

**PERSPECTIVES ON THE 340B
DRUG PRICING PROGRAM**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING PERSPECTIVES ON THE 340B DRUG DISCOUNT PROGRAM

MARCH 15, 2018

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PERSPECTIVES ON THE 340B DRUG PRICING PROGRAM

Thursday, March 15, 2018

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, presiding.

Present: Senators Alexander [presiding], Isakson, Cassidy, Young, Roberts, Murray, Casey, Bennet, Baldwin, Murphy, Warren, Kaine, Hassan, Smith, and Jones.

The CHAIRMAN. The hearing will come to order.

Senator Murray has an important engagement that she needs to go to.

We are going to explore today the 340B Program. We welcome our witnesses.

I have asked Senator Murray if she will make her opening statement first, and then I will make mine. Then we will hear from the witnesses, and then as Senators come and go, we will have 5 minutes. We will have rounds of questions.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Mr. Chairman, thank you very much for that accommodation. I really appreciate it.

Thank you to all of our witnesses who have come today to talk about the 340B Program, which has helped a lot of our hospitals and health centers stretch their resources and serve their communities.

Today's hearing is very important and long overdue. For over a quarter of a century, the 340B Program has been a critical safety net for health providers that bear the burden of caring for some of our patients and communities with the greatest needs and fewest resources.

The 340B Program was started in 1992 with a simple goal: to stretch scarce Federal resources to provide more comprehensive services to vulnerable populations.

The way it works is equally simple: it requires pharmaceutical companies to make drugs more affordable for certain health providers serving vulnerable populations and low income patients. Those savings can help those providers stretch their resources even further.

Like at St. Mary Medical Center in Walla Walla, Washington. In 2016, 2 out of every 5 patients they saw were on Medicare; another 1 in 5 was either on Medicaid or uninsured. 340B savings helped that hospital support basic school-based health clinics for at-risk elementary and high school students, run a drive-through flu clinic to provide free vaccines to hundreds of low income families, and provide low cost or free medications.

At Sacred Heart Medical Center and Children's Hospital in Spokane, one-third of their 2016 patients were on Medicare, another third on Medicaid or uninsured.

When one of their elderly patients did not know how he could afford a \$400 medicine, 340B savings helped the hospital charge only \$80, one-fifth of the cost; that is a price he could manage. He is not the only one. Sacred Heart gives away as much as \$55 million a year in free and discounted care.

You can also see 340B at work at the University of Washington, which has used 340B savings to stretch its reach with innovative initiatives, like the University's tele-pain program, which is combating the opioid epidemic through innovative audio and video conferencing support for providers treating rural patients who struggle to manage chronic pain. This program does not just work in Washington. Participants cover Wyoming, Montana, Oregon, Idaho, and beyond.

The University also runs the Third Avenue Center, which provides physical and mental healthcare to women who experience homelessness. The center is co-located at the YWCA Angeline's Women's Shelter, so that vulnerable women can access coordinated care in a safe environment.

These great programs are made possible by 340B savings, and they are just a few examples of how the 340B Program can be a great resource for doing good.

Of course, for us to ensure this Program does good, we have to ask whether it is implemented well, and we have to ask whether we can make it better.

Accountability and transparency are important to address concerns about whether entities are using the 340B savings appropriately, and whether pharmaceutical manufacturers are providing discounts fairly. We can, and should, provide accountability in a way that strengthens and preserves this Program.

Unfortunately, despite President Trump's repeated promises to tackle drug prices, when it comes to the 340B Program—which actually helps reduce drug costs—his record shows only broken promises and backward steps. Like when he sabotaged an attempt to make sure drug companies play by the rules.

When Congress passed the Affordable Care Act, we gave the Health Resources and Services Administration, HRSA, new tools to keep the 340B Program accountable.

HRSA has taken steps to provide greater education and conduct more audits to prevent hospitals and providers from taking advantage of the system. After the HHS Inspector General found many drug companies were overcharging, HRSA finally drafted a rule to make sure drug companies were actually giving the full discounts required.

However, President Trump continues to delay that rule designed to hold drug companies accountable for overcharging. And President Trump took another enormous step backward when his Administration implemented a significant cut to the 340B Program.

The Centers for Medicare and Medicaid Services has traditionally reimbursed 340B eligible hospitals for drugs at the same rate as all other hospitals. However, this year, they are making unnecessary cuts and paying less than 80 percent of market price, reducing the ability of 340B providers to offer the outstanding services patients and families count on.

Skyrocketing drug prices are a dire problem and they deserve our urgent attention and serious solutions. Needless to say, rolling back rules to prevent overcharging from drug companies, and cutting back programs that help make drugs more affordable, is not going to get the job done.

The cost of 340B discounts to the pharmaceutical industry is about 1 percent of the total U.S. drug market. That is by no measure a big dent. It is a single penny out of every dollar. But that small penny, that small percent, can make a big difference.

It can make a difference to the low-income patients and communities who could not otherwise afford the treatment they need.

It can make a difference to the hospitals and health centers who could not otherwise stretch their resources far enough to care for these communities.

I really appreciate all of our witnesses who are here today to talk about how we can make sure this 340B Program is accountable enough to fulfill its intent and strong enough to continue serving our communities for generations to come.

Thank you very much, Mr. Chairman, for accommodating me. My staff is here. I will submit my questions for the record.

We have other Senators here as well, again we appreciate all of your contributions.

The CHAIRMAN. Thank you, Senator Murray.

I know you have an important engagement I appreciate your extra effort in being here early.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The 340B Drug Pricing Program was created by Congress in 1992 to help qualifying hospitals and clinics that treat low-income patients.

The program requires drug manufacturers that participate in Medicaid to provide discounts on prescription drugs or treatments, including treatments for cancer, diabetes, or HIV to qualifying hospitals and clinics.

The hospitals and clinics may then provide the drugs at the reduced price to low-income patients. Or they can sell the drugs at a higher price to patients who have insurance and keep that money and use it to provide care to low-income patients or for other purposes.

According to the Government Accountability Office, approximately 40 percent of all hospitals in the United States participate in the 340B Program. In just the last 5 years, the number of hospitals and treatment sites participating in the 340B Program has nearly doubled to almost 38,000 in 2017.

Today's hearing will focus on two things:

First, what is the purpose of the 340B Program and is it fulfilling that purpose?

Second, should there be changes in the law so that the Program can fulfill its purpose?

First, we need a better understanding of that purpose, and why the 340B Program exists, and how it is being used.

Today, there is confusion about that. Confusion about the program's goals and requirements because Congress did not make clear in the 1992 law creating it what the purpose of the Program actually is.

The closest the law came to defining the purpose is a House of Representatives' report, to which Senator Murray referred, which accompanies the legislative text, and which says the program was created, "To permit covered entities to stretch scarce Federal dollars as far as possible, reaching more eligible patients and providing more comprehensive services."

This has usually meant helping low-income patients afford their medications and healthcare, and to ensure that qualifying health centers can provide care to their most vulnerable patients.

Here is an example of 340B in practice from Saint Thomas Hickman Hospital in Hickman County, Tennessee. The hospital participates in the 340B Program.

A Hickman County resident with diabetes was unable to afford the \$332 cost of insulin, and went into a diabetic coma. He was told about the 340B Program at Saint Thomas Hickman, and was able to buy the insulin for \$8.90.

According to Saint Thomas Hickman, the 340B Program has also helped the hospital expand mental healthcare services and reduce emergency room visits.

The Health Resources and Services Administration, the Health and Human Services agency that oversees the Program, estimates that hospitals and clinics purchased \$12 billion of discounted prescription drugs through the 340B Program in the year 2015.

The House Energy and Commerce Committee has estimated that just a year later, in 2016, the 340B hospitals and clinics spent more than \$16 billion on discounted drug purchases, up from \$12 billion; a 30 percent increase.

340B hospitals saved about \$6 billion in 2015, according to those figures, by buying prescription drugs at a discount. That \$6 billion represents about 1.3 percent of the total purchases of prescription drugs in the United States in 2015.

In other words, about 1.3 percent of the total amount spent on prescription drugs in the United States is devoted to the hospitals and clinics that qualify for the 340B Program.

Hospitals will point out that, according to the Department of Health and Human Services, hospitals spent more than \$50 billion in 2013 on uncompensated care; that is, services to patients that are not reimbursed.

Hospitals and clinics use the \$6 billion in savings that they generate through the 340B Program to help offset the money they spend in uncompensated care.

On the other hand, we also know there are instances where 340B hospitals and clinics may not be using the savings directly to help low-income patients afford their medications or provide care.

There is no limit in the statute that says what hospitals may or may not spend the money on.

Some have criticized this, such as Dr. Rena Conti from the University of Chicago and Dr. Peter Back from Memorial Sloan-Kettering who have found that, “The 340B Program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics.”

This is why there have been reports—including from the Health and Human Services Office of the Inspector General, the Government Accountability Office, the National Academies, and the House Energy and Commerce Committee—that suggest that while the 340B Program does provide real benefits, there needs to be more clarity around what the program allows and does not allow.

For example, one 2011 report by the Government Accountability Office recommended increased oversight of the Program and that the Health Resources and Services Administration, or HRSA, issue and finalize guidance on the definition of a 340B patient.

Last year, the National Academies recommended more oversight and regulation to ensure that the program directly benefits patients.

I hope today we can learn more about the Program, and how it might be improved so hospitals and clinics can continue to provide low-income patients with help to afford their health care.

Now, I would like to ask the four of you if you could summarize your comments in about 5 minutes. It will then allow more time for questions and conversation with Senators.

First, we will hear from Bruce Siegel, the President and Chief Executive Officer of America’s Essential Hospitals. Dr. Siegel leads AEH, a trade association that represents more than 300 safety net hospitals and health systems.

Second, we will hear from Lori Reilly, the Executive Vice President of Policy, Research, and Membership at PhRMA, the Pharmaceutical Research and Manufacturers of America. Ms. Reilly leads the Policy and Research Department at PhRMA, a trade association of brand drug manufacturers.

Third, we will hear from Sue Veer, President and Chief Executive Officer of Carolina Health Centers, Inc. Ms. Veer leads Carolina Health Centers, which serves as the medical home for over 27,000 patients in the State of South Carolina.

Finally, we will hear from Joseph Hill, the Director of the Government Relations Division for the American Society of Health-System Pharmacists. Mr. Hill leads the Government Relations Division for that trade association that represents 45,000 member pharmacists, student pharmacists, and primary technicians.

We welcome, again, all of our witnesses.

Dr. Siegel, let us begin with you. Welcome.

STATEMENT OF BRUCE SIEGEL, M.D., MPH, PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICA’S ESSENTIAL HOSPITALS, WASHINGTON, DC

Dr. SIEGEL. Thank you.

Chairman Alexander, Ranking Member Murray, and honorable Members of the Committee.

Thank you for the opportunity to speak today about how the 340B Program supports our hospitals, and the many people and communities they serve.

My name is Dr. Bruce Siegel, President and CEO of America's Essential Hospitals. We represent 325 hospitals and health systems that form the backbone of the Nation's healthcare safety net.

Our members are public and nonprofit hospitals across the Nation from the Appalachian foothills of Tennessee, to Center City Philadelphia, to the Louisiana bayou, to Utah's Great Salt Lake. They are the trauma centers, and burn units, and neighborhood clinics for these and hundreds of other communities.

Our hospitals are diverse, but they share one defining mission: to care for all people regardless of social, financial, or health status.

Hospitals with this mission are precisely those Congress targeted when it created 340B more than 25 years ago. Congress' intent was explicit and clear: to protect hospitals from runaway drug prices.

What was a problem then, remains a problem today. Remember that 340B grew from an urgent need for action when drug prices surged as manufacturers reacted to Medicaid's Rebate program.

We are no less at-risk now than we were then. Skyrocketing drug costs threaten our hospitals and patients, and the 340B Program is still our best defense against high drug prices.

Our hospitals care for the poorest and most complex patients. About half of their patients are uninsured or Medicaid beneficiaries. These are people who face daunting barriers to good health and to healthcare access in communities where 4.6 million families live below the poverty line. They struggle with food insecurity, homelessness, and other social challenges.

Meeting this mission means our hospitals operate with thin margins. Many barely break even and in some States—Colorado, Indiana, Louisiana, Utah, Washington and others—they operate at a loss.

Our average member hospital provides \$61 million a year in uncompensated care, more than 8 times that of other hospitals. You can see why our hospitals depend on 340B savings.

How they use those savings reflects another clearly stated congressional goal for 340B: to stretch scarce resources and provide more comprehensive services. Our hospitals stay true to this mission. Here are some examples.

Medication adherence programs for cancer and HIV patients at Boston Medical Center; medical homes for the uninsured at VCU Health in Richmond, Virginia; oncology and stroke services for underserved at Erlanger Medical Center in Chattanooga; AIDS drug assistance at the University of Utah; treatment for cancer patients at East Alabama Medical Center; home infusion therapy at the University of Kentucky HealthCare; home health dialysis at the University of Virginia; and medication therapy management at Hennepin County Medical Center in Minneapolis.

We would be happy to share other examples with the Committee.

Our hospitals take stewardship of the 340B Program seriously because their patients and communities depend on it. They comply

with rigorous Program audits, including significant data requests, and also address concerns.

Since 2012, HRSA has conducted more than 800 audits of 340B providers mostly hospitals. Yet, the agency has conducted only 11 audits of drug makers since manufacturer audits began in 2015, and the agency has not shared its protocol for those audits.

Because 340B supports hospitals with manufacturer discounts—not with Government spending—it saves taxpayer dollars. In fact, any limit on 340B access would leave local, state, and Federal Governments on the hook for a larger share of uncompensated care costs.

We need 340B today as much as we needed it in 1992 and for the same reason: high and rising drug prices. Consider this: our hospitals cannot dictate to Medicaid how much the program will pay for their services. But one 340B stakeholder can, and does, dictate its prices and no amount of misdirection from the drug industry will change that simple fact.

We stand ready to work with this Committee, and other policy-makers, to preserve and strengthen the 340B Program without restricting its support for hospitals that serve our most vulnerable patients.

Thank you.

[The prepared statement of Dr. Siegel follows:]

PREPARED STATEMENT OF BRUCE SIEGEL

Chairman Alexander, Ranking Member Murray, and honorable Members of the Committee, thank you for the opportunity to speak today about how the 340B Drug Pricing Program helps low-income patients and their hospitals—and how we can work together to strengthen this vital program.

My name is Dr. Bruce Siegel, president and CEO of America's Essential Hospitals. We are an association of 325 hospitals and health systems that form the backbone of the Nation's health care safety net. Essential hospitals care for millions of people in every corner of our country—from the largest cities to broad regions of urban, suburban, and rural communities. In fact, one in 10 U.S. residents are born at an essential hospital.¹ Essential hospitals are diverse: large academic medical centers with statewide or regional scope and unique specialty services, multi hospital systems with extensive outpatient networks, and city and county public hospitals that anchor communities.

But underlying this diversity is a shared and defining mission: to provide care to all people, regardless of social, financial, or health status.

It was precisely for hospitals with this mission that Congress created the 340B program more than 25 years ago. The historical record is clear: The legislative authors of this program were explicit in their language and unequivocal about their intention to protect hospitals of the safety net from the existential threat of unsustainable drug costs.

To understand our ardent support for the 340B program, you first must understand the patients and communities our hospitals serve. About half of our hospitals' patients are uninsured or Medicaid beneficiaries.² Nearly half of essential hospitals' discharges in 2015 were for racial and ethnic minorities.³ On average, each of our member hospitals cares for more than 17,000 inpatients annually, more than 67,000 emergency department (ED) patients, and more than 350,000 outpatients.⁴ In states represented by HELP Committee Members, our hospitals saw 1.3 million inpatient discharges, 4.9 million ED visits, and 28 million non-emergency outpatient visits in 2016. In the context of 340B, it is important to note hospital outpatient clinic patients are nearly four times as likely as those treated at physician offices to be Med-

¹ Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. www.essentialdata.info. Accessed March 12, 2018.

² *Ibid.*, 11.

³ *Ibid.*, 10.

⁴ *Ibid.*, 18.

icaid, self-pay, or charity care patients, and almost twice as likely to live in high-poverty communities.⁵

The communities our hospitals serve are no less disadvantaged. They are home to an estimated 4.6 million families living below the Federal poverty line and more than 21.5 million individuals without health insurance.⁶ Social determinants of poor health also loom large: Federal data show essential hospitals serve communities where more than 275,000 individuals struggle with homelessness and 8.5 million people have only limited access to healthful food.⁷

Essential hospitals work diligently not only to care for patients who face financial hardships, but also to help everyone in the community overcome social and economic factors that contribute to poor health. For example, they provide medical respite programs for the homeless and, for those living in hunger, food pantries, community gardens, and meal delivery services. Typically, they do these things on their own dime.

This dedication to mission and to reaching beyond their walls requires essential hospitals to commit resources always in short supply. Our hospitals operate with a margin of only 3.2 percent, less than half that of other U.S. hospitals.⁸ Many barely break even, and in many states—Colorado, Indiana, Louisiana, Utah, and Washington, for example—they operate at a loss. Our 325 hospitals represent only about 6 percent of all U.S. hospitals but bear nearly 17 percent, or about \$6 billion, of the Nation’s uncompensated care.⁹ Our average member sustains about \$61 million annually in uncompensated care—more than eight times that of other U.S. hospitals.¹⁰

Wide gaps often exist between those average uncompensated care costs and 340B savings at these hospitals. In Tennessee, for example, Regional One Health, in Memphis, reports uncompensated care costs eight times greater than its 340B savings. Grady Health System, in Atlanta, reported more than \$174 million in unreimbursed and uncompensated costs in 2015, more than four times its 340B savings. These gaps between uncompensated costs and 340B savings are not atypical, and collectively provide one example of how essential hospitals more than meet their responsibility to vulnerable patients as good stewards of the 340B program.

With these numbers in mind, it is not surprising our hospitals and the patients and communities they serve depend on every available source of support. These hospitals rely on a patchwork of Federal, state, and local support, and losing any piece puts the whole at risk. The savings our members achieve through the 340B Drug Pricing Program is a key piece of that patchwork. The program is vitally important not only to providing vulnerable patients with affordable drugs, but to sustaining the many comprehensive services on which these people and their communities depend.

Congress envisioned 340B as supporting this broader mission, and lawmakers explicitly stated this as their intention for the program. In the 1992 House report that accompanied legislation establishing the 340B program, they wrote, “In giving these ‘covered entities’ access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and *providing more comprehensive services.*”

I added emphasis to those last words to underscore a critical point: Congress designed the 340B program to do more than reduce drug costs for entities serving low-income patients. Lawmakers also intended for it to support a variety of *comprehensive services* consistent with the mission of safety-net providers, such as essential hospitals, and that our members provide daily.

We have few tools as effective as 340B for countering high drug prices. And we have no tools as cost-effective as 340B for the Federal Government and taxpayers: Support to hospitals comes from manufacturer discounts, not taxpayer dollars. In fact, restricting 340B likely would leave state and local governments picking up the tab for uncompensated care, or necessitate further Federal investments.

⁵ Comparison of Cancer Patients Treated in Hospital Outpatient Departments and Physician Offices. KNG Health Consulting, LLC. November 2014.

⁶ Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America’s Essential Hospitals 2015 Annual Member Characteristics Survey. America’s Essential Hospitals. June 2017. www.essentialdata.info. Accessed March 12, 2018.

⁷ *Ibid.*, 12.

⁸ *Ibid.*, 15.

⁹ *Ibid.*, 14.

¹⁰ *Ibid.*

How Essential Hospitals Use 340B Savings for Vulnerable Patients

Our hospitals' work to care for low-income patients and provide entire communities with high-intensity, lifesaving services—trauma care, burn units, disaster response, and others—reflects Congress' vision for the 340B program. The list of comprehensive services made possible by 340B savings is long: free clinics and community programs for primary and chronic condition care; cancer and transplant care, including costly chemotherapy and anti-rejection drugs; medical respite care for the homeless and case management for underserved patients; training for rural hospital partners in high-risk labor and delivery and other specialized care.

Not only do 340B savings support more services, they result in better care and better care outcomes. Boston Medical Center (BMC) fills more than 1 million prescriptions annually at its pharmacies, with three-quarters provided through the 340B program. The hospital's 340B savings support its successful Specialty Pharmacy Program for more than 1,000 cancer, HIV, and other patients. Patients enrolled in this and other BMC programs reliably have medications in hand thanks to 340B—95 percent receive their medication compared with only 40 percent community-wide.

Particularly impressive are the improvements to access and outcomes for the hospital's cancer and HIV patients due to 340B. BMC has decreased the time it takes patients to get cancer drugs from an average of 11 days using outside pharmacies to the same day, using the hospital's 340B-supported pharmacy. Medication adherence has improved significantly, too, through use of the hospital's pharmacy: More than 90 percent of oncology and HIV patients have and take their medications compared with previous rates of 50 percent to 70 percent. Better health outcomes have followed, such as those for patients with hepatitis C. Patients who complete hepatitis C therapy have nearly a 100 percent chance of full recovery, and 340B has driven therapy compliance from a community-wide average of 60 percent to 99 percent at BMC.

Our hospitals across the country have similar patient stories of better access to care, better health, and cost savings through their participation in the 340B program, including these examples:

East Alabama Medical Center (EAMC), Opelika, Alabama—At EAMC, a patient mix that includes a high number of uninsured and Medicaid patients contributed to \$50 million in uncompensated care costs in 2016. Although falling well short of covering this gap, the 340B savings the hospital achieved—\$10 million that same year—helped EAMC make cancer treatment available to indigent, uninsured, and underinsured patients.

Hennepin County Medical Center (HCMC), Minneapolis—HCMC admitted a homeless, uninsured man nine times over 4 months at a cost of \$225,000, or more than \$56,000 a month. Pharmacists in a hospital medication therapy management program made possible by 340B savings taught the man how and when to take his medications. After regular clinic visits and improved care management, his medical expenses dropped to \$36,000—\$4,000 a month—in just 9 months.

UK HealthCare, Lexington, Kentucky—UK HealthCare's 340B savings allow the health system to maintain dedicated pharmacy staff to help indigent, self-pay, and underinsured patients receive needed medications through copayment assistance and other financial support programs. The system, which lacks its own home infusion pharmacy, extends care through a contract home infusion pharmacy with the help of the 340B program.

Erlanger Health System, Chattanooga, Tennessee—Without its 340B savings—\$9 million in 2014, or about a tenth of its \$92 million in uncompensated care costs—Erlanger could not have provided some trauma, oncology, and stroke services programs to underserved patients. The health system's 340B savings also fully fund a pharmacy at its Dodson Avenue Community Health Center, which offers face-to-face counseling on medication therapy, adherence, and chronic disease management.

University of Utah Health Care, Salt Lake City, Utah—With its 340B savings, University of Utah Health Care provides an AIDS drug assistance program in which patients receive drugs at cost plus a minor fee. It also partners with rural hospitals to help them successfully care for patients with peripherally inserted central catheter lines or with high-risk pregnancies, increasing capacity for emergency and critical care and improving operating room procedures. This keeps patients in their communities and avoids costly transfers to other hospitals.

University of Virginia (UVA) Health System, Charlottesville, Virginia—UVA Health System has one of the highest case mixes in the United States, evidence that it cares for many of the sickest patients. It also provides more than \$250 million in uncompensated care annually. The health system's 340B savings are vital

to maintaining specialty services, such as home health and dialysis, and access to specialized pharmacy services for patients at high-risk of readmission.

VCU Health, Richmond, Virginia—Savings from the 340B program made possible the VCU Health Virginia Coordinated Care program, which contracts with primary care providers to offer a medical home for 23,000 low-income, uninsured people. The program has lowered ED use and costs and made medications available to the 80 percent of outpatients who otherwise lack prescription drug coverage.

Essential Hospitals as Good Stewards of 340B

Since its inception, the 340B program has incorporated rigorous requirements for how hospitals and other covered entities qualify for and use the program. Rules implementing the program control how hospitals procure and dispense 340B drugs, maintain 340B drug inventories, ensure only eligible patients receive discounted drugs, and avoid duplicate discounts through the Medicaid Drug Rebate Program.

The program also has adequate safeguards to prevent hospitals from diverting 340B drugs to ineligible patients and to ensure they make appropriate contractual arrangements with outside pharmacies to extend the reach of 340B discounts to more vulnerable patients and underserved communities.

In short, the 340B program is subject to substantial oversight and monitoring. The Health Resources and Services Administration (HRSA), the Federal agency that oversees the program, conducts regular audits of hospitals and other covered entities to ensure compliance with program requirements. HRSA employs a comprehensive audit process, with pre-audit, onsite, and post-audit phases, an evolving notice and hearing process for findings, and a corrective action plan and repayment component. Since it began auditing covered entities in 2012, HRSA has conducted 825 audits, mostly of hospitals. Audit reports, including the agency's findings and corrective actions by covered entities, are publicly available on the HRSA website.

By contrast, HRSA has conducted only 11 manufacturer audits since 2012, the first year the agency began actively checking drug maker compliance. This stark disparity suggests a need for more work to bring parity to the audit process and protect hospital and their patients from overcharges and inappropriately denied discounts.

Our member hospitals and health systems undergo HRSA audits regularly to ensure their compliance with 340B program rules, and they provide substantial data and respond to many questions as part of these audits. When auditors find problems, essential hospitals diligently correct shortcomings in their programs and, if warranted, return savings to manufacturers. Our members work daily to be good stewards of the 340B program because they know their patients and communities depend on it.

340B: Necessary in 1992, Necessary Today

The 340B program grew from an urgent need for action after manufacturers responded to the Medicaid Drug Rebate Program with changes in discounting practices that caused drug prices to surge nationally. We are no less at risk today of unsustainable drug costs, and the 340B program remains our best hedge against high prices.

Again, stories from our hospitals illustrate the point. Without the 340B program, a UVA Health System patient with diabetes, hypertension, high cholesterol, and heart disease could not afford the high cost of insulin and 11 other medications necessary to treat the patient's chronic illnesses—medications that otherwise would cost \$24,000 a year, or well more than double the patient's annual income.

It is unfortunate that stories like this are more the rule than the exception at our hospitals. The patients our hospitals serve are those least able to afford the crushing cost of prescription medications and physician-administered drugs, especially those with cancer and other devastating diagnoses. Restricting access to affordable drugs through the 340B program would irrevocably harm care, destabilize hospitals on which millions of Americans rely, and put patients at risk—maybe gravely so.

America's Essential Hospitals and its members thank the Committee for its interest in ensuring program integrity and transparency for the 340B Drug Pricing Program. We share those goals and stand ready to work with this Committee and all stakeholders to strengthen the 340B program without restricting access to it by hospitals that care for our most vulnerable patients.

Thank you.

[SUMMARY STATEMENT OF BRUCE SIEGEL]

America's Essential Hospitals represents 325 hospitals and health systems that form the backbone of our Nation's health care safety net. They serve communities of all sizes and include nonprofit health systems of every stripe—from city and county public hospitals to major teaching institutions. But they share a defining mission: to care for all people, regardless of social, financial, or health status. This mission is reflected in essential hospitals' patients, who are poorer, sicker, and more complex than those at other hospitals. The communities these hospitals serve, where social and economic hardships challenge health and access to care, also reflect this mission.

It was for hospitals with this mission that Congress created the 340B Drug Pricing Program more than 25 years ago. The historical record of 340B is clear: Lawmakers intended to protect the safety net and its hospitals from the existential threat of runaway drug prices. The 340B program was Congress' answer to surging drug prices caused by manufacturer discounting practices in reaction to Medicaid drug rebates. We are no less at risk today than we were then of unsustainable drug costs and rising prices threatening our hospitals and their patients. The 340B program is as necessary today as it was in 1992.

Essential hospitals' commitment to serving the Nation's most vulnerable patients comes with severe demands on resources. The average essential hospital operates with a margin less than half that of other U.S. hospitals and sustains about \$61 million annually in uncompensated care, more than eight times that of other hospitals. So, it is no surprise these hospitals depend on 340B savings as part of a patchwork of support they need to meet their mission.

Essential hospitals use their 340B savings consistent with Congress' intent that the program help hospitals "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Our hospitals do this by providing affordable drugs and many comprehensive services made possible by 340B savings, including free clinics and community programs for primary and chronic condition care; cancer and transplant care; medical respite care for the homeless and case management for underserved patients; and many other valuable programs. Hand in hand with this service, our hospitals work to protect 340B program integrity, routinely complying with rigorous program audits and correcting shortcomings. Our members strive to be good stewards of the 340B program because they know their patients and communities depend on it.

We have few tools as effective as 340B for countering high drug prices, and no other tools as cost-efficient: 340B support comes from manufacturer discounts, not taxpayer dollars. In fact, restricting 340B likely would leave state and local governments picking up the tab for uncompensated care, or necessitate further Federal investments. We look forward to working with lawmakers and all stakeholders to strengthen and preserve the 340B program.

The CHAIRMAN. Thank you very much.
Ms. Reilly, welcome.

STATEMENT OF LORI M. REILLY, EXECUTIVE VICE PRESIDENT, POLICY, RESEARCH, AND MEMBERSHIP, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WASHINGTON, DC

Ms. REILLY. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee for inviting me to participate in today's hearing.

I want to be clear from the outset that PhRMA, and its member companies, are supportive of the 340B Program and we are proud of the discounts that we provide to community health centers, Ryan White Clinics, and other grantees that are good stewards of this Program and are essential to America's safety net.

At the same time, we believe this program in its current form and, in particular, its nearly unregulated use by DSH hospitals is deeply flawed and in need of reform.

The 340B Program began over 25 years ago to address an unintended consequence of the Medicaid Rebate statute. As a condition of participating in Medicaid, pharmaceutical companies are obligated to provide discounts that average around 50 percent to entities that participate in 340B.

In recent years, the Program has experienced explosive growth and now constitutes 8 percent of all branded prescriptions in this country. And when you consider certain classes of medicine, for example, breast cancer medicine, it is about 33 percent of all sales in this country.

While growth of the Program alone may not be concerning, it becomes alarming when you couple it with a growing body of evidence that demonstrates this Program has become a market-distorting Program that is raising costs for patients and the entire healthcare system, including the Government.

Here is why you should care.

First, under this Program, there is absolutely no obligation that hospitals use the revenue they derive from this Program and share those discounts back with patients no matter how indigent those patients may be.

340B hospitals can, and often do, charge uninsured patients the full list price, or sticker price, for a medicine even after receiving 340B discounts.

Not only is there no requirement to share and pass along those 340B discounts to patients, research shows that hospitals mark up medicines, on average, 500 percent and are reimbursed two-and-a-half times what they buy those medicines for.

While some advocates argue that 340B hospitals provide a disproportionate share of uncompensated care, the data show that just 25 percent of 340B hospitals are providing 80 percent of all charity care that is being provided. And 64 percent of 340B hospitals are providing below average charity care relative to the national average.

Second, the current structure of the 340B Program is leading hospitals to use more medicines and more expensive medicines compared to non-340B hospitals.

The GAO and research published in the "New England Journal of Medicine" found that hospitals in the 340B Program are using more expensive medicines and more medicines without differences in uncompensated care or quality.

While the Administration took an important step to address these incentives in Part B in its recent Hospital Outpatient Prospective Payment Rule, those changes only apply to drugs paid for in Medicare Part B and not in the commercial market. In fact, it only represents about 13 percent of profit margins in the 340B Program.

Yesterday, Milliman released a study that mimicked the GAO study, but instead of looking at Medicare claims, looked at commercial claims and found that in 340B hospitals, per capita spending on drugs is three times higher for patients in 340B versus non-340B hospitals. These incentives lead to higher costs for patients and higher costs for the Government and the broader healthcare system.

Third, 340B is providing greater provider consolidation, which also increases costs for everyone. DSH hospitals have strong incentives to purchase off campus physician clinics because every time they do, those prescriptions automatically become eligible for discounts that average 50 percent. But once a clinic is acquired by a hospital, costs go up, not down for patients in the healthcare system.

Drugs for patients with cancer and autoimmune diseases are twice as high in the hospital setting relative to the physician office, according to a study by Magellan Health. As a result, economists believe 340B's perverse incentives are accelerating consolidation and purchasing of community clinics by 340B hospitals.

Change is clearly needed in this Program.

Given the evidence that this Program is driving up healthcare costs, and is not required to directly benefit patients, updated standards focused on DSH hospitals are necessary to ensure that patients, and that those providers that are providing care for true safety net patients, are helped.

We believe there are five key areas of reform that Congress should be focused on, and my testimony goes into great detail about the changes that we believe are necessary to things like the patient definition, eligibility criteria for DSH hospitals and the "child sites" they acquire, as well as contract pharmacies.

Last, but not least, we need greater accountability and reporting requirements. I applaud Senator Cassidy's leadership, that of Congressmen Bouchard and Peters, as well as Senator Grassley for the work they are doing in this regard.

Thank you, again, to the Committee for holding this hearing, and I look forward to your questions.

[The prepared statement of Ms. Reilly follows:]

PREPARED STATEMENT OF LORI M. REILLY

Chairman Alexander, Ranking Member Murray and Members of the Committee, thank you for inviting me to participate in today's hearing and thank you for devoting a full Committee hearing to the 340B program, which is an important topic that deserves attention from everyone concerned about rising health care costs.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the United States: Since 2000, PhRMA member companies have invested more than half a trillion dollars in the search for new treatments and cures, including \$65.5 billion in 2016 alone.

The 340B Program Plays a Critical Role in America's Safety Net

PhRMA and our member companies strongly support the 340B program and the important role it plays in our health care safety-net. The 340B program is particularly crucial to supporting the care provided by recipients of Health Resources and Services Administration (HRSA) grants (known as "grantees"). Grantees—including Community Health Centers, Ryan White clinics and hemophilia treatment centers—serve our Nation's most vulnerable patients, many of whom are often without other sources of care. These grantees are on the front lines of public health threats and represent a lifeline for many vulnerable patients—treating serious conditions like HIV, hemophilia and hepatitis C or providing lifesaving cancer screenings and other health services. The 340B program needs to be modified so that it is on a sustainable path and can continue to support grantees and other true safety-net providers. Any changes must seek to eliminate the growing abuses of recent years that distort markets and increase health costs without contributing to its safety-net mission.

I'm pleased to be testifying today with Carolina Health Centers, a community health center grantee. Community Health Centers (CHCs) serve as the primary medical home for more than 27 million people in 10,400 rural and urban communities across America.¹ The 340B discounts our member companies and other biopharmaceutical manufacturers provide to these health centers help CHCs deliver free and reduced cost medicines and other services to their patients. Consistent with the purpose of the 340B program, CHCs and other grantees typically serve a population heavily skewed to low-income or vulnerable patients.

We also want to recognize the important public health role of our Nation's public hospitals. Public hospitals play a crucial role as a source of care for those with nowhere else to turn. Often these are the hospitals providing high levels of charity care to low-income patients. Analysis of Medicare data shows that 24 percent of 340B disproportionate share hospitals (DSH) provide 80 percent of the charity care provided by all 340B DSH hospitals. That same small percentage of 340B DSH hospitals represent only 50 percent of total patient costs and 45 percent of total hospital beds in all 340B facilities, meaning that they are providing a disproportionately high level of charity care relative to their size.² Many of the hospitals that are shouldering this disproportionate burden are public hospitals. The 340B program was designed to help support this type of care.

When Congress created the 340B program a quarter of a century ago,³ it was intended to assist Federal grantees, like CHCs, and true safety-net hospitals serving large numbers of uninsured or otherwise vulnerable patients. Under the terms of the program, hospitals and safety-net clinics that meet certain eligibility criteria are entitled to discounts that average about 50 percent of the cost of outpatient prescription medicines.⁴ As a condition of participating in Medicaid, biopharmaceutical companies must also participate in the 340B program.⁵

A key distinction between grantees and hospitals is in their reporting requirements. Safety-net clinics must generally meet Federal requirements of reinvesting their revenue into care for uninsured or vulnerable patients as part of their grant requirements. In contrast, current 340B program rules lack any standards for how 340B discounts should be used by 340B hospitals or even how much hospitals can reap in profits by marking up prices charged to patients and payers when administering them medicines acquired at the discounted 340B price mandated by law (see Figure 1).

The lack of program standards for use of 340B discounts by DSH hospitals, combined with the significant growth of the program driven by these hospitals, has greatly transformed the 340B program. It is no longer accurate to characterize the program as primarily focused on care for vulnerable patients by safety-net providers. Instead, 80 percent of the sales are to DSH hospitals and their child sites, more than two thirds of which provide below average levels of free and reduced cost treatments to uninsured or vulnerable patients.⁶ As a 2014 *Health Affairs* study on 340B put it, the program has evolved "from [a program] that serves vulnerable communities to one that enriches hospitals."⁷

¹ National Association of Community Health Centers, "About Our Health Centers," Available at: <http://www.nachc.org/about-our-health-centers/> (accessed March 11, 2018).

² Alliance for Integrity and Reform of 340B, "Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.

³ Public Law 102-585, Veterans Health Care Act of 1992.

⁴ Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Programs," June 2005.

⁵ 42 U.S.C. § 1396r-8(a)(1), (a)(5).

⁶ Alliance for Integrity and Reform of 340B, "Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.

⁷ R. Conti, P. Bach. "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities," *Health Affairs* 33, no. 10 (2014): 1786-1792.

Figure 1:



While grantees like CHCs rely on the 340B program to help them provide care to underserved or vulnerable populations, growing DSH hospital abuse of 340B drives up health care costs for others in the health care system. Economists publishing in *The New England Journal of Medicine*⁸ and *JAMA*,⁹ along with the Government Accountability Office (GAO),¹⁰ have concluded that 340B creates hospital incentives that increase costs for patients, insurers and the government, while reducing the viability of community-based physicians. For example, recent evidence points to the role of 340B in hospitals buying up community-based physicians in wealthy areas¹¹ and shifting care to the hospital outpatient setting where it is often more expensive.¹² At the same time, hospitals are also able to sharply mark-up the price of medicines accessed through 340B when treating privately insured patients at acquired clinics, with no obligation to reinvest those resources in safety-net services. In fact, a recent *New England Journal of Medicine* study reports DSH hospital eligibility was associated with lower proportions of low-income patients treated for the conditions studied and “no significant differences in hospital provision of safety-net or inpatient care for low-income groups. . .”¹³ In sharp contrast, evidence shows CHCs and other grantees are using the 340B program as intended due to the requirements of their HRSA grants.

There is a clear need for improvements to the 340B program to avoid abuses while sustaining its focus on strengthening the safety net. Improvements must reflect the critical role of grantees, who need continued access to the program without being burdened by new restrictions. At the same time, there is an urgent need to modernize the program to assure that patients benefit and to reduce the unintended distortion of markets and promotion of higher costs in the health care system that have emerged as the program has strayed from its intent.

⁸ S. Desai and J.M. McWilliams, “Consequences of the 340B Drug Pricing Program,” *N Engl J Med* 2018.

⁹ R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA: The Journal of the American Medical Association*, 2013;309(19):1995–1996. doi:10.1001/jama.2013.4156.

¹⁰ Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015.

¹¹ R. Conti and P. Bach, “The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities,” *Health Affairs*, Vol. 33, No. 10, October 2014; Avalere Health, “Hospital Acquisitions of Physician Practices and the 340B Program,” June 2015, available at: <http://avalere.com/expertise/life-sciences/insights/avalere-white-paper-hospital-acquisitions-of-physician-practices-and-the-34> (accessed March 11, 2018).

¹² P. Bach and R.H. Jain, “Physician’s Office and Hospital Outpatient Setting in Oncology: It’s About Prices, Not Use,” *Journal of Oncology Practice* 2017 13:1, 4–5.; IMS Institute for Healthcare Informatics. Global Oncology Trend Report: A Review of 2015 and Outlook to 2020, June 2016.

¹³ S. Desai and J.M. McWilliams, “Consequences of the 340B Drug Pricing Program,” *N Engl J Med* 2018.

Today's 340B Program is Nearly Unrecognizable From the Program Congress Enacted in 1992; Changes Have Contributed to the Many Problems Now Associated With the Program

Congress enacted the 340B drug pricing program in 1992, as part of the Veterans' Health Care Act,¹⁴ in part to address the unintended consequences of the Medicaid rebate statute enacted in the Omnibus Budget Reconciliation Act (OBRA) of 1990.

As enacted in 1990, the Medicaid rebate statute required biopharmaceutical manufacturers to provide Medicaid with steep rebates to give State Medicaid programs the "best price" among most purchasers. Consequently, sales to clinics and hospitals previously receiving generous voluntary manufacturer discounts were suddenly required under the Medicaid rebate law to be included in manufacturer rebate calculations and potentially setting a new Medicaid "best price" that had to be offered to the entire Medicaid program. As described in the House Energy and Commerce Committee's 1992 report, the "best price" provision created a disincentive for manufacturers to offer lower prices to safety-net facilities, because that price could trigger higher Medicaid rebates nationwide. The report cites testimony and other information indicating loss of manufacturer discounts or special pricing practices at federally funded clinics and public hospitals after OBRA 1990.¹⁵

As a result, the 340B drug pricing program arose because of the Medicaid statute's unanticipated impact on safety-net facilities and helped ensure discounted medicines for specified covered entities.

Original intent of the program

Congress did not create the 340B program to benefit a random assortment of hospitals that might or might not serve as a safety net for low-income uninsured patients. Nor does it appear that Congress sees the program's purpose that way today. Some have suggested the 340B program was intended to benefit hospitals, with no regard for patients. In fact, the statute and its legislative history reflect an express congressional intent to create a program with a very important and targeted purpose. Meanwhile, the silence in the 340B legislative history about practices that have become common in the program today is noteworthy:

- There are *no* indications that 340B was expected to become a program dominated by DSH hospitals rather than focused on Federal grantees who operate in an entirely different manner, generally using 340B to provide care to uninsured or vulnerable patients as part of their grant requirements.
- There are *no* statements that the 340B program was designed to be a new and unaccountable revenue stream funding any spending a hospital selects.
- There is *no* indication that hospitals were expected to charge patients and their insurers markups equal to 200 percent or more above a medicine's discounted 340B acquisition price, or often fail to provide discounts to the people who need them.
- There is *no* suggestion that the program would grow to include hospital outpatient facilities in affluent communities or cover more than 60 percent of total Part B hospital drug purchases.¹⁶
- There is *no* suggestion that 340B was intended to drive utilization patterns and health system consolidation that increases the cost of health care for all patients and insurers.

PhRMA believes that the large discounts biopharmaceutical manufacturers provide under the 340B program should serve a targeted purpose—helping low-income uninsured and other vulnerable patients obtain the outpatient medicines they need—and true safety-net hospitals qualifying for the program should be accountable for using its benefits properly.

Medicaid expansion and growth in coverage for medicines has changed the environment

¹⁴ Public Law 102-585, Veterans Health Care Act of 1992.

¹⁵ H.R. Rep. 102-384, Pt. 2 (1992), pp. 9–11.

¹⁶ Alliance for Integrity and Reform of 340B, "340B Hospitals Vs. Non-340b Hospitals: Growth and Distribution of Physician-Administered Drug Reimbursement Across Ten Therapeutic Areas," Feb 2016, available at: <http://340breform.org/userfiles/02.02.16%20BRG%20340B%20Part%0B%20Fact%20Sheet.pdf> (accessed March 13, 2018).

Dramatic changes in health coverage in the quarter of a century since 340B was created mean the program is operating in a very different environment today. Some of these changes have contributed to the rampant growth in the program and raise questions about how the program is being used today. For example, Medicaid enrollment has increased from 29 million individuals in 1992 to more than 72 million individuals in 2016,¹⁷ and the share of the U.S. population on Medicaid has increased from 11 percent to 22 percent over that same period.¹⁸ This has contributed to a sharp increase in the number of hospitals eligible to participate in the 340B program because of the use of the DSH metric to determine DSH hospital eligibility for the program. While 340B is an outpatient-only program, the DSH metric looks at inpatient care. Consequently, more and more hospitals now qualify for 340B discounts as the proportion of inpatient stays covered by Medicaid increases. There is no indication in the legislative history of 340B that this significant expansion in Medicaid eligibility and enrollment and the resulting impact on 340B's size and character were foreseen when the program was created. Nor is there any indication in the 340B law's legislative history that Congress focused on the fact that the DSH metric would expand hospital 340B eligibility if individuals shifted from being uninsured to being covered through Medicaid, an anomalous result of the current formula.

Insurance coverage for prescription medicines has also changed dramatically in the last couple decades. In 1992, 57 percent of prescription medicine costs were paid out of pocket by patients, making it crucial that biopharmaceutical manufacturers could provide free and discounted medicines to safety-net facilities so that patients who could not afford the out-of-pocket costs could still obtain access to needed medicines.¹⁹ By 2016, 14 percent of costs were paid out of pocket by patients,²⁰ in part due to Medicare patients benefiting from the Part D program and medicines being recognized as integral to good health care. Even as coverage of medicines expanded, the 340B program has grown dramatically—sharply outpacing overall prescription drug sales.²¹ This growth has been fueled by DSH hospitals' use of the 340B program,²² including their ability to take advantage of increased prescription medicine coverage through markups on 340B medicines used by insured patients.

HRSA's choices in administering the program have fueled dramatic program growth

The 340B program has expanded well beyond congressional intent in part because of administrative actions by HRSA and lack of appropriate oversight in four key areas, leading to unintended consequences:

1. Patient definition;
2. Hospital eligibility;
3. Hospital-purchased outpatient sites (called "child sites"); and
4. Contract pharmacies

These administrative actions and the unwillingness to course-correct, coupled with changes in the health system, have contributed to a transformation in the 340B program. As previously noted, today's program is unrecognizable in size and character as compared to the program that was created in 1992. And it's unrecognizable in many of its current effects—for instance, promoting consolidation of services under hospital ownership and the accompanying higher costs.

The change in the 340B program's size and character are seen in the following points:

- It took 15 years after 340B's enactment (2007) for annual 340B sales to reach \$3.9 billion. Yet in the next 9 years, between 2007 and 2016, 340B

¹⁷ MACStats: Medicaid and CHOP-Data Book, "Section 2, Exhibit 10: Medicaid Enrollment and Total Spending Levels and Annual Growth, FYs 1966–2016," December 2017. Available at: <https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-10.-Medicaid-Enrollment-and-Total-Spending-Levels-and-Annual-Growth-FYs-1966%E2%80%932016.pdf>.

¹⁸ Analysis of MACStats: Medicaid and CHOP-Data Book, "Section 2, Exhibit 10: Medicaid Enrollment and Total Spending Levels and Annual Growth, FYs 1966–2016," December 2017 and Census Bureau Population estimates, July 1992 and 2016.

¹⁹ Analysis of National Health Expenditure Accounts data.

²⁰ Analysis of National Health Expenditure Accounts data.

²¹ A. Vandervelde and E. Blalock, "Measuring the Relative Size of the 340B Program: 2012–2017," Berkeley Research Group, July 2017.

²² Aaron Vandervelde and Eleanor Blalock, "340B Program Sales Forecast: 2016–2021," 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

sales grew more than fourfold to \$16.2 billion at the 340B price.²³ The Medicare Payment Advisory Commission's (MedPAC) May 2015 Report to Congress provides data showing that between 2005 and 2013, 340B sales grew seven times faster than total U.S. medicine spending.²⁴

- In 2004, more than a decade after enactment, Federal grantees accounted for 55 percent of 340B sales and hospitals accounted for 45 percent. By 2016, grantees' share of sales had dropped to just 13 percent while hospitals' share of 340B sales increased to 87 percent.²⁵ The clear majority of 340B sales to hospitals are to DSH hospitals, accounting for about 80 percent of 340B hospital sales.²⁶
- 340B purchases as a share of hospitals' total drug purchases (both inpatient and outpatient) inched above 10 percent in 2005, over a decade after the program began.²⁷ Over the next 11 years, 340B purchases as a share of hospitals' total drug purchases has consistently and steadily increased.²⁸
- Between 1994 and 2016, the number of child sites increased from 34 to over 15,000.²⁹ While some of that growth is due to changes in guidance from HRSA regarding how 340B child sites should register for 340B, there was dramatic growth in the program even before that guidance changed. For example, a *Health Affairs* study found that "in 2011 there were 16,500 340B entity sites that were affiliated with approximately 3,200 unique 340B entities. That is roughly double the number of sites reported in 2001."³⁰
- Between 2002 and 2017, the number of contract pharmacy arrangements increased from 279 to 51,963.³¹ Nearly 90 percent of the growth came after HRSA's 2010 subregulatory guidance authorizing unlimited contract pharmacy networks. In 2017, two-thirds of contract pharmacy locations were owned by one of just a few large pharmacy chains.³²

The 340B Program Creates Market Distorting Incentives That Increase Consumer Prices for Medicines, Shift Care to More Expensive Hospital Settings and Accelerate Provider Consolidation

The 340B program is distorting the health care market by leading to higher costs for patients and payers, according to economists and independent government auditors. The program has been growing at an alarming rate that is poised to continue, absent needed changes.³³ It is likely that 340B market distortions will have an expanding influence if the program is left unchecked. Several factors described below are contributing to these unintended consequences.

Distorting market prices for prescription medicines

In an analysis of prescription medicine pricing published in the *New England Journal of Medicine*, economists at Harvard and the University of Chicago identified the 340B program as one factor that was leading to higher prescription medicine prices. These economists concluded that "lawmakers could lower the price of prescription drugs by reforming the Federal 340B Drug Pricing Program. [. . .] The

²³ A. Fein, "EXCLUSIVE: The 340B Program Hits \$16.2 Billion in 2016; Now 5 percent of U.S. Drug Market," *Drug Channels Blog*, May 18, 2017.

²⁴ Analysis of data from *MedPAC*, "Report to the Congress: Overview of the 340B Drug Pricing Program," May 2015, pp. 11–12.

²⁵ Mathematica, *The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities*, August 2004. Apexus, *340B Health Summer Conference*, July 2016; Apexus, *340B Health Summer Conference*, July 2016.

²⁶ Chris Hatwig, *Apexus Update*, 340B Health Summer Conference, 2016.

²⁷ A. Fein "340B Purchases Hit \$12 Billion in 2015—and Almost Half of the Hospital Market," *Drug Channels Blog*, February 23, 2016.

²⁸ A. Fein, "340B Purchases Were More than Half of the Hospital Market in 2016," *Drug Channels Blog*, May 19, 2017.

²⁹ HRSA OPA Data base, January 2017.

³⁰ R. Conti and P. Bach, "The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities," *Health Affairs*, vol. 33 no. 10.

³¹ HRSA OPA Data base, January 2017.

³² Chains included are Walgreens, Albertsons, Kroger, Rite Aid, Walmart and CVS. A. Fein, "The Booming 340B Contract Pharmacy Profits of Walgreens, CVS, Rite Aid, and Walmart," *Drug Channels*, July 11, 2017.

³³ Aaron Vandervelde and Eleanor Blalock, "340B Program Sales Forecast: 2016–2021," 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

scope of the 340B program is currently so vast for drugs that are commonly infused or injected into patients by physicians that their *prices are probably driven up for all consumers*” (emphasis added).³⁴ Another study in *JAMA* noted that list prices for medicines are likely higher than they otherwise would be “to offset revenue losses incurred as a larger number of drug sales become eligible for 340B discounts (and thus fewer drugs are sold at full price).”³⁵

These economists’ concern that drug prices are being driven up for everyone because of the size of the 340B program is borne out by data analyzing the relative share of the 340B program. Overall, 340B sales accounted for about 8 percent of all branded outpatient drug sales in 2017, but certain therapeutic categories were disproportionately impacted.³⁶ For example, for certain types of cancer medicines, sales to 340B hospitals account for 33 percent of *all* Medicare Part B reimbursement.³⁷ 340B Health, which represents hospitals that participate in 340B, has erroneously reported that 340B discounts constitute a much smaller share of drug sales, but their analysis uses several methodological sleights of hand to artificially lower that number.³⁸ For example, they only include a portion of legally mandated 340B discounts and artificially decrease the value of the 340B discounts they do include, and they compare 340B discounts to total net pharmaceutical sales—including generics—even though 340B discounts are largely concentrated in brand sales. They also ignore that 340B sales are heavily concentrated in certain therapeutic areas.

340B creates incentives that drive up spending on prescription medicines and undermine efforts to promote more efficient, high-quality care

A range of studies demonstrate that the 340B program is creating incentives for hospitals to drive up treatment costs. It has evolved into a vehicle for hospitals to keep markups earned from arbitrage: buying medicines at a legally mandated 340B ceiling price and reselling them at a higher price. This means that in many cases, the program has provided hospitals the opportunity and incentive to increase and maximize 340B revenue by either prescribing more medicines or more expensive medicines.

A 2015 GAO study investigated whether this incentive was leading to higher drug spending at 340B hospitals and found that “Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals.”³⁹ The differences the GAO found “did not appear to be explained by the hospital or patient population characteristics.”⁴⁰ Instead, GAO suggested that the higher spending was likely due to the financial incentive to obtain more 340B revenue from patients having higher spending on medications.⁴¹

As noted earlier, a recent *New England Journal of Medicine* article found similar patterns in the areas of hematology-oncology and ophthalmology. Strikingly, the study also found that despite the increase in Medicare Part B spending on prescription drugs, DSH hospital eligibility for 340B was associated with “*lower proportions of low-income patients* in hematology-oncology and ophthalmology and with no significant differences in hospital provision of safety-net or inpatient care for low-income groups or in mortality among low-income residents of the hospitals’ local service areas.” (emphasis added)⁴² Thus, costs were higher at 340B hospitals, but these hospitals were not treating more low-income patients and were not achieving lower mortality rates for this vulnerable group.

While the Administration took a first step last year toward addressing these incentives in Part B with their changes in the hospital outpatient prospective pay-

³⁴ R. Conti and M. Rosenthal, “Pharmaceutical Policy Reform—Balancing Affordability with Incentives for Innovation,” *N Engl J Med* 2016; 374:703–706.

³⁵ R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA: The Journal of the American Medical Association*, 2013;309(19):1995–1996. doi:10.1001/jama.2013.4156.

³⁶ A. Vandervelde and E. Blalock, “Measuring the Relative Size of the 340B Program: 2012–2017,” Berkeley Research Group, July 2017.

³⁷ Drugs sold to 340B hospitals account for 33 percent of *all* Part B reimbursement for breast cancer and multiple myeloma drugs. A. Vandervelde and E. Blalock, “Measuring the Relative Size of the 340B Program: 2012–2017,” Berkeley Research Group, July 2017.

³⁸ A. Dobson, K. Murray, J.E. DaVanzo, “Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers” Dobson/DaVanzo for 340B Health, July 2017.

³⁹ Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO–15–442, June 2015.

⁴⁰ *Ibid.*

⁴¹ *Ibid.*

⁴² S. Desai and J.M. McWilliams, “Consequences of the 340B Drug Pricing Program,” *N Engl J Med* 2018.

ment system rule,⁴³ the same incentives that drive up costs continue to exist when hospitals serve patients insured in the commercial market. In fact, a study from the actuarial firm Milliman that used commercial market data found similar patterns to those GAO highlighted in Part B. That Milliman study found average per patient outpatient drug spending for commercially insured patients at 340B DSH hospitals is nearly *three times* the spending at non-340B DSH hospitals (\$457 and \$159, respectively) (emphasis added).⁴⁴ These cost differences are not explained by differences in overall health of populations treated at 340B and non-340B hospitals. Higher health care spending is ultimately paid by insurers and beneficiaries, who pay cost sharing and premiums. Thus, these results can be used to infer that the 340B program may be contributing to higher healthcare costs for everyone with private insurance through higher premiums and, for a smaller subset of patients, through higher out-of-pocket costs.

Many policymakers, including several Members of this Committee, have publicly stated their interest in redesigning the health care system to create incentives for efficient and quality health care that rewards providers for outcomes of care, instead of volume of care provided. As these studies demonstrate, 340B is working at cross-purposes with those health care system goals by providing hospitals with a large revenue stream that is derived from perverse incentives that raise treatment costs.

Incentives that shift care from community-based physicians to more expensive settings

Many hospitals have further expanded their ability to generate revenue from 340B purchases by buying community-based physician practices and then obtaining 340B discounts for prescriptions written by those physicians. These acquired practices are often geographically located in wealthier areas than the 340B hospitals themselves⁴⁵ and have no requirement to treat uninsured or vulnerable patients. Increasingly, hospital acquisitions of independent community-based physician practices are leading to the closure of community cancer clinics across the country.⁴⁶ Care in hospital outpatient settings is notoriously more expensive overall. One study found hospitals charge five times their acquisition costs for medicines administered in the outpatient setting, and commercial payers reimburse these drugs at rates that are 252 percent of average hospital acquisition costs (without factoring in 340B discounts).⁴⁷ Because 340B hospitals acquire drugs at prices far below average, their charges and reimbursements are even higher compared to their acquisition costs.

In looking at cancer care specifically, an analysis by IMS Health found that average costs for administering cancer medicines are typically twice as high at hospital outpatient departments compared to community-based oncologists, which can lead to “higher patient cost responsibility.”⁴⁸ A recent article published in JAMA Oncology had similar findings and the authors note that “[w]hile patients may receive the same treatment in either setting, insurers typically reimburse payments to HOPDs [hospital outpatient departments] at a higher rate than to physician offices.”⁴⁹ There is no evidence to suggest that differences in payment are attributable to patient characteristics or the type of care received.⁵⁰ Hospitals are able to receive higher payments than physician practices from commercial payers for the same services due to market power. This market power is often driven by vertical integration, specifically the purchase of oncology practices by hospitals and health systems, that gives hospitals leverage to charge higher prices when negotiating with commer-

⁴³ 80 Fed. Reg. 59216, (Dec. 14, 2017).

⁴⁴ Milliman, “Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Hospitals,” March 2018.

⁴⁵ R. Conti and P. Bach, “The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities,” *Health Affairs*, vol. 33 no. 10.

⁴⁶ National Cancer Policy Forum; Board on Health Care Services; Institute of Medicine. *Ensuring Patient Access to Affordable Cancer Drugs: Workshop Summary*. Washington (DC): National Academies Press (US); 2014 Dec 23. Workshop Summary. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK268684/>; T. Hagen, “COA: Trend of Oncology Practice Closures, Consolidations Softens,” Nov. 2016.

⁴⁷ The Moran Company, “Hospital Charges and Reimbursement for Drugs: Analysis of Markups Relative to Acquisition Cost,” October 2017.

⁴⁸ IMS Institute for Healthcare Informatics. *Global Oncology Trend Report: A Review of 2015 and Outlook to 2020*, June 2016.

⁴⁹ A.N. Winn, N.L. Keating, J.G. Trogdon, et al. “Spending by Commercial Insurers on Chemotherapy Based on Site of Care,” 2004–2014. *JAMA Oncology*. Published online February 22, 2018. doi:10.1001/jamaoncol.2017.5544.

⁵⁰ Wynn, Barbara O., Peter Hussey, and Teague Ruder. *Policy Options for Addressing Medicare Payment Differences Across Ambulatory Settings*. Santa Monica, CA: RAND Corporation, 2011. Available at: https://www.rand.org/pubs/technical_reports/TR979.html.

cial payers.⁵¹ Lee Newcomer (UnitedHealthcare) notes this when talking about hospital systems by stating that the hospitals can say, “If you want our beds, you have to take our prices for oncology treatment.”⁵²

Economists have concluded that 340B’s role in shifting care to more expensive settings will drive higher costs. For example, according to economists at the University of Minnesota, the current 340B program—if not changed—“*will ultimately end up increasing health care costs for everyone*, as patients are shifted from cheaper, community-based care to more expensive hospital settings. . . .” (emphasis added).⁵³ Similarly, researchers at Memorial Sloan Kettering have noted that 340B is helping to drive consolidation of physician practices into hospitals and that in the absence of changes “the trend toward consolidation will continue to *drive up the cost of commercial insurance*. . . .” (emphasis added).⁵⁴ Similarly, the recent Energy and Commerce report on 340B concludes that the 340B program has contributed to the marked increase in the consolidation of private oncology practices, that this consolidation is often profit driven, and “in some instances, negatively impacts the quality of patient care and can result in increased patient cost.”⁵⁵

A 2015 change to the Medicare statute designed to promote site neutrality⁵⁶ has led to most *new* off-campus provider-based sites being paid under the Physician Fee Schedule⁵⁷ instead of the hospital outpatient prospective payment system (OPPS). However, this change does not affect those grandfathered off-campus sites that were billing under OPPS before November 2, 2015,⁵⁸ which includes thousands of off-campus departments of 340B hospitals. Nor does this Medicare site neutral payment policy apply to commercial payers.

Recent Administrative Action Is a Step Forward, But More Action Is Needed to Modernize the 340B Program

Mounting evidence from the GAO and other independent economists indicates that DSH hospitals’ use of the 340B program is driving up health care costs,⁵⁹ has led to a steady drumbeat of calls to modernize the program. Members of the House and Senate have taken steps to do so by introducing three bills to provide needed reporting and accountability into how DSH hospitals use the 340B program.⁶⁰ These bills vary in their scope, but all three bills exempt rural-designated hospitals and 340B-eligible grantees from the new requirements, an exception that PhRMA supports. We agree with the authors of the legislation that the issue with abuse of the 340B program are not the grantees or rural hospitals, but large DSH hospitals and their associated child sites, many of which are in well-off communities.

One such piece of legislation is S. 2312, the Helping Ensure Low-income Patients have Access to Care and Treatment (HELP ACT) introduced by Sen. Cassidy. The HELP ACT includes many important and common-sense reporting and accountability measures that will help all stakeholders better understand how DSH hospitals are using the 340B program and which of their patients are accessing 340B discounts. This legislation also includes much-needed standards for how DSH hos-

⁵¹ R.M. Conti, M.B Landrum, and M. Jacobson. “The impact of provider consolidation on outpatient prescription drug-based cancer care spending,” Available at: <http://www.healthcostinstitute.org/wp-content/uploads/2016/08/HCCI-Issue-Brief-Impact-of-Provider-Consolidation.pdf>.

⁵² L.N. Newcomer. Those who pay have a say: A view on oncology drug pricing and reimbursement. *The Oncologist*. 2016 Jul 1;21(7):779–81.

⁵³ S.T. Parente and M. Ramlet, “Unprecedented Growth, Questionable Policy,” Carlson School of Management at University of Minnesota.

⁵⁴ P.E. Bach and R.H. Jain, “Physician’s Office and Hospital Outpatient Setting in Oncology: It’s About Prices, Not Use,” *Journal of Oncology Practice* 2017 13:1, 4–5.

⁵⁵ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

⁵⁶ Social Security Act § 1833(t)(1)(A)(v), (21).

⁵⁷ These sites are paid under a special variant of the Physician Fee Schedule that CMS developed for the off-campus hospital facilities that no longer can bill under OPPS.

⁵⁸ Social Security Act § 1933(t)(21)(A)(99).

⁵⁹ R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA: The Journal of the American Medical Association*, 2013;309(19):1995–1996. doi:10.1001/jama.2013.4156.; Government Accountability Office, Medicare Part B Drug; P. Bach and R.H. Jain, “Physician’s Office and Hospital Outpatient Setting in Oncology: It’s About Prices, Not Use,” *Journal of Oncology Practice* 2017 13:1, 4–5.”

⁶⁰ 340B PAUSE Act, H.R. 4710, 115th Cong. (2017); HELP ACT, S. 2312, 115th Cong. (2018); Ensuring the Value of the 340B Program Act of 2018, S. 2453, 115th Cong. (2018) H.R. 4570, S. 2312, and S. 2453 (see detailed description later in testimony).

pitals and their child sites qualify for the 340B program, responding to findings from the GAO.⁶¹

In addition to congressional interest in increasing accountability in the 340B program, the Trump Administration has also sought to address concerns that 340B is increasing government and patient spending on physician administered medicines⁶² through changes in the Hospital Outpatient Prospective Payment System at 340B hospitals.⁶³ Their changes lower Medicare reimbursement for 340B medicines paid for under the Medicare Part B Hospital Outpatient Prospective Payment System.⁶⁴ This policy change is expected to reduce incentives created by the 340B program that may cause hospitals to administer more and higher cost medicines in Part B. While this change is an important first step, Medicare Part B represents less than one-quarter of total hospital revenue from 340B.⁶⁵ Because half hospital's total 340B revenue is derived from 340B physician administered medicines purchased by commercial payers and others outside of fee-for-service Part B, 340B's incentives to drive up cost without adding value for patients remain intact.⁶⁶

Improvements to 340B are Urgently Needed in Five Key Issue Areas: (1) Patient Definition; (2) DSH Hospital Eligibility Standards; (3) Standards for Off-Site Hospital Clinics (“Child Sites”); (4) Contract Pharmacy Arrangements; and (5) Program Integrity

Issue Area 1: The 1996 patient definition should be clarified to better define who is entitled to manufacturer discounts on 340B medicines.

The 340B program was originally created to make prescription medicines more accessible to low-income, uninsured, and other vulnerable patients through safety-net facilities. Under the 340B law, a covered entity may only claim a 340B discount under the program if the medicine is used for the covered entity's own “patient.”⁶⁷ The 340B law further prohibits covered entities from reselling or otherwise transferring medicines purchased under the 340B program to anyone but a “patient” of the covered entity (a practice commonly referred to as “diversion”).⁶⁸

Despite this centrality of “patient” to defining the program's scope and assuring that statutory program integrity requirements are met, throughout the history of the 340B program, there has been a lack of meaningful standards as to when an individual qualifies as a “patient” of a covered entity. In fact, the current patient definition is more than two decades old despite how much the health care landscape in the United States has evolved during that time. This has contributed to well-documented program abuses and violations. For example, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) observed in a report focused on contract pharmacy arrangements:

Covered entities . . . reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements. Covered entities appear to have differing interpretations of what HRSA guidance requires . . . there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.⁶⁹

Despite these concerns raised by government watchdog agencies, HRSA's patient definition has not been updated or modified since 1996, over 20 years ago.⁷⁰ As

⁶¹ Government Accountability Office, “Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,” Sept. 2011.

⁶² Government Accountability Office, “Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals,” June 2015.

⁶³ 82 FR 52356.

⁶⁴ 82 FR 52356.

⁶⁵ A. Vandervelde and E. Blalock, “Site of Care Shift for Physician-Administered Drug Therapies,” Berkeley Research Group, Oct. 2017.

⁶⁶ A. Vandervelde and E. Blalock, “Site of Care Shift for Physician-Administered Drug Therapies,” Berkeley Research Group, Oct. 2017.

⁶⁷ 42 U.S.C. § 256b(a)(5)(b).

⁶⁸ 42 U.S.C. § 256b(a)(5)(B).

⁶⁹ OIG, Contract Pharmacy Arrangements in the 340B Program, OIE-05-13-00431 at 16, Feb. 2014.

⁷⁰ See 61 Fed. Reg. 55156 (Oct. 24, 1996). Under HRSA's current guidance, the patient definition requires that: (1) the covered entity have a relationship with the individual “such that the covered entity maintains records of the individual's health care”; (2) the individual receives health care services from a health care professional who is an employee of the entity or provides care under contract or other arrangements with the 340B entity, “such that responsibility for

highlighted by HRSA itself along with GAO and OIG, the 1996 patient definition is vague and lacks the specificity needed to provide clear direction to covered entities and manufacturers about who is a patient for 340B discount purposes. This has allowed covered entities to take broad interpretations of the patient definition guidance and use 340B medicines for individuals who in many instances would not be considered true “patients” in any traditional sense of the word, i.e., someone who relies on a provider for ongoing and routine medical care.

Included in the 1996 patient definition is overly broad language that “the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or *other arrangements* (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity” (emphasis added).⁷¹ HRSA itself noted problems with the “other arrangements” language in its 2007 proposed patient definition clarification, which was never finalized:

“Some [hospitals] have been contracting with health care providers to create a loose affiliation model for outpatient health care services. . . . *This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits.*”⁷²

In 2011, GAO reported HRSA’s own stated concern that the “other arrangements” language in the 1996 patient definition was too vague:

“HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through “other arrangements,” as long as the responsibility for care provided remains with the entity. However, HRSA does not define “other arrangements,” and officials told us that what is meant by responsibility for care also needs to be clarified. Because of the lack of specificity in the guidance, *the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity . . . does not actually have the responsibility for care.*”⁷³

Recommendations to improve the current patient definition

A clear definition of “patient” is required under the law and critical to the integrity and long-term sustainability of the 340B program. HRSA should update its 340B patient definition so that it has clear and enforceable standards for hospitals. A revised definition of a patient for 340B purposes should require that there is an established relationship between the hospital and the patient such that the patient receives medical care at the hospital’s onsite facilities registered with HRSA. HRSA has correctly recognized that an “individual’s health care relationship with the covered entity is the most important factor in determining” whether an individual is a patient of a 340B covered entity.⁷⁴ The patient definition should be more explicit about identifying the factors for which a hospital is responsible for an individual’s care and treatment, including documenting and maintaining medical records for an individual. These elements include:

(1) Clear relationship between hospital and health care provider

A revised patient definition must make clear the *relationship between the hospital and the health care professional seeing the patient*. A revised patient definition should also eliminate the language in the 1996 patient definition referring to a patient as one who receives health care services from a provider under “contractual or other arrangements.” As discussed above,

the care provided remains with the covered entity”; and (3) the individual receives care from the covered entity that is consistent with the service or range of services for which the entity receives Federal grant funding or FQHC look-alike status (this requirement does not apply to DSH hospitals). An individual is not considered a patient of a covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug for subsequent self-administration or for administration in the home setting. Different criteria for defining “patients” apply to AIDS Drug Assistance Programs.

⁷¹ 61 Fed. Reg. at 55157.

⁷² Fed. Reg. at 1546–47 (emphasis added).

⁷³ GAO, “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvements,” Sept. 2011, *supra*, at 23.

⁷⁴ 72 Fed. Reg. at 1544.

this loose “other arrangements” language has been a long-standing concern for GAO and HRSA due to the potential for abuse it creates.

HRSA should clarify in its patient definition that only an employee or independent contractor of the hospital are considered health care professionals who can treat a patient *on behalf* of the hospital. A provider connected to a hospital through a looser affiliation is not acting on behalf of the hospital and that provider’s patients are not the covered entity’s patients for 340B purposes.

(2) Location of services provided

The revised definition also should make clear that a patient must receive outpatient care at a covered entity’s facilities. This service should go beyond dispensing or administration of a medication and include the prescribing or administration of the medicine for which the covered entity receives a 340B discount. As HRSA has said in the past, this means discounts are not available when only dispensing discounted medicines to an individual for subsequent self-administration.⁷⁵

(3) Requirements for hospitals eligible through a government contract

The revised patient definition should make clear that if the individual is receiving care from a covered entity that has a contract with a state or local government, such care must be within the scope of the contract that bestows that covered entity 340B eligibility under subsection (a)(4)(L)(ii) of the 340B statute (42 USC 256b). This would more closely align the patient definition for *grantees* (already subject to this element in the current patient definition) and *DSH hospitals*. It would also ensure that the patient remains an individual who receives services from a covered entity *consistent with the reason why the entity is 340B eligible*. For example, HRSA should specify that where a private nonprofit hospital is 340B eligible because it has a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid, a 340B patient of the hospital must receive services *under that contract*. Likewise, for a private nonprofit hospital that is 340B eligible because it has been formally granted governmental powers, a 340B patient of the hospital should be an individual who receives health care services furnished by the hospital in connection with its governmental powers.

Requiring that a patient of a 340B hospital receive the services for which Congress made the hospital 340B eligible would promote the purposes of the 340B law (to provide discounted medicines to a private nonprofit hospital that contracts to care for “low-income individuals who are not eligible for Medicaid or Medicare,” but *not* for a private nonprofit hospital with “a minor contract to provide indigent care which represents an insignificant portion of its operating revenues”).⁷⁶ It would also make the patient definition more symmetrical between grantees and hospitals.

HRSA has never sought to explain why it applied this principle to grantees but not hospitals, and we see no rational basis to treat covered entity grantees differently from hospitals on this important element of the definition of who is a 340B patient. Accordingly, HRSA should specify in a revised definition that a patient of a private hospital that is 340B-eligible through a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid, must receive care *under that contract*. Similarly, the revised definition should specify that a hospital eligible because of “formally granted powers” can only receive discounts for patients who receive care *in connection to such powers*.

HRSA has authority to issue a revised patient definition

In 2015, in response to the criticism received around the program’s lack of clear standards, HRSA issued a proposed omnibus guidance covering many aspects of the 340B program, including changes to the patient definition. At that time, HRSA believed it had legal authority to issue guidance on a new patient definition, and we continue to believe that HRSA can issue a new patient definition without statutory

⁷⁵ 72 Fed. Reg. at 1544 (“An individual will not be considered a ‘patient’ of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self administration or administration in the home setting.”).

⁷⁶ H.R. Rep. 102–384 (II) (1992), 12.

rulemaking authority. Congress should encourage HRSA to exercise this authority or seek clarity from HRSA on areas where they think they lack authority. In general, PhRMA supported these proposed changes to the patient definition and believes finalizing such a definition would make important strides in clarifying the patient definition and resolving many of the inconsistencies in the way stakeholders have interpreted this key term. We appreciate HRSA's efforts to spell out the elements of the patient definition, which are essential to ensuring compliance with the law regarding diversion and duplicate discounts and to maintaining overall program integrity. However, we believe there are some instances where entities—particularly small or rural covered entities and grantees—need additional flexibility from the proposed patient definition and should be allowed to continue to use the definition now in place given their focus on safety net populations.

Key Takeaway: The GAO, OIG and HRSA have all noted that the current patient definition is overly vague and allows DSH hospitals to obtain 340B discounts for patients who Congress never intended to qualify for the program. HRSA should finalize a new patient definition that, at a minimum, includes the important elements discussed above and makes exceptions for grantees. If HRSA does not release a new patient definition in short order, Congress should step in and create a new patient definition that reflects these important elements in statute.

Issue Area 2: Hospital eligibility standards are outdated, and the requirements in statute are not well enforced.

With 45 percent of all acute care hospitals participating in a program that was first intended for true safety-net facilities,⁷⁷ the eligibility criteria for DSH hospitals must be reexamined. While some of the eligibility standards are set in statute and Congress would have to intervene to update those criteria, HHS also has an important role to play in ensuring that only true safety-net hospitals are eligible for the 340B program.

Recommendations to improve DSH hospital eligibility standards

(1) Revisiting the DSH Metric

Under the 340B statute, hospitals can qualify for the 340B program based in part on their DSH percentage,⁷⁸ an inpatient measure relating to the number of Medicaid and low-income Medicare patients treated in a hospital's inpatient unit. Paradoxically, this means that hospitals are *more* likely to qualify for 340B as more of their patients gain Medicaid coverage and are no longer uninsured. As discussed previously, more hospitals have become eligible for 340B due to significant expansions in Medicaid eligibility, which could not have been anticipated in 1992. In addition, a 340B DSH hospital designation has no direct relationship to the amount of care that a hospital provides to low income, indigent, or uninsured populations.

Analysis of the amount of charity care DSH hospitals provide points to the fact that some of these hospitals have a low charity care obligation. Hospitals report the amount of charity care they provide on their Medicare Cost Reports. Charity care is the cost of providing free or discounted care to low-income individuals who qualify for the hospital's charity care program. These programs are focused on helping low-income patients access health care that would otherwise be unaffordable. PhRMA believes it is important to examine the relative amount of charity care 340B hospitals provide as part of an examination of whether 340B eligibility is truly targeting true safety net hospitals. For example, according to hospitals' own data, 64 percent of 340B DSH hospitals provide a *lower level of charity care* than the national average for *all* hospitals.⁷⁹ This raises questions as to whether the DSH hospitals participating in the program are in fact the hospitals treating large numbers of vulnerable or uninsured patients. Additionally, in a 2015 report, the GAO found that there were "notable numbers" of 340B DSH hospitals that provided low amounts of charity care.⁸⁰ MedPAC also

⁷⁷ MedPAC, "Report to the Congress: Overview of the 340B Drug Pricing Program," May 2015.

⁷⁸ See 42 U.S.C. § 256b(a)(4)(L)-(O).

⁷⁹ Alliance for Integrity and Reform of 340B, "Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.

⁸⁰ Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442, June 2015.

reported that it had found little correlation between hospitals' DSH adjustment percentages and whether they had either high-cost patients or a high percentage of uninsured patients.⁸¹ Finally, the 2018 Energy and Commerce report reached the conclusion that "it is unclear whether the DSH metric ensures that the program is available for hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients."⁸²

It is also important to note that because DSH is an *inpatient* measure being used to determine eligibility for the *outpatient* 340B program, it is not impacted when 340B hospitals add child sites that serve relatively wealthy patients. As noted above, analysis has shown that often these child sites are geographically located in wealthier areas than the DSH hospitals themselves.⁸³ The 2018 Energy and Commerce report issued a recommendation for reforms to the 340B program, suggesting that "Congress should reassess whether DSH is the appropriate measure for program eligibility, or whether a metric based on outpatient population would be more appropriate."⁸⁴

These flaws in the DSH metric suggest that Congress should reexamine the eligibility criteria for 340B to better link eligibility for the program to an entity's actual *provision* of a disproportionate share of outpatient charity care. Because hospitals already report charity care in their Medicare Cost Reports, such a metric could be relatively simple to operationalize.

(2) Revising Current Loose Eligibility Standards for Hospitals Not Owned or Operated by a state or Local Government

All 340B hospitals must be owned or operated by a unit of state or local government or a private nonprofit hospital that (a) has been formally granted governmental powers by a state or local government; or (b) has a contract with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. Unfortunately, there is little guidance, transparency, or oversight to enforce these requirements. In fact, HRSA does not even review or collect the contracts that make some hospitals eligible for 340B discounts. Instead, the responsibility falls on hospitals to self-report if they believe they no longer meet the requirements. GAO noted that "hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicare or Medicaid could claim 340B discounts, which may not be what the agency intended."⁸⁵ This lack of oversight makes it difficult to ensure that contracts are meeting congressional intent. The legislative history states that a private nonprofit hospital that had "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues" could not qualify for 340B under the state and local government contract test.⁸⁶ Yet HRSA is not enforcing this requirement which could easily be done routinely when HRSA recertifies a hospital's 340B eligibility.

At a minimum, HRSA should collect these contracts and post them online. Strong and transparent standards are needed for private DSH hospitals' contracts that confer 340B eligibility. These contracts should not be minor contracts and instead should represent a sizable investment of hospital resources. Similarly, HRSA should set clear standards for how hospitals qualify for 340B if they have been formally granted "governmental powers." The governmental powers that confer 340B eligibility to a hospital should be made publicly available by each hospital. Merely providing health care services is not sufficient to meet this standard.

⁸¹ Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (Washington, DC: MedPAC, March 2007).

⁸² House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

⁸³ R. Conti and P. Bach, "The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities," *Health Affairs*, vol. 33 no. 10.

⁸⁴ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

⁸⁵ *Manufacturer Discounts in the 340 Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept.2011), p 23.

⁸⁶ U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).

Recently introduced legislation offers important improvements in hospital reporting requirements

Several Members of Congress have recently introduced bipartisan legislation to address some of the deficiencies in hospital reporting and accountability. S. 2312, the HELP ACT would impose reporting requirements on DSH, cancer and children's hospitals that increase the understanding of how the program is used. For example, these hospitals would report the insurance status of patients who receive 340B medicines. This will show whether uninsured patients are receiving 340B medicines both at the DSH hospital itself and separately for each child site. The HELP ACT would also strengthen government oversight with GAO and OIG reports on key areas in need of being revisited, including an evaluation into the state and local government contracts that bestow 340B eligibility on certain private DSH hospitals. The legislation would also implement clear eligibility standards for private DSH, children's and cancer hospitals and their offsite outpatient facilities. Representatives Larry Bucshon and Scott Peters have introduced legislation, H.R. 4570, the 340B PAUSE Act, that would take many similar steps to increase understanding of how 340B hospitals qualify for the program and which patients are receiving 340B prescriptions. Both bills also include a commonsense temporary moratorium on the enrollment of new DSH hospitals while data is being collected.

The commonsense reporting requirements included in the HELP ACT and 340B PAUSE Act are focused on basic information hospitals are likely already collecting for other purposes. For example, the data on the insurance status of patients already is needed for payment purposes. Further, the data requirements included in both pieces of legislation are in line with the level of reporting already required of many grantees as a condition of the Federal grants they receive. Federal grantees, like Ryan White clinics, are already subject to additional HRSA oversight as a Federal grantee. Importantly, in its January 2018 report on the 340B program, the House Energy and Commerce Subcommittee on Oversight and Investigations interviewed numerous HRSA grantees who told the committee that "they found the additional [340B] program requirements manageable."⁸⁷

Key Takeaway: The current lax DSH hospital eligibility standards are contributing to the growth of 340B that has led to higher costs for patients and the health care system. Both Congress and HRSA should update the current eligibility criteria for DSH hospitals. Specifically, Congress should review the use of the DSH metric and HRSA should develop and enforce eligibility standards for hospitals not owned or operated by a state or local government.

Issue Area 3: Current guidance on eligibility criteria for child sites is outdated and is driving up costs and should be updated.

The 340B law defines the types of hospitals that can participate in the program with great specificity⁸⁸ but never mentions participation of off-campus outpatient facilities associated with these hospitals (also known as child sites). Although there is no basis in the statute for including these sites, in 1994, HRSA unilaterally issued guidance dramatically expanding the 340B program by permitting child sites to participate—even if as hospitals have interpreted, they are only loosely connected to the parent hospital and do not serve a needy population.⁸⁹ Child sites have become a major source of the program's growth and incentives. In 1994, there were a total of 34 child sites. By 2016 this had increased to over 15,000.⁹⁰

These hospital child sites are a key factor accounting for the 340B program's explosive growth and its shift away from the program's original goal of helping get discounted medicines to uninsured and vulnerable patients.⁹¹ For example, a 2014 *Health Affairs* study found that child sites are converting 340B "from [a program]

⁸⁷ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf.

⁸⁸ 42 U.S.C. § 256b(a)(4)(L)-(O).

⁸⁹ 59 Fed. Reg. 47884, 47885 (September 19, 1994).

⁹⁰ HRSA OPA Data base, October 2016.

⁹¹ A. Vandervelde and E. Blalock, "340B Program Sales Forecast: 2016–2021," 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

that serves vulnerable communities to one that enriches hospitals.”⁹² The authors of a recent *New England Journal of Medicine* Perspective on 340B state that “hospitals have purchased community practices in part . . . to expand their footprint into wealthier neighborhoods to ‘profit’ from the 340B program.”⁹³ As discussed earlier in this testimony, hospitals purchasing physician practices leads to higher costs for many payers and other patients because commercial reimbursement for hospital-owned practices are typically higher due to their market power.⁹⁴

Recommendation for addressing concerns with child sites

(1) Implement new eligibility standards and requirements for child sites

At a minimum, HRSA should revisit its 1994 guidance given the rampant growth in the number of child sites, the lack of any requirements that these clinics serve a safety-net role and the evidence that they are leading to higher costs for many patients. Congress, too, should consider revising the current child site eligibility rules.

The new standards for child site eligibility should be developed to help prevent 340B from being an incentive for the broad consolidation of community-based providers, which drives up health care costs. Child sites should also be required to provide a broad range of services and have a sliding fee scale that shares 340B discounts with low-income patients.

Recently introduced legislation takes an important first step to improve hospital reporting requirements for child sites

Both the HELP ACT and the 340B PAUSE Act would help improve visibility into how child sites are using the 340B program by requiring hospitals to report insurance status of the patients treated at each child site and the costs of charity care provided at each site. Currently, there is no data available about the patients treated at child sites, and as discussed above, these patients are not factored into the hospital’s DSH metric. Such data will be valuable in determining whether child sites are serving communities in need of safety-net services.

Both bills also include a commonsense temporary moratorium on the enrollment of new child sites while data is being collected. The HELP ACT would also require that a child site of any 340B DSH, children’s or free-standing cancer hospital meet several requirements, including adhering to the charity care policy and any sliding fee scale of its parent hospital. These new standards would help ensure that patients directly benefit from 340B discounts at the child site.

Key Takeaway: The current eligibility criteria for offsite outpatient facilities (“child sites”) associated with 340B DSH hospitals are leading to consolidation that raises health care costs and increasing the presence of 340B sites in wealthy areas, which is not consistent with the program’s mission. Criteria must be revised and new reporting requirements must be implemented to ensure these sites are serving communities that need safety-net services.

Issue Area 4: Rampant growth of hospital use of contract pharmacy arrangements must be reined in through updated guidance.

Contract pharmacies are for-profit, retail pharmacies that 340B hospitals partner with to dispense 340B medicines to patients of the covered entity who fill prescriptions at the pharmacy. The contract pharmacy and the hospital then share the profit generated through the distribution of a 340B discounted medicine, with no guarantee that patients benefit from the 340B discount.

The 1992 statute creating the 340B program did not authorize or even mention contract pharmacies. To address requests from covered entities without an in-house pharmacy, HRSA issued guidance in 1996 allowing covered entities without an on-

⁹² Rena M. Conti and Peter B. Bach. The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities, *Health Affairs* 33, no. 10 (2014): 1786–1792.

⁹³ http://www.nejm.org/doi/full/10.1056/NEJMp1716139?query=recirc_curatedRelated-article.

⁹⁴ As discussed earlier, while the administration recently made changes to address 340B hospitals’ incentives to increase spending in Medicare Part B, that change will likely have a minimal impact on incentives for future provider consolidation. The new Part B reimbursement changes are by definition limited to the less than one quarter of DSH hospitals’ 340B profits derived from Part B fee-for-service sales and the new policy will not impact newly acquired outpatient sites that are not paid under the Outpatient Prospective Payment System.

site pharmacy to contract with one offsite pharmacy.⁹⁵ In 2010, the use of contract pharmacies was dramatically expanded through Obama administration sub-regulatory guidance.⁹⁶ The 2010 guidance eliminated the one pharmacy limitation and permitted 340B entities that have an onsite pharmacy to also use an unlimited number of contract pharmacies. This change dramatically increased the number of contract pharmacies but did nothing to ensure that patients benefited from this expansion. A 2014 report by the OIG stated that at the time, “the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent” since 2010.⁹⁷ In 2017, there were more than 50,000 contract pharmacy arrangements.⁹⁸

There is no evidence patients consistently benefit from contract pharmacies

Pharmacies can generate higher returns by dispensing 340B prescriptions than non-340B prescriptions, however uninsured patients are not always offered the 340B discounted price at contract pharmacies.⁹⁹ Despite the fact that the 340B program was designed to ensure increased access to prescription medicines for vulnerable or uninsured patients, the 2014 OIG report found that the majority of hospitals in their study did not ensure that they passed 340B discounts back to uninsured patients who filled their prescriptions at a contract pharmacy.¹⁰⁰ In contrast, the grantee covered entities in the OIG study were more likely to have developed systems for their contract pharmacies to pass 340B discounts on to uninsured patients.¹⁰¹ Additionally, 340B Health, the trade association representing 340B hospitals, has stated that contract pharmacies are typically unable to determine who is eligible for 340B discounts at the time a prescription is filled. In a letter to New York State, 340B Health stated, “the overwhelming majority of these [contract] pharmacies do not know at the time a claim is processed whether or not it relates to a 340B drug.”¹⁰²

Recommendations for reining in contract pharmacy arrangements

(1) Increase and improve HRSA oversight of the contract pharmacy program

HRSA’s oversight of 340B, and particularly the contract pharmacy program, is insufficient. In 2012, as part of its efforts to improve 340B program integrity, HRSA began conducting covered entity audits. Many of these audits focus on covered entities’ usage of contract pharmacies, however they are limited in scope and the fact that they continue to result in adverse findings demonstrates that audits are not enough to ensure program integrity. While the 2010 HRSA contract pharmacy guidance recommends that covered entities perform annual independent audits of their contract pharmacies, in practice, this guidance has not resulted in meaningful action on the part of covered entities. The 2014 HHS OIG report on contract pharmacies found that “[f]ew covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.” HRSA’s current approach to overseeing contract pharmacy arrangements relies heavily on this covered entity self-policing, yet there are no rules in place that compel processes that would ensure compliance with the 340B statute. The OIG report states that covered entities must notify HRSA if they find that duplicate discounts or diversion have occurred in their contract pharmacy arrangements, however OIG found that only 7 of 30 covered entities they reviewed even reported that they retained HRSA’s recommended independent auditors, let alone reported findings of diversion or duplicate discounts. OIG’s overall assessment of the current state of the contract pharmacy program was that “without adequate oversight, the complication created by contract pharmacy arrangements may in-

⁹⁵ Fed. Reg. Vol. 61, No. 165.

⁹⁶ Fed. Reg. Vol. 75, No 43.

⁹⁷ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

⁹⁸ HRSA OPA Data base, March 2017.

⁹⁹ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

¹⁰⁰ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

¹⁰¹ *Ibid.*

¹⁰² Safety Net Hospitals for Pharmaceutical Access Dec. 19, 2011 letter to Jason A. Helgerson, Medicaid Director & Deputy Commissioner Office of Health Insurance Programs, New York State Department of Health.

roduce vulnerabilities to the 340B program.” This level of self-policing and the lack of a framework for program compliance is not appropriate for such a large (and growing) aspect of the 340B program. We urge HRSA to focus its audits efforts on contract pharmacy arrangements with DSH hospitals, given that these hospitals represent 80 percent of 340B sales and rely on arrangements that make them more vulnerable to possible diversion of 340B discounts to non-patients.

Additionally, HRSA currently has no oversight efforts of covered entity arrangements with the 340B services providers (e.g., third party administrators or TPAs) who manage most of the back-end administration of the 340B program. Instead, as discussed above, HRSA cites its recommendations that covered entities conduct independent audits to ensure compliance in these arrangements. But the lack of clear program rules and a reliance on this covered entity self-policing approach has been insufficient to ensure the integrity and the intended patient impact of the 340B program.

(2) Revise lax regulations that have enabled middlemen to benefit from the contract pharmacy program

Contract pharmacy expansion is a troubling example of middlemen diverting resources from 340B’s intended purpose of assisting low-income or vulnerable patients. An industry of for-profit pharmacies and their third-party administrators and consultants has developed since 2010 with the goal of maximizing 340B dispensing. Their only apparent motive is to financially benefit from taking a share of the markup between the legally mandated 340B price and the higher price paid by patients and insurers.

There are multiple examples of the third-party marketing strategies that boast of the revenues they can help hospitals generate through expanded use of contract pharmacies. In 2013, the LinkedIn profile of a Walgreens employee came to Senator Grassley’s attention. In his profile, the employee boasts about Walgreens’ ability to help clients “Generate revenue from your 340B patients.”¹⁰³ Senator Grassley’s subsequent letter to the Walgreens CEO seeking additional information about Walgreens’ participation in 340B sums up the problem with the contract pharmacy program succinctly, as he states, the 340B program “is not intended to subsidize pharmacies that team up with covered entities to turn a profit.”¹⁰⁴

Additionally, other third-party vendors like Talyst, a for-profit vendor which provides a software platform for pharmacies, make 340B profitability the cornerstone of their sales pitch to prospective contract pharmacy clients. Talyst tries to sell its services by telling clients that 340B drugs generate higher pharmacy markups than non-340B drugs and that Talyst is the one to help them leverage that profit potential, while underscoring that savings don’t need to be passed through to patients.¹⁰⁵ In fact, Talyst highlights that “the covered entities are allowed to use the benefit of these substantial savings in any way they choose.” Talyst is one of hundreds of for-profit middlemen taking a cut of a program designed to help the safety-net population. Little to no oversight exists to monitor contract pharmacies and these third-party vendors. HRSA and Congress must take steps to determine how and if patients are benefiting.

(3) Address 340B program integrity concerns driven by the contract pharmacy program

The contract pharmacy program inherently raises program integrity concerns. A 2014 OIG report found that contract pharmacy arrangements make it more difficult for HRSA and others to identify diversion and duplicate discounts.¹⁰⁶ The 340B program prohibits covered entities from purchasing a medicine at a 340B discount that generates a Medicaid rebate claim.¹⁰⁷ Consequently, the law creates an absolute prohibition on dupli-

¹⁰³ The link has been taken down but it was previously at <http://www.linkedin.com/pub/timothy-hong/28/651/511>.

¹⁰⁴ Senator Charles Grassley, Letter to Walgreens CEO Gregory Watson, July 21, 2013. Available at http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf.

¹⁰⁵ http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf.

¹⁰⁶ HHS Office of the Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

¹⁰⁷ 42 U.S.C. § 256b(a)(5)(A).

cate discounts. However, despite this clear statutory imperative, current prevention methods do not stop or prevent duplicate discounts. The increasing use of contract pharmacies coupled with expansion of Medicaid rebates for medicines used by Medicaid Managed Care Organization (MCO) enrollees have exacerbated the problem of duplicate discounts—with HRSA and the Centers for Medicare & Medicaid Services (CMS) thus far not taking effective steps to prevent this statutory violation. In fact, HRSA released 2014 guidance that expressly excluded Medicaid managed care utilization from the only mechanism HRSA has developed to prevent duplicate discounts (the Medicaid Exclusion File), stating that it “recognizes the need to address covered entities’ role in preventing duplicate discounts under Medicaid Managed Care, and is working with CMS to develop policy in this regard.”¹⁰⁸ As of 2018, this policy has yet to be developed. This leaves a critical gap in enforcing the law’s duplicate discount ban as about 55 million Americans are covered by Medicaid managed care plans. Half of all Medicaid spending on prescription medicines was through MCOs in 2014¹⁰⁹ and that share has likely increased in recent years.

Continued expansion of 340B contract pharmacy arrangements is expected to keep driving growth in the 340B program. Due to several factors, under current law, it is projected that by 2023, contract pharmacy utilization will exceed \$10 billion of the estimated \$31.5 billion in sales at the 340B price.

¹¹⁰ This growth comes against a backdrop of a contract pharmacy program operating in a largely unregulated environment.¹¹¹

Key Takeaway: The current unlimited use of contract pharmacies by hospitals is not sustainable and diverts savings from 340B to for-profit pharmacies and other middlemen. There is also no evidence that contract pharmacies are directly benefiting patients. HRSA should revisit its current contract pharmacy policy for hospitals. Any new policy must consider what role, if any, hospitals’ contract pharmacies should play in a program that has grown significantly over the past 8 years.

Issue Area 5: Better enforcement is needed of current 340B program rules and guidance.

Given the important role that the 340B program plays in the health care safety net, it is imperative that participants have a clear understanding of the program’s requirements and are adhering to the program’s statutory requirements. Unfortunately, this is not common practice.

Six years ago, in 2012, as part of agency-wide efforts to improve program integrity, HRSA began covered entity and manufacturer audits. The fiscal year 2017 HRSA data show that two-thirds of all DSH hospitals audited were noncompliant in at least one area and many were noncompliant in multiple areas.¹¹² Currently, there are no real repercussions for hospitals if they are found to be noncompliant with program guidelines. For example, hospitals that obtain 340B discounts for which they were not eligible may have to pay back those discounts, but there are no additional penalties that would create a true incentive to diligently prevent duplicate discounting or diversion. To date, we are not aware of any covered entity HRSA has terminated for violation of 340B program rules.

Additionally, the current lack of clear program standards makes it difficult to conduct meaningful audits of covered entities. As mentioned earlier in this testimony,

¹⁰⁸ HRSA, 340B Drug Pricing Program Release No. 2014–1 (Dec. 12, 2014). The Medicaid Exclusion File mechanism requires that 340B covered entities either “carve in” (provide 340B drugs to Medicaid patients and report this practice to HRSA, so that these entities are listed on the Exclusion File and State Medicaid programs do not bill manufacturers for rebates on drugs furnished by these entities) or “carve out” (do not provide 340B drugs to Medicaid beneficiaries, so that drugs supplied by a 340B entity to a Medicaid patient triggers a Medicaid rebate, but not a 340B discount). Under the 2014 guidance, this mechanism no longer applies to prevent double discounts on 340B drugs provided to MCO beneficiaries.

¹⁰⁹ KFF, “Total Medicaid Managed Care Enrollment, 2014” available at: <https://www.kff.org/medicaid/state-indicator/total-medicare-mc-enrollment/currentTimeframe=0&sortModel=%B%22colId%22-%2Location%22,%22sort%22-%2asc%22%7D> (accessed March 11, 2018); MACPAC, “Medicaid Spending for Prescription Drugs,” January 2016. Available at: <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>.

¹¹⁰ Berkeley Research Group unpublished estimates for PhRMA, December 2017.

¹¹¹ A. Vandervelde and E. Blalock, “340B Program Sales Forecast: 2016–2021,” BRG, December 2016.

¹¹² HRSA OPA Data base Program Integrity fiscal year 2017 Audit Results (Accessed March 6, 2018).

the OIG and GAO continue to state that the current definition of a 340B patient lacks specificity, leading to program integrity issues. While HRSA audits for incidences of diversion, it is unclear what HRSA is auditing for since there are not sufficiently clear standards for who constitutes a 340B patient.

A recent paper from the Berkeley Research Group shows that the 340B program more than doubled in size from 2010 to 2015. BRG predicts that exponential growth will continue for at least the next 5 years. At current staffing levels, each HRSA auditor will be responsible for providing oversight of an average of \$1B in drug purchases at over 4,000 distinct covered entity or contract pharmacy locations by 2021.

¹¹³ Similar to our earlier comments specific to contract pharmacy, we urge HRSA to focus its audits on contract pharmacy arrangements with DSH hospitals, given that they represent 80 percent of 340B sales and rely on arrangements that make them more vulnerable to possible diversion of 340B discounts to non-patients.

Key Takeaway: A lack of clear and enforceable standards combined with no adverse consequences for entities that violate 340B requirements mean that the hospital audits currently taking place do not assure program compliance. HRSA and Congress should consider ways to improve clarity and enforcement of program rules.

Changes are Needed to Previous Administration Proposals for the 340B Drug Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

The 340B Drug Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) Regulation, developed under the Obama administration, was set to go into effect on March 6, 2017, with enforcement scheduled for April 1, 2017. Due to the widespread concerns it raised, the final rule's effective date has been delayed four times since the Trump Administration took office in January 2017.¹¹⁴

Last fall, HRSA delayed the effective date of the 340B Ceiling Price and CMP Rule until July 1, 2018. In the notice announcing the delay, HRSA stated that it intends to engage in further rulemaking on issues covered in the rule. PhRMA supports rulemaking on this issue, but we believe any HRSA rule must be consistent with the statute and not impose undue burdens on manufacturers. Our concerns with the previous ceiling price/CMP regulations are outlined below.

Problems with the delayed ceiling price and CMP regulation

(1) *Penny pricing:* One key concern PhRMA has with the delayed rule is that it finalizes a 340B program “penny pricing” policy, which would require biopharmaceutical manufacturers to effectively give away their medicines to covered entities for free by permitting a manufacturer to only charge a penny in many cases. Penny pricing typically occurs in specific instances when the 340B ceiling price formula results in a zero 340B ceiling price for a particular medicine. The statutory formula for a medicine's 340B ceiling price is a medicine's average manufacturer price (AMP) minus its Medicaid rebate. When a medicine's Medicare rebate equals its AMP, the resulting 340B ceiling price is zero. The 340B statute cannot be read as requiring manufacturers to “sell” their medicines for a penny to 340B entities, because under the law, the discount only applies to bona fide “purchases.” However, we note that forced transfers of medicines at 1 cent to covered entities are not true “purchases.” Further, penny pricing creates incentives for 340B entities to stockpile medicines, which can create artificial shortages that make it difficult for patients to get the medications they need.

In PhRMA's comment letters to HRSA, we suggested three reasonable alternatives to penny pricing: the prior quarter (non-penny) 340B ceiling price, the Federal Ceiling Price or nominal price—which manufacturers could use as their 340B ceiling prices instead of a penny price. These alternatives would give effect to the statutory language limiting the 340B statute to true “purchases”—not forced transfers.

(2) *Refund Requirements:* The delayed rule includes two separate sets of administratively burdensome refund requirements. Under the first refund requirement, manufacturers must estimate 340B prices for new medicines

¹¹³ A. Vandervelde and E. Blalock, “340B Program Sales Forecast: 2016–2021,” 2016, available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf> (accessed March 11, 2018).

¹¹⁴ Delays were issued on 3/21/2017, 5/22/2017, 10/1/2017, and 7/1/2018.

and then make refunds to all 340B covered entities that purchased the new medicine during its initial quarters on the market if a recalculated “actual” ceiling price turns out to be lower than the “estimated” ceiling prices. Under the second refund requirement, manufacturers must recalculate 340B ceiling prices from past quarters based on restatements of Medicaid rebate metrics and then initiate and make refunds to covered entities on past sales based on the recalculated ceiling price. Both refund requirements would call for manufacturers to make costly changes to their pricing systems and business procedures to come into compliance and waste manufacturer resources due to their needless complexity.

The delayed rule also requires manufacturers to pay refunds to 340B covered entities without subtracting any amounts that the covered entity owes to the manufacturer (unless the entity voluntarily agrees to the offset, which seems unlikely). This policy in effect would require a manufacturer to pay a covered entity more than it owes to the entity. Companies cannot be required to pay more than they owe; this policy is wrong, was not authorized by the 340B law and needs further review.

(3) *CMPs*: Finally, this delayed rule would permit the OIG to impose CMPs against manufacturers without specifying any clear standards for imposing these penalties. This omission heightens risk for manufacturers that already are operating in a complex program lacking clear ground rules. The 340B statute, as amended by the Patient Protection and Affordable Care Act (ACA), authorizes CMPs against a manufacturer that “knowingly and intentionally charges a covered entity a price for purchase of a medicine that exceeds the [340B ceiling] price” (up to \$5,000 for each “instance” of overcharging), provided that CMPs “*shall be assessed according to standards established in regulations.*”¹¹⁵

The delayed rule failed to establish standards for assessing CMPs. For one thing, it does not even define “knowingly and intentionally.” HRSA instead gives unfettered discretion to OIG to define “knowing and intentionally.” The resulting uncertainty will cause manufacturers unnecessary costs, as the Final Rule essentially concedes, and will not satisfy the statute’s requirements for “standards established in regulations.”¹¹⁶

Separately, PhRMA wishes to note our support for HRSA finalizing and launching a new password-protected website that would provide a secure way for 340B covered entities to access ceiling prices. Some of our members were involved in testing this system and we urge HRSA to launch this website as soon as possible, with appropriate safeguards given the sensitive nature of the pricing information that will be available on the website. The ACA requires that this site be developed,¹¹⁷ and we look forward to covered entities having confidential access to this information.

In Summary, PhRMA Urges Action to Bring the 340B Program in Line with the Current Health Care System and Ensure Its Sustainability for the Future

PhRMA strongly believes that the 340B program should continue, and we recognize how the program helps support true safety net entities and their patients that currently rely on the program. However, we urge both Congress and the Administration to make changes to the program so that its structure and rules are consistent with its roots as a safety-net program and serve the mission of supporting access to care for uninsured or vulnerable patients.

Currently DSH hospitals’ use of the program is not serving that mission. Instead, economists are finding that the 340B program is raising costs for all patients and that low-income patients are not seeing better health outcomes at 340B hospitals. They suggest these higher costs are due to three reasons: (1) hospitals earn more 340B revenue when patients take more medicines and more expensive medicines; (2) 340B is contributing to the shift in care from community-based physicians to more expensive hospital outpatient facilities; and (3) the large share of 340B-discounted medicines purchased by hospitals for certain conditions is driving up prices. To make matters worse, hospitals do not have to pass along 340B savings to low-income patients or even make them aware of the discounts. This means that uninsured or vulnerable patients may be *worse off* due to the 340B program.

¹¹⁵ 42 U.S.C. 256b(d)(1)(B)(vi) (emphasis added).

¹¹⁶ 42 U.S.C. § 256b(d).

¹¹⁷ PPACA § 7102(d)(1)(B)(iii).

These market distortions are due in part to the lack of clear program standards that would limit 340B eligibility to true safety-net hospitals and the patients who rely on these hospitals for their care. Instead, a combination of guidance that is either vague or overly broad coupled with a lack of HRSA oversight has fueled dramatic growth in the program. Unfortunately, none of this growth seems focused on ensuring that patients benefit. Instead, this growth is centered on increasing profits for hospitals, retail pharmacies and middlemen.

PhRMA once again thanks this Committee for its interest in the 340B program. We urge you to continue taking a closer look at this program, encouraging HHS and HRSA to fully consider their oversight responsibilities and authorities, and to consider critical legislative changes to the 340B program, not only to increase transparency and reporting, but also to ensure the program is being executed in a way consistent with its original intent that benefits patients, the safety net, and the health care system as a whole.

[SUMMARY STATEMENT OF LORI M. REILLY]

This is a summary of the testimony of Lori M. Reilly on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), which reiterates our support for the 340B program and recognizes the importance of the program to our safety net. In particular, PhRMA recognizes the crucial role 340B grantees play in providing care to the most vulnerable among us but also highlights how flaws in the program's current structure are distorting the health care marketplace and not helping patients. The testimony makes the following key points:

(1) Today's 340B Program is Nearly Unrecognizable from the Program Congress Enacted in 1992; Changes Have Contributed to the Many Problems Now Associated with the Program (page 4). The 340B program was created to restore voluntary discounts to grantees and safety net hospitals that had unintentionally been impacted by the passage of the Medicaid rebate law. At first, grantees made most of the 340B purchases, but over time DSH hospitals have come to dominate the program. Nothing in the 340B statute suggests the program was designed to be a major revenue source for DSH hospitals that provide little charity care with no accountability for how the revenue is used. A combination of expansions in Medicaid coverage and flawed guidance under the Health Resources and Services Administration (HRSA) have caused explosive growth and led to this program straying from its origins.

(2) The 340B Program Creates Market Distorting Incentives That Affect Consumer Prices for Medicines, Shift Care to More Expensive Hospital Settings and Accelerate Provider Consolidation (page 8). A growing body of evidence from nonpartisan, independent sources, including *The New England Journal of Medicine*, *JAMA*, the GAO and others, points to data showing the 340B program has now grown so large that it is distorting market prices, affecting patterns of utilization, leading to more provider consolidation, and driving up health care costs for everyone.

(3) Recent Administrative Action Is a Step Forward, But More Action Is Needed to Modernize the 340B Program (page 13). PhRMA supports the recent Trump Administration change to Medicare Part B reimbursement at 340B hospitals as a good first step toward addressing one of the perverse incentives in the 340B program that the Government Accountability Office (GAO) and others have found leads to higher costs for patients and the entire health care system. However, because Medicare Part B represents less than one-quarter of total DSH hospital revenue from 340B, the incentives remain intact. More needs to be done to address other aspects of the program that are driving up costs. Three bills recently introduced in Congress would help by addressing concerns with how disproportionate share (DSH) hospitals are misusing the 340B program.

(4) Improvements to the 340B Program Are Urgently Needed in Five Key Areas: (1) 340B Patient Definition; (2) DSH Hospital Eligibility Standards; (3) Standards for Off-Site Hospital Clinics ("Child Sites"); (4) Contract Pharmacy Arrangements; and (5) Reporting Requirements (page 14). Guidance released by HRSA in these five areas have led to lax standards in fundamental parts of the program, such as setting standards for which patients and private DSH hospitals are eligible for 340B discounts. PhRMA believes strong requirements are needed to limit 340B eligibility to true safety-net hospitals and the patients who rely on these hospitals for their care. In other areas, such as offsite outpatient facilities (also known as child sites) and contract pharmacy arrangements, HRSA should revisit policies that vastly expanded the 340B program and contributed to the mar-

ket distortions we see today. The program needs reporting requirements to ensure program reforms are based on accurate data and to give HRSA better insight into how the program is currently being misused.

In our testimony, PhRMA urges Congress and the Administration to make changes to the 340B program so that its structure and rules are consistent with its roots as a safety-net program and serve the mission of supporting access to care for uninsured or vulnerable patients. We urge you to take a fresh look at how DSH hospitals are now using this program and to work with HRSA to ensure the enactment of common-sense changes that protect 340B grantees while curbing the excesses in many DSH hospitals' use of the 340B program.

The CHAIRMAN. Thank you, Ms. Reilly.
Ms. Veer, welcome.

STATEMENT OF SUE VEER, MBA, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CAROLINA HEALTH CENTERS, INC., GREENWOOD, SC

Ms. VEER. Thank you.

Good morning and thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee for the opportunity to share the perspective of Health Centers.

My name is Sue Veer, and I am the President and CEO of Carolina Health Centers, which is a federally qualified health center serving as the primary care medical home for 27,000-plus patients in rural South Carolina.

Today, however, I am here in my capacity as a consultant for the National Association of Community Health Centers, commonly referenced as NACHC, which represents over 1,400 health centers that serve as the primary care medical home for 27 million patients in 10,000 medical sites across the country.

As a member of NACHC, I have worked to promote pharmacy services as an integral part of the community health center model of care, including the effective implementation and compliant use of the 340B pharmacy program.

Largely due to my experience with my own health center pharmacy, for the past 2 years I have served as a NACHC consultant providing 340B training and technical assistance to health centers and primary care associations all across the country.

I am here today to share my perspective, as well as that of my colleagues at NACHC, as it relates to the value of the 340B Program for health centers and the patients we serve.

I would like to start with an underlying premise, and that is, there is a direct correlation between access to affordable primary care and the ability to manage both acute illness and chronic disease. I believe there is also an undeniable relationship between well-managed chronic disease and a reduction in the use of more costly care like specialty care and in-patient services.

Thus, it can be concluded that access to affordable primary care services improves both individual and population health, which, in turn, promotes cost effectiveness.

Community health centers, also known as a federally qualified health centers, serve as primary care medical homes and share a commitment to increasing access, improving health outcomes, and driving cost effectiveness.

To that end, health centers provide access to affordable primary care regardless of the ability to pay with a focus on populations that would otherwise be underserved.

The 340B Program is a core element of achieving that goal as it supports our health centers' efforts to ensure that all patients have access to and can afford essential primary care services, including prescription medication.

Whether through the implementation of an in-house pharmacy, or by expanding access through contract pharmacy arrangements, without 340B, health centers like mine would not be able to provide effective pharmacy services for their patients. In addition, the savings achieved enable health centers to support essential primary care services that would otherwise be unavailable for our patients.

This Program was originally created to enable providers like mine, a community health center, to fulfill our mission and serve as the Nation's primary care safety net. We have proven to be exceptional stewards of that Program. Our mission is consistent with the congressional intent of the 340B Drug Pricing Program, which the Chairman stated earlier this morning.

We serve vulnerable patients. We ensure that they can afford their medications. We reinvest 340B savings toward purposes that advance the safety net mission, and we adhere to extensive reporting and oversight requirements to demonstrate increased access to care and improved health outcomes.

It is important to note that health centers are accountable to HRSA for both our community health center program and participation in the 340B Program.

On the health center side, HRSA approves what is called our "scope of project," and holds us accountable for Program expectations that are detailed in a 92-page compliance manual.

It is also important to note that health center implementation of the 340B Program is guided by each health center's congressionally mandated community-based, majority patients' board ensuring a focus on the needs of our patients and the communities we serve.

Related to 340B, our boards establish mechanisms to ensure access to affordable medication, like sliding fee scales and participation in prescription assistance programs. And they also require that we reinvest all of our savings into programs that expand access to underserved patient populations. Our boards play a majority role in identifying where those needs are.

I want to close by assuring you that everyone in the health center community wants Congress to have confidence in the integrity of the 340B Drug Pricing Program, and I am happy to answer your questions today.

However, as you hear various perspectives on the Program, I hope you will recognize that the Program is working exceptionally well for health centers, which serve as the fabric of the Nation's healthcare safety net.

For that reason, we encourage policymakers to work with health centers to best understand the responsibilities and requirements that are unique to the community health centers and the patients we serve.

Thank you.

[The prepared statement of Ms. Veer follows:]

PREPARED STATEMENT OF SUE VEER

Good morning Chairman Alexander, Ranking Member Murray and Members of the Committee.

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 27,705 patients in the west central area of South Carolina known as the Lakelands. However, today I am here representing the 1,400 community health center organizations that serve as the primary care medical home for more than 27 million patients at over across 10,000 sites across the country.

Included in my testimony is an overview of the unique characteristics of health centers and how the creation of the 340B Drug Pricing Program (340B program) was critical in enabling many health centers to start providing their patients with access to affordable pharmaceuticals. My testimony continues with an overview of the training and technical assistance work I and others at NACHC have been doing specific to the 340B program, and concludes with four key perspectives on this important program, including how health centers use the program and the resulting savings to expand access to essential primary care and drive improved clinical outcomes.

Thank you for the invitation to serve as a witness at this hearing and to highlight the vital importance of the 340B program to health centers nationwide.

Background on Health Centers and the Creation of the 340B Program

Community Health Centers ensure that underserved patients have access to quality comprehensive primary care

Community Health Centers—also known as health centers, federally Qualified Health Centers or FQHCs—are the backbone of our Nation’s primary care safety net. Our fundamental characteristic is a commitment to ensuring everyone has access to high-quality, comprehensive primary care regardless of demographic, geographic, and socioeconomic barriers. By law and by mission, health centers serve areas and populations that the Federal Government has determined to be medically underserved, and we are required to provide services without regard to a patient’s ability to pay. Nationally, almost a quarter of health center patients are uninsured, and over 70 percent of them have incomes below the Federal Poverty Level (FPL); for those patients with incomes below the FPL, they pay no more than a nominal fee for the full range of services we provide. An additional 20 percent of patients have incomes between 101 percent and 200 percent FPL, these patients are charged discounted rates based on a sliding fee scale.

All health centers provide their patients with access to a comprehensive range of primary and preventive health care services, and many also provide dental, mental health, and substance use disorder services. In addition, health centers provide a wide array of care management, patient education, and assistive services that support access to care, promote enhanced clinical outcomes, and reduce total costs across the health care system. Over two-thirds of health centers serve as Primary Care Medical Homes, which demonstrates health centers’ commitment to patient-focused quality and comprehensive care.

Another core characteristic of health centers is how they are governed—namely, by their patients. Each health center organization is an independent, non-profit corporation governed by its own Board of Directors, and a majority of each Board’s members must be actual patients of that health center. This structure ensures that each health center remains directly responsive to the unique needs of its patients and community. In an era of increasing consolidation among health care providers, health centers are local, community-based organizations.

The creation of 340B reduced drug prices for health centers and expanded access for their patients

The creation of the 340B program in 1992 played a critical role in health centers’ ability to provide affordable care for underserved populations. Prior to that time, the majority of health centers were unable to offer pharmaceutical services for their patients, as the costs of the drugs were often beyond their reach. Thus, the health centers wrote prescriptions for medically necessary drugs that patients often could not afford to fill at commercial pharmacies. As small, community-based providers, health centers lacked the market power to negotiate significant discounts off the sticker price. And while Patient Assistance Programs (PAPs) were available, the amount of paperwork involved and the narrow scope of the programs significantly

limited the degree to which health centers could help their patients access the drugs they needed.

This situation was compounded in 1991 upon creation of the Medicaid Drug Rebate Program (MDRP). An unintended consequence of the MDRP resulted in drug manufacturers becoming concerned that selling drugs to non-Medicaid purchasers at discounted prices could increase their exposure to higher Medicaid rebates. That fear caused them to pull back on some of the discounts they had historically provided to safety net providers. In response, Congress created the 340B program as part of the Veterans Health Care Act of 1992, which also provided similar relief to the VA.

The 340B program established maximum prices that manufacturers could charge safety net providers for drugs. For those health centers that had the resources to operate their own pharmacies, the creation of 340B was a critical moment in their ability to offer affordable medications to their patients. As discussed below, the ability to realize savings on 340B drugs provided to insured patients also provided resources to expand access to other services for health centers' low-income, medically underserved population.

NACHC Activities to Support Health Centers' 340B Operations and Compliance

My interest in maintaining the scope and integrity of the 340B Drug Pricing Program relates to my dual role as both a health center CEO and a NACHC consultant. As President and CEO of Carolina Health Centers, Inc. (CHC) I provide leadership and oversight for a comprehensive health center program of which pharmacy services are an integral part. CHC opened its first in-house pharmacy, Carolina Community Pharmacy (CCP), in 2005. Our pharmacy program has grown to include two stand-alone community pharmacy locations, daily delivery of prescriptions to our 12 medical practice sites for our patients living in very rural areas, and a new initiative to integrate clinical pharmacists into the patient care teams at our medical practices. My health center made the strategic decision to implement 340B using an in-house model, meaning that we own and operate the pharmacy and manage it under the governance of CHCs' community-based/patient majority Board of Directors. We operate as an "open" pharmacy meaning that prescriptions are filled for both health center patients and the general public, although only prescriptions for CHC patients may be filled using 340B purchased inventory. This "open" model 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. Of all prescriptions dispensed through CHCs' sites in 2016, only 33 percent were covered by a third-party payer and 17 percent were delivered to outlying rural practice sites where patients have limited access to retail pharmacies.

My individual health center's experience is offered as context for my role as a NACHC consultant. Approximately 5 years ago, NACHC convened a 340B Work Group, in recognition of the importance of pharmacy to health centers' overall model of care, and the vital role of the 340B Drug Pricing Program in enabling health centers to implement pharmacy services. I was honored to be asked to chair the Work Group, which meets face to face twice a year at major NACHC conferences as well as by teleconference on an as needed basis. Since that time, we have also convened a 340B Key Contacts group comprised of at least one representative from each of the state and regional Primary Care Associations (PCA). Together, these two groups provide tremendous insight into how different health centers across the Nation operationalize their 340B program as they work to increase access to care and expand services in response to the needs of the communities they serve. These groups have also helped NACHC to identify best practice models and develop strategies for training and technical assistance (TA) focused on 340B implementation and compliance, as well as identifying challenges health centers encounter in their attempts to optimize the value of the program for their patients.

In 2016, I became an official consultant for NACHC, and my activities since that time have included the following:

- *Fourteen state-specific 340B Summits:* These Summits, which included health centers covering 16 states, last from 1–2 days at the discretion of the PCA, and are targeted to both the C-Suite and pharmacy leadership. In advance, I research the state-specific environment, including by surveying the health center membership, to ensure that the material is reflective of their specific situations. To date, we have provided this training for health centers in 16 states, and three more are scheduled for the near future.

- *NACHC conferences and trainings:* NACHC has incorporated 340B program elements throughout its training curriculum. For example, later this week I will be speaking about the 340B program at two different sessions as part of NACHC's spring conference, and next week I will be presenting on-line as part of NACHC training for Chief Financial Officers. Also, we recently launched a monthly teleconference called "340B Office Hours" which allows the health center 340B community to have a dialog around operational and compliance questions.
- *Health-center-specific sessions at 340B Coalition Conferences:* Because of the unique issues that health centers encounter when operating a 340B program, we collaborate with 340B Health—the organization that coordinates the twice-yearly 340B Coalition Conference—to include sessions that are specific to health centers during their semi-annual conferences.
- *340B technical assistance email:* We have created an email address for health centers seeking technical assistance with 340B issues. To date, we have responded to hundreds of individual questions and requests for assistance via this email.

Note that NACHC consults with Apexus—the 340B Prime Vendor—to ensure that all training and technical assistance activities are aligned. I serve as faculty for the Apexus' in-person trainings (called "340B University") and serve on one of its Advisory Councils. Apexus also serves as a first line of response when addressing individual TA requests, and has recently created a special version of 340B University to specifically address health centers' unique circumstances.

What follows are four observations related to health center participation in the 340B Drug Pricing Program—notably, the value it brings to patients and communities served.

Four Health Center Perspectives on the 340B Program

1. Health centers are good stewards of the 340B program.

The health center mission and model of care are consistent with the congressional intent of the 340B Drug Pricing Program—"to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." As such, since its establishment in 1992, health centers have worked hard to ensure that they are good stewards of the 340B program. To that end, health centers ensure that vulnerable patients can afford their medications; reinvest 340B savings toward purposes that advance health centers' safety net mission of expanding access for underserved populations; and adhere to extensive reporting and oversight requirements to demonstrate that health centers are increasing access to affordable primary health care.

- **Health centers work to ensure that low-income uninsured and underinsured patients can afford to access their medications purchased through 340B.** As discussed above, a fundamental characteristic shared by all health centers is the commitment to ensure that patients can access appropriate medical care, regardless of their insurance status or ability to pay. As a result of this commitment, health centers use 340B savings to ensure that low-income patients can afford their medications. Specifically, health centers use 340B savings both to offset the cost of providing prescriptions to uninsured and underinsured patients on an income-based sliding fee scale, and to finance the considerable resources necessary to leverage PAPs on behalf of their patients.
- **Health centers must reinvest all 340B savings into activities that advance their HHS-approved mission of expanding access for underserved populations.** As the Committee is aware, the 340B statute does not specify how providers should use the savings they accrue under 340B. However, the authorizing statute for the health center program—Section 330 of the Public Health Service Act requires in Subsection 330(e)(5)(D)—that health centers must reinvest all 340B savings into activities that further the goals of the health center project and enable the health center to provide high quality, affordable care to medically underserved populations. Later, I will discuss some of the many ways in which health centers use 340B savings to expand access and improve outcomes for their patients.
- **Health centers are subject to extensive Federal oversight and reporting requirements.** Each of the more than 1,400 health center orga-

nizations are subject to extensive and on-going oversight from the United States Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA).

- The HRSA requirements with which health centers 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 of these requirements through a variety of mechanisms, including: onsite compliance reviews, frequent interactions with project officers, and regularly scheduled reporting obligations.
- HRSA also approves health centers' "Scope of Project", meaning those primary care delivery sites, services, and providers that are considered part of the health center's program operations. Only those approved delivery sites and services that have undergone HRSA scrutiny and are subject to HRSA's ongoing oversight are eligible to participate in the 340B program—and 340B savings can only be used to support activities which are consistent with and advance our health center project.
- Each year, health centers must submit extensive data to HRSA on a wide range of measures, including but not limited to: patient characteristics, payer mix, services, costs, and clinical outcomes. The manual with instructions for how to compile this data is 200 pages long, and each health center's data is posted publicly on the HRSA website.

2. The 340B program is essential to each health centers' ability to achieve their congressionally mandated mission of providing affordable access to care for underserved populations.

Access to affordable prescription medications is recognized by most medical providers as one of the primary drivers of improved health outcomes. This point was made emphatically by the Chief Medical Officer of my health center when he stated: "To diagnose and not be able to treat the patient effectively is always an exercise in futility and sometimes a death sentence." Health centers serve as patient-centered medical homes and are responsible for the overall management of the health of their patients; however, if patients cannot afford their prescriptions, health centers will be limited in their ability to treat acute conditions, manage chronic disease, and optimize their patients' health outcomes.

Beyond ensuring access to affordable pharmaceuticals, health centers use 340B savings to support other activities that increase access and improve outcomes. Here are some examples of ways in which health centers use 340B savings to increase access to high-quality, affordable care for their patients:

- Implementing delivery systems and mail order pharmacy programs to ensure access to affordable prescription medication for health center patients in outlying rural communities with limited or no access to affordable pharmacy resources. One such service makes over 25,000 affordable prescriptions accessible to low-income and underserved persons.
- Establishing multidisciplinary Care Transition Teams providing care management for patients at high risk for repeat hospital admissions. The model for this program resulted in savings to their local health care delivery system of over \$1.4 million in the first year of the program.
- Subsidizing the cost of behavioral health counseling provided by a local partnering agency onsite at the health center to low income, uninsured, and underinsured patients who would either not qualify for, or have long delays in receiving care from the local mental health agency.
- Establishing a pharmacist led interdisciplinary controlled substance review process with the goal of decreasing inappropriate prescribing of opioids and the associated patient morbidity and mortality. This initiative resulted in a 66.2 percent reduction of patients on chronic opioids and cut premature deaths in half over a 3-year period.
- Covering the cost of uncompensated care provided to patients in communities with high rates of poverty for which the health center's Section 330 grant funds are inadequate.

¹For a complete listing of all requirements, see the 92-page Compliance Manual available at: <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>.

- Maintaining health center operations in sites where mitigating circumstances result in higher cost and subsequent operational losses. Examples of mitigating circumstances are disproportionate need for unfunded enabling services such as social work, translation, transportation, and care coordination or increased cost of provider staffing in difficult to recruit to rural and frontier areas.

3. The contract pharmacy model enables health centers to expand access to affordable prescription medications.

While most health centers likely would prefer to implement the 340B program using an in-house pharmacy, operating an in-house pharmacy can be daunting and sometimes presents insurmountable barriers. Health centers might lack space, technology, ability to recruit professional staff and availability of operating capital to sustain the in-house pharmacy operation until it reaches a break-even point. Further, providing access to medications after clinic hours and on weekends may present an additional drain on limited health center resources.

The ability to contract with more than one pharmacy further improves health centers' ability to provide for their patients and ensure access to affordable medications. Health centers with in-house pharmacies, often find contract pharmacies to be useful tools to expand patient access, as patients have more pharmacies to choose from, including those that are closer to their home or work, and have longer hours than an in-house pharmacy can provide.

Based on my experience with health centers across the country, there are three primary drivers of a health center decision to implement 340B using a contract pharmacy arrangement:

- Lack of capital and operational resources, as well as the organizational capacity to support the implementation and ramp-up to a financial viable pharmacy operation;
- Geographic dispersion of the health center's patient population in small rural areas unable to support a full-scale pharmacy operation within the health center site; and
- Potential disruption to small, locally owned independent pharmacies, as it would pull away too many customers for them to remain economically viable, especially in rural areas.

It is worth noting that savings that health centers achieve through a 340B contract pharmacy arrangement may provide the resources necessary to implement an in-house pharmacy program moving forward, which, in my experience, appears to be an evolving trend.

4. A "one size fits all" approach to program changes could have unintended consequences.

At present, approximately 15 types of health care providers are eligible to participate in 340B. From an administrative perspective, it might seem simpler to implement a single set of rules that apply equally to all 15 types of eligible providers. However, a "one-size-fits-all" approach when making changes to the 340B program could potentially have unintended consequences for one entity and even further unintended consequences for another type of entity.

For example, health centers do not provide "charity care" in the generally understood manner of a designated, and perhaps limited, charity care fund. All FQHCs, by law and by mission, are required to see all patients, regardless of ability to pay. If health centers were required to report the amount of "charity care" provided, the broader concept of community benefit would be a more appropriate measure, though not likely comparable to other covered entity types.

For this reason, when considering any potential 340B changes, we encourage policymakers to work with health centers to best understand the responsibilities and requirements that are unique to health centers and the patients we serve.

Conclusion

As my testimony demonstrates, the 340B program is vital to the Nation's community health centers, 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.

[SUMMARY STATEMENT OF SUE VEER]

A fundamental characteristic of all health centers is the commitment to ensure access to affordable health care for all individuals, regardless of ability to pay, with a focus on caring for populations who would otherwise be underserved. By definition, all health centers must be located in a medically underserved area and/or in communities designated as having medically underserved populations. An effective 340B program is a core element of achieving the goal of ensuring affordable health care, as it supports the health center's efforts to ensure that all patients have access to, and can afford, the medications that they are prescribed. Without the 340B program, many health centers patients would have no other access to affordable medication, which plays an essential role in improving individual patient outcomes as well as overall population health measures.

The relationship between 340B and financial viability is complex and multidimensional. As mentioned above, access to affordable medication is essential to the effective treatment and management of chronic disease, which in turn reduces the need for costly specialty and inpatient care; thereby reducing the financial burden on the health care delivery system. The 340B program also enables health centers to support key patient care services that would otherwise be unfunded, and therefore unavailable to patients. Finally, access to affordable prescription medication drives improved clinical outcomes which, in turn, enable the health center to deliver the results necessary to secure optimal reimbursement and remain financially viable in a value based health care delivery system.

My testimony will support the following perspectives:

- Health centers are good stewards of the 340B program, ensuring that low-income uninsured and underinsured patients can afford to access their medications purchased through 340B.
- Health centers reinvest all remaining 340B savings into activities that advance their HHS-approved mission of expanding access for underserved populations.
- Health centers are subject to extensive Federal oversight and reporting requirements.
- The 340B Drug Pricing Program is essential to health center's ability to achieve their congressionally mandated mission of providing affordable access to care for underserved populations.
- The contract pharmacy model enables health centers to expand access to affordable prescription medication into communities with limited or no affordable pharmacy resources.
- To avoid unintended negative consequences, program changes must be made with consideration of the responsibilities and requirements unique to the health centers.

The CHAIRMAN. Thank you, Ms. Veer.
Mr. Hill, welcome.

STATEMENT OF JOSEPH M. HILL, III, MA, DIRECTOR, GOVERNMENT RELATIONS DIVISION, AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS, BETHESDA, MD

Mr. HILL. Thank you, Chairman Alexander, Ranking Member, and distinguished Members of the Committee for the opportunity to testify today.

My name is Joseph Hill, and I am the Director of Government Relations at the American Society of Health-System Pharmacists. I am here today to provide ASHP's perspective on the 340B Drug Pricing Program.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the fore-

front of efforts to improve medication use and enhance patient safety.

ASHP has a longstanding history of support for the 340B Drug Pricing Program. Many of our members serve as patient care providers in hospitals and health systems that are 340B eligible and have seen, firsthand, the benefits of the Program to the patients they serve.

Congress enacted the 340B Program 25 years ago with bipartisan support. Since that time Congress, under control and support of both parties, has expanded the Program beyond hospitals to other safety net providers. Together, these providers serve tens of millions of uninsured and underinsured people every year.

The increasing shift throughout healthcare toward ambulatory care and more outpatient pharmacy services has also contributed to the growth of the 340B Program and has allowed for better access to medications by low income and uninsured patients.

It is important to note that the drugs subject to the 340B Drug Pricing Program make up a fraction of the Nation's total drug expenditures.

Further, the Program also reduces Government expenditures and reduces taxpayer burden that would otherwise be responsible for the indigent care financed through the 340B Program.

Today, the 340B Program continues to meet Congress' original intent of enabling these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services.

Access to primary care, behavioral health services, pharmacist-led substance abuse treatment, provision of naloxone to law enforcement, discounted or free prescription medications, and other services for many uninsured and underinsured patients are made possible only by the savings realized through the 340B Program. In some communities, there would be limited or no access to healthcare services without the 340B Program.

ASHP also recognizes the great importance of Program compliance and we endorse programs that support both covered entities and manufacturers. ASHP has partnered with Apexus, HRSA's contracted 340B Prime Vendor, to improve compliance through the use of educational training sessions such as the 340B University. This training is available at our midyear clinical meeting, the largest meeting of pharmacists in the world, our summer meetings, and our annual conference for pharmacy leaders.

To date, around 30,000 individuals have participated in the 340B University. The goal of these sessions is to educate our members and other stakeholders about the Program's requirements, as well as to provide a forum to discuss compliance challenges and solutions.

These educational sessions are typically done in panel format, which allows the unique opportunity for covered entities to interface with peers, faculty, and pharmaceutical wholesaler and manufacturer representatives in live sessions.

ASHP believes these programs have had a positive influence on improving compliance within the 340B Program.

ASHP remains supportive of the 340B Program. We believe it is a critical component in providing care to uninsured and underinsured patients, often our Nation's most vulnerable population.

We also think the Program is especially critical in our Nation's rural areas where access and ability to pay for care are often compromised.

We remain committed to working with Congress, HRSA, and other stakeholders to ensure that the requirements of the Program are being met and that the Program functions as intended.

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

Again, we thank the Committee for the opportunity to provide input, and I look forward to answering any question you may have.

[The prepared statement of Mr. Hill follows:]

PREPARED STATEMENT OF JOSEPH M. HILL III

Good morning, and thank you, Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee, for the opportunity to testify today. My name is Joseph Hill, and I am the Director of the Government Relations Division for ASHP, the American Society of Health-System Pharmacists. I am here today to provide ASHP's perspective on the 340B Drug Pricing Program.

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

ASHP appreciates the opportunity to provide our views to the Committee on the 340B Drug Pricing Program. ASHP has a longstanding history of support for the 340B drug-pricing program, as many of our members serve as patient care providers in hospitals and health systems that are 340B-eligible and have seen, firsthand, the benefits of the program to the patients they serve.¹ At a time when Federal budgets are stretched thin, the Federal 340B program helps maximize Federal resources while providing access to lifesaving medications.

Congress enacted the 340B drug-pricing program 25 years ago with bipartisan support.² The program requires pharmaceutical manufacturers participating in the Medicaid or Medicare Part B programs to enter into a pharmaceutical pricing agreement (PPA) with the Federal Government.³ The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified safety net providers, known as "covered entities," that serve the Nation's most vulnerable patient populations. On several occasions since that time, Congress, under the control and support of both parties, has expanded the program to other hospitals that are part of the Nation's safety net. Covered entities include not only hospitals

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

² Veterans Health Care Act of 1992, Public Law No. 102-09585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b

³ HRSA, Pharmaceutical Pricing Agreement, available at <http://www.hrsa.gov/opa/manufacturers/pharmaceuticalpricingagreement.pdf>.

servicing many low-income patients (disproportionate share hospitals [DSHs], rural referral centers, critical access hospitals [CAHs], children's hospitals, and cancer hospitals), but also several other types of safety net providers including federally qualified health centers (FQHCs), state and local health departments, HIV clinics, and hemophilia treatment centers.⁴

Together, these providers serve tens of millions of uninsured and underinsured people every year.

The increasing shift throughout healthcare toward ambulatory care including more outpatient pharmacy services has contributed to the growth of the 340B program and has allowed for better access to medications by low-income and uninsured patients. It is important to note that drugs subject to the 340B drug-pricing program make up a fraction of the Nation's total drug expenditures. Further, the Federal 340B program also reduces government expenditures and lessens the burden on taxpayers who would otherwise be responsible for financing the indigent care that Federal 340B-participating hospitals provide.

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

In September 2011, the Government Accountability Office (GAO), issued a study of the Federal 340B program and found that, in large part, the program is operating as originally intended.⁵ Specifically, the GAO found that "all covered entities reported using the program in ways consistent with its purpose" and that "all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients." GAO did make several recommendations for improving program oversight and specifically called on the Health Resources and Services Administration (HRSA) to be more proactive in administering the program. As a result, HRSA has significantly increased the number of audits of covered entities to help ensure compliance with program requirements.

ASHP also recognizes the great importance of program compliance, and we endorse programs that support the covered entities as well as manufacturers. ASHP has partnered with Apexus, HRSA's contracted 340B prime vendor, to improve compliance through the use of educational training sessions. ASHP continues to collaborate with Apexus to provide training programs, known as the 340B University, at our prominent and widely attended Midyear Clinical Meeting, the largest gathering of pharmacists in the world; our Summer Meetings; and our annual Conference for Pharmacy Leaders. To date, about 30,000 individuals have participated in the 340B University. The goal of these sessions is to educate our members and other stakeholders about the program's requirements as well as to provide a forum to discuss compliance challenges and solutions. These are typically done in panel format, which allows the unique opportunity for covered entities to interface with peers, the faculty, and pharmaceutical wholesaler and manufacturer representatives in live sessions. ASHP believes these programs have had a positive influence on improving compliance within the 340B program.

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

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

⁴ 42 U.S.C. § 256b(a)(4).

⁵ GAO-11-836: Published: Sep 23, 2011. Publicly Released: Sep 23, 2011.

[SUMMARY STATEMENT OF JOSEPH HILL III]

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ASHP has a longstanding history of support for the 340B drug-pricing program. Many of our members serve as patient care providers in hospitals and health systems that are 340B-eligible and have seen, firsthand, the benefits of the program to the patients they serve. Congress enacted the 340B program 25 years ago with bipartisan support. Since that time, Congress, under the control and support of both parties, has expanded the program beyond hospitals to other safety-net providers. Together, these providers serve tens of millions of uninsured and underinsured people every year.

The increasing shift throughout healthcare toward ambulatory care including more outpatient pharmacy services has contributed to the growth of the 340B program and has allowed for better access to medications by low-income and uninsured patients. It is important to note that drugs subject to the 340B drug-pricing program make up a fraction of the Nation's total drug expenditures. Further, the program also reduces government expenditures, and it reduces taxpayer burden that would otherwise be responsible for the indigent care financed by the 340B program.

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

ASHP also recognizes the great importance of program compliance, and we endorse programs that support both covered entities and manufacturers. ASHP has partnered with Apexus, HRSA's contracted 340B prime vendor, to improve compliance through the use of educational training sessions, such as the 340B University. This training is available at our Midyear Clinical Meeting, the largest gathering of pharmacists in the world; our Summer Meetings; and our annual conference for Pharmacy Leaders. To date, about 30,000 individuals have participated in the 340B University. The goal of these sessions is to educate our members and other stakeholders about the program's requirements as well as to provide a forum to discuss compliance challenges and solutions. These educational sessions are typically done in panel format, which allows the unique opportunity for covered entities to interface with peers, faculty, and pharmaceutical wholesaler and manufacturer representatives in live sessions. ASHP believes these programs have had a positive influence on improving compliance within the 340B program.

ASHP remains supportive of the Federal 340B program. We believe it is a critical component in providing care to uninsured and underinsured patients—our nation's most vulnerable population. The program is especially critical in our Nation's rural areas, where access and ability to pay for care are often compromised. We remain committed to working with Congress, HRSA, and other stakeholders to ensure that the requirements of the program are being met and that the program functions as intended.

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

The CHAIRMAN. Thank you, Mr. Hill, and thanks to all four of you for being here and for excellent testimony. We will read the statements that you submitted.

We will now begin a 5 minute round of questions beginning with Senator Cassidy.

Senator CASSIDY. Thank you all for being here.

First, let me establish my street credentials. I worked in a public hospital in Louisiana taking care of the uninsured for 25 years and still am nominally, at least, still go to clinic every now and then. And so, I know the importance of what Ms. Veer and Dr. Siegel speak of. And I actually think that is common ground.

Everybody recognizes that there are patients, and community health clinics, and safety net hospitals that appropriately benefit from the 340B. I do not think that is the issue.

But it is important to move beyond, if you will, rhetoric and anecdote and look at objective facts.

If I may, Mr. Chairman, I ask unanimous consent to issue a few of the following studies, which are rigorous analyses, nonpartisan, third party researchers regarding the problems with 340B.

First, an NYU-Harvard research published in the "New England Journal of Medicine," of February this year found no evidence that 340B revenue went to help lower income patients in ways that reduce mortality, and that 340B eligibility prompted hospitals to treat fewer Medicaid patients without increasing quality; "New England Journal of Medicine," Harvard, and NYU.

Secondly, a 2017 "Journal of Oncology" article showing that physician practices being consolidated due to 340B hospitals using the revenue to buy up their practices drives up the cost of commercial insurance.

Next, the "New England Journal of Medicine" article from the University of Chicago and Harvard from 2016 suggesting, quote, "Lawmakers could lower the price of prescription drugs by reforming the Federal 340B Drug Pricing Program."

Next, 2014, from a Memorial Sloan-Kettering "Health Affairs" article, researchers from the University of Chicago also, quote, "Support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics."

2014, the Office of Inspector General found that some covered entities that dispense 340B-purchased drugs to Medicaid beneficiaries through contract pharmacies did not report methods to avoid duplicate discounts.

Next, GAO, "Our work suggests 340B hospitals may be responding to financial incentive associated with the Program to maximize Medicare revenue."

2011, the GAO concluded, quote, "Program integrity issues may take on greater significance unless effective mechanisms to monitor and address Program violations are put into place."

Finally, 2017, OIG testimony noting that a continued lack of transparency that prevents accurate payments by 340B providers, State Medicaid programs, and manufacturers; and two, a lack of clarity regarding Program rules.

The CHAIRMAN. They will be included in the record.

Senator CASSIDY. I will note that some of these 340B hospitals are actually extending the Program benefit to cosmetic clinics, and into clinics and hospitals that serve wealthy clientele using the primary site; which may be 340B buying hospitals in wealthy suburbs

and then taking a program, ostensibly for the poor, and making it a cash cow for the system.

Now, Dr. Siegel, I admire the work your hospitals do. Obviously, we have hospitals in Louisiana as part of your coalition.

But when you say there should be no restrictions or changes to the 340B Program, can you really defend a cosmetic clinic benefiting from 340B?

Dr. SIEGEL. Thank you, Senator, and thank you for your leadership, and also for the work you did at our member systems and hospitals in Louisiana. Greatly appreciate that.

I cannot speak to the cosmetic clinic, although if a cosmetic clinic were dealing with burn patients, many of whom——

Senator CASSIDY. Usually, those would be in a burn unit. It would not be a place doing blepharoplasty.

Dr. SIEGEL. But it might also be, sir, a place which has post-discharge patients.

Senator CASSIDY. Let us just take the theoretical. It is a cosmetic clinic that does blepharoplasty. It is all cash. It is 340B.

Should they benefit from the 340B Program?

Dr. SIEGEL. They should benefit from the 340B Program if they fall under the rules of the Program.

Senator CASSIDY. You want no change in the rule, even though I have this stack tumbling out of my hands showing that there are abuses that are driving up the cost of drugs for others, and the cost of commercial insurance for all.

There should be no change in the 340B?

Dr. SIEGEL. Those studies are deeply flawed studies. Let me speak to a couple of them.

Senator CASSIDY. Now hang on. Just so I may say.

Dr. SIEGEL. Yes.

Senator CASSIDY. I think I did ten studies: NYU, Harvard, Memorial Sloan-Kettering, the University of Chicago, OIG, GAO, and each of these are deeply flawed?

Dr. SIEGEL. Yes.

The GAO study, for instance, talks about the increased Part B spending for 340B hospitals. Does it account for the difference in health status of the patients who go to 340B hospitals rather than others? It does not.

Senator CASSIDY. It did a regression analysis looking at the difference in patient populations.

Dr. SIEGEL. Actually, HHS actually critiqued that study on those same grounds, the ones I just noted.

Senator CASSIDY. The one recently in the “New England Journal of Medicine”?

Dr. SIEGEL. Excluded many 340B hospitals from consideration and also——

Senator CASSIDY. No, I know. So I accept that there are——

I am sorry. I am out of time and I will yield back after this point.

That is the trick. I do not want to offend you, but there is a certain lack of forthrightness.

Your good work is presented as typical of all 340B’s. Clinics, safety net hospitals, this is the face of 340B, when there is a whole stack of evidence that non-340B hospitals may provide more charity care than many 340B hospitals.

Although you are the face, and you are a very good face; nice face, Dr. Siegel.

[Laughter.]

Dr. SIEGEL. Thank you. I appreciate that.

Senator CASSIDY. But we have to concede, or maybe you do not have to concede, but the evidence concedes that there are hospitals, which are not taking care of charity patients, and which come upon your coattails, if you will, to justify that which is an income stream, but not serving the original purpose.

I may stay around for a second round, and I apologize to my colleagues for going over.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator HASSAN.

Senator HASSAN. Well, thank you very much, Mr. Chairman.

Thank you and the Ranking Member for holding this hearing.

Dr. Siegel, because I do not want to use up too much of my time, I may try to give you some opportunity to respond a little bit more to Senator Cassidy's comments in just a minute.

First of all, I just want to note that in New Hampshire, we have 13 340B hospitals that rely on the Program in order to help them stretch Federal dollars, so that they can help provide benefits to other communities.

Dartmouth-Hitchcock, for example, is one of the few rural academic medical centers in the country, and 340B is vitally important to them and the communities that they serve.

Because of 340B, Dartmouth-Hitchcock saves about \$43 million each year. And in 2016, they provided more than \$172 million in community benefits to help improve the health of the Granite State. In New Hampshire, this includes helping to fight the opioid epidemic.

In fact, just at the beginning of this month, Dartmouth-Hitchcock made a contribution to a community organization in Claremont, New Hampshire to assist with the opioid epidemic after programs were forced to scale back because of a lack of state funding.

Dr. Siegel, can you comment on the role of the 340B Program specifically for rural hospitals like Dartmouth-Hitchcock and how it impacts their ability to provide community benefits?

Dr. SIEGEL. Thank you, Senator. I appreciate the question.

A place like Dartmouth-Hitchcock, or other 340B hospitals, has a really unique role to play in their community.

Unfortunately, opponents of the Program have continued to characterize the Program as simply existing only to provide charity care to people. If you look at a Dartmouth-Hitchcock, it goes far beyond that.

Senator HASSAN. Yes.

Dr. SIEGEL. These hospitals are providing not just charity care. They are providing care, under-reimbursed care, to Medicaid patients. They are suffering through bad debt, bills that are not paid, for they provide that care readily and happily.

They provide the burn unit, the trauma center. They are out in the community dealing with food insecurity, dealing with housing; just a whole range of things that make communities better and more vibrant.

Senator HASSAN. Yes.

Dr. SIEGEL. We need to keep that in mind when we talk about the benefits of the 340B Program.

Charity care is one measure; just one.

Senator HASSAN. Yes, and it is really important for people to understand that charity care is often care for people who do not have insurance, but there is a whole lot of under reimbursed care like Medicaid. New Hampshire is one of the lower Medicaid reimbursers in the country, for instance.

I also want to touch a little bit on some of the criticism around transparency because I think it is really important that we make sure that the 340B Program is operating as Congress intended and helping support these safety net providers, so that they can provide care, as you have just described.

We have heard about transparency as it relates to 340B, but I have to say, I think the place we most need transparency is in drug pricing. I wish stakeholders, with all due respect to Ms. Reilly, like PhRMA, advocated as strongly for transparency in the pricing of their own members' products as they have advocated for transparency in 340B.

For example, the big drug makers claim to set their prices to recoup research and development costs, but many think much of the money goes to things like marketing campaigns and profits.

But there is no transparency in their pricing. So they get away with hiking up prices to reap profits without being held accountable, all while everyday Americans struggle with drug prices.

Dr. Siegel, I am interested in your thoughts about that.

Dr. SIEGEL. Thank you, Senator.

First, I want to just note that as we talk about prices, and you mentioned marketing and those sorts of things, the top ten drug makers in America spend about \$100 billion a year on marketing every year and advertising.

The discount of this Program is \$6 billion. Let us just make sure we compare those two.

We talk about transparency. Hospitals are leaders in transparency. I mean, we really began the movement toward transparency in the National Voluntary Hospital Reporting Initiative 20 years ago. We are proud of that and we still stick to that. When we look at the drug manufacturers, we do not see that.

Just today, if you look at something like the average manufacturer price, which is how we set this ceilings price for the 340B programs, we do not know where that number comes from. There are legal things that allow in law drug companies not to disclose that data and the information is not even reviewed in the few audits that HRSA has done of manufacturers. It is a black box.

Senator HASSAN. Well, thank you. I want to just get your thoughts.

If the 340B Program were restricted or rolled back in any way, do you think manufacturers would reduce drug costs?

Dr. SIEGEL. No.

Senator HASSAN. Thank you.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Smith.

Senator SMITH. Thank you, Chairman Alexander.

Thank you all for being here today.

I appreciate hearing about the 340B Program today, which is such an important strategy for lowering the cost of drugs, especially for rural hospitals and community health plans. Ms. Veer, I appreciate your comments about community health plans.

Just today, I had an opportunity to meet with a large group of them from Minnesota and their message was loud and clear on how important it is and also they are really providing a foundation access to healthcare all over the state.

I wanted to just say, yesterday I heard from a woman from Minnesota, her name was Rachel, who visited my office. She is a military vet and a new mom. She was diagnosed with Stage IV lung cancer at the age of 31.

Now last year, the price for just one of her drugs was \$16,000 every month. And this year, the cost of her drug increased to \$20,000 every month. So even with insurance, she is paying over \$15,000 out of pocket for her medicine, which is just completely unconscionable, it seems to me.

Given that the huge burden of drug prices that have been placed on families like Rachel's, it seems like we ought to be doing everything we can to lower drug prices and bring those prices down.

Yet, in the United States, spending adjusted after net prices—that is the actual amount that the manufacturers get back from selling their products—on prescription drugs reached \$323 billion in 2016 and it grew by almost 5 percent from the previous year.

It seems like prices are just out of control and as I said, it is the No. 1 thing I hear about in Minnesota, the No. 1 economic issue.

Last month it was reported by Axios, that the number of leading pharmaceutical organizations, companies, are using a large portion of the windfall from the tax bill, not to lower drug prices, but to improve stock prices and to benefit their investors.

My question to you, Ms. Reilly, is can you help me understand why the American people like Rachel, like my constituent, should not be outraged that they are paying so much for prescription drugs when revenues for the big drug companies are going up nearly 25 percent?

Over \$55 million is being spent on lobbying, this is according to a "Politico" article, and that the salaries of your CEO's range from \$2 million to \$17 million a year. Help me understand how that can make sense for Americans.

Ms. REILLY. First of all, thank you for your question and also, thank you for raising an important issue.

In my mind, we do have an issue in terms of patients often being able to afford and access their therapies. There is no doubt about that.

We have been strongly on record to say that we believe that the discounts and rebates that our companies provide—whether it is to hospitals that participate in the 340B Program where discounts range at 50 percent, or to commercial payers where often the average rebate is 40 percent—actually make it back to those patients who are in need of being helped.

Today, unfortunately, there is no requirement that those rebates, whether they are in 340B or whether they are provided to commercial payers, actually are passed back to patients who need them. In fact, quite the opposite is happening.

In hospitals today, the average hospital mark-up on a prescription medicine is 500 percent. They are then reimbursed two-and-a-half times what the manufacturer receives. Patients' co-insurance and co-pays are based off of that amount. Patients' premiums are taken into account.

Yes, more does need to be done to ensure that patients can access and afford their medicine. But today, unfortunately, many policies that are in place by insurance companies, hospitals, and others are not mandating that the discounts we are providing make it to the patients that need them.

Senator SMITH. But my question to you is when people are just trying to figure out how to pay their bills, and they are looking at the amount of money that your organization is spending on lobbying and the amount of money.

The head of your organization, according to "Politico," made somewhere in the neighborhood of \$2.8 million last year.

How can we explain that to people?

Ms. REILLY. Again, I think for patients who cannot afford their medicines, that is the purpose of insurance.

But today what we have going on is a perversity of insurance where instead of healthy people subsidizing the sick, we have turned our system into one where sick people are subsidizing healthy with the incidence of high deductible health plans, high co-insurance.

Many patients today with cancer, when they go to pick up their medicine, they are asked to pay 40 percent of a list price of a medicine that is not reflective of the rich discounts and rebates that our companies provide. That needs to change, because patients are struggling to afford their medicines.

We are committed to helping them, whether it is through the discounts we provide in 340B, to commercial payers, or the free programs that our companies provide to patients that lack insurance.

Senator SMITH. Mr. Chairman, I know I am out of time, but I want to just close by noting that the average Minnesotan makes about \$65,000 a year; half of them make less than that.

That means that the head of your organization is making as much in a week as they are making in a year, and I think that is what people are looking at as they are trying to understand what is going on with prescription drug prices.

Thank you very much.

The CHAIRMAN. Thank you, Senator Smith.

Senator Kaine.

Senator Kaine. Thank you, Mr. Chairman.

Thank you, to the witnesses.

Mr. Chairman, if I might. This panel is a very important one because this Program is important and I appreciate the Committee calling this hearing. It does strike me that the first five questions I have had pop into my mind, as I have heard the witnesses testify, are questions that I want to direct to HRSA.

I hope we might consider having, at least, another hearing where we could engage HRSA on the same discussion.

The CHAIRMAN. Well, thanks, Senator Kaine. We will have at least one more hearing on 340B, and that is a very good suggestion about inviting HRSA, and we will try to do that.

Senator Kaine. Excellent. Thank you, Mr. Chairman.

This is a critical Program. Others have talked about its importance in their own state. In Virginia, there are 22 hospitals that are participants in the 340B Program and a whole range of other safety net providers, community health centers, free clinics, and others.

One example, just to give you one, Riverside Hospital Health System in Virginia receives about \$36 million of discounts a year under the 340B Program. They are very, very active including in some really hard to reach parts of the state. There is only one hospital on the Eastern Shore of Virginia, for example. That is a Riverside hospital and the 340B Program is absolutely critical to them. We have had rural hospitals in Virginia close. A lot of them are just on-the-edge.

We have a community health center in Tangier, which is an island in the middle of the Chesapeake Bay that is extremely hard to get to. Riverside helps staff it. It is a community health center; 340B is very, very important to that program.

I wanted to ask, this is a question probably for Dr. Siegel and Ms. Veer and Mr. Hill, but Ms. Reilly, you may want to address it as well.

HRSA announced, I guess, January 1 as the subject of litigation that there is going to be a 28.5 percent reduction in the reimbursement rate under the 340B. I know that is in their litigation and going back and forth.

But if that were to go into effect today, talk about the effect that would have upon the institutions and companies that you are here to represent.

Dr. Siegel. Thank you, Senator.

First of all, I can say that cut, as unfortunate as it is, is going to lead to individual hospitals, some of them losing millions of dollars a year in payment for services they are already providing. That cut boggles the mind.

It basically says, "If you have more than your share of Medicaid patients and poor people," and that is why you are in the Program. The rules are pretty clear. "We have decided as a matter of policy, we are going to pay you less under Medicare. We are going to punish you."

They have made a rationale that the reason we are doing this is because we are going to save beneficiaries money. Over 80 percent of beneficiaries will see no change because of supplemental insurance that they have.

Senator Kaine. This is a cut in this program, which just affects the safety net hospitals. That there is not an equivalent cut, for example, that has been announced on reimbursement rates to non-340B hospitals.

Dr. Siegel. That is correct. It is a targeted cut that affects 340B hospitals.

By the way, drug companies will probably recoup because it is about \$70 million potentially. And that was a MedPAC projection.

Let us be clear about what this is and how really unconscionable it is.

Senator Kaine. I only have a minute left. Ms. Reilly, I will have you next. Maybe I will just go in order.

Ms. Reilly, go ahead.

Ms. REILLY. I would say our discounts do not change under this policy, so nothing about that policy impacts the discounts that we have to provide.

I would also just say that while it is a cut to hospitals in one sense, it only affects 13 percent of the profit margin hospitals receive from 340B, and that money is redistributed to hospitals.

I think 75 percent of all hospitals come out at the same, if not slightly better, than what they do under the current rule.

Senator KAINE. But the 25 percent that come out worse are the ones that are the safety net hospitals.

Ms. REILLY. I do not know that is accurate. Twenty-five percent of hospitals will receive less money than they did under the current plan. But again, they still have 87 percent of their profit coming from outside of that cut.

Senator KAINE. Ms. Veer.

Ms. VEER. Yes. This rule does not directly affect the health centers, but I think what we are concerned about is the signal that it sends regarding the concept of discriminatory pricing from the payers.

Senator KAINE. Mr. Hill, how about from your perspective?

Mr. HILL. I think our view would be mainly around how the program allows pharmacists to provide more advanced patient care services. We could be talking about pharmacist-led opioid stewardship program. In some cases, pharmacists actually make house calls, involves other health professional too, but we work for a pharmacy group, so I am going to focus on pharmacists.

I think our concern is the ability of hospitals to utilize clinical pharmacists and not have the proper funding to account for this.

Senator KAINE. The cut may restrict their ability to use pharmacy services.

Mr. HILL. Right.

Senator KAINE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine, and we will follow-up on your suggestion.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

The 340B Program helps hospitals and clinics providing care to the most vulnerable patients—the uninsured, the underinsured, people with HIV or AIDS, children with cancer—by requiring drug companies to provide medications at a discounted price. So, of course, the drug companies are fighting to limit the program.

I get it. No one likes to be forced to handout a discount. And I understand why drug companies want to make sure that these discounts are only going to hospitals that treat people in need.

But the drug companies have now started attacking the 340B Program, a drug discount program. I started following the press reports on this. The argument is that it is contributing to the problem of high drug prices. That is, that the 340B Discount Program contributes to the problem of high drug prices.

I just want to look at this for just a second.

Ms. Reilly, your organization called PhRMA, I think is how it is pronounced, represents drug companies. According to HRSA, the Government agency that administers the 340B Program—and I

think these were the same data that Senator Alexander just quoted—drug companies were required to give roughly \$6 billion in 340B discounts in 2015.

Is that about right?

Ms. REILLY. There were \$16 billion of sales in 2016 of 340B.

Senator WARREN. No, I am not asking a question about sales. I am asking the question about you were required to give about \$6 billion in discounts.

Ms. REILLY. That is 2015 data. It would be \$8 billion in 2016.

Senator WARREN. Okay.

Ms. REILLY. You are looking at just the discount, but not the sales.

Senator WARREN. Yes, but that is what I want to know. I want to know how much you had to give up for this because that is what creates, to me, the big problem with PhRMA's argument that the 340B Program raises drug prices.

If 340B did not exist, drug companies would have an extra \$6 billion in their pocket. That is less than 1 percent of global pharmaceutical sales revenue, which also in 2015 was \$775 billion. Or, if you do not like that comparison, we could use the size of the U.S. drug market, about \$457 billion in 2015. Here the discounts worked out, as Senator Alexander pointed out, to a whopping 1.3 percent.

But no matter what denominator you use, it is clear that the total loss to these drug companies, the loss that they are kicking and screaming about right now, is a tiny fraction of the many billions of dollars that they pull down every year in profits.

Dr. Siegel, according to an analysis by the Government Accountability Office, the average profit margin for drug companies in 2015 was 17.1 percent.

You represent hospitals that serve a large share of uninsured patients and patients receiving coverage through Medicaid.

How do the profit margins of the drug companies compare to the profit margins at your hospitals?

Dr. SIEGEL. Thank you, Senator Warren.

The drug companies' margins are about 6 times ours, on average. Our average member is 3 percent. And let me be clear, many of our members are, frankly, losing money sometimes millions of dollars per year.

Senator WARREN. Ms. Veer, if health centers lost access to these discounted drugs, do you believe that patients would be better off or worse off?

Ms. VEER. They would be far worse off. I can think back to a time when my health center, we are very geographically disbursed, our patients are, and we implemented a delivery service to get affordable medication out in those areas.

I think back to before that happened and we had a very difficult time managing the chronic disease of those patients.

I would also say as it goes to the margin issue, I operate on anywhere from a 1 to 3 percent margin in my health center at best. And without 340B, we would see that drop, probably, into the negative double digits, which would, of course, mean the resultant cut in services that we could provide.

Senator WARREN. A 1 to 3 percent margin compared with a 17.1 percent margin—

Ms. VEER. Yes.

Senator WARREN.—profit margin for the drug companies.

I think it is always fair to look for ways to improve a program like 340B, to make sure it is supporting those who need it the most. But that is not what the drug companies are doing right now.

The drug companies are pulling out a trusted Washington lobbying playbook. They shift the blame for the skyrocketing cost of prescription drugs onto someone else, blame the Pharmacy Benefit Managers, blame the insurers, blame the hospitals, blame anyone else.

But whatever happens, make sure that no one focuses on the out of control drug prices that the drug companies are charging; charging, simply because they can.

I believe we should spend some time focusing on the high cost of prescription drugs instead of chasing around wherever the drug companies want us to go.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Jones.

Senator JONES. Thank you, Mr. Chairman.

Thank you to our panelists.

I have to be honest about this. I feel to some extent what I am hearing today is just a small microcosm of some of the biggest dysfunctions that we have in Washington, where we have one side saying one thing, and another side saying almost completely the opposite.

It is almost like you are not talking to each other. I would encourage everybody to try to talk together a little bit to each other.

But let me just ask a couple of specifics.

Dr. Siegel, we have seen the studies, and I am not sure I agree with you that the studies that Senator Cassidy—which I appreciate being put in the record—are all as deeply flawed as you say.

Do you recognize that there needs to be some changes and there needs to be some oversight of this Program to make it more efficient? And if so, briefly, give me some ideas of what you can do.

Dr. SIEGEL. I absolutely do recognize that there needs to be oversight and we are truly stewards, good stewards of the Program. We go through audits every year or frequently. We go through annual recertification to be in the Program.

I mean, you do not just wander in to the 340B Program randomly because somebody said you should be. You have to meet some rules and meet those every year. And then when you are audited, you are under potential penalty if you find a problem.

As a matter of fact, if you have three strikes against you in an audit, you can be thrown out of the Program. So we have to be stewards of this Program.

Senator JONES. Ms. Reilly, I noticed on several occasions you shake your head. You did then and I am going to give you a chance, but I would like for you to go back to Senator Smith's question which, quite frankly, she gave you two times to answer and you did not.

Both times, she asked you specifically about the amount of money being spent on either advertising or other things that are going to CEO executives, stock buybacks, stock prices, those kinds of things. And each time, you kind of flipped it back on the hospitals and the providers.

I would like for you to address what Dr. Siegel just said, as well as the issue where I first noticed it, where you were talking about the amount of advertising money that is being spent, \$100-something billion versus \$6 billion.

Kind of reconcile that for me a little bit.

Ms. REILLY. Sure.

Senator JONES. Because I think Senator Warren adequately pointed out, and rightly so, you make a ton of money. I mean, it is a ton of money.

Complaining about the \$6 or \$8 billion dollars and the global things just is not computing for the people of Alabama, where 80 percent of the hospitals that are in the 340B Program are underwater, and we are losing our hospitals every day. They are trying to stretch those Medicaid dollars every day.

I want to give you a chance to respond to that.

Ms. REILLY. Sure. In terms of what our companies spend on advertising, it is less than \$5 billion a year. I would note that many hospitals also advertise, so I am sure they are proud of the advertising that they do as well.

I want to be clear, and I said it at the outset of my testimony, that we do not want the 340B Program to go away. I think often our position is characterized as one that we think it is a terrible program and it should go away; far from the truth.

This Program was started because our companies had voluntarily provided large discounts to public hospitals, community health centers, and others. Passage of the Medicaid Rebate statute created unintended consequences. Congress stepped in and created this Program. There is nothing wrong with this Program.

I think what we are saying is there needs to be rules about how this Program operates. Our goal in providing deep discounts is also to ensure that the patients who need them can actually afford them.

Us providing a 50 percent discount, and an uninsured patient walking into a hospital and paying full list price for the medicine rings wrong to me and, I think, to many patients.

Senator JONES. Would you expect if the reforms that you want to see implemented are, in fact, implemented, would you expect to see the dollars, not the percentages, but would you expect to see the total dollars of discounts provided go from \$8 billion less, or stay the same, or more?

Ms. REILLY. They could go down, but quite honestly, if you froze the Program today and said that this is the dollar amounts that we have to live with, our companies could live with this.

I think the problem is what we have seen is the paradoxical nature of the fact that over the past few years, we have dramatically increased insurance coverage for patients. Hospitals are spending less as a percentage of total expenses on compensated care than they were years ago. They are spending less on charity care.

If these resources are needed, and for many institutions they absolutely are needed, but one would assume that uncompensated care costs, charity costs, would be increasing.

If they are not increasing, then I think we have to ask the questions: where are those dollars going and are they actually going to patients to reduce their out of pocket costs? Which we believe is a strong goal of the Program: let us help patients.

I would be very remiss in not saying that the grantees, like community health centers that live under this program, are operating under very different rules. A patient walks into a community health center. They are charged on a sliding fee scale. They have an obligation under Federal law to reinvest the resources that they get from this Program back to helping uninsured and vulnerable patients.

Those same requirements do not apply in the hospital setting and we think that is a change that makes sense. If we are going to hold grantees accountable for using these resources in a certain way, certainly we should be holding hospitals accountable for use of this Program in a similar way.

Senator JONES. Dr. Siegel, I notice your hand, but my time is up. Mr. Chairman, I appreciate your indulgence.

The CHAIRMAN. Thank you, Senator Jones.

Senator Young.

Senator YOUNG. Thank you, Mr. Chairman.

Dr. Siegel, I would like to discuss the 340B Program. It allows many hospitals, in my State of Indiana, to help some of our most vulnerable and complex patients.

In your testimony, you describe how hospitals use their 340B savings, including free clinics, comprehensive services, and other things.

How do you obtain this information from your hospitals?

Dr. SIEGEL. We ask them and they are glad to provide it.

Senator YOUNG. Do you survey the hospitals? Is that how?

Dr. SIEGEL. No. We literally go to them, "Tell us how you are using your savings. Tell us what you are doing in your community," and they are proud to talk about it.

Senator YOUNG. Is there a form you fill out? How rigorous is this?

Dr. SIEGEL. Some organizations have had forms, but we just ask them to, "Tell us what you are doing."

I will also note that recently when the Energy and Commerce Committee had hearings on this, hospitals were happy to provide this information, including detailed financial information.

Senator YOUNG. Well, I am not going to linger on that question for a period of time. It strikes me as a bit loosey-goosey.

Why can hospitals not report directly to us about how they use their 340B dollars? If they are reporting to you, however formal or informal that process might be, why can they not just report it to us?

Dr. SIEGEL. I hear your concern about loosey-goosey and there was some loosey-goosey just now when somebody used an advertising number that does not really talk about all the marketing that drug companies do.

Senator YOUNG. I have no idea—

Dr. SIEGEL. I will leave that be.

Senator YOUNG. Please address my question, please.

Dr. SIEGEL. We totally support transparency. We are leaders in transparency. But I will say one thing.

Senator YOUNG. You would support direct reporting?

Dr. SIEGEL. If we are going to have transparency in the hospital industry on these issues, we need to have transparency on the drug industry as well.

Senator YOUNG. That is fair to go down that line of questioning. That is not my line of questioning.

It sounds like we are just taking your word for it with respect to the 340B's. Maybe you can disabuse me of this notion, but if there is not direct reporting, and you are going around, I cannot even use the word "surveying".

You are having conversations with hospitals about 340B usage, and the data, and so forth. We are taking your word for it. Right?

Dr. SIEGEL. Take your hospitals' words for it. Take the word of people who spend every day in their community and caring for people who really need these services.

Senator YOUNG. We could take our hospitals' word for it through direct reporting. Right?

Dr. SIEGEL. Any kind of direct reporting, any kind of increased transparency has to have two things. One, it has to be on all players. This needs to be a two-way street. We have a black box on one side of this equation right now, which we are not addressing.

Second, we need to make sure that any reporting we do is not a backdoor—

Senator YOUNG. "We," meaning who?

Dr. SIEGEL. Government, policymakers, whoever requires anything is not a backdoor way to restrict the Program, which exactly what opponents of the Program want.

Because when we restrict a program through some backdoor form, we are going to stick it to local taxpayers. We are going to stick it to state government. We are going to stick it to the Federal Government.

Senator YOUNG. You regard yourself as a guardian, as the gatekeeper and guardian at once of the 340B Program.

Dr. SIEGEL. Our hospitals are excellent stewards of this Program and are proud of it.

Senator YOUNG. I am going to essentially mention the rest of the panel a number of times. I am going to open this up to the entire panel.

What do you feel are responsible reporting requirements, so we can properly oversee this Program and ensure vulnerable patients are benefiting from it, No. 1? And what can be done to have more transparency in the Program?

Ms. REILLY. I am happy to.

Senator YOUNG. Yes, Ms. Reilly.

Ms. REILLY. Sure. I think, for one, having access to the insurance status of the patients that are being seen. Not just at the hospital, but also for the numerous offsite clinics that participate in this Program who often have a patient mix that looks very different from the hospital that ultimately qualifies for the Program.

Reporting on charity care; again, not just for the hospitals as a whole, but also for the individual sites that participate.

We think that there should be transparency into the contracts that hospitals enter into. So nonpublic hospitals, those private hospitals that are not-for-profit, have a requirement under law that in order to participate, they need to have a contract with a state or local government, or they need to be performing governmental powers.

Today, there is a black box in terms of those contracts.

Senator YOUNG. Okay, so that is a black box. Thank you, Ms. Reilly.

Ms. Veer.

Ms. VEER. Yes. As you know, health centers are held accountable to reporting to HRSA on a variety of metrics. Currently, 340B is not one of those, but I do think we are held accountable.

Senator YOUNG. Should it be?

Ms. VEER. I think there are ways to do that, but keep in mind that there are a number of things that are not taken into account.

For example, the reference to payer mix does not take into account the large percentage of our patients that are insured, but have high deductibles, high co-pays and they actually have a low enough income to qualify for our sliding fee scale.

Senator YOUNG. Perhaps direct reporting, but provide that context.

Ms. VEER. Provide context.

Senator YOUNG. All right. Yes, sir.

Mr. Hill.

Mr. HILL. I think it would be an opportunity, frankly, for covered entities to be able to tell their story and how they care for patients. I think thus far, we have not done as good of a job of telling that story.

One of the misconceptions on this Program is, I think, people focus solely on the drug, and what they fail to account for are all the services that go into serving a patient.

You may have a patient that cannot get to the hospital or has to take a drug with three meals a day, only they do not eat three meals a day, so they have to seek out a social worker.

These things probably, I think, could help the Program in the long run if we were able to tell that story of, "How do you touch these patients?" And, "What are the things you do to improve their care?"

Senator YOUNG. All right. I think I am out of time here.

The CHAIRMAN. Yes.

Senator YOUNG. We could dialog later.

Thank you so much.

The CHAIRMAN. Thank you, Senator Young.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much.

I want to thank the panel for your testimony and for your presence here today.

In my home State of Pennsylvania, we have a long, long list of hospitals that depend upon the 340B Drug Pricing Program. It is not just a long list; it is a diverse list. We have, of course, big cities

like Philadelphia that have institutions that are dependent upon this Program, but also small population communities.

I just was going through a list this morning and looking at everywhere from, it must be by way of population as small a population as Potter County about 17,000 people, all the way to Philly which is, of course, well over 1 million-and-a-half people. So it is a critically important program.

Dr. Siegel, I am going to start with you and I am not sure if we will get through more than this, but I wanted to focus on those safety net hospitals and charity care, and just a very specific and precise question. Let's give you the predicate first.

There is a lot of discussion, and of course, proposed legislation, that focuses on comparing the 340B savings that are accrued by these safety net hospitals to the charity care that they provide.

As you know, and others have spoken to this, I guess, charity care has both a specific and very narrow meaning. It is care that is provided to a patient or qualifies under the hospital's charity care policy for free or reduced care. There is much that is not captured by that measure.

For example, bad debt expenses or other uncompensated care that was not reduced to bad debt.

Third, are unreimbursed costs for Medicaid and children's health insurance.

Fourth, are subsidies that many safety net hospitals provide to physicians to compensate them for losses incurred on Medicaid beneficiaries and care provided to the uninsured. So it is a much broader list of challenges.

In developing greater transparency in the 340B Program, and a meaningful assessment of the degree of economic challenge faced by these safety net hospitals, should we look to all forms of economic contribution and burden facing those participants, those hospitals rather than one specific measure that does not accurately reflect the circumstances?

Dr. SIEGEL. Yes, Senator, we need to look at the full array of benefits that hospitals can provide, thankfully, with the 340B Program supporting that; two quick examples from your state.

If you look at Einstein Medical Center in Philadelphia, because of the 340B Program, they can fill prescriptions for discharged patients regardless of their ability to pay, help them with post-discharge counseling, and eliminate access to care issues. Keep them out of the hospitals. That saves us all money. Keep them out of the emergency rooms.

That would not be necessarily captured in a charity care metric. If I go to Temple, right down the street, a big trauma center, they have to spend money out of the hospital's pockets to pay doctors to take care of their patients because nobody else is going to pay them.

Nobody is fighting for our patients. They just left us with the burden and these are great examples of that.

These are both benefits, that I just mentioned, which would not be captured in this narrow definition of charity care that the opponents of the Program want to put forth as the only measure of whether or not you are doing good stuff.

Senator CASEY. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey.
Senator Cassidy.

Senator CASSIDY. I am glad for a second shot at this, Mr. Chairman.

Again, as a physician, let me just start over.

The emphasis should not be upon a hospital. The emphasis should be upon a patient. We need to think as Senator Smith did, what does it mean to a patient paying \$16,000 a year? So, Dr. Siegel, would you—

By the way, and just to emphasize, if we are speaking about patients, this is some of the data I quoted, “340B eligibility prompted hospitals to treat fewer Medicaid patients. The consolidation of practices associated with this has increased prices without ostensibly improving quality consolidation driven by 340B.” That is data. It is not anecdote. It is not rhetoric.

The “New England Journal of Medicine” article from the University of Chicago and Harvard, “Lawmakers could lower the price of prescription drugs by reforming the Federal 340B Drug Pricing Program.”

Lastly, from the University of Chicago, Memorial Sloan-Kettering, “It supports the criticism that the 340B Program is converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics.”

As regards hospitals, are they unable to survive without this Program?

There is an Axios analysis of the 84 largest not-for-profit hospitals, which I suspect maybe 100 percent of those are 340B hospitals, and they found that cumulatively, they had \$535.5 billion in annual revenue. Taking all things into account, there was a 6.7 percent total profit margin.

It is not like these hospitals cannot make it work. They are making it work very nicely. If you focus upon the patient, this is driving up the cost.

Mr. Hill, would you support a law that said that the discount associated with 340B pricing had to be passed on to the patient? So that Senator Smith’s patient paying \$16,000 a year—whatever per month—would get the 340B price, which may be \$2,000 instead of the \$16,000? Would you support such a law?

Mr. HILL. Senator, I think our potential concern with that approach is that although we completely understand passing along the discount to the patient, I think our concern is that what has to be sacrificed on the care side in order to do that.

Senator CASSIDY. Going back to it, ostensibly, 340B is about lowering costs and making medicines more available, and we have heard data that indeed 340B hospitals may be less likely to treat Medicaid patients.

By the way, here is an article from the Office of the Inspector General, that some 340B entities do not even offer the discounted 340B price to uninsured patients and any of their contract pharmacies. They make them pay the full list price.

Now, if you are the patient, and as we heard, you are the sick person supporting the system, you would not support them being forced to pass that discount onto the patient, the uninsured patient?

Mr. HILL. I think we would have to look at it closely to make sure that the—

Senator CASSIDY. Dr. Siegel, would you support just allowing the uninsured patient to get the discount that the hospital is currently reaping?

Dr. SIEGEL. Our hospitals often go beyond that discount.

Senator CASSIDY. No, but would you support a law that would require those hospitals to pass that discount on to the uninsured patient who is paying thousands of dollars for a drug the hospital is acquiring for a fraction of that cost?

Dr. SIEGEL. I am much more worried about drug prices. I am much more worried—

Senator CASSIDY. Yes or no. Somehow I am talking about—

Just a yes or no, would you support a law that would require the hospitals to pass their 340B discount to the uninsured patient?

Dr. SIEGEL. Cannot support or oppose it without knowing more.

Senator CASSIDY. That settles that.

Dr. SIEGEL. Cannot support or oppose it either way without knowing more.

Senator CASSIDY. Well, I had some other questions.

I think this is more about the hospitals than it is about the patients. That is the crazy thing here. And everybody speaks about—

Believe me, since the Affordable Care Act passed—and for all of you who love the Affordable Care Act, I am not taking shots—the market cap value of pharma, hospitals, and insurance companies has skyrocketed. Just look it up.

Now that said, again, even not-for-profits are doing so well that “The Wall Street Journal” says, “They are behaving like Fortune 500 companies.” This is “The Wall Street Journal” based on an Axios report, “Not like nonprofit hospitals.”

Last, Mr. Hill, Chuck Grassley asked, I think, the Carolina Medical Center in Charlotte to report how they used their 340B, transparency, and how they used their 340B revenue.

Do you think your members would report how they used 340B? What percentage of their profit is related to 340B? How much goes back to direct patient care and how much goes to just profit margin of a contract pharmacy?

Mr. HILL. We are open to having this discussion. Again, it goes back to being able to tell the story and to demonstrate what you do with the discounts.

We do not have a formal position yet, but we are having, at least, some internal discussions on how something like that might work. So we are open to discussing it.

Senator CASSIDY. I yield back.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

I have long supported the 340B Program. It is critical for about 71 hospitals in my home State of Wisconsin. They rely on it to help provide affordable medications, as well as essential services for their vulnerable, and often rural, communities.

One of our rural hospitals in Wisconsin told me that thanks to their 340B savings, they have been able to expand a remote dis-

pensing site in Mountain, Wisconsin, which otherwise does not have a pharmacy at all anywhere in the community.

It is important to strengthen and improve this Program to ensure it continues to fulfill its purpose, which is why I am concerned with recent actions by the Administration and proposals that unfairly single out and target hospitals for cuts under the 340B Program.

A hospital pharmacist in Madison, Wisconsin recently told me that 340B is vital to the hospital's bottom line and lets him focus on what is best for his patients.

Not long ago, his hospital treated a woman for anaphylactic shock after she was exposed to an unknown chemical at work. She said she had to get back to work or she would be fired. So he wrote her a prescription for an EpiPen, in case she had another exposure. But she could not afford the \$400 price because she was uninsured.

The 340B Program allowed her to receive this lifesaving medication for free.

Dr. Siegel, can you discuss why the 340B Program is financially critical in helping hospitals focus on delivering quality care, while bearing the burden of high drug prices and all the costs of treating low income and uninsured patients?

Dr. SIEGEL. Thank you, Senator.

The 340B Program, which includes only public and nonprofit hospitals—I want to be clear about that—is a vital piece of the fabric to allow our hospitals to perform exactly the mission you talked about. And do that in an era when, in the last 10 years, they have seen the price of the EpiPen quadruple.

It was created initially, this Program, to deal with exactly the issue of rising, surging drug prices and their impact on hospitals.

This discount, which is a little over 1 percent of the total national drug spend—that is what we are talking about here today—is absolutely critical in these very targeted approaches, and we have got to defend it.

Senator BALDWIN. Thank you.

Ms. Reilly, I share your concern with high drug prices, and agree with you that we need to do more to advance commonsense reporting and accountability measures to better understand drug spending.

You noted your support for legislation introduced by my colleague, Senator Cassidy, requiring more hospital transparency under the 340B Program. But my constituent, Diane, who suffers from M.S., wants to know more about why drug companies are raising the prices of prescription drugs.

As you know, I have championed bipartisan legislation with Senator John McCain, the Fair Drug Pricing Act, that holds drug companies accountable to basic transparency when they raise their prices.

I ask you, do you support advancing my bipartisan bill to help Diane better understand the rising prices and to enhance accountability for drug companies as part of this larger discussion about accountability and transparency?

Ms. REILLY. Well, I think the point about transparency is an important one, and I think what we have been consistency saying is

we support transparency that is holistic across our healthcare system.

Drugs are sold in many different forms. In the case of hospitals, we know from recent data that hospitals are marking up a drug—that they purchased for one price—500 percent, and then getting reimbursed two-and-a-half times more than the manufacturer.

We need transparency there as well.

Senator BALDWIN. You are the representative for PhRMA, and so I am really asking about transparency with the drug corporations.

Would you support additional transparency, like the Fair Drug Pricing Act?

Ms. REILLY. We are open to talking about different transparency measures. Again, I think part of our ground rule is if we are going to have transparency, we need to have it holistically across the system. It does not make sense to focus on one piece of a larger supply chain when it comes to prescription drugs.

I would also say that, with regard to prescription drug prices, last year they increased by 2.5 percent, well below what they have been in recent years. I think oftentimes when people look at price increases, they are looking at list or sticker price increases, which are not net of the significant rebates and discounts that we provide.

Senator BALDWIN. But I look at the stories of my constituents who come and tell me about their out of pocket costs. And Diane, who I just mentioned, saw her M.S. drug go up to \$90,000 a year.

Ms. REILLY. Well, I would very much agree with you that out of pocket costs for patients today need to be examined.

We have a perversity of insurance going on in this country where patients who need drugs, like M.S., rheumatoid arthritis drugs, are being asked to pay oftentimes 40 percent of a list price of a medicine, which is not reflective of the rich discounts that are provided on those medicines. And they also face very high deductibles before they can get access, and that is not our goal for a healthcare system.

We want patients to be able to afford and access our medicine.

The CHAIRMAN. Thank you, Senator Baldwin.

Ms. Reilly, is it correct that the savings, the discounted savings that is available to the hospitals and the clinics amounted to about \$6 billion in 2015 and you said about \$8 billion in 2017?

Ms. REILLY. Yes, in 2016, correct, \$8 billion in discounts.

The CHAIRMAN. Just so I can keep all of this in perspective, so that would be about 1 or 1.3 percent of the \$457 billion figure from 2015 of what Americans spent on prescription drugs in this country.

Ms. REILLY. Well, I would say the problem with that number is a couple of things.

The CHAIRMAN. Is that right? Well, what is wrong with it?

Ms. REILLY. Yes, let me explain.

The \$457 billion that is often used was a projected number. It was not actual spend.

The CHAIRMAN. All right. What was the number?

Ms. REILLY. It was in the \$390 billion range, I believe. It was projected.

The CHAIRMAN. The total amount spent on prescription drugs in the United States in 2015 was three?

Ms. REILLY. Three. I will get you the exact number.

The CHAIRMAN. Well, I would like to know.

Ms. REILLY. But it is a high three.

The CHAIRMAN. Well, what was it last year?

Ms. REILLY. In 2016, it was \$323 billion.

The CHAIRMAN. Three hundred.

Ms. REILLY. It was \$323 billion in 2016.

The CHAIRMAN. Okay. Who is the source for that?

Ms. REILLY. That is a report from IQVIA, which is an IMS subsidiary that tracks data.

The CHAIRMAN. What are all those numbers?

Ms. REILLY. \$323 billion in actual sales in 2016. That includes all sales, brand and generic.

The CHAIRMAN. All sales within the United States?

Ms. REILLY. Correct. All sales within the United States.

The 1 percent number, again, not only is the number that was used an estimated number, it also does not include all of the sales that are sold, the discounted number that you mentioned, the \$6 billion. It does not exclude direct sales that pharmaceutical companies make to hospitals, about 10 percent of all fills is 340B.

The CHAIRMAN. But that is not 340B, is it?

Ms. REILLY. Yes.

The CHAIRMAN. What is the number that you would like us to use?

Ms. REILLY. Well, we believe 8 percent is the right number for 2016 and let me explain why we believe that is the case.

The CHAIRMAN. Well, just give me the numbers, not the percent.

Ms. REILLY. Okay. If you look at apples to apples comparison, we use a \$28 billion figure for 2016 and that is at the WAC price or the list price.

The CHAIRMAN. That is the total sales—

Ms. REILLY. Sales.

The CHAIRMAN.—of drugs subject to a discount, subject to a 340B discount.

Ms. REILLY. Subject to a 340B discount, and that is an important point. As you know, inpatient drugs are not subject to 340B.

The CHAIRMAN. Of that \$28 billion, how much was the actual savings?

Ms. REILLY. It would be about half of that because the discounts are, on average, 50 percent. Sometimes they are 99 percent and sometimes they are 30 percent.

The CHAIRMAN. Half of \$28 billion; so \$14 billion.

Ms. REILLY. Correct, at the WAC price or list price, but yes.

The CHAIRMAN. Those are public sources from the pharmaceutical companies?

Ms. REILLY. They are estimates based on HRSA data.

The CHAIRMAN. Those are based on HRSA data.

Ms. REILLY. Correct.

The CHAIRMAN. Dr. Siegel, do you disagree with the \$14 billion discounted number?

Dr. SIEGEL. I do, sir.

The CHAIRMAN. What is your evidence for disagreement?

Dr. SIEGEL. Yes, so this sort of sounds like the new math that my kids were learning.

The CHAIRMAN. No, no. Do not give me a joke. Tell me what your evidence is for disagreement.

Dr. SIEGEL. We use numbers that come from HRSA. We use numbers that were reported to GAO.

The CHAIRMAN. Well, give me the numbers.

Dr. SIEGEL. 1.3 percent. The \$6 billion discount on a \$457 billion spent nationally, 1.3 percent. That is the number that has been used again, and again, and again.

The CHAIRMAN. She said that is an estimate, not a fact.

Ms. REILLY. It is projected sales.

Dr. SIEGEL. This is, much of this is news to me, sir. I have not reviewed her numbers.

The CHAIRMAN. You do not know. So you do not know what the number is and you are representing the hospitals.

Dr. SIEGEL. Oh, I do know. I go—

The CHAIRMAN. Well, but you do not know whether it is an estimate or whether it is a fact.

Dr. SIEGEL. I cannot question numbers which I have just seen here for the first time.

The CHAIRMAN. Yes, but do you know whether the number you just used is an estimate or a fact?

Dr. SIEGEL. I believe it is a fact.

The CHAIRMAN. Yes. She says it is an estimate.

Dr. SIEGEL. I disagree with her.

The CHAIRMAN. But you said you did not know.

Ms. REILLY. It is from ASPE. It is an estimate based on spending.

The CHAIRMAN. May I ask you each to provide me with? I would like to know what percent of the amount Americans spend on prescription drugs is available to safety net hospitals and to clinics for the purposes of 340B, whether it is \$6 billion, whether it is \$8 billion, whether it is \$14 billion, and what percent it is of the total amount we spend.

If it is 1 or 2 percent, you could think of that either way. You could say, "Well, that is just a tax on the pharmaceutical companies that we are spending for a good purpose." If it is 6 or 8 percent, you would have to say, "That is a pretty big tax on a pharmaceutical or on any business," particularly on revenues for that purpose.

I would like to get those figures right.

Do either of you have any more concrete evidence on those? Or are those the two people I should ask about that?

Ms. VEER. I would say I actually have questions about the numbers, but I will follow-up with my fellow panelists on that.

The CHAIRMAN. Yes.

Ms. VEER. Just because I am not sure I understand clearly, for example, the \$28 billion. Is that accounting for wholesaler volume points and that type of thing?

The CHAIRMAN. Well, we will get into that.

Ms. VEER. Yes.

The CHAIRMAN. But if you would provide us the evidence. I mean, one of the things that this hearing would like to do is to establish some facts upon which we can make some decisions.

Now, the second question would be, Ms. Veer, I gather because of the various rules that apply to community health centers—in fact, I met with a whole bunch of them in my office this morning before I came here—I asked them the question about, “How much of the discount money available to you goes directly to the patient who is buying a prescription drug?”

The guess was about 80 percent. They said, “We guess about 80 percent of the savings available goes directly to the patient and the rest we use for other expenses at the community health center.”

Does that sound right or do you know of some evidence that would show what that number would be?

Ms. VEER. I do not know that we could point to an exact number. I guess my philosophical response would be: all of it goes to the patients because, quite frankly, when you—

The CHAIRMAN. No. I am talking about going to the patient when the prescription drug is filled, does it reduce the cost of the drug to X amount?

If 100 percent of it goes to that, what percent of the money goes to that and what percent goes to, say, paying salaries at the community health center or for other functions?

Ms. VEER. That is a great question and I think it differs from health center to health center. I can give you the example at my health center.

The CHAIRMAN. Sure.

Ms. VEER. We operate on a net margin idea with regard to how we use our savings. So last year, 2016, the end of year our savings were \$561,620. Previous to that, we have discounted the drug to the patient on a cost-plus basis.

For example, we pass on the savings of the ingredient cost of the drug and charge a highly discounted dispensing fee.

Out of that \$561,000 the majority of that goes to things like affordable prescription programs, some of the things Mr. Hill mentioned about the clinical services that are available to help promote—

The CHAIRMAN. Well, I understand, but what I am getting at is when Congress passed the law in 1992, it did not say that the money has to be used solely to reduce the price of a prescription drug when a patient comes in and buys one.

Correct?

Ms. VEER. Correct.

The CHAIRMAN. Most of what this hearing is about is what the hospitals, and to a lesser extent, I think, the clinics do with the other money. I mean, that is what people are asking questions about.

My sense is that because of the variety of regulations on clinics, probably most of the money you get goes back directly to the patient for the cost of prescription drugs. Not to say that the other services you provide are not beneficial to that patient.

But I think one thing that I would like to have more information on is: how much of the discounted savings goes directly to the patient who walks in the door with a prescription?

Now, what would you estimate, Dr. Siegel, that would be at hospitals, at safety net hospitals?

Dr. SIEGEL. I do not have an estimate for that.

The CHAIRMAN. Would anybody have an estimate for that?

Dr. SIEGEL. I do not know.

The CHAIRMAN. We do not have any idea? So we do not know how much of the money goes directly to patients or how much is spent for other services that, presumably, benefit patients?

Would that not be something we should know?

Dr. SIEGEL. I think that is something we should know along with many other things we should know about this program, Mr. Chairman.

The CHAIRMAN. Well, what are the other things?

Dr. SIEGEL. As I noted before, if we want to have more transparency, let us make sure that all of us who are partners in this Program, I hope, live to that same level.

The CHAIRMAN. Yes, but that is called passing the buck. I think what we need to understand is how much? What I want to know is—

I am very sympathetic to the 340B Program and the role of safety net hospitals. I think our community health clinics do a magnificent job of primary healthcare in our state and, I suspect, all over the country.

I suspect that the so-called tax we put on prescription drugs—in order to provide some extra funds for safety net hospitals and clinics—is something that I would approve of, but I think it is a reasonable question to ask.

If the money is not going directly to lower the cost of the specific prescription that is filled, where is it going or what categories of things is it paying for?

That could lead to the question of whether we should restrict that to some extent or another, which most hospitals and clinics would not like for us to do. But I would think one way to avoid the restrictions would be to help us know better what the money is going for.

If it is \$6 or \$8 billion in discounted savings, surely at the clinics more than half of it is going directly to the prescriptions to the patients. I am just guessing that.

That only leaves \$2, or \$3, or \$4 billion throughout this whole huge system that would go to things other than lowering the cost of the prescription that is being purchased at the moment.

Do you think it is reasonable, Dr. Siegel, to explore legislation, if necessary, that would ask hospitals and clinics, who receive 340B discounts, to tell us what they are using the money for?

Dr. SIEGEL. I would be concerned about legislation that only singles out hospitals and clinics—

The CHAIRMAN. Well, who would you single out?

Dr. SIEGEL.—rather than the full range of the Program including our partners in the drug manufacturing industry.

I am concerned about legislation that would serve to intentionally, or unintentionally, begin to restrict the Program.

The CHAIRMAN. Yes. I think you are passing the buck. That is not a very good answer to me, and you are talking to somebody who is very sympathetic to you.

Why should I not want to know why a discounted program, that benefits hospitals and clinics, what the money is going for? I can ask the pharmaceutical companies all the questions I want to ask them, and I ask the pharmacists questions, and I can ask other people questions too, but I can ask you questions as well.

Why should I not know that and other Senators, especially those of us who are sympathetic to what you are doing?

Dr. SIEGEL. As I support transparency, we think we embrace it. We want to make sure that any transparency is some way respecting the Program, which we care deeply about.

The CHAIRMAN. Well, first, we would like to know what you are spending the money for, then we can decide if there is any need or any rationale for restricting the spending for.

The hospital heads I have talked to very vehemently say, "We are using the money to help people."

Dr. SIEGEL. Yes.

The CHAIRMAN. "And we lose a lot more in uncompensated care." Well, if that is true, that is a good story to tell.

But if you come up here and say, "Well, we cannot tell you because we do not know, and we do not really want to tell you until you ask everybody else a whole bunch of questions." That is not a very good answer for me.

What I would appreciate asking you in follow-up questions is if you could consider, please, both for the hospitals and for the clinics, giving whatever information you think already is available about how much money, how much of the savings, how much of the discount goes for something other than reducing the price of the specific prescription when the patient shows up at the hospital or clinic. How much is that?

Then, the second question would be, what are the uses of the money that does not go for the specific prescription, to the extent you know what that is?

Ms. Reilly, I would like to have a good, clear understanding of what the size of the discount is.

Dr. Siegel, if you would like to give your version of that too, I would welcome it so that I would be able to operate on if that it is 1 percent, or 2 percent, or 8 percent, or 4 percent of the total revenues of prescription drugs.

This has been very helpful to me, and I thank you for reasonable questions, and lots of support for safety net hospitals, and community mental health clinics, and the work that you do. We want to make sure that we are good stewards of this money and having that information would help us do it.

The hearing record will remain open for 10 days. Members may submit additional information for the record within the time, if they would like.

The CHAIRMAN. Thank you for being here.

The Committee will stand adjourned.

[Whereupon, at 11:47 a.m., the hearing was adjourned.]