with nutritious food that supports the health of the patients we serve. 340B program savings also allow ARCW case managers to do home delivery of food for patients who are too ill to travel or are otherwise home bound. In 2016, ARCW made more than 502,000 meals available to our patients and their families, with roughly 1/3 of this total

¹⁵ Kalar, P, et al; Comprehensive and Medically Appropriate Food Support Is Associated with Improved HIV and Diabetes Health; Journal of Urban Health; <https://doi.org/10.1007/s11524-016-0129-7>; accessed October 4, 2017



delivered. Such a robust food program would not be possible without the savings ARCW realizes through the 340B program.

Table 4 – ARCW funding from the Ryan White Program, expenses and programmatic deficit

	FY 2015	FY 2016
<u>Savings</u>		
340B Program Savings	\$6,659,664	\$7,429,666
<u>Investments</u>		
Medical, Dental, Mental Health, and Drug Treatment Services	\$1,717,871	\$2,128,262
Case Management, Food Services, and Legal Assistance	\$1,167,499	\$1,135,366
Housing Services	\$108,892	\$86,730
Pharmacy Services	\$1,948,943	\$1,967,918
Health Information Technology, Quality Assurance, & Other Federally Allowable Costs	<u>\$1,716,459</u>	<u>\$2,111,390</u>
<u>TOTAL</u>	\$6,659,664	\$7,429,666



340B Program Integrity at ARCW:

ARCW takes very seriously its role in ensuring 340B Program integrity in its role as a covered entity. 340B program integrity and compliance guidelines are outlined in the ARCW 340B Policies and Audit Procedures. It is the stated policy of ARCW that it will *"comply with all applicable laws and regulations related to the 340B program. The 340B program has a substantial impact on ARCW's ability to sustain and enhance needed treatment and care services that would otherwise not be addressed by other providers."*

Implementation and oversight of these policies and procedures start with the ARCW President and Chief Executive Officer. Additionally, several senior management staff at ARCW including the ARCW Vice President of Compliance and General Counsel, the ARCW Vice President and Chief Financial Officer, the ARCW Vice President of Pharmacy Services, the ARCW Director of Health Care Revenue and the ARCW 340B Coordinator.

In addition to strict adherence to stated policies, ARCW also conducts monthly audits of its 340B program to ensure 340B program activities. These monthly audits are in place to ensure ARCW does not inadvertently engage in diversion of 340B medications to ineligible patients and make sure that information supplied to the State of Wisconsin Medicaid program is accurate to avoid duplicate discounts. Since ARCW initiated monthly audits, it has achieved more than 99% adherence with 340B program requirements. ARCW is dedicated to achieving 100% compliance in this area.

Additionally, every year, ARCW has an independent audit conducted by external auditors. These audits have not identified any significant deficiencies related to 340B program internal controls at ARCW, and have found 99.57% adherence to HRSA drug eligibility requirements. ARCW continues to refine the



program integrity of its 340B program and the most recent 9 months of operation show 99.9996% compliance with program requirements.

All staff at ARCW who are involved in implementation of the 340B program at ARCW are required to complete Apexus' 340B University on Demand within 90 days of hire and again every two years subsequent to that.

340B and HRSA's Policy Clarification Notice 15-03 – limitations on the use of 340B income at ARCW:

According to HRSA's claims, as a Ryan White Program grantee, ARCW and other Ryan White funded clinics participating in the 340B program are limited in how 340B savings can be used. The limitations on the use of 340B revenue by Ryan White grantees are outlined by HRSA in *Policy Clarification Notice 15-03: Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income*¹⁶ and the corresponding Frequently Asked Questions document issued by HRSA: *Frequently Asked Questions, March 21, 2016, Policy Clarification Notices (PCNs) 15-03 and 15-04*¹⁷ as well as PCN 16-02: *Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds*.¹⁸ This appears to run contrary to the testimony of HRSA before the Subcommittee during the July 18, 2017 hearing in which HRSA stated that it does not have the authority to regulate how covered entities utilize their 340B program savings.

The ability of HRSA to regulate 340B savings stems from its conclusion (which we dispute) that 340B savings fall under the definition of "program income" as defined by 45 C.F.R. Section 75.2. According to

¹⁶ HRSA PCN 15-03; https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf; accessed Sept. 25, 2017

¹⁷ HRSA,; <https://hab.hrsa.gov/sites/default/files/hab/Global/faq15031504.pdf>; accessed Sept. 25, 2017

¹⁸ HRSA; https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf; accessed Sept. 25, 2017



HRSA's issued guidance, "program income is gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance (or grant year) except as provided in 45 C.F.R. Section 75.307(f)."¹⁹

Under HRSA's guidance:

"program income must be used for the purposes and under the conditions of the Federal award. For Parts A, B, and C, program income must be used for core medical and support services, clinical quality management (CQM), and administrative expenses (including planning and evaluation) as part of a comprehensive system of care for low-income individuals living with HIV."

The effect of this interpretation constricts how 340B savings could be used to support additional programs and services that can support aggressive HIV prevention, care and treatment programs across the United States.

For example, while 340B savings at a Ryan White funded clinic can support a physician dedicating additional time to working with an HIV patient doing adherence counseling to ensure a patient understand why they need to take their medications regularly (a service that may not be billable to a public or private insurer), 340B savings cannot support that same physician doing any work to support Pre-Exposure Prophylaxis (PrEP) uptake and adherence among individuals who are HIV negative, but at significantly high risk for contracting HIV.

¹⁹ HRSA, <https://hab.hrsa.gov/sites/default/files/hab/Global/faq15031504.pdf>; accessed Sept. 25, 2017



This counterproductive situation is created because Ryan White funds are limited to supporting medical care and treatment for people who are not living with HIV and because of HRSA's interpretation of 340B savings as an extension of the Ryan White grant.

Moreover, because HRSA mandates that 340B savings be classified as program income, and because program income is additive in nature, HRSA requires that these savings be 'spent' before a grantee can request additional federal awards. The potential 'death spiral' created within the logic of this program is that the very grant award that affords organizations the ability to participate in the 340B program can be taken away should an organization not spend all of its 340B savings within the identified grant period. Organizations would potentially lose their eligibility for both Ryan White funding and 340B program participation simultaneously, leading to insolvency of their operations and putting patient health and lives at risk. All of this is organizational centric regulations that is devoid of the needs of the people we serve.

Future changes in 340B program regulations:

ARCW and similar Ryan White funded grantees across the United States are using the 340B program to win the fight against the HIV epidemic. By implementing a patient-centered, continuum of care model, Ryan White clinics, with the help of 340B savings, are achieving clinical results that surpass the rest of the nation. The patient outcomes at Ryan White funded grantees are helping to reduce the number of new HIV infections, increase the number of people living with HIV who are living long, healthy lives, and drive down overall health care costs.

In order to maintain 340B program eligibility, Ryan White funded grantees are subject to extremely detailed reporting requirements, including reporting program income on the Federal Financial Report (FFR) as well as programmatic information on their Ryan White Services Report (RSR). Additionally,



when submitting applications for funding, prospective grantees are required to submit their most recently completed independent financial audit and proof of 501(c)3 non-profit status. Lastly, all Ryan White grantees are subject to periodic programmatic and financial audits by HRSA that while are not specific to the 340B program, certainly include substantial information about the use of 340B savings to support patient care and treatment.

Additional oversight of Ryan White grantees participating in the 340B program will do little in identifying misuse of the 340B program, but will create a tremendous additional compliance and reporting burden on ARCW and other similar organizations. At ARCW, more than 93% of expenses go directly into patient services and access to medications. Increasing the reporting burden on ARCW and other grantees will have the impact of reducing support for patient and client services – the exact opposite of the intent.

Statutory and regulatory changes to the 340B program that would impact the ability of Ryan White funded organizations to participate in the program should be rejected. These changes include restrictions on the definition of a patient that would result in fewer resources, worse clinical outcomes, higher overall health care costs and substantial difficulties for the people we serve.

Changes to regulations related to the use of contract pharmacies for Ryan White funded covered entities should also be rejected. It is critical to assure patient choice, easy access to medications and high levels of clinical outcomes for patients that 340B programs can be implemented in both owned and contracted pharmacies. This assures the patients do not have to overcome geographic and transportation barriers to get their medications, can access medications around work and other schedule demands, and receive integrated care as much as possible. ARCW and many Ryan White covered entities successfully implement the program in both owned and contracted pharmacies to better services patients. Any new 340B program oversight requirements that constrict or eliminate



contracted pharmacies will limit access to care and the financial benefits of the program for people with HIV.

To the contrary, changes should be made to federal law that allow Ryan White funded grantees to use 340B savings to expand services beyond those listed in PCN 16-02 including the ability to offer PrEP, expand clinical infrastructure or ensure long-term organizational sustainability. These changes are necessary in order for Ryan White funded organizations to meet the continually evolving demands of the AIDS epidemic.

Mr. GRIFFITH. Thank you.

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 5 of the past 6 years by IBM Watson. Mission Health is a significant provider of medical education and training, serving as a branch campus of the UNC Chapel Hill School of Medicine and as a clinical training site for the numerous primary care residencies like family practice, OB/GYN, general surgery, and psychiatry.

Our community board members, clinicians, and staff focus each and every day on the delivery of compassionate high-quality care to everyone, without regard to their ability to pay. The weight of our safety net responsibility is sometimes heavy but it is always real. Our patients are disproportionately older, poorer, sicker, and less likely to be insured than state and national averages, with nearly 70 percent covered by Medicare, Medicaid, or having no insurance at all.

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

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

We have also implemented a novel community investment program that identifies and funds external programs that are not Mission Health to address the most urgent, underserved health needs

that serve the uninsured or are either not covered by insurance or are not reimbursed at a financially viable level. We require for those investments a real business plan, metrics, and forecasts as if it were a real investment and we are seeing real results.

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

Now what are some examples? C3@356. This is a walk-in urgent care center for those with behavioral health needs that we helped fund and create on behalf of the community. The Mountain Child Advocacy Center, which supports and treats child abuse victims and their families. The Dale Fell Health Center, a Federally-Qualified Health Center that provides primary care to the most vulnerable in our community with a particular focus on homeless families and individuals. The Family Justice Center, which provides wrap-around 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:]

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STATEMENT
OF
RONALD A. PAULUS, MD
PRESIDENT AND CHIEF EXECUTIVE OFFICER
MISSION HEALTH
BEFORE THE
OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE OF THE
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES
“EXAMINING HOW COVERED ENTITIES UTILIZE THE 340B DRUG PRICING PROGRAM”
OCTOBER 11, 2017

EXECUTIVE SUMMARY

Mission Health is a not-for-profit, independent, community-governed health system providing high quality, compassionate medical care to the residents of western North Carolina for more than 130 years. We have had only one mission: *to improve the health of the citizens of western North Carolina and the surrounding region*. As the region's only safety net organization, Mission Health proudly provides medical care for all without regard to the ability to pay, including those with no or limited access to care. That's important, because like many Southern Appalachian communities, we face significant challenges. Our residents are older, poorer, and sicker and are disproportionately covered by Medicare, Medicaid, or are uninsured. Many patients present in late stages of illness while simultaneously dealing with complex social issues. Our system has grown in response to community needs, by supporting struggling hospitals and physicians, and by opening new clinics and health centers in significantly underserved areas and for underserved populations.

Congress established the 340B program to generate outpatient drug savings for safety-net providers and to allow those savings to stretch scarce federal resources. At present, six Mission Health hospitals qualify to participate in the 340B Program based on either DSH or critical access hospital status. Our use of 340B Program savings directly reflects the intent and design of the 340B Program, going to support high quality, safety net services and programs many of which are otherwise unavailable in the region and would be unavailable absent the 340B program. For our uninsured and underinsured patients, Mission Health provides robust financial assistance and charity care. Mission Health also manages an innovative Community Investment program that identifies and funds programs and organizations working to address the most urgent, underserved health needs region-wide. Flexibility to meet local needs is important, and funds provided by 340B program savings are integral to our work and critical to Mission Health's future. Mission Health sincerely appreciates the opportunity to participate in this dialogue to enhance and improve the 340B Program, and we remain at your service.

STATEMENT OF RECORD

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee, I am Dr. Ronald A. Paulus, and I have the privilege of serving as the President and CEO of Mission Health. On behalf of our employees and the nearly one million patients we serve in western North Carolina, thank you for inviting me to be here today to discuss our participation in the 340B Drug Pricing Program. As our region's only safety net organization, we greatly appreciate the opportunity to share our work in this critically important program.

Mission Health is a not-for-profit, integrated healthcare system with its principal offices located in Asheville, North Carolina. Mission Health is a community-governed, locally run, independent health system providing services to 18 mostly rural, mountainous counties in western North Carolina. Our residents are older, poorer, sicker and less likely to be insured than state and national averages.

Today, Mission Health operates six acute care hospitals, including two Disproportionate Share Hospitals (DSH), and four Critical Access Hospitals (CAH). The system also includes numerous outpatient centers, an ambulatory surgery center, and a diversified post-acute care provider delivering home health, hospice, physical/occupational therapy, adult day, private duty nursing, inpatient rehabilitation services, and a long-term acute care hospital. Mission Hospital is the region's only tertiary/quaternary referral center and operates the region's only Level II trauma center, children's hospital, Level III NICU, cardiac surgery, comprehensive interventional cardiology and neurointerventional radiology programs, and more. Mission Health operates the only two air ambulances in western North Carolina and operates the only Cyberknife west of Raleigh, North Carolina.

Through our 132 years of service to the region, we have had the same mission: *to improve the health of the citizens of western North Carolina and the surrounding region*. Our BIG(ER) Aim in pursuit of that mission is to get each person to their desired outcome, first without harm, also without waste and always with an exceptional experience for every patient, family and team member. Mission Health

continues to focus on providing, maintaining, and investing in access to high quality health, wellness and medical care services close to home for citizens in the region without regard to their ability to pay.

Mission Health has established a national reputation for high quality, safe, effective and low cost care. As just one example, Mission has been named one of America's Top 15 Health Systems by Truven/IBM Watson¹ in five of the past six years (2012-2017). As a group, the Top 15 Health Systems outperformed their peers in a number of ways, including: saving 66,000 more lives and causing 43,000 fewer patient complications; following industry-recommended standards of care more closely (>97%); released patients from the hospital a half day sooner; readmitted patients less frequently and experienced fewer deaths within 30 days of admission; had nearly 18% percent shorter wait times in their emergency departments; had over 5% lower Medicare beneficiary cost per 30-day episode of care; and scored nearly 7 points higher on patient overall rating of care. Even among this esteemed group, Mission Health performed in the Top 2% of the entire nation in the most recent award period.

To that end, maintaining the integrity of the mission critical 340B drug pricing program is absolutely vital in order for our population to receive the services they so desperately need. Many of the high quality, advanced safety net services that we provide are otherwise unavailable in the region and would be unavailable absent the 340B program. For our uninsured and underinsured patients, Mission Health provides robust financial assistance and charity care. Western North Carolina residents are disproportionately covered by Medicare, Medicaid, or are uninsured when compared to most regions of the state and nation. In fact, sixty-seven percent of Mission Health's hospitalized patients are uninsured or covered by Medicare and Medicaid. In 2016, Mission Health saved \$37.4 million through the 340B program, and this year we expect to save a little more than \$38 million. These savings go directly into programs for our community. In fact, the total value of Mission Health's charity and subsidized government care was nearly \$105 million in 2016, and our total community investments were more than \$183 million for that same year.

¹ <http://truvenhealth.com/products/15-top/studies-winners>

As you can see in Tables A and B, we have had growth in both our 340B program savings as well as our charity care and community benefit activities; one supports the other, and both are a direct result of the growth of our system, which has been driven by the need to support struggling or failing hospitals and physicians in rural areas of our community. We have also opened new clinics and health centers in significantly underserved areas or for underserved populations.

Table A: Mission Health 340B Value

Mission Health 340B Value	Estimated FY 2017	FY 2016	FY 2015	FY 2014	FY 2013	FY 2012
Angel Medical Center	\$ 1,506,789	\$ 616,670	\$ 577,926	\$ 677,790	\$ 172,435	\$ -
Blue Ridge	\$ 230,234	\$ 272,710	\$ 388,420	\$ 981,228	\$ 513,651	\$ -
Highland-Cashiers	\$ 227,505	\$ 120,897	\$ 270,535	\$ 147,015	\$ -	\$ -
McDowell	\$ 2,169,798	\$ 1,613,072	\$ 736,712	\$ 837,572	\$ 814,498	\$ 96,892
Mission	\$ 26,490,110	\$ 28,099,335	\$ 24,246,755	\$ 20,860,377	\$ 13,483,493	\$ 2,735,834
Transylvania Regional	\$ 684,568	\$ 523,758	\$ 467,016	\$ 240,278	\$ 385,907	\$ 286,657
TOTAL Hospital Savings	\$ 31,311,004	\$ 31,246,440	\$ 26,416,829	\$ 23,597,245	\$ 15,369,984	\$ 3,119,383
WAC Penalty (WAC Purchases at DSH Hospitals vs. GPO Pricing)	\$ (594,799)	\$ (628,674)	\$ (614,476)	\$ (441,872)	\$ (173,735)	\$ -
Contract Pharmacy Value	\$ 7,614,686	\$ 6,822,307	\$ 9,548,399	\$ 8,265,335	\$ 2,818,104	\$ -
TOTAL 340B Value to Mission Health	\$ 38,330,891	\$ 37,440,073	\$ 35,350,752	\$ 31,420,708	\$ 18,014,353	\$ 3,119,383
Average 340B Value FY13-FY17	\$ 32,111,355					

Table B: Mission Health Charity Care and Community Benefits

Mission Health Community Benefit and 340b Savings						
Mission Health Community Benefit Activities	Estimated FY 2017	From Form 990				
		*FY 2016	*FY 2015	*FY 2014	*FY 2013	*FY 2012
Charity Care (at Cost)	\$ 42,498,415	\$ 29,750,529	\$ 27,963,715	\$ 40,139,588	\$ 26,813,896	\$ 21,895,452
Unreimbursed Medicaid	\$ 5,741,221	\$ (6,170,764)	\$ (10,480,943)	\$ (19,128,851)	\$ (7,868,431)	\$ -
Unreimbursed costs (other means tested government programs)	\$ 5,517	\$ 7,570	\$ 7,187	\$ -	\$ -	\$ -
Charity Care Patients	25,352	21,710	17,462	10,131	7,882	
# Charity Care Claims	68,764	52,790	42,105	22,571	17,286	
Community Health Improvement Programs & Services	\$ 17,064,874	\$ 13,564,349	\$ 12,046,512	\$ 10,936,554	\$ 8,853,316	
Health Professions Education	\$ 2,820,332	\$ 2,511,965	\$ 2,764,242	\$ 3,119,558	\$ 2,708,593	
Subsidized Health Services	\$ 48,384,369	\$ 49,801,556	\$ 46,789,957	\$ 44,089,252	\$ 28,000,280	
Research	\$ 1,891,197	\$ 1,499,907	\$ 1,449,897	\$ 1,783,655	\$ 1,652,313	
Cash and in-kind Contributions	\$ 7,418,685	\$ 5,884,532	\$ 4,344,779	\$ 3,757,505	\$ 4,048,301	
TOTAL Mission Health Community Benefit Activities per 990	\$ 113,176,724	\$ 95,062,831	\$ 97,060,919	\$ 71,381,568	\$ 69,289,734	
Unreimbursed Medicare per Audit	\$ 64,323,000	\$ 55,832,000	\$ 44,504,000	\$ 60,033,000	\$ 39,339,000	
Other Estimated Community Benefits per Audit*	\$ 5,928,276	\$ (2,013,831)	\$ 10,833,081	\$ 12,139,432	\$ 14,272,286	
TOTAL Mission Health Community Benefit Activities per AFS*	\$ 183,428,000	\$ 148,881,000	\$ 152,398,000	\$ 143,554,000	\$ 112,901,000	
Cost of Treating Bad Debt Patients	\$ 37,730,278	\$ 39,679,272	\$ 36,983,206	\$ 33,143,490	\$ 36,159,388	\$ 31,487,323
Total Uncompensated Care (Charity + Bad Debt, A+D)	\$ 80,228,693	\$ 69,429,801	\$ 64,946,921	\$ 73,283,078	\$ 62,973,283	\$ 53,382,775
Average Charity Care FY13-FY17	\$ 33,433,228					
Average Uncompensated Care FY13-FY17	\$ 70,172,355					

The 340B Program supports the many ways that safety net providers, like Mission Health, provide health care in meaningful ways to those who find themselves unable to afford, access, or navigate needed care. The 340B Program is invaluable to providers like Mission Health in meeting these otherwise unmet needs. In brief summary, Mission Health's total charity care and bad debt alone is

more than double the value of our 340B savings. And our 340B savings are only one-fifth of our total community benefit provided in the most recent year.

Mission Health is a community health leader. As part of our work, we manage a forward-thinking Community Investment program that identifies and funds programs and organizations working to address the most urgent, underserved health needs in the region. Examples of Mission Health's recent collaborative work, aimed at reaching the most vulnerable in our community, include:

- C3@356, a walk-in urgent care center for those with acute behavioral health needs now seeing more than 275 walk-in behavioral health patients every week;
- The Dale Fell Health Center, a federally qualified health center that provides primary care to vulnerable community members with a particular focus on homeless patients and families;
- The Mountain Child Advocacy Center, which supports and treats child abuse victims and their families; and
- The Family Justice Center, which provides wraparound services for victims of domestic and sexual violence in a trauma-informed care setting.

Services and programs like those above are unique in our community, they provide a vital role to support the most vulnerable in our region, and they highlight the crucial safety net role that Mission Health plays in our service area. Mission Health routinely provides, or otherwise makes available, critical services in the community that are either not covered by insurance or are not reimbursed at a financially viable level.

Today, six Mission Health hospitals participate in the 340B Program. A more detailed description of each of our 340B eligible hospitals is below. Our flagship hospital, Mission Hospital, qualifies to participate in the 340B Program based on its high-DSH and non-profit status, and has participated in the program since 2004. The other five participants include four critical access hospitals and a smaller DSH-eligible hospital.

Our CAHs, located in some of the most rural areas of the state, are eligible for the program under statute based on their designation and heavily rely on the savings to provide 24-hour health care services to our rural patients. The 340B program enables eligible hospitals to use dollars saved on rapidly growing pharmaceutical costs to support the delivery of medical care and other necessary health services for our patients, especially for the uninsured, Medicaid, and other vulnerable patients. Given our patient demographics, many present for care in late stages of illness while also dealing with complex social issues requiring a wide range of care and services to manage their medical situations to get well. The 340B program allows flexibility for eligible hospitals (and other covered entities) to use the savings to best meet the critical needs of their communities.

At Mission Health, we take compliance with all programs, including all 340B program requirements very seriously. Like other 340B-eligible hospitals, our programs have been audited by HRSA/OPA. In those situations, we have successfully worked through the audit process and have implemented corrective action plans to insure continued improvement and compliance with HRSA guidance. Our most recent audit was at Mission Hospital in May 2016. That audit found no problems related to duplicate Medicaid discounts, accuracy of our HRSA 340B Directory, or 340B use in mixed-use settings of the hospital. The audit did identify an issue with the use of 340B medications for “in-eligible patients” in our owned community and contract pharmacies. That is not surprising because the definition of “eligible patient” has been elusive and fraught with lack of regulatory clarity. We take these issues very seriously, and immediately created a Corrective Action Plan which was subsequently approved by HRSA.

We have hired dedicated and well-trained employees specifically to operate our 340B Program and those individuals help to ensure that we are and remain knowledgeable and competent to operate this complex program both appropriately and effectively. In support of program compliance, the system has invested in core 340B staff to oversee the program for the health system. The multidisciplinary 340B team includes more than 75 total staff, with five of those staff members having completed 340B

University training², an in-depth educational program designed by Apexus³ to meet the practical needs of the 340B Prime Vendor Program (PVP) participants and other program stakeholders. Topics covered in the training include statutory ceiling price calculations, fundamentals in implementing a compliant pharmacy program, and hands-on training with tools and resources available to assist with program integrity.

In addition, we hold a multidisciplinary 340B Council Meeting every other month to update key staff and leaders on our most recent self-audit findings, new policies or procedures, new guidance from HRSA, as well as our dashboard of key metrics used to continuously monitor compliance issues. The 340B Council is comprised of our Associate General Counsel, Chief Compliance Officer, Internal Audit Managers of Member Hospitals, VP of Pharmacy Services, Director of Pharmacy Supply Chain, 340B Pharmacy Specialist, Information Technology Specialist for 340B, Regional Finance Directors, Director of Community Pharmacies, and Presidents of the Member Hospitals. Also, recognizing the importance of technology in our compliance efforts, we have worked to educate our technology partner around improvements to its software systems to help hospitals remain in full and complete compliance in the day-to-day operations of the program.

As I stated previously, Mission Health is a non-profit, safety net provider situated in western North Carolina, a part of Southern Appalachia, where residents are older, poorer, sicker and less likely to be insured than state and national averages. As such, they are disproportionately covered by Medicare, Medicaid, or are uninsured. To help meet the needs of our community, Mission provides robust financial assistance and significant charity care to those living in our region. All patients who have or anticipate a bill with Mission Health may apply for financial assistance at any time (before, during, or after services), regardless of their insurance status. The 340B program allows Mission to provide this much-needed assistance to our patients and families.

² Guidance from HRSA: only answers from Apexus or HRSA should be considered appropriate guidance for 340b entities.

³ Apexus: A non-government organization that works closely with HRSA to answer all 340b related questions.

As a health system facing a tsunami of need, Mission's targeted and continuing investment in its own programs and in those community programs that Mission supports clearly demonstrates that it is dedicated to using all of its resources to improve the health of the people of western North Carolina. Funds provided by 340B program savings are absolutely essential and integral to our work. Mission Health also uses its resources – including 340B savings resources – to offer multiple Community Health Improvement programs and services, with additional detail provided below.

- A Medication Assistance Program;
- A robust and forward-thinking Community Investment process;
- Extensive medical education and research programs focused on training medical students and residents with an interest in rural practice including family practice, obstetrics and gynecology, general surgery and psychiatry; and
- Community Building Activities, including regional and local programs funded by Mission Health, but that do not generate revenue. These programs, such as children's services, MAMA and EMS, are essential to the health and wellbeing of the communities we serve.

Additional information on Mission's charity and community investment programs is provided on the following pages. Thank you for the opportunity to highlight the great services that Mission Health provides to our community.

Mission Health participates in the 340B program at each of the following hospitals:

Mission Hospital, our flagship hospital, is a 763-bed tertiary-quaternary care, nonprofit medical center located in Asheville, NC. Mission is a disproportionate share hospital and is the largest hospital in the state west of Charlotte.

Mission Hospital serves a critical role in the health care safety net of Western North Carolina. The hospital includes, as part of its inpatient beds, 32 pediatric beds, 51 neonatal intensive care beds, and 62 psychiatric beds, including child and adolescent psychiatry. As the region's only tertiary and quaternary care medical center, Mission Hospital provides a comprehensive range of inpatient and outpatient services, with eight Centers of Excellence: behavioral health, cardiology, pediatrics, orthopedics, oncology, women's services, neurology and trauma. Mission Hospital is the only State of North Carolina designated Level II Trauma Center in western North Carolina and operates two emergency air ambulances to bring critically ill and injured patients from throughout the region for highly advanced care.

Mission Hospital also operates Mission Children's Hospital, which features both neonatal and pediatric intensive care units and a broad staff of pediatric subspecialists addressing the full spectrum of childhood diseases and conditions. In 2012, Mission opened the region's only pediatric imaging center. Mission's Cancer Center provides comprehensive cancer treatment to residents of western North Carolina including multidisciplinary cancer care with two linear accelerators, the region's only CyberKnife Radiosurgery facility, dedicated pediatric oncology and an infusion suite.

Among the specialized programs and referral services offered at Mission Hospital are a state-designated high-risk pregnancy center, interventional cardiology (including cardiac catheterization, electrophysiology and stents), cardiac surgery (including transcatheter aortic valve replacement, left ventricular assist device placement, and structural heart and bypass surgeries), inpatient dialysis and many others.

Blue Ridge Regional Hospital is a nonprofit, 25-bed critical access hospital located in Spruce Pine, North Carolina, approximately 50 miles northeast of Asheville. Blue Ridge qualifies to participate in

the 340B program based on its critical access status and has participated in the program since 2005.

Blue Ridge also operates clinics in Yancey and Mitchell Counties and is the only hospital in these counties. Blue Ridge Regional Hospital has been providing acute health care services to the population of Mitchell, Yancey and surrounding counties since 1955. In 2008, the hospital was expanded through a construction and renovation project, offering private patient rooms, a new and expanded emergency department and imaging services and an expanded chemotherapy unit. More recently, Mission built a state-of-the-art medical office building to replace badly outdated ambulatory space. Blue Ridge employs physicians in three provider-based, federally-designated rural health centers.

Angel Medical Center is a 25-bed, nonprofit critical access hospital serving Macon County, and the area surrounding Franklin, North Carolina, approximately 67 miles from Asheville. Angel qualifies to participate in the 340B program as a critical access hospital and has participated in the program since 2012. Angel Medical Center is the only hospital in Macon County and offers inpatient services that include: medical and surgical care and an intensive care unit. Outpatient services include: a wound clinic, a foot clinic, chemotherapy services, a full-service laboratory, digital mammography, CT, MRI, nuclear medicine, and rehabilitation therapy, as well as surgical and endoscopy services. Angel also operates an urgent care center and provides home health and hospice. Mission Health recently completed a clinical program plan for Angel Medical Center and is pursuing the construction of a new inpatient facility to serve the community long term, as the existing hospital, originally built in 1956, is in need of replacement.

Transylvania Community Hospital is a 25-bed nonprofit critical access hospital serving Transylvania County, North Carolina and the surrounding area. Transylvania qualifies to participate in the 340B program based on its critical access status, and has participated in the program since 2010. Transylvania is the only hospital in Transylvania County. Its operations, including inpatient skilled nursing, has been providing health care in and around Transylvania County since 1933. In September 2016, Transylvania began construction on an expansion of its Emergency Department.

The McDowell Hospital is a nonprofit 49-bed acute care hospital located in Marion, North Carolina, approximately 40 miles east of Asheville. McDowell qualifies to participate in the 340B program based on the indigent care population served through the hospital and rural health clinics, and has participated in the program since 2005. McDowell Hospital has been providing acute healthcare services to the residents of McDowell County since 1927. Construction of a new replacement hospital will be completed in the first quarter of 2018 and will house 25 patient beds, five labor, delivery, recovery and postpartum rooms (including a dedicated C-section Room), operating suites, one endoscopy suite, an imaging center, a 15-bed Emergency Department, an infusion center, and physician clinic space. Five of McDowell Hospital's primary care practices have been recognized by the Centers for Medicare & Medicaid Services as Rural Health Clinics.

Highlands-Cashiers Hospital is a nonprofit 24-bed critical access hospital serving Highlands and Cashiers, North Carolina and surrounding communities. Highlands-Cashiers Hospital qualifies to participate in the 340B program based on its critical access status, and has participated in the program since 2010. Highlands-Cashiers Hospital provides inpatient beds, a 24-hour emergency room, and a range of diagnostic services. An 80-bed center offers extended nursing care. In May 2017, Highlands-Cashiers completed construction on a new Emergency Department.

Mission Health Community Health Improvement Programs, Services, and Investments:

Enabling Access to Care for Everyone

ABCCM Medical Ministry: For more than 25 years, Mission has supported this local free medical clinic to assure access to care for our community's most vulnerable individuals. The partnership has included a financial commitment to sponsor 50 percent of the clinic budget (over \$2 million from 2012-2016). Support for the clinic also includes in-kind medical services (including labs, radiology, and medication expenses) at over \$2.7 million from 2012-2016.

EMS & Transportation Services – In our rural and mountainous region, transportation continually



emerges as a priority need across western North Carolina, and is a primary catalyst for communities identifying "Access to Care" as a top health issue. Mission Health provides EMS services in three local, rural communities – Madison, Mitchell, and Yancey Counties. Mission Health

also provides more than \$3M in regional transport services each year, including Behavioral Health transport.

Mountain Area Medical Airlift (MAMA): MAMA has been providing critical care transport through



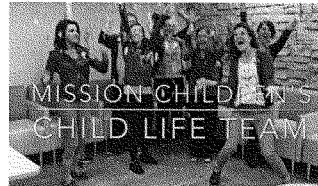
Mountain Area Medical Airlift (MAMA) since 1986. With two helicopters available 24 hours a day from bases in Asheville and Franklin, NC, MAMA provides air medical services to 18 western North Carolina counties, eastern Tennessee, northeast Georgia and northern

South Carolina. MAMA covers roughly 10,000 square miles in 2-3 flights a day (about 90 flights each month) and has transported more than 21,000 patients.

Children's Services



Mission Children's Hospital is the only full-service children's hospital in western North Carolina employing the only pediatric subspecialists for the region. Mission Children's provides a wide variety of child-specific services to ensure the highest quality care for our smallest friends and neighbors. As just one example, **Mission's Child Life Program** uses play and developmentally appropriate education to help reduce anxiety and stress for procedures and diagnoses. Mission provides this critical, unfunded program at a cost of more than \$300,000 a year.



Mission's Fullerton Genetics Center provides comprehensive genetic counseling and evaluations for all



genetic indications, including preconception, prenatal, pediatric and cancer. At a cost of more than \$700,000 each year, the Genetics Center performs evaluations for children with birth defects, unique physical features, developmental delays, metabolic conditions, atypical development, and family history of genetic conditions, among many other needs.

The Olson Huff Center for Child Development provides specialty services including audiology, autism services, learning disabilities, Down syndrome, birth defects and congenital anomalies as well as occupational, physical, and speech therapy, at a cost of more than \$750,000 each year.

The Mountain Child Advocacy Center: located within the child-friendly setting of Mission Children's



Hospital, the Mountain Child Advocacy Center provides support and treatment for child victims of abuse, and was established in coordination with the Family Justice Center. Mission donates \$68,000 annually through the provision of space for the Mountain Child Advocacy Center and support for its operating expenses. Sadly, Mission provides significant services for child abuse medical evaluation and counseling, with each hand print representing an abused child (partial photo shown).

Family Support Network (FSN) helps ensure families of children with special needs have a place to turn

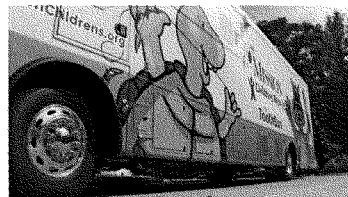


**Family Support
Network® of WNC**

for advice, guidance, and peer support. FSN serves more than 900 families a year, on average, at a cost of

over \$100,000. Staff with FSN support families in the Neonatal Intensive Care Unit, provide formal peer mentoring and connection for parents and caregivers, and also offer monthly family group nights with educational workshops.

Mission Children's Hospital ToothBus: Mission Children's Hospital operates two 40-foot-long mobile



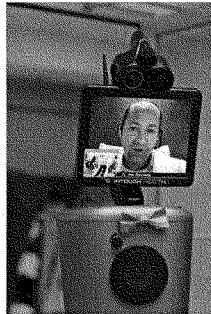
oral care programs that provide free preventive and restorative oral care to school-aged children throughout the region. The ToothBuses are set up to provide the same services offered in a traditional dental office in remote areas that have no other access to care. The buses travel the rural, mountainous roads to take care of

children during the day at their elementary school site so that parents do not have to take time off from work.

General Services

Primary Care Medical Homes - When a survey of primary care availability showed a deficit of more than 130 primary care physicians to meet basic access requirements for the people we serve, and high rates of end-stage disease being diagnosed in the Emergency Department, Mission Health responded with a commitment to recruit physicians and develop practices. Since then, Mission has invested more than \$5 million in the recruitment of 164 primary care physicians and advanced practitioners to support critical access to care region-wide. We have done so through Mission Medical Associates (MMA), a wholly-owned physician-led subsidiary of the Mission Health, which was incorporated in 2008 to serve as a patient-centered organization dedicated to providing tools and support to help physicians enhance the quality of care in a cost-effective manner. As of July 31, 2016, Mission Medical Associates employed over 625 physicians and advanced practitioners (physician's assistants, nurse practitioners or certified registered nurse anesthetists).

Region-wide Stroke Program – Mission Health's neurological services provide highly specialized care for



stroke patients throughout the region at a cost of more than \$300,000 each year, ensuring patients across western North Carolina have access to timely, state-of-the-art care. Mission Hospital earned the Joint Commission's Gold Seal of Approval and the American Heart Association/American Stroke Association's Check Mark for Advanced Certification for Comprehensive Stroke Centers. Additionally, Angel Medical Center, a Mission Health member hospital and Critical Access Hospital, earned Acute Stroke Ready

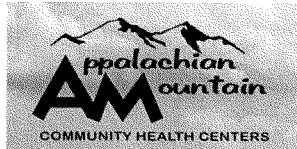
Hospital recognition.

To support remote patients even at non-Mission hospitals, Mission provides 24X7X365 TeleStroke coverage for the region. Mission Health's service area is rural or suburban, and mountainous

terrain can make it challenging to access care any day of the week. Mission's investment in Telemedicine for stroke care, called TeleStroke, enables neurologists to treat patients remotely, providing the quick response and quality care that can be the difference between life and death for a patient experiencing a stroke. Because of the improvement in time between onset of symptoms and treatment, TeleStroke patients have more favorable outcomes.

Support for Independent Physician Practice Quality – Mission Health initiated and enabled the formation of an Accountable Care Organization, **Mission Health Partners**, that provides support and resources to providers across western North Carolina, enabling them to offer higher quality, safe and efficient care to their patients. Given our population, this means providing high quality, coordinated care for people dealing with (typically) more than one chronic disease.

Tallulah Community Health Center is a rural family practice clinic serving a small community in western



North Carolina. Acquired in 2010, Mission provided care and developed the practice into a primary care medical home model at a loss of \$1.2 million each year. The Tallulah Community Health

Clinic is currently managed in partnership with Appalachian Mountain Community Health Centers, providing primary care for both adult and pediatric patients.

Behavioral Health Programs

Behavioral Health Transport: Patients receiving Behavioral Health services at Mission often require transportation between inpatient facilities, or from the Emergency Department to other facilities on campus. This transportation is provided by Mission and operates at a full annual loss, with a value of \$4,000-\$5,000 each year since 2014.

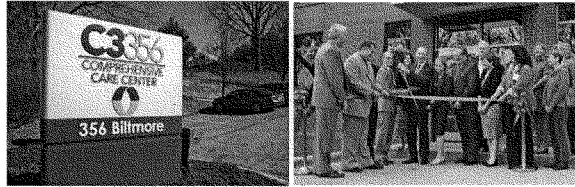
Behavioral Health Integration – Through telehealth and staff positions, Mission Health is working to integrate behavioral health care resources and support into primary care practices across western North Carolina. Our Behavioral Health Consultants provide support in local primary care practices, using the Primary Care Behavioral Health (PCBH) model. This population health strategy uses assessment, triage, and skills-building to extend the reach of care to any patient whose condition has a behavioral component, not just those with mental health needs.

This program was established in 2015 and currently provides Behavioral Health Consultants in four clinics, at a cost of \$330,000 each year. Behavioral Health Consultants are qualified Masters or Ph.D. level providers working in-person to bridge primary care with broader behavioral health services. Our partnership with Meridian Behavioral Health Services allows placement of Meridian therapists in primary care practices to bridge between consultation and broader services and create full-service, wrap-around care.

We also provide telehealth services in four primary care clinics to extend access to behavioral health care, with a goal of providing this care in every Mission primary care clinic by the end of 2018. Behavioral Telehealth provides real time access to behavioral health providers, in the clinic where a patient's need has been identified. This care is provided using a tele-health cart, at a cost of \$12,708 per year for each cart. Currently, telehealth carts are in use in four primary care locations for provision of behavioral health care services. Mission additionally provides 1.2 FTE team members to staff these telehealth sites five days per week, at a cost of roughly \$100,000 each year.

A dedicated 0.5 FTE staff person, at a cost of \$41,500 per year, develops education curriculum and Continuing Education Units for Behavioral Health Team members at Mission Health, and primary care providers have access to BH-specific education opportunities, including a summer series on psychiatry and behavioral health. Rural Health Clinics serve a large portion of western North Carolina residents, and these clinics are often under-resourced. Mission is targeting new growth in Behavioral Health Integration toward providers with Rural Health Clinic designations to help ensure broader access to behavioral services for patients.

C3@356 Comprehensive Care Center: a walk-in urgent care center for those with behavioral health



needs, including 24-hour urgent care unit, mobile crisis management team, a mental health and substance use crisis

facility, a community pharmacy and outpatient services. Mission provided \$1 million toward the establishment of this facility, which was matched by a grant from the North Carolina Department of Health and Human Services totaling almost \$1 million more. This center was established in collaboration with local officials, law enforcement, local behavioral health and safety net providers, the local management entity (LME/MCO – effectively a behavioral health managed care organization), and the local chapter of NAMI (National Alliance on Mental Illness).

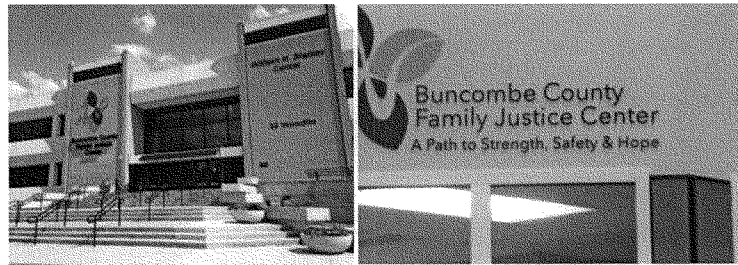
Perinatal Substance Use Workgroup

The urgency of substance use issues in western North Carolina gave rise to the development of the Perinatal Substance Use Workgroup in December of 2015. This regional group is hosted by Mission, in partnership with Mountain Area Health Education Center, Vaya Health, local behavioral health providers, and state and local government representatives. The workgroup aligns services to better address the needs of pregnant women with substance use disorders and support them through healthy pregnancy, delivery, and post-partum. The workgroup meets monthly and Mission has invested \$22,000 in in-kind staff time to this effort.

Emergency Department Psychiatric Services – By placing much-needed psychiatrists in emergency departments, Mission increased the availability of psychiatric evaluations to help quickly identify patients in need of behavioral health services. This annual investment of more than \$1.3 million is a

service provided by Mission in response to the growing need for better access to behavioral health care for uninsured behavioral health patients in crisis.

Family Justice Center: a centrally located, living-room style safe place for victims of interpersonal violence and sexual assault, providing wrap-around care in a trauma-informed setting. The Family Justice Center is home to numerous agencies providing support to victims and survivors, as well as legal aid, on-site SANE nurses, and on-site childcare. Mission outfits on-site medical examination rooms and provides SANE Forensic Nursing services to clients of the Family Justice Center and Mountain Child Advocacy Center, at a value of more than \$105,000 annually. This center was a collaboration of local community agencies, law enforcement, city and county officials, and health services partners. The Family Justice Center serves individuals from across WNC.



Medication Assistance Program: Mission Health primarily utilizes a centralized Medication Assistance Program for hospitals in the system. The program serves all patients and all hospitals in Mission Health. The program is not limited to 340B eligible patients/340B eligible drugs. The program utilizes a



combination of 340B, WAC purchases, and donations to meet the medication needs of the specific patient. The combined WAC value of

these medications for Mission Health patients in FY 17 ending September 30, 2017 is projected to be \$4,464,000. The cost to Mission to staff this program in FY 17 is projected to be \$563,590.

In addition to the Mission MAP program, our support of the Asheville Buncombe Community Christian Ministry (ABCCM) Medical Clinic provides medications at no cost to patients in need. ABCCM does not qualify for 340B drug pricing, but despite this, will provide over \$1.4 million in free medications (valued at WAC pricing) in 2017. The labor costs to staff this program are \$336,000 per year.

In addition to these two programs, Angel Medical Center uses a contract pharmacy agreement, and 340B or WAC priced medications to assist patients in need of medications. Angel pays the contract pharmacy their usual and customary charge, and hopes to recoup a portion of this cost if the prescription eventually qualifies for 340B pricing.

Sexual Assault Nurse Examiners (SANE): Mission employs forensic nurse examiners that are specially



trained, registered nurses who provide comprehensive care for victims of sexual assault, domestic violence, and child, elder, and dependent-adult abuse and neglect, and other violent crimes. Forensic nurses are also involved

in community outreach and educational programs designed to raise public awareness of sexual assault, safe relationships, and recognizing and dealing with intimate partner violence. These nurses are on duty 24/7/365 and have a presence at each Emergency Department in Mission Health System. In 2016, operational costs of the SANE program were valued at just over \$660,000.

Rathbun House: Mission's Rathbun House provides a home-like environment where families or



caregivers coming with a patient to Asheville can stay for free close to their loved ones, in a comfortable and supportive setting. Patients from around the region come to Asheville to receive care or medical treatment at Mission Hospital and the Rathbun House helps to

ease the burden of being away from home.

Dale Fell Health Center: Mission enabled the creation of a new, federally qualified health center (FQHC) focused on the homeless and located in Asheville, NC. It is a part of a network of health centers across the region and provides a primary care medical home for our most vulnerable community members. The development of this health center, designed to help meet the needs of the medically underserved, homeless, migrant or seasonal farmworkers, community-based health centers, and community agencies serving the homeless and other at-risk members of the community. For its role in this partnership, Mission's commitment \$750,000 to support the creation and development of the Dale Fell Health Center, and continues to provide leadership and partnership as the center grows to meet the needs in our community.

Community Investment Grants

Mission Health provides roughly \$1 million in grants to community agencies each year for programs that improve health across the region. Mission Health's investments into the 18-county western North Carolina region, made possible by savings from programs like 340b, are guided by the priority health needs identified in each county's Community Health Assessment Process.

The Grant Process

Every three years, hospitals and health departments are required, as part of the Affordable Care Act, to collaborate with community members and key stakeholders to assess the community's needs, prioritize the top health issues, and strategize together about how to address them. To facilitate this process, Mission Health invests more than \$100,000 annually the **WNC Health Network (WNCHN)**, an alliance of 17 hospitals in western North Carolina working together to improve health and healthcare. As



part of this alliance, WNCHN coordinates **WNC Healthy Impact** to coordinate partnership between hospitals and local public health, designed to align

the Community Health Assessment process across western North Carolina and increase capacity to have a greater impact on critical health improvement efforts. WNC Healthy Impact conducts regional and local primary and secondary data collection, stratifies and analyzes data for each partner, and works to infuse Results Based Accountability™ into the process to ensure our successes are evaluated and measured. WNC Healthy Impact aligns the work of 16 counties in western North Carolina and the Eastern Band of Cherokee Indians.

Western North Carolina Identified Health Priorities – 2012-2016

- Mental Health & Substance Use
- Access to Care
- Chronic Disease Prevention & Management
- Healthy Lifestyles – Physical Activity, Healthy Weight, Nutrition

Community Investments

Regional Asthma Disease Management Program – One of Mission Children’s outreach services, The



Regional Asthma Disease Management Program (RADMP), is an

award-winning, multi-faceted approach to help families build skills in managing environmental triggers and connects them with other community resources. Serving all children in western North Carolina, the program has a special focus on Native American, African American, and Hispanic children who may not receive intervention on a regular basis. The program strives to form an active, educated and aware partnership with each family, appreciating the role of cultural beliefs and adapting to educational and literacy levels. Healthcare cost-savings 12 months post-intervention were roughly \$880,000, and Mission has invested more than \$700,000 in the program since 2012.



Mammograms – Mission Cancer Services provides the Ladies Night Out program to make mammograms accessible for women in western North Carolina. Women who are uninsured or underinsured can access a mammogram, as well as additional screenings and health checks, in a friendly environment. Mission’s investment in Ladies Night Out is roughly \$40,000 each year.

Camp Bluebird for Cancer Survivors – Camp Bluebird a 2-night, 3-day retreat for adult cancer survivors



held twice a year in the beautiful mountains of western North Carolina. Sponsored by Mission Health, in partnership with AT&T Telephone Pioneers (the volunteer organization of the telephone company), the camp is available to anyone aged 18 or older with a

past or current diagnosis of cancer. Mission Health nurses volunteer at the camp, and help create a supportive environment in which campers experience unparalleled peer support, as well as counseling and spiritual support, and learn coping skills in addition to the many fun activities they participate in. Mission’s costs for Camp Bluebird run between \$10,000-20,000 annually, though the value of the camper’s experience cannot be quantified.

Community Partnerships & Other Investments

Physician Education & Innovative Care Models – Mission Health partners extensively with **Mountain Area Health Education Center (MAHEC)** to provide educational opportunities to local providers and the community. The partnership has also supported implementation of a Centering Pregnancy model for routine prenatal care provided by MAHEC OB/GYNs, and expanded to regional providers; this model supports pregnant women and their families and connecting them with a full spectrum of resources to improve wellbeing. In FY16, Mission supported \$4.9m of net community benefit attributed to medical education and grants.

YMCA Summer Camp for Low-Income Kids – Mission Health supported construction of the medical



building at the YMCA of WNC's Camp Watia summer camp for kids. Mission invested \$250,000 over 5 years in

the project, helping to ensure that kids from across the region who attend summer camp have high quality medical care during their stay.

Capacity-building for Local Nonprofits – As part of a collaboration of local funders, Mission invests



\$25,000 annually in WNC Nonprofit Pathways, a capacity-building organization that supports the growth and development of local nonprofits.

Through assessment, education and training

opportunities, consultant services, on-site training, and coaching in financial and sustainability issues,

WNC Nonprofit Pathways creates a support system for western North Carolina's community agencies.

Local nonprofits working to improve their communities' health have the support they need to be

healthy themselves.

Mr. GRIFFITH. Thank you very much.
Mr. Reuland now for a 5-minute opening.

STATEMENT OF CHARLES REULAND

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

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

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

Our history as a participant in the 340B Program is much more recent, only since 2002 but the value of the program is just as inherent, just as vital to our mission.

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

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

As a safety-net hospital, we respond to emerging crises, provide ongoing care, and disease prevention for the most vulnerable patients in Baltimore and invest in improvements in our city, all made possible in no small part by the savings afforded to us by the 340B program. We have many examples of those programs, which I will be glad to tell you more about but, in general, they fall into two basic categories of action.

The first category is providing wraparound support for patients when the normal processes of diagnosis and treatment may not be enough. Patients returning to homes without running water may have greater difficulty following through on instructions to keep wound dressings clean and sterile. Children with asthma may not

be able to avoid secondhand smoke that exacerbates their breathing challenges. And a senior will have difficulty taking the correct dosage of medication, if they can't read the label because of the tiny print.

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

The second is designing and implementing prevention strategy. Picture that proverbial cliff with people sometimes falling off. There are ambulances picking up the patients at the bottom but people continue to fall. The 340B Program allows a hospital to help install a fence at the top of the cliff to prevent further falls and, importantly, to tackle the causes of disease and disability in our community.

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

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

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

Now is the time for the Federal Government to recommit to the 340B Program. The program is as relevant and vital today as it was when first enacted. The legacy of the 340B program is that today JHH, along with the national network of other Disproportionate Share Hospitals and other 340B-covered entities are the bedrock of the national safety net dedicated to saving lives and improving the health of our most vulnerable neighbors.

Thank you for the opportunity to provide these comments and I look forward to your questions.

[The prepared statement of Mr. Reuland follows:]

**Testimony for the Record
Submitted to the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
for the Hearing
“Examining How Covered Entities Utilize the 340B Drug Pricing Program”**

October 11, 2017

**Charles B. Reuland, M.H.S, Sc.D.
Executive Vice President and Chief Operating Officer of The Johns Hopkins Hospital**

Chairman Murphy, 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 (JHH). I began my career at Johns Hopkins in 1990 and have served in a variety of roles over the past three 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 vulnerable individuals and families made possible, in part, by its participation in the 340B Drug Pricing Program.

JHH is the principal teaching hospital for the Johns Hopkins University School of Medicine and has been a 340B-eligible covered entity since 2002. Its mission is “to improve the health of our community and the world by setting the standard of excellence in patient care.”

I. The Johns Hopkins Hospital in Baltimore City, History and Demographics

The bequest left by the philanthropist Johns Hopkins, whose gifts established both the university and hospital, stipulated that both entities be rooted in Baltimore and serve the poor. Located in the heart of East Baltimore for more than 125 years, JHH's mission and commitment extend beyond the walls of the hospital. This dual focus on the city and its residents is as important today as it was in 1889.

Baltimore City, once a blue-collar manufacturing town, is in the midst of an impressive rebirth, but this transition has been slower in certain parts of the city. Currently, nearly one in four Baltimore City residents lives at or below the poverty level,¹ and the unemployment rate is above the national rate.² Jobs that pay a family-sustaining wage are scarce and one in four residents of Baltimore City lives in a “food desert,”³ where they must rely on convenience stores that offer few, if any, healthy food choices. JHH tailors the use of its 340B savings with these grim realities in mind.

II. The Johns Hopkins Hospital and the 340B Program

JHH takes seriously its responsibilities as a covered entity and is committed to being a good steward of the 340B program by fulfilling both the spirit and intent of the law. One of the strengths of the 340B program is the discretion it affords eligible hospitals in tailoring the use of program savings to address the unique needs of their communities. We are cognizant that our efforts take on even greater urgency in uncertain financial times, during public health crises and when rising premiums make health insurance unaffordable for many families.⁴ JHH serves a medically complex patient population with extensive social and clinical needs, including patients who are unable to get necessary care elsewhere.

As a safety net hospital, JHH uses its 340B savings to respond to emerging crises and to continue its work on the front lines of serving the most vulnerable patients in Baltimore. Since 2009, JHH has offered a charity program designed to improve access to effective, compassionate, evidence-based primary and specialty care to uninsured and underinsured patients from the neighborhoods immediately surrounding the hospital. The Access Partnership (TAP), as it is called, has provided medical services to more than 6,000 patients since the inception of the program.⁵ In the midst of the opioid crisis, JHH’s

¹ U.S. Census Bureau, American Community Survey (2015)

² U.S. Bureau of Labor Statistics, Baltimore Area Economic Summary, August 30, 2017

³ Amanda Behrens Buczynski, Holly Freishtat & Sara Buzogany, *Mapping Baltimore City’s Food Environment*, 2015 Johns Hopkins Center for a Livable Future, available at https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/pdf/research/clf_reports/Baltimore-Food-Environment-Report-2015-1.pdf

⁴ Meredith Cohn, *Obamacare Premium Costs in Maryland Set to Jump as State Approves Rates*, Balt. Sun, Aug. 29, 2017 (Business), available at <http://www.baltimoresun.com/business/bs-hs-obamacare-rates-20170829-story.html>

⁵ Johns Hopkins Medicine, *The Access Partnership Medical Director Report* (2017).

investment in transitional housing and substance use treatment is increasingly important for saving lives. In FY2016, over 250 people struggling with drug addiction found stable living conditions and comprehensive recovery services at JHH's Broadway Center for Addiction, a substance use treatment program serving East Baltimore residents regardless of their ability to pay.

JHH provides low-income patients with free and discounted outpatient drugs, but for JHH's most vulnerable patients, affordability is only one in a series of hurdles to experiencing the full health benefit of a prescribed medication. For that reason, JHH uses 340B program savings to fund wrap-around services, including telephone consultations, home visits and transportation as needed for insured and uninsured patients alike. For example, JHH dispatches pharmacists to patient's homes through its *Home-Based Medication Management* project. These specially trained pharmacists work with patients to dispose of expired or discontinued medication, color-code pill containers when labels are too small to read and review medication administration instructions. Importantly, they also ensure that the patient's medication regimen is not only the right choice therapeutically, but also affordable for the patient in the long term. In this program, which began in 2012, JHH has demonstrated a significant reduction (from 17 percent to 8 percent) in readmissions among patients who receive a pharmacist home visit.⁶ JHH also offers a free bedside delivery service to eliminate barriers that could prevent patients from taking medically necessary prescriptions as instructed after a hospital admission, which is vital for good health outcomes and avoiding hospital readmission. More than 9,000 patients benefitted from this service in 2016.

As a not-for-profit hospital, JHH conducts a community health needs assessment (CHNA)⁷ every three years that helps us understand the gaps in care and health status of our closest neighbors. From this work, JHH reinvests 340B savings into evidence-based,

⁶ Pherson, *Development and implementation of a post discharge home-based medication management service*, 71 Am J Health Syst Pharm. 1576-83 (2014).

⁷ Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return, 79 Fed. Reg. 78,953 (Dec. 29, 2014) (codified at 26 C.F.R. pt. 1, 53, and 602).

community-strengthening programs that have had a proven impact on health. These interventions span the life cycle from early maternal and child health to end-of-life care. For instance, JHH is a proud sponsor of Health Leads, a program that enables providers to “prescribe” basic resources such as food and heat just as they do medication. Health Leads advocates work side by side with patients to connect them with community resources such as local food pantries and utilities assistance programs. More than 1,100 patients were served in FY2016.⁸

As an anchor institution and the largest private employer in Maryland, JHH leverages its 340B savings to support employment and investment activities that create a safer, healthier and more vibrant community. Studies show that incomes and employment have a profound impact on health outcomes.⁹ To help narrow the wealth disparities in our community, in 2015 The Johns Hopkins University and The Johns Hopkins Health System Corporation launched *HopkinsLocal*, a comprehensive strategy to promote greater economic growth and employment opportunities by increasing Johns Hopkins design and construction contracts with local minority- and women-owned businesses and expanding the number of new jobs for city residents. In year one, the program resulted in approximately \$5 million more spending with local businesses and 300 new hires from the community.¹⁰

The 340B program gives JHH the flexibility to tackle the *causes* of disease and disability in our community. In addition to providing health care to one patient at a time, JHH uses its 340B savings to help *prevent* disease and injury in the neighborhoods surrounding the hospital. For instance, beyond treating a premature and low birth weight baby in the neonatal intensive care unit, with 340B savings, JHH develops programs for expectant mothers in the surrounding community to increase the likelihood of healthy, on-time deliveries. In addition to prescribing medication to manage a patient’s asthma,

⁸ The Johns Hopkins Hospital, Johns Hopkins Community Benefits Report Narrative (Fiscal Year 2016).

⁹ Robert Wood Johnson Foundation, Achieving Equity in Health. Racial and ethnic minorities face worse health and health care disparities – but some interventions have made a difference. *Health Affairs* (October 6, 2011), available at http://healthaffairs.org/healthpolicy/briefs/brief_pdfs/healthpolicybrief_53.pdf

¹⁰ Ronald J. Daniels & Ronald R. Peterson, *Year One Progress Report HopkinsLocal*, Johns Hopkins University & Health System (2017), available at <http://hopkinslocal.jhu.edu/content/uploads/2017/03/HopkinsLocal-Progress-Single-Pages.pdf>

diabetes or heart disease, with 340B savings, JHH sponsors health promotion activities with local churches and community leaders. The Emergency Department can treat a patient with a gunshot wound, but with 340B savings, JHH can help modify the patient's home to promote independence after injury and support neighborhood violence prevention programs. 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 from the 340B program.

III. Pharmaceutical Market Trends

Nationally, prescription drug spending growth in 2015 (9 percent) outpaced the overall rate of health care spending growth (5.8 percent) and the rate of spending growth on hospital care (5.6 percent) as compared to 2014.¹¹ New medicines introduced in the past three years are a major driver of JHH and national spending growth as clusters of innovative treatments for cancer, autoimmune disease, HIV and diabetes come into the market.

In the generic market, as well, hospitals nationwide struggle to manage unexpected, sustained and irregular price increases. Often these drugs are essential and lifesaving, and in many cases no lower cost alternative exists. For example, at JHH from FY2014 to FY2017, the drug spend for just seven long-standing generic drugs used to treat severe allergic reactions, urgent blood pressure control and cardiac arrhythmias increased by 315 percent, despite purchase volumes at JHH for those same drugs increasing by only 12 percent. Such spikes are not limited to a single drug manufacturer but are instead the result of loss of competition and monopolistic business practices that have been the subject of congressional inquiry in recent years.¹²

¹¹ U.S. Dept. of Health and Human Services, Centers for Medicare and Medicaid Services, *National Health Expenditure Fact Sheet*. Baltimore, MD, 2015.

¹² Susan Collins and Claire McCaskill, Special Senate Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, December 21, 2016.

IV. Conclusion

At no cost to taxpayers, except for modest appropriations to administer the program, the 340B program has been a success for our community, allowing JHH to operate a variety of programs and provide services for vulnerable patients that improve their health and well-being that otherwise would not be possible. Importantly, the savings afforded by the 340B drug discount program allow covered entities to focus on preventive medicine, population health and care throughout the lifespan. These efforts help avoid other, more expensive medical interventions, the cost of which would be borne in large part by federal and state government funds if it were not for the 340B program.

Now is the time for the federal government to recommit to the 340B program. The program is as relevant and vital today as it was when first enacted. Congress, in its wisdom, required pharmaceutical manufacturers to discount the cost of covered outpatient drugs for certain hospitals that serve a disproportionate share of low-income patients to allow those covered entities the flexibility to use those savings to respond to the needs of their communities. The legacy of the 340B program is that today, JHH, along with the national network of other disproportionate share hospital 340B covered entities, are the bedrock of the national safety net dedicated to saving lives and improving the health of our most vulnerable neighbors.

Thank you for the opportunity to provide these comments and I look forward to your questions.

Mr. GRIFFITH. Thank you, very much.
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 an extensive network of healthcare facilities in Georgia. This includes three acute care hospitals, more than 150 ancillary and physician service sites, 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 until 2016, Northside Atlanta's provision of charity and indigent care grew at a rate 63 percent greater than our increase in hospital adjusted gross revenue. During the same period, the number of distinct patients receiving charity care at Northside Atlanta increased 350 percent.

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

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

Northside also operates a Financial Access Surgery Program to provide radiology, cancer, and related surgical services to the uninsured and underinsured who are not otherwise able to afford medically-necessary outpatient care.

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

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

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

In 2016, Northside underwent an audit by HRSA, which confirmed Northside's compliance with 340B Program requirements. Following a thorough review of the 340B Program, HRSA found a single instance of inadvertent diversion, representing less than \$7.

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

[The prepared statement of Shannon Banna follows:]



**Testimony Before the United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

Examining How Covered Entities Utilize the 340B Drug Pricing Program

Testimony of:

Shannon A. Banna
Director of Finance and System Controller
Northside Hospital, Inc.
Atlanta, Georgia

October 11, 2017

Good morning, Chairman Griffith, Ranking Member DeGette, and Members of the Subcommittee. My name is Shannon Banna, and I am the Director of Finance and System Controller for Northside Hospital, Inc. (“Northside”). Thank you for the opportunity to demonstrate to the Subcommittee how Northside utilizes the 340B Drug Pricing Program (the “340B Program”) to serve Georgia communities.

This morning I would like to address three key points related to the 340B Program:

- First, the 340B Program savings empower us to meet Health Resources and Services Administration’s (“HRSA”) goal of reaching our nation’s most vulnerable patients;
- Second, Northside has continued to expand its charity care and community programs. For example, our level of charity care from 2012 to 2016 at Northside Hospital Atlanta (“Northside Atlanta”) was 63 percent greater than Northside Atlanta’s increase in revenue over the same five-year period; and
- Third, a 2016 HRSA audit confirmed Northside’s diligent oversight of and compliance with 340B Program requirements. HRSA found a single instance of inadvertent diversion, representing less than seven dollars (\$7).

In short, since opening our doors in 1970, Northside has continually expanded its commitment to provide higher quality, more compassionate, and more comprehensive health care to patients in our community. 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. Each of these items is discussed in more detail below. Before addressing 340B Program specifics, I would like to make a few general comments about Northside and our role in the Atlanta community.

Introduction and Background

Northside is an independent Georgia non-profit corporation that owns and/or operates an extensive network of health care facilities in Georgia, including (i) three (3) acute care hospitals located across the northern metropolitan Atlanta area with a total of 926 operational beds; (ii) more than 150 ancillary and physician service sites located across the 28 county Atlanta Metropolitan Statistical Area (“MSA”), including diagnostic imaging, ambulatory surgery, cancer care, and physician services; and (iii) supportive services/facilities, including medical office buildings, located throughout the Atlanta MSA. As one of Georgia’s largest and most respected health care delivery systems, Northside offers a full range of services through over 2.5 million patient encounters each year. We have 14,600 employees and over 2,500 employed or affiliated physicians.

High Risk Deliveries & Maternity Services

As the undisputed national leader in maternity services, Northside Atlanta delivers more babies than any other single hospital in the country. In Northside Atlanta’s Level III Neonatal Intensive Care Unit, as many as 100 premature and high-level special care babies are treated daily, with more than 2,000 treated annually. Specializing in the diagnosis and management of high-risk pregnancy, Northside’s Center for Perinatal Medicine offers nationally recognized expertise and innovation in maternal fetal medicine and diagnostic radiology. High-risk mothers-to-be can receive consultations from specialists with advanced training in the management of the most complicated pregnancies. Northside has more board-certified obstetricians and perinatologists on staff than any other hospital in the southeast. In 2009, The Joint Commission distinguished

Northside Atlanta by awarding it a Disease-Specific Certification in High-Risk Obstetrics, which was followed by recertification in 2011. In 2012 and 2015, Northside Atlanta was awarded High-Risk Obstetric Certification in preterm labor prevention, one of the few hospitals in the nation to achieve this recognition.

Cancer Care

Since first providing cancer services in 1975, Northside has become one of the largest and most respected providers of cancer care services in Atlanta. The Northside Hospital Cancer Institute is fully accredited by the American College of Surgeons Commission on Cancer and is one of only 21 community cancer programs nationwide to be selected by the National Cancer Institute, a division of the National Institutes of Health, for participation in the National Cancer Institute Community Oncology Research Program. Selection criteria included scope of patient reach and overall comprehensive delivery of high-quality care. At Northside, more cases of breast cancer are diagnosed and/or treated than at any other hospital in the southeast, and more gynecologic and prostate cancer cases are diagnosed and/or treated than at any other hospital in Georgia. The Northside Blood and Marrow Transplant Program has among the highest survival rates in the nation and is recognized as a premier program throughout the southeast.

Using a multidisciplinary approach, Northside's mission is to employ cutting edge technology, advanced clinical research and compassionate, patient-centered care to defeat cancer. We care for the patient from the moment of diagnosis throughout the course of the disease and survivorship by: (i) educating the patient about their form of cancer and the stages of its development; (ii) discussing treatment options and making recommendations to the patient; (iii)

monitoring the care and treatment of the patient throughout the course of the disease; and (iv) leading multi-disciplinary teams to coordinate patient care.

Northside's 340B Program

Northside Atlanta qualifies for participation in the 340B Program because of its disproportionate share of indigent and low-income inpatient encounters, currently running at approximately 16 percent. This calculation is based on the high percentage of Medicaid inpatient days as a percentage of Total Patient Days. Northside Atlanta began its 340B Program in 2013, and the Program has grown along with the hospital system's operations. Indeed, during the five (5) year period of 2012 to 2016, inpatient case volumes grew approximately 2.1 percent per year on average across the MSA, while inpatient case volume at Northside Atlanta increased approximately 6.2 percent per year on average. During the five (5) year period of 2012 to 2016, outpatient encounters grew 145 percent across Northside Atlanta's hospital outpatient departments. The 340B Program limits the cost of covered outpatient drugs prescribed by eligible physicians to eligible patients within approved locations.

Northside 340B Program Savings/Charity and Community Care

All patients at Northside are treated the same regardless of the insurance they have, if any, or their ability to pay. No patient is ever turned away due to their inability to pay for services. Indeed, over the past five (5) years, Northside has provided almost \$1.4 billion in free or discounted care to uninsured, underinsured or self-pay patients. Northside uses a sliding scale to determine a patient's eligibility for financial assistance. Specifically, patients with annual household incomes at or below 125 percent of the Federal Poverty Income Level qualify to receive

free care. Patients above 125 percent of the Federal Poverty Income Level receive discounted care depending on the sliding scale and whether they meet Northside's Financial Assistance Program guidelines.

From 2012 to 2016, Northside Atlanta's charity and indigent care, as reported on our Annual Hospital Financial Survey, grew at a rate of 177 percent, or 63 percent greater than Northside Atlanta's increase in adjusted gross revenue. Further, the number of distinct patients receiving charity care at Northside Atlanta during this time period increased 350 percent.

Northside monitors its annual drug spend and 340B savings by routinely comparing differences in the average unit pricing of drugs purchased at participating 340B clinic locations against average unit pricing of drugs purchased within non-340B clinic locations (GPO). This difference or "savings" approximated 37 percent in 2016. Northside does not track its annual 340B savings in total dollars or assign these savings to any one program or area.

Under current 340B rules, Northside has elected the Medicaid "carve-in" option. This means that Northside passes 340B savings directly along to the Medicaid patient and program. Northside's savings from the 340B Program enable expansion of clinical services across many service lines and increase our reach to as many disadvantaged patients as possible. Indeed, in addition to uncompensated care, Northside provides a number of services that cater to lower income populations, as outlined below.

- *Oncology* – Since 2013, Northside has made significant improvements in our medical oncology facilities, making state-of-the-art cancer care accessible to more patients in more locations. Northside offers patients affordable, cutting-edge oncology drugs even though the price of such drugs increases faster than the 340B Program discounts. Northside has also expanded the support services it provides to all of its cancer patients, including:

- Patient Assistance – Northside’s Oncology Patient Assistance Office now has 20 employees devoted to patient financial assistance. Their efforts to identify and assist those in need produced a 156 percent increase in financial assistance applied toward the oncology service area from 2013 through 2016. One example of their efforts is our Pharmacy Replacement Program, where hospital staff work with outside vendors to qualify our patients to receive reduced pricing or, at times, free drugs needed for their treatment.
- Oncology Navigation Program – Ensures site-specific Oncology Nurse Navigators to provide patients emotional support and clinical education, enhance access to community resources and facilitate communication with physicians and other health care professionals.
- Community Outreach Program – Coordinates and implements cancer prevention, education and awareness events and activities in the community. During Fiscal Year 2016, Northside Hospital Cancer Institute provided general cancer prevention and breast, prostate, and lung cancer outreach and education to over 32,000 people.
- Oncology Support Services – Offers patients nutrition, rehabilitation and behavioral health services to improve health outcomes and reduce additional costs.
- Hereditary Cancer Program – Provides board-certified genetic counselors that assess patients’ risks of developing cancer and outline ways to minimize future risk.

- National Tumor Registry – Enables continuous improvement and oversight in subspecialty clinical protocols to monitor effectiveness and efficiencies. This program also allows for data analysis that can enhance care, reduce waste and lower costs.
- Survivorship Program – Works to ensure availability and equal access to all patients of the wellness and support services provided by Northside and community partners.
- *FASP* – Northside’s Financial Access Surgery Program (“FASP”) ensures specialty radiology, cancer, and related surgical services for the uninsured and underinsured. Northside entered into arrangements with several charitable organizations to refer patients who would not otherwise be able to afford or obtain medically necessary outpatient surgery. Patients are pre-screened based on financial status and medical necessity, among other factors. The FASP is designed to cover the entire surgical episode of care including pre- and post-operative services and, as needed, related services such as anesthesia, radiology, pharmacy and laboratory. In 2016, the FASP provided 390 participants across 23 counties with medically necessary surgical and endoscopic procedures.
- *Community Benefit Steering Committee* – As an outgrowth of its most recent Community Health Needs Assessment, Northside has established the Community Benefit Steering Committee. The purpose of the Steering Committee is to: (i) evaluate Northside’s current community benefit programs, utilizing a structured systematic approach, to ensure the programs are effectively meeting the identified health needs of the Community, targeting the highest priority needs and populations and utilizing evidence-based interventions; (ii)

identify any gaps (geographic, population, or subject matter) in Northside's community benefit activities and make appropriate modifications; (iii) establish each program's foundation by defining its core components such as the program's theory, goals, and objectives; (iv) connect Northside employees who implement and plan Northside's community benefit programs to foster collaboration and efficiencies; and (v) provide a channel for discussing community feedback on Northside's community health needs assessment, prioritized needs, and community benefit programs. The Committee comprises leadership from Strategic Planning, Charity Outreach, Maternity Services, Oncology Services, Cardiovascular Services, and Corporate and Community Health.

- *Preventive Care* – In 2016, Northside offered free or low-cost disease-specific health screenings at our campuses, providing 349 men with prostate cancer screenings, 521 participants with skin cancer screenings, 130 participants with stroke screenings, and 123 schoolchildren with hearing screenings. In addition, Northside provided audiology screening for all newborns.
- *Maternity* – Northside's MothersFirst Program offers low-cost educational courses on topics related to maternal and infant health, with over 700 classes available and with over 7,000 people having taken advantage of them in Fiscal Year 2016. During the same time period, another 18,500 individuals accessed Northside's free breastfeeding eLearning program, and more than 31,000 women used our free Lactation Support telephone hotline.
- *Financial Counseling* – Northside provides assistance to uninsured and underinsured patients to make sure they can access potential health care insurance coverage through any state or federal program for hospital services in which they may qualify. This assistance includes, but is not limited to, completing the necessary applications and forms, following

up with patients to provide necessary documents, requesting medical records from necessary health care providers, and following up on any submitted applications for approval or denial outcomes.

- *Transitional Care Services* – Northside’s Transitional Care Management program encompasses a broad range of services designed to promote the safe and effective transfer of patients between levels of health care and across care settings. Northside provides comprehensive transitional care services to all patients with multiple chronic conditions and complex therapeutic regimens in need of these services.

340B Program and Related Controls

Northside developed its 340B Program under the guidance and oversight of an independent, third-party consultant. All decisions made regarding the 340B Program are made through Northside’s 340B Steering Committee, with input and guidance from independent consultants and outside counsel. In addition to constant oversight by the Steering Committee, the 340B Program undergoes frequent and rigorous internal and external auditing and monitoring. Although Northside does not have a policy that explicitly provides that certain patients directly benefit from the 340B Program, all savings are used to provide additional and more comprehensive care to the areas serving vulnerable patient populations.

In 2016, Northside underwent an audit by HRSA, which further confirmed Northside’s compliance with 340B Program requirements. Following a thorough review of Northside’s 340B Program, HRSA found a single instance of inadvertent diversion, representing less than seven dollars (\$7). The audit also found the possibility of duplicate discounts by Medicaid due to incorrect or incomplete billing information on the 340B Medicaid Exclusion file. A thorough

review, however, concluded that no drugs were ordered or dispensed from this location and no duplicate discounts had occurred. HRSA's findings demonstrate the success of Northside's diligent oversight of the 340B Program.

Northside 340B Program "Child Sites"

Northside currently has 77 child site locations, which are publicly listed on HRSA's website. Notably, the number of child sites increased substantially over the past year (by nearly 20 sites), due mainly to HRSA's guidance that each separate department, office or suite number be registered as a child site and not only the actual building site locations.

Northside 340B Program Contract Pharmacies

Northside does not have any agreements with any outside pharmacies to dispense drugs purchased through the 340B Program.

Conclusion

Despite declining reimbursements and increased costs across the health system, Northside has continued to expand its charity care and community care programs. Northside is proud of our commitment to charity and the services we provide to our community, the extent of which is made possible through 340B Program savings. Overall, Northside's 340B Program savings empower us to meet the HRSA's broad goal of helping the nation's most vulnerable by "reaching more eligible patients and providing more comprehensive services."

Mr. GRIFFITH. Thank you very much to all of our witnesses. At this point, I ask unanimous consent that the contents of the document binder be introduced into the record and to authorize staff to make any appropriate redactions.

Without objection, the documents will be entered into the record with any redactions that staff determines are appropriate.

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

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

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

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

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

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

Mr. Gifford.

Mr. GIFFORD. Thank you, Mr. Chairman.

We calculate our 340B savings in a very direct and simple way, the cost of the medication at a non-340B rate less the cost of the 340B medications. It is the difference between the two costs that we use.

Mr. GRIFFITH. Thank you, sir.

Dr. Paulus.

Dr. PAULUS. Thank you.

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

Mr. GRIFFITH. All right.

Mr. Reuland.

Mr. REULAND. Thank you, Mr. Chairman.

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

Mr. GRIFFITH. All right.

Ms. Banna.

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

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

And we will start on this end this time so that we try to be more fair. Ms. Banna.

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

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

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

Mr. GRIFFITH. Thank you.

Mr. Reuland.

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

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

Mr. REULAND. One way maybe to think about it, perhaps, is that there is not really a check that comes back, if you will. This is a lower price paid. So there isn't a check that comes back that then you have the opportunity to say where it goes. This is a reflection of paying less for a drug than you otherwise would pay.

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

Mr. GRIFFITH. All right.

Dr. Paulus.

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

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

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

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

Dr. PAULUS. Yes, we do.

Mr. GRIFFITH. All right, thank you.

Mr. Gifford.

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

Mr. GRIFFITH. Thank you.

And Ms. Veer.

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

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

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

But I appreciate that and now I yield 5 minutes to Ms. DeGette for her questions.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

I will just skip around. Dr. Paulus, I would like to ask you, yes or no, Mission Health reported to the committee that it saved about \$37 million through 340B in 2016. Is that correct?

Dr. PAULUS. I believe that is correct.

Ms. DEGETTE. Thank you. And Mission Health spent more than \$183 million providing community benefits, including \$105 million in uncompensated care. Is that correct?

Dr. PAULUS. That is correct.

Ms. DEGETTE. Now, Dr. Reuland, a similar question. In 2016, Johns Hopkins generated about \$109 million in 340B savings. Is that correct?

Mr. REULAND. Yes.

Ms. DEGETTE. And Johns Hopkins provided nearly \$220 million in charitable care for vulnerable populations and other vital community benefits. Is that correct?

Mr. REULAND. Yes.

Ms. DEGETTE. No, Ms. Banna. Your hospital, Northside, reported that it generated nearly \$53 million in 340B savings. Is that correct?

Ms. BANNA. That is correct.

Ms. DEGETTE. And yet Northside reported to the committee that it spent nearly \$370 million in charity care. Is that right?

Ms. BANNA. That is right.

Ms. DEGETTE. Now, let me just say the 340B Program doesn't seem to be some windfall that subsidizes bonuses for senior management but, as you all testified both in your written testimony and in your verbal testimony today, you are using this money to help provide essential benefits that the community needs.

So I want to ask each of you if you can briefly describe what would happen if Congress eliminated the 340B money. I will start with you, Ms. Veer.

Ms. VEER. Thank you because that is a wonderful question. It really gets to the heart of what we are all concerned about and our need for Congress to have confidence in the integrity and——

Ms. DEGETTE. If you could just briefly——

Ms. VEER. Sure.

Ms. DEGETTE [continuing]. Describe some of those services. We, unfortunately, only have 5 minutes and I would like to hear from everybody.

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

Ms. DEGETTE. Thank you.

Mr. Gifford, can you give me some examples?

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

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

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

Ms. DEGETTE. Dr. Paulus?

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

Ms. DEGETTE. Mr. Reuland?

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

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

Mr. REULAND. So there is counseling. There is medication treatment, typical kinds of treatment for substance abuse treatment and recovery. And the supporting housing is a good example of the wraparound project that we provide so that we don't send folks back to the environment from which they came initially while they are trying to recover. That is half a million dollars plus for us that we would have to take out that is an investment we make.

Ms. DEGETTE. And Ms. Banna.

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

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

Mr. GRIFFITH. The gentlelady yields back.

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

Mr. WALDEN. I appreciate it.

I served on a hospital board for 4 1A½, 5 years. Nobody, first of all, if talking about eliminating 340B Program. So, everybody breathe.

Second, I have got to tell you I think when the average American hears what you would cut, not one of you said any overhead, capital construction, salary bonus. It was infants trying to recover from opioids is the first thing. Really?

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? How do we track this? That is what we are trying to figure out here.

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

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

Ms. Banna, we will just start with you.

Ms. BANNA. Absolutely. I do think industry standard is not to reflect the provision of care to the vulnerable population of the percent of just operating expenses, which is what was done in the AJC article. I would say that is inaccurate or at least incomplete. When comparing to expenses, you are including things like overhead, and telephone, and depreciation on your buildings.

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

Mr. REULAND. Mr. Walden, one of the things I might mention is when we set up programs, we tend to set them up from a clinical perspective to manage a disease state or a population with a disease. And so an example might be sickle cell anemia and sickle cell

disease is a disease that you may know disproportionately affects African Americans. And we have set up a very comprehensive program, the only one in the region to manage those kinds of patients.

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

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

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

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

And those are my thoughts.

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

Ms. VEER. I think the term or concept of charity care is one that is not terribly familiar for community health centers or in the community health center world, not because we don't understand that concept but because we operate under a set of statutory requirements that essentially mean we are on the hook for taking care of everyone, regardless of their ability to pay, and for providing a full range of services, regardless of their ability to pay, and have been for decades.

So my health center, the \$4.2 million that is listed as charity care really represents the cost of all care provided to patients for which we receive no compensation.

And I will give you an example. If a patient qualifies for our nominal fee, it is \$10 for a visit, which might encompass a 99205 visit, so a complex visit, plus radiology, plus lab work. And for that, we are receiving \$10.

So the health centers do have a very concrete way of measuring that.

Mr. WALDEN. I appreciate that and I thought your initial answer in the beginning about how much you account for was spot on. So, thank you.

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

I now recognize the ranking member, Mr. Pallone of New Jersey.

Mr. PALLONE. Thank you, Mr. Chairman.

I have been impressed with the responses the committee has received with its inquiries about how covered entities use the 340B

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

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

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

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

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

Mr. PALLONE. Thank you.

Now to Mission Health. Dr. Paulus, you reported that Mission Health provided \$105 million in charity and unreimbursed care. You also reported that Mission Health's community benefits were worth \$183 million that year.

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

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

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

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

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

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

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

Mr. PALLONE. Well, thank you.

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

In a minute or less, how does that work?

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

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

Mr. PALLONE. All right, thank you.

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

Ms. BANNA. Absolutely. I think in its simplest form, 340B reduces our costs. And as a nonprofit hospital, that is what we strive for each and every day. Reducing our costs fuels our ability to expand our mission into our communities. And you are hearing from each of us that our missions are different but we use that savings to empower growth out into the communities that we serve.

Mr. PALLONE. All right, thanks.

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

Mr. REULAND. Well, there are plenty of very direct assistance programs, including a Pharmacy Assistance Program, for example. Patients who show up and if you walk to one of our clinics and they say I cannot pay for my medications or a copayment for them, we have the discretion through a Pharmacy Assistance Program on the spot to make sure that the patient can leave with the medications that they needed. And then we can help them after that to perhaps connect them to some other form of payment going on over time or, sometimes, we continue supporting that right through these dollars.

Mr. PALLONE. That is a good example.

Thank you, Mr. Chairman. Thank you all.

Mr. GRIFFITH. The gentleman yields back.

I now recognize Mr. Walberg of Michigan.

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

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

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

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

Ms. VEER. That is correct.

Mr. WALBERG. Mr. Gifford, for the AIDS Resource Center, it was indicated that the salary for the CEO was \$350,000. Is that correct?

Mr. GIFFORD. That is cash compensation, yes.

Mr. WALBERG. OK, cash compensation. OK.

Let me ask Mr. Paulus, Mission listed at \$1.6 million, approximately.

Dr. PAULUS. I assume that is correct.

Mr. WALBERG. OK. Mr. Reuland, Johns Hopkins lists for that year \$2.6 million.

Mr. REULAND. I also have to assume that is correct.

Mr. WALBERG. OK and then Ms. Banna, it is listed for Northside at \$2.8 million that year.

Ms. BANNA. That is correct.

Mr. WALBERG. OK. Let me plumb a little bit more here. Going back to the net assets for each of your organizations at the end of 2015.

Northside, Ms. Banna, \$1 billion net asset; net income \$157 million.

Ms. BANNA. That is correct.

Mr. WALBERG. Is that correct?

Mr. Reuland, Johns Hopkins listed at \$1.3 billion; net income \$80 million, almost \$81 million.

Mr. REULAND. That is correct, about a 3.6 percent operating margin.

Mr. WALBERG. OK. Mr. Paulus, Mission is listed at \$1.4 billion; net income \$101-102 million.

Dr. PAULUS. Sounds right.

Mr. WALBERG. OK. Mr. Gifford, your AIDS Resource Center \$12.7 million.

Mr. GIFFORD. That sounds correct and it is just a fraction of what our financial advisors are suggesting necessary to assure longevity.

Mr. WALBERG. The net assets of \$12.7 million.

Mr. GIFFORD. Correct.

Mr. WALBERG. Ms. Veer, Carolina Health Centers, \$7.7 million net assets?

Ms. VEER. That sounds correct, yes.

Mr. WALBERG. OK. I just wanted that for the record. Again, there are certainly explanations, and extenuating circumstances, and other things that I am sure you can share with us on those issues but it is good to have those factors in, especially when we are talking about entities listing saving over \$100 million annually through the program.

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

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

Ms. Veer?

Ms. VEER. In our most recent Universal Data System report to HRSA, we reported 231.20 full-time employee equivalent. Of that, 45.40 are pharmacy employees. And since approximately 50 per-

cent of our business in the pharmacy is 340B, I would estimate that our pharmacy staff devoted to 340B is approximately 25.

Mr. WALBERG. Twenty-five, OK.

Mr. Gifford?

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

Mr. WALBERG. Mr. Paulus?

Dr. PAULUS. We have two dedicated full-time people who do nothing but 340B and 76 others that have 340B as part of their job description, including five people who have gone through a complete 340B university training.

Mr. WALBERG. Total employees how many?

Dr. PAULUS. Twelve thousand.

Mr. WALBERG. Twelve thousand total employees.

Mr. Reuland?

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

Mr. WALBERG. OK and Ms. Banna?

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

Mr. WALBERG. Thank you. I yield back.

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

Ms. CASTOR. Thank you, Mr. Chairman. Based upon what I have seen from my hospitals, and providers back home, and the testimony today, I think it is clear that the 340B Program is critical to America's healthcare safety net. And according to HRSA, 340B savings represent less than 2 percent of total drug spending in this country but the benefits here under 340B are so broad where you are able to expand health services, you are able to see more patients, offset losses from uncompensated care.

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

They run the Children's Hospital there, a complex clinic for the medically fragile. And what they are able to do with wraparound services, as has been mentioned, is remarkable. They have had to expand substantially behavioral health and substance abuse services and that is where part of the savings go. And we are all grappling with that.

And they have a care clinic that stretches the federal Ryan White funding to support a continuum of care to maintain a higher

retention rate for HIV patients achieving viral suppression, which is vital for the future.

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

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

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

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

And so to give you our experience, our drug spend grows between 8 to 10 percent a year over the past 5 years, oncologics, new therapies, immunotherapies, and in some cases just explained drug inflation that we can't explain. We had seven very common drugs, the price of which went up 312 percent with volume going up 12 percent. And one of those drugs is commonly found on a crash cart, a cart that we use to resuscitate patients. So the drug spend growth is what leads the savings growth for us and that is a big part of it.

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

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

Ms. CASTOR. DSH hospital for someone that is tuning in—

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

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

Mr. REULAND. Yes.

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

Ms. BANNA. I believe it was 9 percent most recently.

Ms. CASTOR. Most recently 9 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. This goes back to what Dr. Paulus said, the tsunami of need. Should we be looking at purely charity care provided to uninsured individuals or the total uncompensated care borne by hospitals, including bad debt and losses on Medicaid? In Florida we are looking at a governor that wants to slash the reimbursement rate yet again. That is going to make it even more difficult to provide the care that our neighbors need.

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

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

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

Ms. BANNA. We didn't include bad debt and we didn't include other elements of uncompensated care, which includes the care that is not covered that is provided to Medicare and Medicaid beneficiaries. There are entire other populations of care that is provided effectively free to the community.

Ms. CASTOR. Thank you very much.

Mr. GRIFFITH. The gentlelady yields back.

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

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 percent of poverty is based on the 340B discount price plus a deeply discounted dispensing fee.

Mr. COSTELLO. Does your entity provide uninsured or self-pay 340B patients with discounted prices on prescription drugs?

Ms. VEER. Yes.

Mr. COSTELLO. Mr. Gifford.

Mr. GIFFORD. Yes, we do. We operate under a comparable sliding fee scale that FQHCs—

Mr. COSTELLO. Yes to both those questions?

Mr. GIFFORD. Yes.

Mr. COSTELLO. Dr. Paulus?

Dr. PAULUS. Yes, we don't always know who is 340B-eligible at the time of service but we provide, as I said, free care up to 200 percent of the federal poverty guidelines. And we have the Medica-

tion Assistance Program that provides free or discounted drugs to all of those patients.

Mr. COSTELLO. OK, Mr. Reuland.

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

Mr. COSTELLO. Yes to both questions?

Mr. GIFFORD. Yes.

Mr. COSTELLO. Ms. Banna?

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

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

Ms. VEER. Yes, we do.

Mr. COSTELLO. What percentage of your patients receive free medicine from a patient assistance program that is offered by a biopharmaceutical company or other entity? What percentage?

Ms. VEER. I don't have that exact percentage at my fingertips.

Mr. COSTELLO. Do you have that, though, the answer to that, in terms of the percentage?

Ms. VEER. I could obtain that but I don't have it in my documents.

Mr. COSTELLO. Mr. Gifford?

Mr. GIFFORD. Yes, we use financial pharmacy assistance programs and I could obtain the percentage of patients that utilize them for you also.

Mr. COSTELLO. Dr. Paulus?

Dr. PAULUS. We do, from time to time, use that. I do not know what the percentage is. I could try to find out.

Mr. COSTELLO. Mr. Reuland?

Mr. REULAND. Yes, we do use those programs. I don't have 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 dollars 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. OK. 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 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. OK? I look at all of you. You are in it for the right reasons. You want to do good. You are helping people. Totally onboard.

I think the concern, as I read through the materials is that with the 340B funding does not necessarily come the type of accounting accountability that enables us to audit, to ensure that the money is being spent in those programs and in the ways with which it was intended. And so when we read that while we weren't able to unearth through an audit whether compliance was in fact successful or not as a consequence of us not being able to audit, it causes a great deal of frustration and we want to fix that.

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

Mr. GIFFORD. Yes, we have.

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

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

Do you have concerns? Ms. Veer.

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

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

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

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

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

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

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

Ms. CLARKE. Yes, I am.

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

Ms. CLARKE. Thank you very much, Mr. Chairman and I thank our Ranking Member DeGette. I thank our expert panelists for their testimony here today.

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

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

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

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

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

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

On the medical side of our health center, we serve approximately 22 percent of uninsured patients of our 26,000. So for that 22 percent of our patients, I am not sure that they would have access to affordable medication. Affordable medication 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 just grossly inefficient and incompetent, you can't remove that kind of benefit. And again, in our case, the entire benefit for 340B is less than just our charity care.

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

up 20 percent in 2017 over 2016 because those people have no capacity to pay those deductibles.

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

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

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

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

Mr. GRIFFITH. Thank you for yielding back.

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

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

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

As the chairman said earlier, the chairman of the full committee, the reason we are here is because one of the initiatives of this committee, hence, Oversight and Investigations, is to look into programs and see how we can improve those programs.

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

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

Have you got it now?

[Video shown.]

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

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

I want to ask some very quick questions here. Ms. Vanna, I am very familiar with Northside Hospital and I have worked with you in the State Legislature. You enjoy a great reputation in the State of Georgia. I am sure it is hard-earned. I am sure it is well-deserved.

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

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

Mr. CARTER. That is not what I asked and you are under oath. OK, Ms. Banna? Have you increased the number of oncology clinics that you have bought since the 340B Program has come into effect?

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

Mr. CARTER. Does the 340B Program have anything to do with that or are you acquiring the oncology clinics because you have a chance to make more money through the 340B Program, hence, what we have done in Congress is leading to a consolidation in health care inadvertently on our part?

Ms. BANNA. No, and forgive me, that goes back to my prior answer. We are being encouraged to expand our clinically-integrated model past the hospital—

Mr. CARTER. Ms. Banna, can you get me in writing how many oncology clinics Northside Hospital has acquired since 1992? Will you do that for me? I would appreciate that very much.

I want to go now to Mr. Reuland and Johns Hopkins and I want to ask you how many 340B drugs were distributed to Part B beneficiaries last year. Do you know that?

Mr. REULAND. I don't know that.

Mr. CARTER. Can you get me that in writing?

Mr. REULAND. I think so. So what is the question?

Mr. CARTER. The question is how many 340B drugs were distributed to Part B recipients last year through Johns Hopkins?

Mr. REULAND. It might be good to work offline to make sure we know what you mean by how many drugs.

Mr. CARTER. How many drugs, obviously 340B drugs that you got through that.

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

Mr. CARTER. OK, 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 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 pa-

tients are actually more stringent than they are for anywhere else. You seem to be a strong advocate of the program and very supportive of the program.

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

Mr. GIFFORD. I would hope that the community would look at expanding the use of the dollars that we save through 340B and I included that in the written testimony. The current constriction on Ryan White programs are actually inhibiting our ability to—

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

Mr. GIFFORD. If we could loosen this up for Ryan White—

Mr. CARTER. But my question to you was since you have got more stringent requirements, you still benefited from the program. You spoke very highly of the program.

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

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

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

Thank you very much, Mr. Chairman.

Mr. GRIFFITH. The gentleman yields back.

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

Mr. TONKO. Thank you, Mr. Chair.

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

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

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

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

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

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

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

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

Mr. TONKO. OK. So Ms. Banna, can you explain why Northside acquired these sites?

Ms. BANNA. Absolutely. We were approached by a large oncology practice that was seeking integration with the hospital system, as were several other hospital systems in the Atlanta area. We worked with them throughout 2011 and 2012 to determine the model that would provide the right kind of clinically-integrated care that both parties were looking for and completed that transaction in 2012.

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

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

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

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

Ms. BANNA. Absolutely.

Mr. TONKO. And one last question, Ms. Banna. Does Northside place oncology patients into any type of queue through which commercially-insured patients are treated before Medicaid and Medicare patients?

Ms. BANNA. No.

Mr. TONKO. Thank you.

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

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

budget. And by definition, some of the outreach and charity that we do today would have to be curtailed.

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

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

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

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

Ms. VEER. Well, I have spoken to two or three specific programs that are funded by the 340B savings. Our delivery of prescriptions into very rural outlying areas that would be very difficult to sustain. We also provide behavioral health counseling in our sites for people who would experience long delays in accessing the local mental health agency. Both of those areas would be significantly impacted.

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

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

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

Mr. GRIFFITH. The gentleman yields back.

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

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

All of us stipulate the great benefits the 340B—the pharmaceutical companies stipulate that. It has been around a long time. I think what we are starting to look into, though, and I won't use the word abuse because if something is legal, it is not an abuse, but I will use the word loophole. We have seen a huge increase in the number of oncology practices which deliver the most expensive drugs to America being bought up by hospitals, whether it is Johns Hopkins or others. Right in my area, the largest oncology practice was recently purchased by a DSH hospital and, I would say, for only one reason and that is the 340B profit.

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

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

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

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

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

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

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

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

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

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

Mr. Reuland?

Mr. REULAND. Well, what I was going to say is a couple of comments. The State of Maryland is a little bit different in that regard. And the State of Maryland's hospital rates are regulated by the entity called the Health Services Cost Review Commission. And the charges are actually governed to a level that is very close to the cost and so there is no opportunity that you are describing there.

I would also point out that as a comprehensive cancer center, our growth has not been because of the purchase of any practices. Johns Hopkins Hospital has purchased no oncology practices. We grow because there is sort of a limitless demand based on demographics for the treatments that we offer. And so our growth in oncology is a growth in our drug spend that outpaces our revenue growth. And that is why our operating margin has actually been declining in the past couple of years down to—

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

Mr. GRIFFITH. The gentleman yields back.

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

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

I know 340B is essential to people in my district with skyrocketing drug prices or, as the President would say, price gouging prices. 340B is literally a lifesaver and not one of us opposes transparency. I am certainly not for waste, or fraud, or abuse. I am for transparency. But it does raise questions when it is the pharmaceutical companies that are the loudest complainers about the 340B Program.

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

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

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

In my district, Advocate Health has used its 340B savings to provide support for low-income patients through child vaccination programs and the Medication Assistance Program that helps people who are uninsured and underinsured, as some of you do as well.

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

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

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

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

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

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

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

Yes, Dr. Reuland.

Mr. REULAND. Thank you for the question. I mentioned earlier that we have seen seven very common medications. We noticed that our spend on them increased 312 percent with a volume growth of 12 percent. So it was clearly a price increase that we could not explain and these were not medications that were easily substitutable with something else.

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

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

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

Ms. SCHAKOWSKY. Thank you and I yield back.

Mr. GRIFFITH. Thank for yielding back.

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

Mrs. BROOKS. Thank you, Mr. Chairman.

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

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

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

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

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

Ms. BANNA. It was April 2014.

Mrs. BROOKS. And about how long does that process take?

Ms. BANNA. To register them?

Mrs. BROOKS. Yes.

Ms. BANNA. You must demonstrate that you are operating them as a hospital outpatient department. So if you own a location and it appears on your hospital cost report as a hospital department, then you request. You bring it in as a child site and about a quarter later, you can begin operating it as a 340B.

Mrs. BROOKS. And are patients that are treated at these oncology centers charged a facility fee?

Ms. BANNA. If it is a hospital location, they are billed in accordance with hospital standards.

Mrs. BROOKS. And those are billed as hospital sites, then?

Ms. BANNA. Correct.

Mrs. BROOKS. So they would be charged a facility fee.

Ms. BANNA. Correct.

Mrs. BROOKS. And how much is that fee?

Ms. BANNA. I can't quote that.

Mrs. BROOKS. Can you get that for us?

Ms. BANNA. I can, sure.

Mrs. BROOKS. And what other fees are patients charged that maybe those patients didn't pay prior to them becoming hospital sites? Are there other fees that patients are charged once they become hospital sites that they weren't charged previously, oncology patients, for example?

Ms. BANNA. I think you know I can't speak to charges that are not hospital-based. They are charged commensurate with any hospital service area.

Mrs. BROOKS. So are you aware as to what a patient's bill might have looked like prior to them being acquired by the hospital versus what they are after the acquisition, a comparison of the costs?

Ms. BANNA. I understand what hospital charges are, yes. I think it is important, though, to state that charges are not directly related really to what people pay. People pay based on what kind of insurance coverage they have or don't have.

Mrs. BROOKS. And so on the hospital fees and whether there are any other fees, are they all included in the one bill or might there be an additional separate bill to the patient?

Ms. BANNA. Patients may receive bills for non-hospital services.

Mrs. BROOKS. I want to ask each of the panelists what is the DSH percentage of your entities and is that for the parent entity or the DSH percentage compared to the child sites?

And I will just start with you, Ms. Banna. What is your DSH percentage for your parent entity and how does that compare to your child sites?

Ms. BANNA. The DSH percentage is a representation of inpatient days, as was mentioned a moment ago. So the child sites don't have that percentage but our parent has a 16 percent ratio.

Mrs. BROOKS. And how about you, Mr. Reuland?

Mr. REULAND. Johns Hopkins Hospital is 18.97 percent.

Mrs. BROOKS. OK, Dr. Paulus.

Dr. PAULUS. We are between 15 and 16 percent across all sites.

Mrs. BROOKS. Mr. Gifford.

Mr. GIFFORD. That is a requirement that we are not required to adhere to.

Mrs. BROOKS. OK.

Mr. GIFFORD. That is not a part of the Ryan White—

Mrs. BROOKS. OK, thank you.

Ms. Veer.

Ms. VEER. Similar to Mr. Gifford, our eligibility is based on our approved scope of project under HRSA.

Mrs. BROOKS. And so for those of you that maintain the percentages, has that percentage fluctuated over the years? And if so, what kind of fluctuation have you seen?

Dr. Paulus.

Dr. PAULUS. I couldn't quote that off the top of my head. It has been relatively consistent.

If I might add two comments about the oncology practices, our integration in our market has largely been driven by two things. One is physicians who, because of the same demographic challenges that we face, find it hard to exist in that marketplace. And by becoming part of a system and being able to be paid a salary, as an example, are able to do that.

You raised fair points, but one of the additional benefits is all of those patients in that new setting are eligible for all of our charity policies, which did not exist in those practices previously.

The other point is you know we are being pressured by everyone, including the Federal Government and others, to form integrated systems to coordinate care across that network.

Mrs. BROOKS. Right, of course.

Mr. Reuland?

Mr. REULAND. I don't know the history of our roughly 19 percent number. We could, I am sure, provide that.

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

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

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

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

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

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

We are talking about communities that exist with one doctor per 9,000 residents, like in certain areas in my district. We are talking about catchment areas, where even though you may be in a big ter-

tiary 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 things that oftentimes get 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 are 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 aren't still struggling. That doesn't mean that there is more residual uncompensated care out there that 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 or oncology clinics, for example, that otherwise would be inaccessible through other healthcare systems into your mission-driven hospital is a good thing. So now your patients have access to oncology care. For example, the poor and struggling working families also get cancer. They also need the medications. They also need care.

And I think it is misleading to insinuate that you decided to purchase a clinic so that you can dive into the 340B Programs to acquire more money to then line the pockets of CEOs and leadership. So let me just ask you point blank. Did you do that? What was the reason for you purchasing some of these oncology clinics, Dr. Paulus?

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

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

Ms. Veer?

Ms. VEER. We don't operate oncology services. However, I will say the next to the last site that we opened was opened at the re-

quest of a local hospital that 75 percent of their emergency visits were ambulatory care-sensitive. I can give the example of one patient who had 11 visits down to none.

Mr. RUIZ. Well, yes. How do you measure the ability to use some of the cost savings to go into the community to provide nutrition classes, exercise classes, prevention, education for diabetics knowing, that by them participating in these programs, they will prevent going blind, they will prevent leg amputations, they will prevent costly renal insufficiency and hemodialysis? So how do we measure the true value of these cost-saving programs that allow you to do more outreach into underserved communities? And that is where the real problem lies. If we are just narrowly focused on uncompensated care, then we are missing the big picture here.

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

Thank you very much.

Mr. GRIFFITH. The gentleman yields back. I appreciate.

I now recognize Mr. Sarbanes of Maryland.

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

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

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

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

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

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

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

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

The other school I will mention is, you are familiar, but others may not be, with the development work to the immediate north of our campus a very troubled area that has been rebuilt. The Henderson-Hopkins School is something we helped establish as a part of that redevelopment initiative. And it has been an extraordinary success so far. If you were to see that area back in 1989, when you referred to, and look at it today, it is a startlingly better story.

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

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

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

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

I yield back.

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

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

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

As part of our work, it is important to understand how all federal programs intersect and what their interest is with the crisis that has left virtually no American family or community untouched. That being said, can each of you identify what percentage of the 340B prescription opioids represents as a percentage of your program and can you detail for us what steps might be in place to prevent diversion or misuse of these drugs, once they are dispensed to the patients?

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

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

Mr. GRIFFITH. OK.

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

Mr. GRIFFITH. I appreciate it.

Mr. Gifford.

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

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

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

Dr. Paulus?

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

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

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

Mr. GRIFFITH. I appreciate that.

Mr. REULAND. I also don't know our precise percentage but we certainly have plenty of programs in place to prevent diversion.

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

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

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

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

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

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

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

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

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

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

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

Mr. GRIFFITH. My additional 5 minutes is up.

Ms. DeGette, I am happy to yield to you. Did you have any additional questions?

Ms. DEGETTE. No.

Mr. GRIFFITH. All right. Oh, OK. Apparently Dr. Burgess is attempting to come down. Do we know how close he is? You don't. OK.

Well my follow-up material is here that I have to do.

I do appreciate all of you all being here today. If Dr. Burgess walks in, I will yield some time to him but I do appreciate you all being here today. I know it takes a lot of time both to get here, get back, and to spend your time answering questions of a lot of different folks with slightly different opinions.

OK, in conclusion, having thanked you all, I do remind the members that they have 10 business days to submit questions for the record and then I would ask all the witnesses to agree to respond promptly to the questions that members ask.

That being said, this committee is adjourned.

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

[Material submitted for inclusion in the record follows:]



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

October 9, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Examining How Covered Entities Utilize the 340B Drug Pricing Program”

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, October 11, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building, entitled “Examining How Covered Entities Utilize the 340B Drug Pricing Program.”

I. WITNESSES

- Sue Veer, MBA, CMPE, President and Chief Executive Officer, Carolina Health Centers;
- Michael J. 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, MHS, Sc.D., Executive Vice President and Chief Operating Officer, Johns Hopkins Hospital; and
- Shannon A. Banna, Director of Finance and System Controller, Northside Hospital, Inc.

II. BACKGROUND

a. Overview of the 340B Drug Pricing Program

Established by Congress in 1992, the 340B Drug Pricing Program mandates that drug manufacturers provide outpatient drugs to eligible health care organizations (also known as “covered entities”) at reduced prices to remain eligible for reimbursements through entitlement programs such as Medicaid and Medicare. Covered entities are eligible to receive discounts on outpatient prescription drugs from participating manufacturers and report saving between 25 and 50 percent of the average wholesale price for covered outpatient drugs.¹ The Health Resources

¹ 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs*, available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.

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and Services Administration (HRSA) estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year (FY) 2013,² and \$4.5 billion in FY 2014.³ As of October 2016, 12,148 covered entities are actively participating in the program⁴ and roughly 722 pharmaceutical manufacturers are actively participating in the program.⁵

Covered entities do not receive discounts on *inpatient* drugs under the 340B program. Covered entities can realize substantial savings on *outpatient* drugs through 340B price discounts and generate 340B revenue by selling 340B drugs at a higher price than the discounted price at which the covered entity obtained the drug. Moreover, while covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient,⁶ these entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, regardless of whether they are low income, uninsured, or underinsured.

The 340B price for a drug paid by covered entities—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities.⁷ Manufacturers are permitted to audit covered entity records if they suspect product diversion or multiple discounts are taking place. Occasionally, the formula results in a negative price for a 340B drug. In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

In March 2010, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies, referred to as

² *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (March 24, 2015) (statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration).

³ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2017*, available at <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

⁴ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

⁵ There are 1204 manufacturers are listed by HRSA, 706 of which are deemed "active." Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, at 245-46, available at <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf>.

⁶ To be considered a patient of a covered entity, the individual must maintain his or her records with the covered entity, and receive health care services from providers employed by the covered entity. For current definition of a patient, see HRSA's website. Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Eligibility & Registration*, available at <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

⁷ Manufacturers may sell a drug at a price that is lower than the ceiling price, so covered entities may negotiate prices below the ceiling price. The discount is determined by dividing the average total Medicaid rebate percentage of 15.1 percent for single source and innovator multiple source drugs, and 11 percent for non-innovator multiple source drugs by the average manufacturer price (AMP) for each dose and strength. The Medicaid statute defines AMP as the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers are required to report AMP and their best price to the Secretary, but subject to verification, manufacturers calculate the maximum price ("ceiling price") they may charge 340B entities.

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contract pharmacies. Prior to 2010, covered entities were only allowed to contract with one pharmacy – either an in-house pharmacy, or an individual contract pharmacy.⁸ The growth and oversight of contract pharmacies since 2010 has been identified as an issue of concern by the Office of Inspector General of the U.S. Department of Health and Human Services (HHS OIG), and the U.S. Government Accountability Office (GAO) is currently examining this issue.

Many 340B program covered entity parent organizations have multiple associated “child sites.” Child sites can include satellite clinics or facilities, hospital departments, outpatient treatment units, and other facilities. Child sites are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on a hospital’s most recently filed Medicare cost report. As of October 2, 2017, 42,025 covered entity sites were participating in the 340B Program, including 18,737 disproportionate share hospital (DSH) sites.⁹

b. Types of Covered Entities

HRSA is tasked with accepting applications for participation in the 340B Program, determining program eligibility, and overseeing covered entities. Covered entities must recertify their eligibility for the 340B program annually. Eligibility is statutorily defined and is limited to certain qualifying hospitals and federal grantees.¹⁰ Congress has expanded program eligibility over time, most recently through the Patient Protection and Affordable Care Act (PPACA).¹¹

Federal grantees include various types of health centers, HIV/AIDS program grantees, and specialized clinics, including Federally Qualified Health Centers (FQHC), Federally Qualified Health Center Look-Alikes, Native Hawaiian Health Centers, Tribal/Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, and Title X Family Planning Clinics.¹² These entities typically are subjected to additional requirements and federal oversight because of their status as federal grantees. For example, HRSA (which oversees the Ryan White HIV/AIDS Program) has established that any revenue a Ryan White grantee generates through participation in the 340B program is Ryan White program income and therefore subject to HRSA restrictions on how Ryan White program income can be spent.¹³

⁸ 75 Fed. Reg. 10272, 10274–10278 (March 5, 2010).

⁹ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://340bopais.hrsa.gov/coveredentitysearch>.

¹⁰ 42 U.S.C. § 256b.

¹¹ PPACA added the following to the list of covered entities entitled to discounted drug prices under the 340B program: (1) certain children’s and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals. These 340B-eligible facilities also must meet other specified 340B participation requirements.

¹² Health Resources and Services Administration, Eligibility & Registration (last visited Sept. 18, 2017), available at <https://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

¹³ Health Resources and Services Administration, 15-03 Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income, Policy Clarification Notice (PCN) #15-03, Relates to Policy #15-04 (last visited Sept. 19, 2017), https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf.

Hospitals that are eligible to participate in the 340B Drug Pricing Program include certain disproportionate share hospitals, children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Eligible hospitals must meet certain additional requirements to participate in the program. First, an eligible hospital typically must have a minimum disproportionate share adjustment percentage to qualify for program participation (which is based on the share of a hospital's inpatients who are Medicaid and low-income Medicare patients). Furthermore, each eligible hospital must be (1) owned and operated by a state or local government, (2) a public or private nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare. Additionally, as shown in Figure 1 below, certain eligible hospitals must certify that they will not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement.

Figure 1: Hospital Eligibility¹⁴

Hospital Type	Nonprofit/Government Contract Requirement	DSH %	Subject to GPO Prohibition
Disproportionate Share Hospital	Yes	> 11.75%	Yes
Children's Hospital	Yes	> 11.75%	Yes
Free-Standing Cancer Hospital	Yes	> 11.75%	Yes
Critical Access Hospital	Yes	N/A	No
Rural Referral Center	Yes	≥ 8%	No
Sole Community Hospital	Yes	≥ 8%	No

Hospitals' participation in the 340B program has grown markedly in recent years – faster than that of federal grantees, increasing almost three-fold in the number of participants from 2005 to 2011.¹⁵ According to a 2011 report by the GAO, one third of hospitals participated in the program, and DSH hospitals alone represented about 75 percent of all 340B drug purchases.¹⁶ Currently, approximately 40 percent of all U.S. hospitals participate in the 340B program. According to HRSA's database on covered entities, as of July 5, 2017, DSH hospitals accounted for 44 percent of covered entities sites.¹⁷

¹⁴ Apexus, 340B University, *340B Hospital Eligibility Criteria* (2015), available at https://docs.340bpvp.com/documents/public/resourcecenter/Hospital_Eligibility_Criteria.pdf.

¹⁵ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).

¹⁶ *Id.*

¹⁷ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

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c. HRSA's Oversight of the 340B Drug Pricing Program

**i. Unclear Program Requirements and Lack of Transparency Hamper
HRSA's Oversight Capabilities**

According to a committee report from the time the authorizing legislation was adopted, the purpose of the 340B program is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹⁸ Neither the 340B statute nor HRSA guidance, however, explain how 340B entities must use savings from the program. Notably, there is no requirement that the discounted 340B price be passed on to uninsured patients who seek treatment at 340B entities. As a result, the 340B entity will acquire the drug at a discounted price, but the uninsured patient may pay the full list price for the drug. While some 340B entities pass savings on to uninsured patients, it has been reported that some use savings from the 340B program to pay for the operations of the covered entity, such as marketing.

In 2011, GAO issued a report on the savings generated by covered entities through the program.¹⁹ While covered entities reported that 340B savings were used to expand access and services, GAO told committee staff that all but one entity audited was unable to tell GAO the exact number of funds generated from the 340B program and how 340B funds were used. As discussed during the committee's July 2017 hearing, HRSA does not have the authority to require covered entities to report the amount of funds generated from the 340B program, or how the entity spends those funds.

Further, there is little transparency surrounding the ceiling prices set by manufacturers in accordance with a statutory formula. Consistent with an HHS OIG recommendation, PPACA mandated that HRSA share ceiling prices with covered entities through a secure website. HRSA has since testified that it was unable to do so due to a lack of resources, but would undertake that project in 2015. Covered entities, however, still do not have access to that data. Without that data, covered entities are unable to ensure they are paying an appropriate price for 340B drugs. While HRSA has authority to establish a mechanism to share ceiling prices with 340B entities, HRSA does not have the authority to share ceiling prices with states to enable state Medicaid agencies to ensure that they too are paying appropriate prices.

ii. Program Growth Exceeds HRSA's Oversight Capabilities

For most of its existence, the 340B Drug Pricing Program has not been subject to rigorous oversight. After GAO issued a 2011 report critical of the program's oversight, HRSA

¹⁸ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program*, available at <https://www.hrsa.gov/opa/>.

¹⁹ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

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received additional funding of \$6 million in FY 2014 to increase its oversight efforts.²⁰ HRSA had 24 full-time employees (FTEs) for the 340B program in FY 2016, which it reduced to 22 FTEs for FY 2017 and 2018.²¹

The number of participating unique covered entities has grown from 3,200 in 2011,²² to 11,180 in February 2015, to 12,148 covered entities in October 2016.²³ The number of hospitals has grown significantly, from 591 in 2005, to 1,673 in 2011, to 2,871 as of July 2017. The number of child sites has also grown dramatically. In 2011, GAO reported that the number of child sites had nearly doubled over the previous decade, reaching just over 16,500 registered sites.²⁴ According to HRSA, that number had reached 37,496 in October 2016,²⁵ and 40,745 registered sites by July 2017.²⁶

In addition to an increase in child sites, the number of contract pharmacies has grown greatly since HRSA issued its 2010 guidance on contract pharmacies. In 2011, GAO reported that while HRSA did not track individual contract pharmacies in use, there were more than 7,000 contract pharmacy arrangements through the program.²⁷ In its 2018 Budget Justification, HRSA reported that 27 percent of covered entity sites have contract pharmacy arrangements, resulting in approximately 18,078 unique pharmacy locations.²⁸ The GAO has ongoing work that will examine the growth of contract pharmacy arrangements.

The amount that covered entities save on 340B drugs has also increased. In FY 2013,

²⁰ In FY 2016 and FY 2017 HRSA budget was \$10.543 billion and \$10.401 billion respectively. For FY 2018, HRSA has requested \$9.9 billion. Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²¹ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²² U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²³ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁴ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²⁵ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁶ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

²⁷ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²⁸ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

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HRSA estimated that covered entities saved \$3.8 billion on drug expenditures.²⁹ In FY 2014, that estimate rose to \$4.5 billion in savings.³⁰

Despite the rapid growth of the program, HRSA's auditing has remained at or below 200 annual audits of covered entities since 2012, when HRSA's practice of auditing covered entities began.

iii. HRSA's Oversight Reveals High Levels of Non-Compliance

HRSA's annual audits show a high level of non-compliance by covered entities. The HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements in at least one of three ways: duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting.

Figure 2: Program Requirement Violations:

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Duplicate Discounts	18	24	23	47	42
Drug Diversion	16	51	54	94	78
Incorrect Database	15	46	51	100	57
No Adverse Findings	19	20	18	43	59
Total Audits	*51	*94	*99	*200	*175

*Note: numbers do not sum because several entities had more than one type of violation.

1. Duplicate Discounts

Covered entities are prohibited from receiving duplicate discounts.³¹ A duplicate discount occurs when a covered entity receives a 340B discount on drugs provided to Medicaid patients and the state Medicaid agency also receives a rebate for the drug dispensed to the Medicaid beneficiary through the Medicaid Drug Rebate Program. When an entity enrolls in the 340B Program, it must determine whether it will "carve-in" or "carve-out" for Medicaid prescriptions. Entities that "carve-in" agree to buy Medicaid drugs through the 340B program without seeking a Medicaid rebate, while entities that "carve-out" agree to buy Medicaid drugs through the Medicaid Drug Rebate Program or otherwise. Duplicate discounts occur because there is overlap in eligibility for the Medicaid rebate and 340B programs. While Medicaid rebates benefit state Medicaid programs and 340B programs benefit 340B-covered entities, both of these programs

²⁹ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2016*, available at <https://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

³⁰ *Id.*

³¹ Public Health Service Act, 42 U.S.C. 256b(a)(5)(A)(i).

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target the same safety-net population.³² The significant overlap in prescription eligibility makes discount errors likely, and HRSA's audits found duplicate discounts to be quite common. Further, 340B discounts are often determined retrospectively, which can also increase the rate of discount errors. At least 23 percent of 340B-covered entities audited had duplicate discount errors each year, as shown above in Figure 2.

In 2013, HRSA created the 340B Medicaid Exclusion File (MEF) as a strategy to prevent duplicate discounts for drugs subject to both Medicaid rebates and 340B prices for Fee-For-Service claims.³³ The MEF is a list of Medicaid provider number or national provider numbers (NPN) of each entity that has agreed to purchase all drugs billed to Medicaid through the 340B program. The MEF is intended to prevent duplicate discounts by notifying states and manufacturers which drugs are not eligible for Medicaid rebates. This measure counts on the integrity and continued participation of covered entities to disclose accurate and current information.

HRSA lacks a centralized mechanism similar to the MEF to prevent duplicate discounts for Medicaid Managed Care Organizations (MCOs).³⁴ This is a significant problem because an increasing number of Medicaid programs rely on managed care.³⁵ The HHS OIG released a report in June 2016, finding that duplicate discounts are a severe issue for Medicaid MCOs. The data that most states collect for MCO drugs is not granular enough to detect all individual drug claims. Many states still used the MEF for MCO drugs, despite HRSA's guidance to develop alternate strategies, since the MEF only works for fee-for-service drugs. Duplicate discounts for MCOs participating in the Medicaid Drug Rebate Program is a relatively new problem. Prior to PPACA, only Medicaid Fee-For-Service (FFS) claims were eligible for rebates. Unfortunately, the PPACA did not anticipate the issues involved with reconciling duplicate discounts for MCOs, which notoriously under-report Medicaid data to the states.³⁶

2. Diversion

HRSA prohibits the resale or transfer of 340B drugs to ineligible patients, known as diversion. Only individuals who are patients of 340B-covered entities are eligible for drug pricing discounts.³⁷ To be considered a patient of a covered entity, the individual must maintain

³² Jason Hardaway, *340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts*, 41 PHARMACY AND THERAPEUTICS 1, 38 (2016).

³³ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, 3 (Dec. 2014).

³⁴ 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52309 (Aug. 2015); See Office of Inspector General, U.S. Dep't of Health and Human Services, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016).

³⁵ *Medicaid Managed Care Enrollment and Program Characteristics, 2014*, Centers for Medicare and Medicaid Services, available at <https://www.medicare.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/downloads/2014-medicare-managed-care-enrollment-report.pdf>.

³⁶ See e.g., Office of Inspector General, U.S. Dep't of Health and Human Services, *Not All States Reported Medicaid Managed Care Encounter Data as Required*, OEI-07-13-00120 (July 2015).

³⁷ There is one exception: individuals registered in state-operated or funded AIDS Drug Assistance Program who are automatically eligible for 340B benefits. See 340B Prime Vender Program, *Patient Definition*, available at <https://www.340bpvp.com/resource-center/faqs/patient-definition/>.

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his or her records with the covered entity, and receive health care services from providers employed by the covered entity.³⁸ As shown in Figure 2, a large percentage of HRSA's audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016.

The lack of a clear definition of "patient" sheds light on the high number of covered entities who committed diversion violations. HRSA's definition of "patient" has been criticized widely for its vagueness. The HHS OIG has stated that "[there is] a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements."³⁹ The GAO has also offered criticism, explaining that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B."⁴⁰

To identify which 340B-eligible patients received prescriptions, contract pharmacies⁴¹ often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, HHS OIG found wide variation in these eligibility determinations. Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.⁴²

3. Incorrect Reporting

The administration of the 340B program depends on accurate database information. HRSA audits reveal that many covered entities are not fulfilling their obligations of maintaining current database information. With the exception of FY 2012, at least half of the audited entities kept incorrect records all other years, as shown above in Figure 1. The audits show that many times, records include clinic locations or outpatient facilities that are no longer in service. Another common error is that entities include unauthorized facilities in their database.

HHS OIG investigators have warned that incorrect reporting is one way to hide intentional abuses of government programs. Entities seeking reimbursement from Medicaid and Medicare sometimes practice poor bookkeeping to prevent auditors from noticing trends and practices that may alert the auditor to wrongdoing. As a result, it is imperative for program integrity that the covered entities be required to keep detailed records.

d. Medicare Part B and the 340B Drug Pricing Program

Medicare Part B covers services and supplies considered medically necessary to treat a

³⁸ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207 (Oct. 24, 1996).

³⁹ Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).

⁴⁰ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

⁴¹ Covered entities may contract with pharmacies to dispense drugs purchased through the program on their behalf. Such pharmacies are referred to as contract pharmacies.

⁴² Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).

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disease or condition, including a limited number of outpatient prescription drugs.⁴³ Medicare generally pays 106 percent of the Average Sales Price (ASP) for most Part B drugs, regardless of the amount the hospital paid to purchase the Part B drug from the pharmaceutical manufacturer.⁴⁴ Medicare therefore pays the same amount for Part B drugs to both 340B hospitals and non-340B hospitals even though 340B hospitals can purchase outpatient drugs at reduced prices through the 340B Program.

In November 2015, HHS OIG issued a report finding that Medicare Part B payments to covered entities for 340B-purchased drugs substantially exceeded the covered entities' costs to obtain the drugs.⁴⁵ OIG found that "[i]n the aggregate, Part B payment amounts were 58 percent more than the statutorily based 340B ceiling prices [in 2013], which allowed covered entities to retain approximately \$1.3 billion."⁴⁶ The Agency also noted that Medicare beneficiary cost-sharing obligations are not reduced to reflect the discounted 340B prices (Part B beneficiaries typically are responsible for 20 percent of the Part B payments in coinsurance), and Medicare Part B does not share in any of the 340B program savings realized by hospitals.⁴⁷ Moreover, in 2015, GAO issued a report indicating that the financial incentive for 340B hospitals to prescribe more drugs, or more expensive drugs, to Medicare beneficiaries, might be impacting prescribing behavior. More specifically, GAO found that "per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals."⁴⁸

On July 13, 2017, CMS proposed changing how Medicare Part B pays hospitals for drugs that are acquired under the 340B Drug Discount Program. Rather than continue to reimburse 340B entities for certain Part B drugs purchased through the 340B program at ASP plus 6 percent, CMS proposes reducing reimbursement for certain Part B drugs purchased through the 340B program to ASP minus 22.5 percent.⁴⁹ CMS stated its goal is to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs."⁵⁰ The change in reimbursement for certain 340B drugs is limited to separately payable drugs under the outpatient prospective payment system (OPPS), with other additional exclusions.⁵¹

CMS justified its proposed changes by referring to a May 2015 report to Congress issued by the Medicare Payment Advisory Committee (MedPAC). In the report, MedPAC estimated

⁴³ CMS, *What Part B Covers*, Medicare.gov (last visited Sept. 19, 2017), available at <https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html>.

⁴⁴ 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁴⁵ U.S. Dep't of Health and Human Services, *Office of Inspector General, Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030 (Nov. 2015).

⁴⁶ *Id.* at 8.

⁴⁷ *Id.* at 4.

⁴⁸ U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-1442 (Jun. 5, 2015), available at <http://www.gao.gov/products/GAO-15-442>.

⁴⁹ 82 Fed. Reg. 33558, 33634 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁵⁰ 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁵¹ 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

Majority Memorandum for October 11, 2017, Subcommittee on Oversight and Investigations
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that “hospitals in the 340B program receive a minimum discount of 22.5 percent of the average sales price for drugs paid under the outpatient prospective payment system.”⁵² CMS stated that the agency “believe[s] that the MedPAC Analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the OPPS receive.”⁵³ CMS estimates that with the proposed changes, OPPS payments for separately payable drugs, including beneficiary copayment amounts, may decrease by as much as \$900 million.⁵⁴

e. The Committee’s July 18, 2017 Hearing Examining the 340B Drug Pricing Program

On July 18, 2017, the Committee held a hearing examining HRSA’s oversight of the 340B Drug Pricing Program. Witnesses from HRSA, GAO, and HHS OIG answered questions about the size and scope of the program as well as HRSA’s annual program audits.

At the hearing, HRSA testified that the 340B statute does not require that entities report their savings or how those savings are used. Thus, HRSA has no data on how much each entity saves through program participation and how the savings are used, and lacks authority to require that entities use their savings in a specific way. HRSA could not testify as to the amount of charity care provided by covered entities, whether savings are used to serve insured or uninsured patients, whether covered entities used a sliding fee scale to discount drugs based on a patient’s ability to pay, or whether savings were passed along to any patients in the form of discounted prices.

f. The Committee’s September 8, 2017 Letter

Other than media reports, the Committee has limited information about how most covered entities utilize the 340B drug pricing program and the savings generated from the program. In order to better understand the ways in which different entities utilize the program, the Committee sent a letter on September 8, 2017, to a diverse group of covered entities requesting information about purchases made through the program, how the entities track and use program savings, and how patients benefit from the entities’ participation in the program.

III. ISSUES

The following issues may be examined at the hearing:

- How do covered entities track savings from the 340B drug pricing program?
- How do covered entities utilize savings from the 340B drug pricing program?

⁵² Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015), <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>.

⁵³ 82 Fed. Reg. 33558, 33634 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁵⁴ 82 Fed. Reg. 33558, 33711 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

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- What requirements must different types of covered entities meet in order to receive reduced prices through the 340B drug pricing program?
- How do covered entities utilize contract pharmacy arrangements?
- How do covered entities utilize child sites?
- How do covered entities interact with HRSA?

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Brighton Haslett, Brittany Havens, or Natalie Turner at (202) 225-2927.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3927
Minority (202) 225-3841

November 7, 2017

Dr. Ronald A. Paulus
President and Chief Executive Officer
Mission Health
12 Ardmore Street
Asheville, NC 28803

Dear Dr. Paulus:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, October 11, 2017, to testify at the hearing entitled "Examining How Covered Entities Utilize the 340B Drug Pricing Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 21, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations
Attachment

Ronald A. Paulus, MD
President and CEO



November 21, 2017

The Honorable Greg Walden, Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

RE: Additional Questions for the Record

Dear Chairman Walden:

Thank you for the opportunity to provide additional information regarding Mission Health's participation in the 340B Drug Pricing Program. Our responses to The Honorable Morgan Griffith's questions that were provided in your November 7, 2017 letter are attached.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald A. Paulus".

Ronald A. Paulus, M.D.
President and Chief Executive Officer
Mission Health System, Inc.

cc: The Honorable Diane DeGette, Ranking Member, Subcommittee on Oversight and Investigation



Additional Questions for the Record

The Honorable Morgan Griffith

1. Can you provide your opinion as to why the Disproportionate Share Hospital (DSH) metric, which measures Medicare and Medicaid inpatient stays, is or is not appropriate for use in an outpatient drug program targeting underinsured and uninsured patients?

Even though the metric measures inpatient care, the Disproportionate Share Hospital (DSH) metric is appropriate for use in the 340B program, especially with respect to urban DSH and safety net hospitals.

The DSH metric identifies hospitals that provide inpatient services to a larger number of Medicaid and low-income Medicare/SSI patients than other hospitals (as opposed, for example, to hospitals that more routinely provide stabilizing treatment and then transfer or refer those patients to other medical centers for acute care). In other words, the DSH metric percentage identifies hospitals that provide a disproportionate share of inpatient care that is reimbursed below the actual cost of providing that care and correspondingly, identifies those hospitals that consistently serve a larger number of the most vulnerable patients in the community.

These vulnerable patients are often in need of complex care, require more resources, and are almost universally unable to afford the care that they need. The DSH metric, will imperfect, provides direct insight into the culture of the hospital and its commitment to caring for vulnerable, uninsured, and underinsured patients; that culture and philosophy of caring is unlikely to differ between inpatient and outpatient services. Importantly, those unique outpatient settings that are similarly dedicated to providing care to the most vulnerable (e.g., Rural Health Centers) separately qualify for the program.

There is no perfect metric, and perfect is often the enemy of the good. The DSH metric effectively identifies those hospitals providing higher amounts of care to inherently vulnerable populations, as is consistent with the goals of the 340B Program. The data used to support the calculation is readily available to the Health Resources and Services Administration (HRSA) and results in a reliable and clear metric for determining access to the 340B Program.

2. During the hearing, it was clear that covered entities use different definitions for "charity care" and report different data on Medicare forms. Can you provide (1) the data your hospital uses to track charity care, (2) the amount of charity care provided, based on this data, and (3) whether you think this type of charity care metric should be applied uniformly across the program?

Mission has adopted and follows financial assistance policies that are aimed at providing relief from medical expenses to patients and families without adequate resources to pay. The policies apply to services provided in every Mission Health location. Mission provides free care



for those up to 200% of the Federal poverty guidelines and a sliding-scale discount for those between 200-300% of the Federal poverty guidelines. Patients applying for and meeting criteria as identified in our policies are tracked in our patient accounting/billing system, along with all other patients. **Those patient charges are ultimately converted to “cost” for the purposes of IRS Form 990, Schedule H reporting. Also, account balances of patients who fail to provide proof of income and are unable to pay their expenses are classified as “bad debt,” not “charity care,” even though they may have met federal poverty guidelines.**

As a tax-exempt, non-profit organization, Mission tracks its charity care and then reports the information on IRS Form 990, Schedule H each year. It may be reasonable for all 340B eligible hospitals to report charity care using the same methodology (cost vs. charges for example). Since the IRS Form 990, Schedule H definition of “charity care” reported on the basis of cost is a standard already used by tax-exempt hospitals, using this vehicle (or at least its underlying metrics and calculations) would have the added benefit of reducing the burden of creating new or additional reporting tools and definitions.

3. Would you support a new 340B program requirement that mandates a certain level of charity care?

No, we would not. While charity care is obviously an important part of the discussion, data regarding bad debt, Medicaid/Medicare under reimbursement, and community benefit tell the important and much larger story of how hospitals use 340B savings to meet the intent of the 340B Program—to stretch scarce federal resources as far as possible and provide more comprehensive services. Hospitals like Mission are critical public health resources for the communities they serve, and, as such, complete a publicly available Community Health Needs Assessment and Plan every three years to address the health needs of the community. Steps taken, including financial commitments to support elements of the plan, are reported on IRS Form 990 each year.

For example, Mission provided \$1 million toward the establishment of a walk-in, urgent care clinic for those with behavioral health needs, including a 24-hour urgent care unit, a mobile crisis management team, a community pharmacy, and outpatient services. Mission Health's contribution was matched by a grant from the North Carolina Department of Health and Human Service totaling almost \$1 million more. This center was established in collaboration with local officials, law enforcement, local behavioral health and safety net providers, a behavioral health managed care organization, and the local chapter of NAMI (National Alliance on Mental Illness). This center is vital in addressing the behavioral health and opioid crisis in our region. This contribution is not reflected as “charity care,” but it is an example of how we serve our region through targeted community benefit programming. Likewise, our Medication Assistance Program is invaluable to patients but is not included in our projected \$42 million in charity care at cost for FY 2017.



Another example of care that would not be captured in reporting “charity care” is our ownership in an organization operating a local, free medical clinic and free pharmacy to qualifying patients. Mission’s financial support of the clinic exceeded \$2 million from 2012-2016 and in-kind medical services (including labs, radiology, and medication expenses) exceeded over \$2.7 million during the same time period. This work is reported on the community benefit line of IRS Form 990 Schedule H, but is not included on the “charity care” line of Schedule H.

These are only three of many examples where vital services to our community are not captured in the “charity care” definition on IRS Form 990, Schedule H. By creating 340B access solely based on a “charity care” analysis, hospitals that are doing critical work for their communities may not qualify even though they clearly provide important services and programs of the type intended to be supported by the 340B program.

4. Does your hospital have a policy to treat anyone regardless of ability to pay?

Yes, we do. Mission Health treats any patient without regard to the ability to pay, period.

5. During the hearing, you suggested that Congress examine the Schedule H/Community Benefit on IRS Form 990, stating that the information reported on that form may provide “opportunities to define and identify” appropriate reporting requirements. Can you provide more detail about how this IRS form may be used for mandatory reporting in the 340B program?

Schedule H of IRS Form 990 is designed to quantify, in a standardized manner, the community benefit provided by hospitals to support tax-exempt status. We encourage the Committee to build on Schedule H as a component of, or as the standardized reporting tool for, 340B hospitals. Seventy-five percent of 340B savings is realized by hospitals. Including transparent reporting of total 340B savings and comparing those savings in a fair and transparent manner to community benefit contributions by hospitals offers a specific, relatively easy way to track whether hospitals are using the savings in ways that support the intent of the 340B Program—while allowing hospitals to do so in ways that best serve the individual needs of their patients and communities. In addition, because it already exists for a similar purpose, it streamlines the regulatory process and builds upon prior work.

a. Would total unreimbursed care be an appropriate measure of charity care or a separate 340B eligibility metric?

As noted above, we do not agree that that charity care, combined with unreimbursed Medicaid/Medicare costs and bad debt alone, adequately captures and tells the overall story for defining a hospital’s community benefit. It is necessary, but not sufficient.



We do support the use of IRS Form 990, Schedule H, a modification to that Schedule, or a tool based on that Schedule for 340B eligible hospitals to capture, in a standardized manner, the total community benefit of the organization. Once consistent data is captured, that same data could be analyzed by this Committee in the future to help articulate sound 340B policy.

6. Would you support new mandatory reporting /tracking requirements for 340B hospitals to achieve more consistency with respect to program savings?

We support the use of a modified IRS Form 990, Schedule H for hospitals to report 340B savings and contract pharmacy value. 340B savings for hospital-based locations can be obtained through wholesaler reporting data (defined as the difference between the 340B price and GPO price), and the value contribution of contract pharmacies (defined as revenue less dispensing fees less cost of goods sold less 340B vendor fees) is available through the hospital 340B vendor.

7. In your written testimony, you noted that you had a compliance issue with patient eligibility because the patient definition has "been elusive and fraught with lack of regulatory clarity." How would you propose to strengthen the patient definition?

The issuance of clear, statutory language supported by a formal and consistent regulatory and/or rule-making process regarding the "patient" definition would strengthen the 340B Program and help 340B hospitals meet program requirements in a consistent manner. There have been no significant modifications to the 340B statutes over the past 25 years. During this time, HRSA has, due to the state of the applicable statutes, at times dictated or ushered compliance through the issuance of "frequently asked questions" posed on the 340B website and/or through audit findings (instead of issuing regulations and/or through rulemaking), leading to varying interpretations of permissible/impermissible use across the 340B program. This process has made it more difficult to optimally achieve compliance in an already complex program.

By way of example, 340B providers have asked the question as to whether, in owned or contracted community pharmacies, a Medicaid Managed Care patient is eligible for 340B-priced medications. In multiple forums, the verbal answer from HRSA has been that only fee-for-service Medicaid duplicate discounts are prohibited, and a Medicaid Managed Care patient is, therefore, 340B eligible. The Apexus website "frequently asked questions" does not include an answer to the question. The "eligible patient definition" in this situation is not clear, and, accordingly, hospitals must make a decision that could ultimately result in audit findings. Situations like this example are what Mission references as a lack of regulatory clarity, and it is a clear opportunity for improvement.

The "patient" definition concept was meant to ensure that prescriptions qualifying for 340B discounts are adequately tied to services provided by or in relation to a qualifying or eligible



340B hospital and its providers across the continuum, to support those hospitals in their efforts to serve vulnerable populations. This intent should be preserved. This committee might also consider updates to the language to better reflect how hospitals today provide care to patients across a connected continuum of care, geared toward managing the health of a population in addition to individual patients.

a. Would limiting patient eligibility to uninsured patients or patients of a certain income level be an appropriate program change?

We do not think that limiting patient eligibility would be an appropriate program change. The value of the 340B program to Mission Health in FY 2017 was approximately \$40 million. Our FY 2017 operating margin, inclusive of 340B savings, was \$56 million. Self-pay patients are approximately 8% of our patient population. Therefore, limiting 340B use to uninsured patients would drop 340B savings from \$40 million to roughly \$3.2 million per year. Meanwhile, our charity care (at cost) plus bad debt would remain at \$80 million per year, with community benefit for FY 2016 totaling over \$183 million. This policy would clearly punish the very safety net hospitals that are charged with and are serving on the front lines to provide care to those who are not able to afford or access care, to fight the opioid battle, and to help solve the behavioral health crisis—without regard to the overall community benefits they drive and provide to their communities.

Increasingly, “bare bones” insurance policies are being offered to make insurance premiums “more affordable.” The hope is that family members will never have a serious and costly disease. However, when they do, insurance coverage with high deductibles and co-payments pushes important medical care and medications out of reach for many – or even most - middle class families. Proposed changes in the Affordable Care Act will likely exacerbate the problem as coverage mandates are reduced or eliminated to achieve “premium affordability.” These increasingly common situations provide the illusion of an “insured patient” while the patient is effectively uninsured for the bulk of his/her care.

In addition, the cost of important new drugs is defined largely by what the market will bear for the innovation delivered. A vital \$100,000 drug would likely be completely inaccessible to a patient in a household with even an \$85,000 in annual income; 20% coinsurance for this same “insured patient” would likely be out of reach. Even so, the patient’s insurance status and/or income level could preclude participation in the 340B program if we adopted program eligibility based on insurance and/or income level.

Health systems like Mission with 340B drug access play a vital role in this equation, as evidenced by the discussion at the hearing related to private practice versus hospital-based oncology practices. Mission oncology services provide a robust assistance program based on income, with patients up to 200% of federal poverty guidelines receiving free care, and a sliding scale payment system for households 200% to 300% of the federal poverty guidelines.



Mission supports reporting transparency for 340B savings and community benefit, and believes that, once reporting transparency is achieved, data collected can be used to support sound 340B policy discussion and decision-making.

8. During the hearing, you stated that contract pharmacies are "viewed as an extension of our own work." Do you believe all covered entities can make this statement, given the incredibly broad contract pharmacy arrangements managed by some hospitals and the significant distance between the hospital and contract pharmacy?

We can't speak specifically to other health system's pharmacy arrangements, but we would assume it is reasonably likely to be similar. Mission's contract pharmacies are "an extension of our own work" for two important reasons. First, the nexus/episode of care that identified the need for pharmaceuticals occurred at Mission Health. These are Mission Health patients. Second, margins derived by Mission from a contract pharmacy relationship inure to the 340B hospitals and their programming and support the robust and transparent community benefit program we have described, targeted to the specific needs of the people of western North Carolina.

With regard to "broad contract pharmacy arrangements", the pharmaceutical supply chain and how patients receive medications are evolving quickly and create oddities in 340B reporting. For example, while the corner drug store still exists, that corner drug store may be supported by a highly automated, centralized prescription processing facility or warehouse located hundreds of miles away from the hospital or pharmacy. The centralized facility ships medications to the local store every night. That warehouse facility, in order to be eligible for 340B drug shipments on behalf of the corner drug store, has to be listed today as a "contract pharmacy." The process reduces labor and distribution costs, but adds complexity to the supply chain, as well as the Mission 340B HRSA directory. In addition, specialty drugs are very expensive. Due to cost and labeler restrictions, the corner drug store is unable to stock these medications, forcing distribution into overnight mail order Specialty Pharmacies. Suddenly, the Specialty Pharmacy in Las Vegas is highly relevant to the care of patients in rural western North Carolina. To resupply that Specialty Pharmacy, Las Vegas has to be listed as a contract pharmacy for Mission. This dynamic has greatly increased the number of Specialty Pharmacies listed in our HRSA directory over the past six months. These situations are also likely applicable to other covered entities.

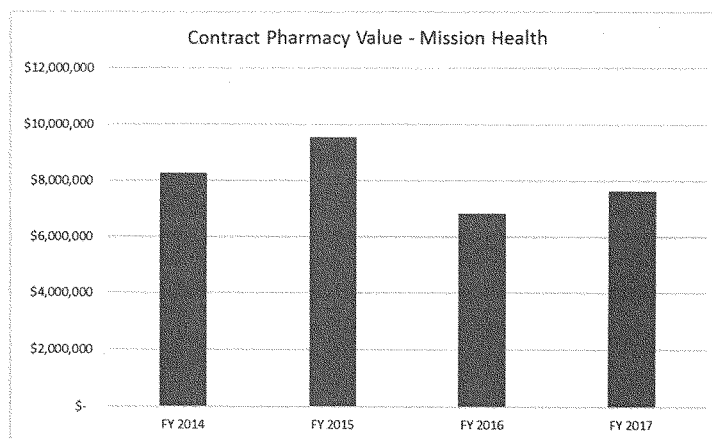
9. You stated during the hearing that several of your contract pharmacies are mail order or specialty pharmacies, which "haven't had a dollars' worth of revenue." Can you explain why this is the case, considering that contract pharmacies typically receive a dispensing fee for their services?



By way of background, Mission's agreements with its community pharmacy partners, including mail order, are based on a fixed dispensing fee model (i.e., we pay a fixed fee per prescription rather than using "revenue-sharing" models). Mission has made the very conscious decision to avoid "profit sharing" models with our contract pharmacies.

When Mission made the decision to add Specialty Pharmacies to our Contract Pharmacy network, the result was that we would be adding 16 new Contract Pharmacy locations, even though we had only signed two new Contract Pharmacy agreements. The reason for this is that each vendor has multiple mail order locations which could potentially provide mail order Specialty Pharmacy services for our patients. **As of October 2017, these sixteen Specialty Pharmacy locations have yet to provide a single qualified 340B prescription.** Specialty medications tend to be low in volume, but high in cost. Therefore, it is not surprising that we would have these contracts in place since July 1, 2017, yet have no qualified prescriptions, and therefore \$0 revenue for Mission or our vendors as a result of these agreements. An additional 10 of our Contract Pharmacies are warehouse/distribution facilities for our Contract Pharmacy partners. **They exist as "Contract Pharmacies" simply to allow for the shipment of bulk pharmaceuticals to a local drug store.** As such, we have not realized any revenue for Mission or these 10 "contract pharmacies" listed in the HRSA Directory for Mission.

Both of these are examples of drivers of the increase in the number of Contract Pharmacies listed in the HRSA 340B Directory and is visible to those studying this metric. Even so, using actual data for Mission Health and despite the increase in the number of contract pharmacies, we have relatively flat or declining contract pharmacy value over the last 4 years. The chart below provides our year-to-year contract pharmacy financials.



GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
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COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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November 7, 2017

Mr. Charles Reuland
Executive Vice President and Chief Operating Officer
Johns Hopkins Hospital
1800 Orleans Street
Baltimore, MD 21287

Dear Mr. Reuland:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, October 11, 2017, to testify at the hearing entitled "Examining How Covered Entities Utilize the 340B Drug Pricing Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 21, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations
Attachment



The Johns Hopkins Hospital's Response to Rep. Carter's Questions
for the Record dated November 7, 2017:

1. How many Part B beneficiaries utilized drugs covered under the 340B program last year at Johns Hopkins facilities?

JHH is not able to separate drug dispensations by payer as requested. Our total number of Part B Beneficiaries for the most recent 12 months is 61,614.

As background, savings for drugs covered under the 340B program are generated at the time of bulk purchase/replenishment rather than at the time of dispensation to patients. Eligibility for replenishment is determined by a third party splitting software based on the location of administration of the drug. Administration in an eligible (appropriately located on the hospital Medicare Cost Report) outpatient clinic provides accumulations of a future purchase at the 340B price. Maryland is an all-payer state and charges are not different for different payers.

2. What was the total dollar amount of 340B drugs dispensed to beneficiaries at Johns Hopkins under Part B under last year?

In FY16, JHH spent \$61,662,227 on 340B drugs. The outpatient Payer Mix% for Medicare for FY16 at JHH is 25.22%. Accordingly, the estimated amount spent on drugs given to Medicare Part B beneficiaries is \$15,551,214.

3. What was the total dollar amount of Part B drugs dispensed to beneficiaries each year from the year you entered the 340B program to last year?

Below is an estimation based on the methodology described above:

	Medicare Payer mix %	Spend	Estimated Medicare Part B spend
FY12:	23.16%	\$38,240,123	\$8,856,412
FY13:	25.13%	\$38,893,751	\$9,774,000
FY14:	25.42%	\$46,592,362	\$11,843,778
FY15:	25.35%	\$46,390,234	\$11,759,924

4. Do you provide a reduction in out of pocket costs for Part B beneficiaries accessing drugs at Johns Hopkins or one of your ancillary sites?

JHH has two policies – financial assistance and medication assistance – that ensure eligible low income patients receive the medications they need, regardless of whether those drugs are bought through 340B or not. (*See Appendix A*). Assuring that patients have access to the medications

they need is inherent in our mission and JHH has numerous programs to directly assist insured, underinsured and uninsured alike.

The Financial Assistance Program, which is made available to patients who have health care needs and are uninsured, underinsured, ineligible for a government program or otherwise unable to pay for medically necessary care and medications based on their individual financial situation; and Medical Financial Hardship Assistance, which is made available to those patients who are eligible for reduced cost care under the financial assistance criteria and also qualify under the Medical Financial Hardship Assistance Guidelines. It stipulates that JHHS hospitals (including JHH) shall apply the reduction in charges that is most favorable to the patient.

The JHH Medication Assistance Policy describes JHH's charity assistance programs, which consist of grants, donations, and other funds designated for assisting patients in obtaining prescription medication; patient assistance programs, which allow patients with limited income and resources access to medications via pharmaceutical companies; and medication access lists, which make available low cost generic alternatives.

- 5. Has there been an annual increase in the number of drugs purchased by Johns Hopkins for dispensing to Part B patients since you have entered the program? Please provide numbers detailing your program.**

Please see response to Question No. 3.

- 6. Can you provide your opinion as to why the Disproportionate Share Hospital (DSH) metric, which measures Medicare and Medicaid inpatient stays, is or is not appropriate for use in an outpatient drug program targeting underinsured and un insured patients?**

The original Disproportionate Share Hospital (DSH) metric established by Congress is an appropriate one to ensure that eligibility for the program is targeted to those hospitals that serve a large proportion of low-income patients. The DSH eligibility criteria set forth in the establishing 340B statute is working as intended. In fact, compared to non-340B acute care hospitals, comparably-sized 340B DSH hospitals not only provide more services to low-income patients (42 percent compared to 26 percent) but also provide a higher amount of uncompensated care than non DSH hospitals. In addition, DSH hospitals are more likely to provide specialized health care services, like pediatric intensive care, alcohol/drug abuse treatment, and community wellness programs.

- 7. According to an October 2017 Health Affairs article, the national median for hospital DSH percentages is 12.0%, which raises questions about the appropriateness of the 11.75% threshold used for the 340B program. What is your DSH percentage?**

The Johns Hopkins Hospital's DSH percentage for FY 2016 is 18.97 percent.

- a. Do you believe the DSH threshold for 340B hospitals should be adjusted to better target those 340B hospitals that have a DSH percentage well-above the national median?

It is difficult to comment at this time without seeing a specific proposal regarding

adjusting the DSH threshold.

8. What is the payer mix at your main 340B hospital site? How many uninsured or Medicaid patients are you serving? What is the percentage of commercially insured and Medicare patients?

The total facility payer mix for The Johns Hopkins Hospital in FY2016 is as follows:

Medicare	28.17%
Medicaid	19.99%
Commercial	48.55%
Uninsured	3.3%

It is also important to note that insurance status is not static, e.g. vulnerable patients may move in and out of insurance based on life-events, and 340B was initially established to help hospitals that treat high numbers of Medicaid and low-income Medicare patients, not just the uninsured.

Additionally, health care insurance status is not always reflective of medication insurance coverage, so those who may have health insurance may be in need of Johns Hopkins medication assistance programs.

9. Would you support a new 340B program requirement that mandates a certain level of charity care?

We have not seen a specific proposal regarding charity care, but in concept, we believe community benefit is a more appropriate indicator than charity care alone of a hospital's overall commitment to its community and to providing free or discounted care to vulnerable patients.

For example, in fiscal year 2016 alone, the total amount spent on community benefit activities at JHH was nearly \$200 million. This figure includes charity care or funding for free or discounted medically necessary care for patients, plus community health improvement programs and health screenings. Community benefit, which is publicly available on a hospital's IRS 990, provides a fuller picture of its investment in improving public health within its community, consistent with 340B original legislative intent.

10. Are you aware of any instances in which your hospital did not pass on 340B savings to uninsured or underinsured patients?

JHH provides low-income patients with free and discounted outpatient drugs, but for JHH's most vulnerable patients, affordability is only one in a series of hurdles to experiencing the full health benefit of a prescribed medication. For that reason, JHH uses 340B program savings to fund wrap-around services, including telephone consultations, home visits and transportation as needed for insured and uninsured patients alike. For example, JHH dispatches pharmacists to patient's homes through its *Home-Based Medication Management* project. These specially trained pharmacists work with patients to dispose of expired or discontinued medication, color-code pill containers when labels are too small to read and review medication administration instructions. Importantly, they also ensure that the patient's medication regimen is not only the right choice therapeutically, but also affordable for the patient in the long term. In this program, which began in 2012, JHH has demonstrated a significant reduction (from 17 percent to 8 percent) in

readmissions among patients who receive a pharmacist home visit.¹ JHH also offers a free bedside delivery service to eliminate barriers that could prevent patients from taking medically necessary prescriptions as instructed after a hospital admission, which is vital for good health outcomes and avoiding hospital readmission. More than 9,000 patients benefitted from this service in 2016.

11. Would you support new reporting/tracking requirements for 340B hospitals to achieve more consistency with respect to program savings?

JHH would be willing to review a proposal to strengthen the program. Any changes to the use of program savings should take into account the greatest feature of the 340B program, which is the discretion it affords eligible hospitals in tailoring the use of program savings to address the unique needs of their communities. The 340B program gives JHH the flexibility to tackle the *causes* of disease and disability in our community. In addition to providing health care to one patient at a time, JHH uses its 340B savings to help *prevent* disease and injury in the neighborhoods surrounding the hospital. For instance, beyond treating a premature and low birth weight baby in the neonatal intensive care unit, with 340B savings, JHH develops programs for expectant mothers in the surrounding community to increase the likelihood of healthy, on-time deliveries. In addition to prescribing medication to manage a patient's asthma, diabetes or heart disease, with 340B savings, JHH sponsors health promotion activities with local churches and community leaders. The Emergency Department can treat a patient with a gunshot wound, but with 340B savings, JHH can help modify the patient's home to promote independence after injury and support neighborhood violence prevention programs. 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 from the 340B program.

12. An October 2017 Health Affairs article found that the national median for hospital operating margins is -0.8%. Can you please provide your hospital operating margin?

The Johns Hopkins Hospital's operating margin was 3.6 percent for FY 2016 according to audited financial statements.


13. Is your payer mix the same at your child sites compared to your main hospital?

The Johns Hopkins Hospital child sites are located within the hospital footprint or "medical campus." They do not represent "off-site" entities that purchase drug product independently. These clinics are organizationally, financially and clinically integrated with the main hospital and the outpatient payer mix in FY 2016 is in line with the total facility payer mix noted in our response to Question 8.

¹ Pherson, *Development and implementation of a post discharge home-based medication management service*, 71 Am J Health Syst Pharm. 1576-83 (2014).

Appendix A

Financial Assistance and Medication Assistance Policies

	The Johns Hopkins Health System Policy & Procedure		<i>Policy Number</i>	FIN034A
	<i>Subject</i> FINANCIAL ASSISTANCE		<i>Effective Date</i>	04-01-16
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POLICY

This policy applies to The Johns Hopkins Health System Corporation (JHHS) following entities: The Johns Hopkins Hospital (JHH), Johns Hopkins Bayview Medical Center, Inc. Acute Care Hospital and Special Programs (JHBMC) and the Chronic Specialty Hospital of the Johns Hopkins Bayview Care Center (JHBCC).

Purpose

JHHS is committed to providing financial assistance to patients who have health care needs and are uninsured, underinsured, ineligible for a government program, or otherwise unable to pay, for medically necessary care based on their individual financial situation.

It is the policy of the Johns Hopkins Medical Institutions to provide Financial Assistance based on indigence or excessive Medical Debt for patients who meet specified financial criteria and request such assistance. The purpose of the following policy statement is to describe how applications for Financial Assistance can be made, the criteria for eligibility, and the steps for processing each application.

JHHS hospitals will publish the availability of Financial Assistance on a yearly basis in their local newspapers, and will post notices of availability at patient registration sites, Admissions/Business Office the Billing Office, and at the emergency department within each facility. Notice of availability will be posted on each hospital website, will be mentioned during oral communications, and will also be sent to patients on patient bills. A Patient Billing and Financial Assistance Information Sheet will be provided to inpatients before discharge and will be available to all patients upon request.

Financial Assistance may be extended when a review of a patient's individual financial circumstances has been conducted and documented. Review for Medical Financial Hardship Assistance shall include a review of the patient's existing medical expenses and obligations (including any accounts placed in bad debt) and any projected medical expenses. Financial Assistance Applications and Medical Financial Hardship Assistance may be offered to patients whose accounts are with a collection agency and will apply only to those accounts on which a judgment has not been granted, so long as other requirements are met.


FINANCIAL ASSISTANCE FOR PHYSICIANS PROVIDING CARE NOTICE:

Attached as **EXHIBIT D** is a list of physicians that provide emergency and medically necessary care as defined in this policy at JHH, JHBMC and JHBCC. The lists indicates if the doctor is covered under this policy. If the doctor is not covered under this policy, patients should contact the physician's office to determine if the physician offers financial assistance and if so what the physician's financial assistance policy provides.


Definitions

Medical Debt

Medical Debt is defined as out of pocket expenses for medical costs resulting from medically necessary care billed by the Hopkins hospital to which the application is made. Out of pocket expenses do not include co-payments, co-insurance and deductibles unless the patient purchased insurance through a Qualified Health Plan and meets eligibility requirements. Medical Debt does not include those hospital bills for which the patient chose to be registered as Voluntary Self Pay (opting out of insurance coverage, or insurance billing).

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Liquid Assets	Cash, securities, promissory notes, stocks, bonds, U.S. Savings Bonds, checking accounts, savings accounts, mutual funds, Certificates of Deposit, life insurance policies with cash surrender values, accounts receivable, pension benefits or other property immediately convertible to cash. A safe harbor of \$150,000 in equity in patient's primary residence shall not be considered an asset convertible to cash. Equity in any other real property shall be subject to liquidation. Liquid Assets do not include retirement assets to which the Internal Revenue Service has granted preferential tax treatment as a retirement account, including but not limited to, deferred compensation plans qualified under the Internal Revenue Code or non qualified deferred compensation plans.
Elective Admission	A hospital admission that is for the treatment of a medical condition that is not considered an Emergency Medical Condition.
Immediate Family	If patient is a minor, immediate family member is defined as mother, father, unmarried minor siblings, natural or adopted, residing in the same household. If patient is an adult, immediate family member is defined as spouse or natural or adopted unmarried minor children residing in the same household.
Emergency Medical Condition	<p>A medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, or other acute symptoms such that the absence of immediate medical attention could reasonably be expected to result in any of the following:</p> <ul style="list-style-type: none"> (a) Serious jeopardy to the health of a patient; (b) Serious impairment of any bodily functions; (c) Serious dysfunction of any bodily organ or part. (d) With respect to a pregnant woman: <ul style="list-style-type: none"> 1. That there is inadequate time to effect safe transfer to another hospital prior to delivery. 2. That a transfer may pose a threat to the health and safety of the patient or fetus. 3. That there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.
Emergency Services and Care	Medical screening, examination, and evaluation by a physician, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a physician, to determine whether an emergency medical condition exists and, if it does, the care, treatment, or surgery by a physician which is necessary to relieve or eliminate the emergency medical condition, within the service capability of the hospital.
Medically Necessary Care	Medical treatment that is necessary to treat an Emergency Medical Condition. Medically necessary care for the purposes of this policy does not include Elective or cosmetic procedures.
Medically Necessary Admission	A hospital admission that is for the treatment of an Emergency Medical Condition.

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Family Income	Patient's and/or responsible party's wages, salaries, earnings, tips, interest, dividends, corporate distributions, rental income, retirement/pension income, Social Security benefits and other income as defined by the Internal Revenue Service, for all members of Immediate Family residing in the household.
Supporting Documentation	Pay stubs; W-2s; 1099s; workers' compensation, Social Security or disability award letters; bank or brokerage statements; tax returns; life insurance policies; real estate assessments and credit bureau reports, Explanation of Benefits to support Medical Debt.
Qualified Health Plan	Under the Affordable Care Act, starting in 2014, an insurance plan that is certified By the Health Insurance Marketplace, provides essential health benefits, follows established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts), and meets other requirements. A qualified health plan will have a certification by each Marketplace in which it is sold.

PROCEDURES

1. An evaluation for Financial Assistance can begin in a number of ways:
For example:
 - A patient with a self-pay balance due notifies the self-pay collector or collection agency that he/she cannot afford to pay the bill and requests assistance.
 - A patient presents at a clinical area without insurance and states that he/she cannot afford to pay the medical expenses associated with their current or previous medical services.
 - A patient with a hospital account referred to a collection agency notifies the collection agency that he/she cannot afford to pay the bill and requests assistance.
 - A physician or other clinician refers a patient for Financial-Assistance evaluation for either inpatient or outpatient services.
2. Each Clinical or Business Unit will designate a person or persons who will be responsible for taking Financial Assistance applications. These staff can be Financial Counselors, Self-Pay Collection Specialists, Administrative staff, Customer Service, etc.
3. Designated staff will meet with patients who request Financial Assistance to determine if they meet preliminary criteria for assistance.
 - a. All hospital applications will be processed within two business days and a determination will be made as to probable eligibility. To facilitate this process each applicant must provide information about family size and income, (as defined by Medicaid regulations). To help applicants complete the process, we will provide a statement of conditional approval that will let them know what paperwork is required for a final determination of eligibility.
 - b. Applications received will be sent to the JHHS Patient Financial Services Department's dedicated Financial Assistance application line for review; a written determination of probable eligibility will be issued to the patient.
4. To determine final eligibility, the following criteria must be met:


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- a. The patient must apply for Medical Assistance or insurance coverage through a Qualified Health Plan and cooperate fully with the Medical Assistance team or its' designated agent, unless the financial representative can readily determine that the patient would fail to meet the eligibility requirements. The Patient Profile Questionnaire (Exhibit B) is used to determine if the patient must apply for Medical Assistance. In cases where the patient has active Medical Assistance pharmacy coverage or QMB coverage, it would not be necessary to reapply for Medical Assistance unless the financial representative has reason to believe that the patient may be awarded full Medical Assistance benefits.
 - b. Consider eligibility for other resources, such as endowment funds, outside foundation resources, etc.
 - c. The patient must be a United States of America citizen or permanent legal resident (must have resided in the U.S.A. for a minimum of one year).
 - d. All insurance benefits must have been exhausted.
5. To the extent possible, there will be one application process for all of the Maryland hospitals of JHHS. The patient is required to provide the following:
- a. A completed Financial Assistance Application (Exhibit A) and Patient Profile Questionnaire (Exhibit B).
 - b. A copy of their most recent Federal Income Tax Return (if married and filing separately, then also a copy of spouse's tax return and a copy of any other person's tax return whose income is considered part of the family income as defined by Medicaid regulations).
 - c. A copy of the three (3) most recent pay stubs (if employed) or other evidence of income of any other person whose income is considered part of the family income as defined by Medicaid regulations.
 - d. A Medical Assistance Notice of Determination (if applicable).
 - e. Proof of U.S. citizenship or lawful permanent residence status (green card) if applicable.
 - f. Proof of disability income (if applicable).
 - g. Reasonable proof of other declared expenses.
 - h. If unemployed, reasonable proof of unemployment such as statement from the Office of Unemployment Insurance, a statement from current source of financial support, etc...
6. A patient can qualify for Financial Assistance either through lack of sufficient insurance or excessive Medical Debt. Medical Debt is defined as out of pocket expenses excluding copayments, coinsurance and deductibles unless the patient purchased insurance through a Qualified Health Plan and meets eligibility requirements for medical costs billed by a Hopkins hospital. Once a patient has submitted all the required information, the Financial Counselor will review and analyze the application and forward it to the Patient Financial Services Department for final determination of eligibility based upon JHMI guidelines.
- a. If the application is denied, the patient has the right to request the application be reconsidered. The Financial Counselor will forward the application and attachments to the Financial

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Assistance Evaluation Committee for final evaluation and decision.

- b. If the patient's application for Financial Assistance is based on excessive Medical Debt or if there are extenuating circumstances as identified by the Financial Counselor or designated person, the Financial Counselor will forward the application and attachments to the Financial Assistance Evaluation Committee. This committee will have decision-making authority to approve or reject applications. It is expected that an application for Financial Assistance reviewed by the Committee will have a final determination made no later than 30 days from the date the application was considered complete. The Financial Assistance Evaluation Committee will base its determination of financial need on JHHS guidelines.
7. Each clinical department has the option to designate certain elective procedures for which no Financial Assistance options will be given.
8. Services provided to patients registered as Voluntary Self Pay patients do not qualify for Financial Assistance.
9. A department operating programs under a grant or other outside governing authority (i.e., Psychiatry) may continue to use a government-sponsored application process and associated income scale.
10. Once a patient is approved for Financial Assistance, Financial Assistance coverage shall be effective for the month of determination and the following six (6) calendar months. If patient is approved for a percentage allowance due to financial hardship it is recommended that the patient make a good-faith payment at the beginning of the Financial Assistance period. Upon a request from a patient who is uninsured and whose income level falls within the Medical Financial Hardship Income Grid set forth in Appendix B, JHHS shall make a payment plan available to the patient. Any payment schedule developed through this policy will ordinarily not last longer than two years. In extraordinary circumstances and with the approval of the designated manager a payment schedule may be extended.
11. Presumptive Financial Assistance Eligibility. There are instances when a patient may appear eligible for financial assistance, but there is no financial assistance form on file. Often there is adequate information provided by the patient or other sources, which could provide sufficient evidence to provide the patient with financial assistance. In the event there is no evidence to support a patient's eligibility for financial assistance, JHHS reserves the right to use outside agencies in determining estimated income amounts for the basis of determining financial assistance eligibility and potential reduced care rates. Once determined, due to the inherent nature of presumptive circumstances, the only financial assistance that can be granted is a 100% write-off of the account balance. Presumptive Financial Assistance Eligibility shall only cover the patient's specific date of service and shall not be effective for a six (6) month period. Presumptive eligibility may be determined on the basis of individual life circumstances. Unless otherwise eligible for Medicaid or CHIP, patients who are beneficiaries/recipients of the means-tested social service programs listed by the Health Services Cost Review Commission in COMAR 10.37.10.26 A-2 are deemed Presumptively Eligible for free care provided the patient submits proof of enrollment within 30 days of date of service. Such 30 days may be extended to 60 days if patient or patient's representative request an additional 30 days. Appendix A-1 provides a list of life circumstances in addition to those specified by the regulations listed above that qualify a patient for Presumptive Eligibility.
12. Financial Assistance Applications may only be submitted for/by patients with open and unpaid hospital accounts.
13. Patients who indicate they are unemployed and have no insurance coverage shall be required to submit a Financial Assistance Application unless they meet Presumptive Financial Assistance

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Eligibility criteria. If patient qualifies for COBRA coverage, patient's financial ability to pay COBRA insurance premiums shall be reviewed by the Financial Counselor and recommendations shall be made to Financial Assistance Evaluation Committee. Individuals with the financial capacity to purchase health insurance shall be encouraged to do so, as a means of assuring access to health care services and for their overall personal health.

14. Patients who receive coverage on a Qualified Health Plan and ask for help with out of pocket expenses (co-payments and deductibles) for medical costs resulting from medically necessary care shall be required to submit a Financial Assistance Application if the patient is at or below 200% of Federal Poverty Guidelines.
15. If a patient account has been assigned to a collection agency, and patient or guarantor request financial assistance or appears to qualify for financial assistance, the collection agency shall notify PFS and shall forward the patient/guarantor a financial assistance application with instructions to return the completed application to PFS for review and determination and shall place the account on hold for 45 days pending further instruction from PFS.
16. Beginning October 1, 2010, if within a two (2) year period after the date of service a patient is found to be eligible for free care on the date of service (using the eligibility standards applicable on the date of service), the patient shall be refunded amounts received from the patient/guarantor exceeding \$25. If the hospital documentation demonstrates the lack of cooperation of the patient or guarantor in providing information to determine eligibility for free care, the two (2) year period herein may be reduced to 30 days from the date of initial request for information. If the patient is enrolled in a means-tested government health care plan that requires the patient to pay-out-of-pocket for hospital services, then patient or guarantor shall not be refunded any funds that would result in patient losing financial eligibility for health coverage.
17. This Financial Assistance policy does not apply to deceased patients for whom a decedent estate has or should be opened due to assets owned by a deceased patient. Johns Hopkins will file a claim in the decedents' estate and such claim will be subject to estate administration and applicable Estates and Trust laws.
18. JHHS Hospitals may extend Financial Assistance to residents with demonstrated financial need, regardless of citizenship, in the neighborhoods surrounding their respective hospitals, as determined by the hospital's Community Health Needs Assessment. The zip codes for JHH and JHBMC are: 21202, 21205, 21206, 21213, 21218, 21219, 21222, 21224, 21231 and 21052. Once a patient is approved for Financial Assistance, Financial Assistance coverage shall be effective for the month of determination and the following six (6) calendar months. Financial Counselors will refer these patients to The Access Partnership program at Hopkins (see FIN057 for specific procedures).

REFERENCE¹


JHHS Finance Policies and Procedures Manual

Policy No. FIN017 - Signature Authority: Patient Financial Services

Policy No. FIN033 - Installment Payments

Charity Care and Bad Debts, AICPA Health Care Audit Guide


¹ NOTE: Standardized applications for Financial Assistance, Patient Profile Questionnaire and Medical Financial Hardship have been developed. For information on ordering, please contact the Patient Financial Services Department. Copies are attached to this policy as Exhibits A, B and C.

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Code of Maryland Regulations COMAR 10.37.10.26, et seq
 Maryland Code Health General 19-214, et seq
 Federal Poverty Guidelines (Updated annually) in Federal Register

RESPONSIBILITIES - JHH, JHBMC

Financial Counselor (Pre-Admission/Admission/In-House/Outpatient) Customer Service Collector Admissions Coordinator Any Finance representative designated to accept applications for Financial Assistance	Understand current criteria for Assistance qualifications.
	Identify prospective patients; initiate application process when required. As necessary assist patient in completing application or program specific form.
	On the day preliminary application is received, fax to Patient Financial Services Department's dedicated fax line for determination of probable eligibility.
	Review preliminary application, Patient Profile Questionnaire and Medical Financial Hardship Application (if submitted) to make probable eligibility determination. Within two business days of receipt of preliminary application, mail determination to patient's last known address or deliver to patient if patient is currently an inpatient. Notate patient account comments.
	If Financial Assistance Application is not required, due to patient meeting specific criteria, notate patient account comments and forward to Management Personnel for review.
	Review and ensure completion of final application.
	Deliver completed final application to appropriate management.
	Document all transactions in all applicable patient accounts comments.
	Identify retroactive candidates; initiate final application process.

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Management Personnel
(Supervisor/Manager/Director)

Review completed final application; monitor those accounts for which no application is required; determine patient eligibility; communicate final written determination to patient within 30 business days of receiving completed application. If patient is eligible for reduced cost care, apply the most favorable reduction in charges for which patient qualifies.

Advise ineligible patients of other alternatives available to them including installment payments, bank loans, or consideration under the Medical Financial Hardship program if they have not submitted the supplemental application, Exhibit C. [Refer to Appendix B - Medical Financial Hardship Assistance Guidelines.]

Notices will not be sent to Presumptive Eligibility recipients.

Financial Management Personnel
(Senior Director/Assistant Treasurer
or affiliate equivalent)
CP Director and Management Staff

Review and approve Financial Assistance applications and accounts for which no application is required and which do not write off automatically in accordance with signature authority established in JHHS Finance Policy No. FIN017 - Signature Authority: Patient Financial Services.

SPONSOR

Senior Director, Patient Finance (JHHS)
Director, PFS Operations (JHHS)


REVIEW CYCLE

Two (2) years

APPROVAL


Sr. VP of Finance/Treasurer & CFO for JHH and JHHS

Date

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APPENDIX A
FINANCIAL ASSISTANCE PROGRAM ELIGIBILITY GUIDELINES


1. Each patient requesting Financial Assistance must complete a JHM/Financial Assistance Application (also known as the Maryland State Uniform Financial Assistance Application) Exhibit A, and Patient Profile Questionnaire, Exhibit B. If patient wishes to be considered for Medical Financial Hardship, patient must submit Medical Financial Hardship Application, Exhibit C.
2. A preliminary application stating family size and family income (as defined by Medicaid regulations) will be accepted and a determination of probable eligibility will be made within two business days of receipt.
3. The patient must apply for Medical Assistance or insurance coverage through a Qualified Health Plan and cooperate fully with the Medical Assistance team or its designated agent, unless the financial representative can readily determine that the patient would fail to meet the eligibility requirements. A Patient Profile Questionnaire (see Exhibit B) has been developed to determine if the patient must apply for Medical Assistance. In cases where the patient has active Medical Assistance pharmacy coverage or QMB coverage, it would not be necessary to reapply for Medical Assistance unless the financial representative has reason to believe that the patient may be awarded full Medical Assistance benefits.
4. The patient must be a United States of America citizen or permanent legal resident (must have resided in the U.S.A. for a minimum of one year)
5. Proof of income must be provided with the final application. Acceptable proofs include:
 - (a) Prior-year tax return;
 - (b) Current pay stubs;
 - (c) Letter from employer, or if unemployed documentation verifying unemployed status; and
 - (d) A credit bureau report obtained by the JHM affiliates and/or Patient Financial Services Department.
6. Patients will be eligible for Financial Assistance if their maximum family (husband and wife, same sex married couples) income (as defined by Medicaid regulations) level does not exceed each affiliate's standard (related to the Federal poverty guidelines) and they do not own Liquid Assets *in excess of \$10,000 which would be available to satisfy their JHHS affiliate bills.
7. All financial resources must be used before the Financial Assistance can be applied. This includes insurance, Medical Assistance, and all other entitlement programs for which the patient may qualify.
8. Patients who chose to become voluntary self pay patients do not qualify for Financial Assistance for the amount owed on any account registered as Voluntary Self Pay.
9. Financial Assistance is only applicable to Medically Necessary Care as defined in this policy. Financial Assistance is not applicable to convenience items, private room accommodations or non-essential cosmetic surgery. Non-hospital charges will remain the responsibility of the patient. In the event a question arises as to whether an admission is an "Elective Admission" or a "Medically Necessary Admission," the patient's admitting physician shall be consulted and the matter will also be directed to the physician advisor appointed by the hospital.
10. Each affiliate will determine final eligibility for Financial Assistance within thirty (30) business days of the day when the application was satisfactorily completed and submitted.

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11. Documentation of the final eligibility determination will be made on all (open-balance) patient accounts. A determination notice will be sent to the patient.
12. A determination of eligibility for Financial Assistance based on the submission of a Financial Assistance Application will remain valid for a period of six (6) months for all necessary JHM affiliate services provided, based on the date of the determination letter. Patients who are currently receiving Financial Assistance from one JHM affiliate will not be required to reapply for Financial Assistance from another affiliate.
13. All determinations of eligibility for Financial Assistance shall be solely at the discretion of the JHHS affiliate.

Exception

The Director of Patient Financial Services (or affiliate equivalent) may make exceptions according to individual circumstances.

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FREE OR REDUCED COST CARE FINANCIAL ASSISTANCE GRID

TABLE FOR DETERMINATION OF FINANCIAL ASSISTANCE ALLOWANCES						
Effective 3/1/16						
# of Persons in Family	Income Level*	Upper Limits of Income for Allowance Range				
1	\$ 23,760	\$ 26,136	\$ 28,512	\$ 30,888	\$ 33,264	\$ 35,640
2	\$ 32,040	\$ 35,244	\$ 38,448	\$ 41,652	\$ 44,856	\$ 48,060
3	\$ 40,320	\$ 44,352	\$ 48,384	\$ 52,416	\$ 56,448	\$ 60,480
4	\$ 48,600	\$ 53,460	\$ 58,320	\$ 63,180	\$ 68,040	\$ 72,900
5	\$ 56,880	\$ 62,568	\$ 68,256	\$ 73,944	\$ 79,632	\$ 85,320
6	\$ 65,160	\$ 71,676	\$ 78,192	\$ 84,708	\$ 91,224	\$ 97,740
7	\$ 73,460	\$ 80,806	\$ 88,152	\$ 95,498	\$ 102,844	\$ 110,190
8*	\$ 81,780	\$ 89,958	\$ 98,136	\$ 106,314	\$ 114,492	\$ 122,670
**amt for each mbr	\$8,320	\$9,152	\$9,984	\$10,816	\$11,648	\$12,480
Allowance to Give:	100%	80%	60%	40%	30%	20%

* 200% of Poverty Guidelines

** For family units with more than eight (8) members.

EXAMPLE: Annual Family Income \$55,000
 # of Persons in Family 4
 Applicable Poverty Income Level 48,600
 Upper Limits of Income for Allowance Range \$58,320 (60% range)
 (\$55,000 is less than the upper limit of income; therefore patient is eligible for Financial Assistance.)

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Appendix A-1

Presumptive Financial Assistance Eligibility

There are instances when a patient may appear eligible for financial assistance, but there is no financial assistance form on file. Often there is adequate information provided by the patient or through other sources, which could provide sufficient evidence to provide the patient with financial assistance. In the event there is no evidence to support a patient's eligibility for financial assistance, JHHS reserves the right to use outside agencies in determining estimate income amounts for the basis of determining financial assistance eligibility and potential reduced care rates. Once determined, due to the inherent nature of presumptive circumstances, the only financial assistance that can be granted is a 100% write off of the account balance. Presumptive Financial Assistance Eligibility shall only cover the patient's specific date of service and shall not be effective for a six (6) month period. Presumptive eligibility may be determined on the basis of individual life circumstances that may include:

- Active Medical Assistance pharmacy coverage
- QMB coverage/ SLMB coverage
- Homelessness
- Medical Assistance and Medicaid Managed Care patients for services provided in the ER beyond the coverage of these programs
- Maryland Public Health System Emergency Petition patients
- Participation in Women, Infants and Children Programs (WIC)*
- Supplemental Nutritional Assistance program (SNAP) or Food Stamp eligibility *
- Households with children in the free or reduced lunch program*
- Low-income household energy assistance program participation*
- Eligibility for other state or local assistance programs which have financial eligibility at or below 200% of FPL
- Patient is deceased with no known estate
- The Access Partnership Program at Hopkins (see FIN057 for specific procedures)
- Patients that are determined to meet eligibility criteria established under former State Only Medical Assistance Program
- The Pregnancy Care Program at JHBMC (see FIN053 for specific procedures)

*These life circumstances are set forth in COMAR 10.37.10.26 A-2. The patient needs to submit proof of enrollment in these programs within 30 days of treatment unless the patient requests an additional 30 days.

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APPENDIX B MEDICAL FINANCIAL HARDSHIP ASSISTANCE GUIDELINES

Purpose

These guidelines are to provide a separate, supplemental determination of Financial Assistance. This determination will be offered to all patients who apply for Financial Assistance.

Medical Financial Hardship Assistance is available for patients who are not eligible for Financial Assistance under the primary section of this policy, but for whom:

- 1.) Medical Debt incurred over a twelve (12) month period exceeds 25% of the Family Income creating Medical Financial Hardship; and
- 2.) who meet the income standards for this level of Assistance.

For those patients who are eligible for reduced cost care under the Financial Assistance criteria and also qualify under the Medical Financial Hardship Assistance Guidelines, JHHS shall apply the reduction in charges that is most favorable to the patient.

Medical Financial Hardship is defined as Medical Debt for medically necessary treatment incurred by a family over a twelve (12) month period that exceeds 25% of that family's income.


Medical Debt is defined as out of pocket expenses for medical costs for Medically Necessary Care billed by the Hopkins hospital to which the application is made, the out of pocket expenses mentioned above do not include co-payments, co-insurance and deductibles, unless the patient is below 200% of Federal Poverty Guidelines.

The patient/guarantor can request that such a determination be made by submitting a Medical Financial Hardship Assistance Application (Exhibit C), when submitting JHM/Financial Assistance Application, also known as the Maryland State Uniform Financial Assistance Application (Exhibit A), and the Patient Profile Questionnaire (Exhibit B). The patient guarantor must also submit financial documentation of family income for the twelve (12) calendar months preceding the application date and documentation evidencing Medical Debt of at least 25% of family income.

Once a patient is approved for Medical Hardship Financial Assistance, Medical Hardship Financial Assistance coverage shall be effective starting the month of the first qualifying service and the following twelve (12) calendar months. It shall cover those members of the patient's Immediate Family residing in the same household. The patient and the Immediate Family members shall remain eligible for reduced cost Medically Necessary Care when seeking subsequent care at the same hospital for twelve (12) calendar months beginning on the date on which the reduced cost Medically Necessary Care was initially received. Coverage shall not apply to Elective Admissions or Elective or cosmetic procedures. However, the patient or the patient's immediate family member residing in the same household must notify the hospital of their eligibility for the reduced cost medically necessary care at registration or admission.

General Conditions for Medical Financial Hardship Assistance Application:

1. Patient's income is under 500% of the Federal Poverty Level.
2. Patient has exhausted all insurance coverage.
3. Patient account balances for patients who chose to register as voluntary self pay shall not counted toward Medical Debt for Medical Financial Hardship Assistance.
4. Patient/guarantor do not own Liquid Assets *in excess of \$10,000 which would be available to satisfy their JHHS affiliate bills.
5. Patient is not eligible for any of the following:
 - Medical Assistance

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- Other forms of assistance available through JHM affiliates
6. Patient is not eligible for The JHM Financial Assistance Program or is eligible but the Medical Financial Hardship Program may be more favorable to the patient.
 7. The affiliate has the right to request patient to file updated supporting documentation.
 8. The maximum time period allowed for paying the amount not covered by Financial Assistance is three (3) years.
 9. If a federally qualified Medicaid patient required a treatment that is not approved by Medicaid but may be eligible for coverage by the Medical Financial Hardship Assistance program, the patient is still required to file a JHHS Medical Financial Hardship Assistance Application but not to submit duplicate supporting documentation.

Factors for Consideration

The following factors will be considered in evaluating a Medical Financial Hardship Assistance Application:


- Medical Debt incurred over the twelve (12) months preceding the date of the Financial Hardship Assistance Application at the Hopkins treating facility where the application was made.
- Liquid Assets (leaving a residual of \$10,000)
- Family Income for the twelve (12) calendar months preceding the date of the Financial Hardship Assistance Application
- Supporting Documentation

Exception

The Director or designee of Patient Financial Services (or affiliate equivalent) may make exceptions according to individual circumstances.

Evaluation Method and Process

1. The Financial Counselor will review the Medical Financial Hardship Assistance Application and collateral documentation submitted by the patient/responsible party.
2. The Financial Counselor will then complete a Medical Financial Hardship Assistance Worksheet (found on the bottom of the application) to determine eligibility for special consideration under this program. The notification and approval process will use the same procedures described in the Financial Assistance Program section of this policy.

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MEDICAL HARDSHIP FINANCIAL GRID

Upper Limits of Family Income for Allowance Range

TABLE FOR DETERMINATION OF FINANCIAL ASSISTANCE ALLOWANCES			
Effective 3/1/16			
# of Persons in Family	Income Level**		
# of Persons in Family	300% of FPL	400% of FPL	500% of FPL
1	\$ 35,640	\$ 47,520	\$ 59,400
2	\$ 48,060	\$ 64,080	\$ 80,100
3	\$ 60,480	\$ 80,640	\$ 100,800
4	\$ 72,900	\$ 97,200	\$ 121,500
5	\$ 85,320	\$ 113,760	\$ 142,200
6	\$ 97,740	\$ 130,320	\$ 162,900
7	\$ 110,190	\$ 146,920	\$ 183,650
8*	\$ 122,670	\$ 163,560	\$ 204,450
Allowance to Give:	50%	35%	20%

*For family units with more than 8 members, add \$12,480 for each additional person at 300% of FPL, \$16,640 at 400% at FPL; and \$20,800 at 500% of FPL.

Exhibit A

Johns Hopkins
3910 Keswick Road, Suite S-5100
Baltimore, MD 21211



Maryland State Uniform Financial Assistance Application

Information About You

Name _____
First Middle Last

Social Security Number _____ - ____ - ____
US Citizen: Yes No

Marital Status: Single Married Separated
Permanent Resident: Yes No

Home Address _____

Phone _____

City State Zip code

Country _____

Employer Name _____

Phone _____

Work Address _____

City State Zip code

Household members:

Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____
Name _____	Age _____	Relationship _____

Have you applied for Medical Assistance Yes No

If yes, what was the date you applied? _____

If yes, what was the determination? _____

Do you receive any type of state or county assistance? Yes No

Exhibit A

I. Family Income

List the amount of your monthly income from all sources. You may be required to supply proof of income, assets, and expenses. If you have no income, please provide a letter of support from the person providing your housing and meals.

	Monthly Amount
Employment	_____
Retirement/pension benefits	_____
Social security benefits	_____
Public assistance benefits	_____
Disability benefits	_____
Unemployment benefits	_____
Veterans benefits	_____
Alimony	_____
Rental property income	_____
Strike benefits	_____
Military allotment	_____
Farm or self employment	_____
Other income source	_____
Total	_____

II. Liquid Assets

	Current Balance
Checking account	_____
Savings account	_____
Stocks, bonds, CD, or money market	_____
Other accounts	_____
Total	_____

III. Other Assets

If you own any of the following items, please list the type and approximate value.

Home	Loan Balance _____	Approximate value _____
Automobile	Make _____ Year _____	Approximate value _____
Additional vehicle	Make _____ Year _____	Approximate value _____
Additional vehicle	Make _____ Year _____	Approximate value _____
Other property		Approximate value _____
Total		_____

IV. Monthly Expenses

	Amount
Rent or Mortgage	_____
Utilities	_____
Car payment(s)	_____
Credit card(s)	_____
Car insurance	_____
Health insurance	_____
Other medical expenses	_____
Other expenses	_____
Total	_____

Do you have any other unpaid medical bills? Yes No

For what service? _____

If you have arranged a payment plan, what is the monthly payment? _____

If you request that the hospital extend additional financial assistance, the hospital may request additional information in order to make a supplemental determination. By signing this form, you certify that the information provided is true and agree to notify the hospital of any changes to the information provided within ten days of the change.

Applicant signature

Date

Relationship to Patient


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EXHIBIT B PATIENT FINANCIAL SERVICES PATIENT PROFILE QUESTIONNAIRE

HOSPITAL NAME: _____

PATIENT NAME: _____

PATIENT ADDRESS: _____
(Include Zip Code)

MEDICAL RECORD #: _____

1. What is the patient's age? _____
2. Is the patient a U.S. citizen or permanent resident? Yes or No
3. Is patient pregnant? Yes or No
4. Does patient have children under 21 years of age living at home? Yes or No
5. Is patient blind or is patient potentially disabled for 12 months or more from gainful employment? Yes or No
6. Is patient currently receiving SSI or SSDI benefits? Yes or No
7. Does patient (and, if married, spouse) have total bank accounts or assets convertible to cash that do not exceed the following amounts? Yes or No
Family Size:
 Individual: \$2,500.00
 Two people: \$3,000.00
 For each additional family member, add \$100.00
 (Example: For a family of four, if you have total liquid assets of less than \$3,200.00, you would answer YES.)
8. Is patient a resident of the State of Maryland? Yes or No
 If not a Maryland resident, in what state does patient reside? _____
9. Is patient homeless? Yes or No
10. Does patient participate in WIC? Yes or No
11. Does household have children in the free or reduced lunch program? Yes or No
12. Does household participate in low-income energy assistance program? Yes or No
13. Does patient receive SNAP/Food Stamps? Yes or No
14. Is the patient enrolled in Healthy Howard and referred to JHH? Yes or No
15. Does patient currently have? Yes or No
 Medical Assistance Pharmacy Only Yes or No
 QMB coverage/ SLMB coverage Yes or No
16. Is patient employed? Yes or No
 If no, date became unemployed. _____
 Eligible for COBRA health insurance coverage? Yes or No


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EXHIBIT C MEDICAL FINANCIAL HARDSHIP APPLICATION

HOSPITAL NAME: _____

PATIENT NAME: _____

PATIENT ADDRESS: _____
(Include Zip Code)

MEDICAL RECORD #: _____

Date: _____

Family Income for twelve (12) calendar months preceding date of this application: _____

Medical Debt incurred at The Johns Hopkins Hospital (not including co-insurance, co-payments, or deductibles) for the twelve (12) calendar months preceding the date of this application:

Date of service	Amount owed
_____	_____
_____	_____
_____	_____
_____	_____

All documentation submitted becomes part of this application.

All the information submitted in the application is true and accurate to the best of my knowledge, information and belief.

Applicant's signature _____ Date: _____

Relationship to Patient _____

For Internal Use:


Reviewed By: _____ Date: _____

Income: _____ 25% of income= _____

Medical Debt: _____ Percentage of Allowance: _____

Reduction: _____ Balance Due: _____

Monthly Payment Amount: _____ Length of Payment Plan: _____ months

	The Johns Hopkins Hospital Pharmacy, Outpatient Retail Finance <i>Subject</i> Medication Assistance	Version 4.0	
		<i>Policy Number</i>	FIN013
		<i>Effective Date</i>	07/08/2014
		<i>Approval Date</i>	07/08/2014
		<i>Page</i>	1 of 2
		<i>Supersedes</i>	07/01/2011

Keywords: medication assistance, charity care, vouchers, Social Work,

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II. INDICATIONS FOR USE	1
III. RESPONSIBILITY	1
IV. PROCEDURE	1
V. DEFINITIONS	2

I. OBJECTIVES

- A. Outpatient pharmacy will take part in Johns Hopkins Medicine initiatives that assist patients and families in seeking access to take-home medication.

II. INDICATIONS FOR USE


- A. Outpatient pharmacy leadership and staff will not discriminate on the basis of socioeconomic status. This policy outlines how outpatient pharmacy collaborates with groups both internal and external to Johns Hopkins Medicine to assist patients accessing take-home medications in the event the patient is unable to afford medication costs.

III. RESPONSIBILITY

Patients	<ul style="list-style-type: none"> Patients are accountable for informing health care providers of their need for assistance in accessing take-home medications. Patients are accountable for providing supporting documentation as required (ex. proof of income).
Department of Social Work	<ul style="list-style-type: none"> Responsible for authorizing the use of charity funds for medication access.

IV. PROCEDURE

- A. Potential opportunities are available to patients seeking financial aid or assistance with take-home medication costs.
1. Charity Assistance Programs
 1. All patients presenting to outpatient pharmacy who need assistance with a take home medication will be referred to the Department of Social Work. A member of the Department of Social Work completes a screening process that may include verifying insurance status and discussing patient finances before funds are assigned to a patient. Charity assistance program funds will be authorized by the Department of Social Work.
 2. Prescription quantities covered by Charity Assistance Programs may differ from those ordered by the prescriber.

	The Johns Hopkins Hospital		Version 4.0	
	Pharmacy, Outpatient Retail Finance		<i>Policy Number</i>	FIN013
			<i>Effective Date</i>	07/08/2014
			<i>Approval Date</i>	07/08/2014
	<i>Subject</i> Medication Assistance		<i>Page</i>	2 of 2
			<i>Supersedes</i>	07/01/2011

2. Patient Assistance Programs (PAP)
 1. Pharmaceutical companies are responsible for establishing enrollment criteria for each medication available through a PAP. Eligibility criteria may be based upon the current Federal Poverty Level (FPL), the number of dependents in a household, or the total income per household.
 2. PAP medication may only be dispensed to the patient for whom it was authorized.
 3. PAP medication may never be re-sold.
3. Low Cost Generic Drug Plan
 1. Outpatient pharmacy offers a generic drug discount list that contains commonly prescribed generic medications available to uninsured patients.
 2. The drug discount list is maintained at http://www.insidehopkinsmedicine.org/pharmacy/11_medication_list.pdf.
 3. The low cost generic drug plan may only be used by uninsured patients.
- B. Co-payment Assistance for Patients with Medicaid or Medicaid MCO Coverage
 - i. In the event a patient with Medicaid or Medicaid MCO Coverage does not have access to funds for their co-payment(s), the patient could be eligible for a co-payment(s) waiver. In order to be eligible for a co-payment(s) waiver, the patient must complete a Patient Profile Questionnaire or have a previously completed Patient Profile Questionnaire on file.

V. DEFINITIONS

Charity Assistance Programs	Charity Assistance programs consist of grants, philanthropic donations, and other funds designated for assisting patients in obtaining prescription medication.
Patient Assistance Programs (PAP's)	Through PAP's, pharmaceutical companies provide select brand-name medications to patients with limited income and resources. Eligibility criteria for PAP may include current Federal Poverty Level (FPL) guidelines, number of dependants in the household, or the total income per household.
Low Cost Generic Drug Plans	Commonly prescribed generic medications (medications no longer under patent and available from multiple manufacturer(s) for various disease states are available in quantities from one to three months at pharmacies.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (201) 225-2927
Minority (201) 225-3641

November 7, 2017

Ms. Shannon A. Banna
Director of Finance and System Controller
Northside Hospital, Inc.
1000 Johnson Ferry Road, N.E.
Atlanta, GA 30342

Dear Ms. Banna:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, October 11, 2017, to testify at the hearing entitled "Examining How Covered Entities Utilize the 340B Drug Pricing Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, November 21, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment



November 21, 2017

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Morgan Griffith
Chairman
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

RE: Northside Hospital, Inc. ("Northside")

Dear Chairman Walden and Chairman Griffith:

Thank you again for the opportunity to demonstrate to the Committee and Subcommittee how Northside utilizes the 340B Drug Pricing Program (the "340B Program") to serve patients and Georgia communities. Please find below Northside's responses to the questions raised during the hearing conducted on October 11, 2017 and follow up questions received on November 7, 2017.

QUESTIONS FROM REPRESENTATIVE CARTER –

1. Since 2010, how many independent practices has Northside Hospital acquired?

Since 2010, Northside has acquired 61 independent practices. Northside developed and implemented a strategic plan to acquire physicians from various specialties as a result of the significant changes and quality mandates included in the Patient Protection and Affordable Care Act, and the implementing regulations thereunder, as amended by the Health Care and Education Reconciliation Act of 2010, and the implementing regulations thereunder (collectively, the "ACA"). Quality initiatives and outcomes are an important component of Northside's success and, therefore, beginning in 2010, Northside pursued potential employment of physicians and physician practices in the community.

a. **What is the practice breakdown for specialties?**

Cardiology	2
Internal Medicine	25
Pulmonary & Sleep	6
Oncology	5
Surgical	23
	61

b. **Of those independent practices, how many were specialized in providing oncology services to the community?**

Five.

2. **Since entering the 340B Program in 2013, how many practices and physician sites have you acquired?**

Since entering the 340B Program on April 1, 2013, Northside has acquired 40 physician practices, with a total of 56 physician sites.

a. **How many of those acquired sites or practices focused on oncology services?**

Northside has not acquired any practices or physician sites that focus on oncology services since it joined the 340B Program on April 1, 2013.

3. **In your testimony, you mention that you have 150 ancillary and physician sites located across the 28 county Atlanta Metropolitan Statistical Area. Can you provide a geographic breakdown of those locations?**

Please see Attachment 1 attached hereto and incorporated herein.

4. **What is the percentage of patient referrals from your ancillary sites that are eligible and utilize drugs covered under the 340B program?**

All eligible patients (those who qualify under the 340B Program) that are seen at a Northside 340B outpatient ancillary site receive 340B drugs.

5. **How many independent practices have been acquired since 1992?**

Northside has acquired 61 practices since 1992.

a. **How many were acquired between 1992 and 2013?**

Northside acquired 29 practices between January 1, 1992 and December 31, 2013.

6. **Can you provide your opinion as to why the Disproportionate Share Hospital (DSH) metric, which measures Medicare and Medicaid inpatient stays, is or is not appropriate for use in an outpatient drug program targeting underinsured and uninsured patients?**

It is Northside's opinion that requiring hospitals to serve a disproportionate share of low income patients as a precondition to participation in the 340B Program is appropriate because it captures the goal of the 340B Program – benefiting covered entities, including hospitals, that serve low-income and needy patients and “stretch[ing] scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services” to the community. In the last five years Northside has served a steadily growing number of low-income patients across the spectrum of care and has leveraged savings from the 340B program towards supporting thousands of patients in a variety of treatment settings, including reduction of prescription drug costs.

7. **Would you support a new 340B program requirement that mandates a certain level of charity care?**

From 2012 to 2016, Northside provided almost \$1.4 billion in indigent and charity care, and the number of patients receiving free or discounted care at Northside Atlanta increased approximately 350 percent over this same time period. Northside supports the 340B Program requirement which requires hospitals to serve a disproportionate share of low income patients as a precondition to participation in the 340B Program, and does not see a need to change this requirement. Northside's disproportionate share adjustment percentage substantially exceeds the statutory minimum of 11.75 percent. 42 U.S.C. § 256b(a)(4)(L).

8. **Would you support new mandatory reporting/tracking requirements for 340B hospitals to achieve more consistency with respect to program savings?**

Northside would support any reporting or tracking requirements that further the goals of the 340B Program.

QUESTION FROM REPRESENTATIVE BROOKS –

What is the “facility fee” at a provider-based clinic?

Before 2014, hospitals would assign clinic visits to one of ten HCPCS codes (99201 to 99205 and 99211 to 99215) for the facility component. Each code was designed to match the resources required for the visit. The resulting facility fee ranged from approximately \$57 to \$176 per visit. Beginning in 2014, codes for hospital outpatient clinic visits collapsed into a single new HCPCS code (G0463). The new G0463 code has a fixed payment rate for the facility component. Medicare currently pays Northside \$79.67 for this code regardless of the hospital system's resources required.

QUESTION FROM REPRESENTATIVE GRIFFITH –

What percentage of your 340B drugs are opioids and what steps do you take to prevent diversion?

In 2016, 3.4 percent of the 340B drugs purchased by Northside were opioids. Northside employs external as well as internal resources to combat potential abuse by both patients and employees. Northside participates in Georgia's Prescription Drug Monitoring Program, an electronic database designed for monitoring the prescribing and dispensing of controlled substances. With this resource, Northside is able to track the type and quantity of prescription drugs used by Northside's patients and detect and address any concerns. Because this database only covers insured patients, Northside uses additional tracking measures to ensure that potential concerns in both insured patients and self-pay patients are addressed. Specifically, Northside internally monitors its patients to ensure that issues such as early requests for refills or any possible "doctor shopping" for prescriptions are handled appropriately.

In accordance with state and federal law, only licensed personnel have access to controlled substances. In addition to training and education, Northside maintains an internal monitoring process for any employee who accesses or administers these drugs.

* * *

Northside appreciates this opportunity to provide this information to the Committee and Subcommittee.

Sincerely,



Shannon A. Banna
Director of Finance and System Controller
340B Steering Committee Member
Northside Hospital, Inc.
1000 Johnson Ferry Road, N.E.
Atlanta, GA 30342

cc: The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette, Ranking Member
Committee on Oversight and Investigations

Jorge J. Hernandez, Vice President of Administration and Chief Compliance Officer
Northside Hospital, Inc.

Attachment 1

Number of sites operated by Northside in the Atlanta MSA:

County	Number of sites
Barrow	1
Bartow	2
Carroll	1
Cherokee	12
Clayton	3
Cobb	15
Coweta	1
Dawson	3
DeKalb	10
Douglas	3
Fayette	3
Forsyth	15
Fulton	41
Gwinnett	22
Henry	4
Paulding	2
Pickens	3
Rockdale	3
Spalding	2
Total	146