

**EFFECTIVE ADMINISTRATION OF  
THE 340B DRUG PRICING PROGRAM**

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

SECOND SESSION

ON

EXAMINING EFFECTIVE ADMINISTRATION OF THE 340B DRUG PRICING  
PROGRAM

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JUNE 19, 2018

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## **EFFECTIVE ADMINISTRATION OF THE 340B DRUG PRICING PROGRAM**

**Tuesday, June 19, 2018**

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

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

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

### **OPENING STATEMENT OF SENATOR ALEXANDER**

The CHAIRMAN. The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

Senator Murray and I will each have an opening statement. Then, I will introduce the witness and then we will hear from the witness. Senators will each have 5 minutes to ask questions.

We have three Appropriations bills on the floor; unusual development. I am managing the Energy and Water Appropriations bill. We even have the prospect of several amendments that may be offered and voted on today including, hopefully, one or two at 11:45 a.m.

I will be leaving the hearing after a while and going to the floor to manage that bill, but Senator Cassidy has agreed to chair the hearing from that point forward.

I want to acknowledge at the outset that this is a hearing suggested by Senator Kaine, as a result of our earlier hearings on 340B. We appreciate the suggestion and look forward to it.

At Methodist Hospital, in downtown Memphis, five employees working as community navigators go to events in Memphis to give local residents preventative cancer tests and refer them to the Methodist cancer treatment center if necessary.

Saint Thomas Hospital, in Nashville, operates four Dispensary of Hope pharmacy sites across the State of Tennessee, providing low income, uninsured patients with free or low-cost prescription drugs.

The Erlanger Health System, in Chattanooga, delivers prescription drugs at no cost to low income patients at their homes to ensure they are receiving and taking their medications.

Methodist, Saint Thomas, and Erlanger are all able to provide these services because of the money they save by participating in the 340B Drug Pricing Program, which requires drug manufactur-

ers that participate in Medicaid to provide discounts on prescription drugs to qualifying hospitals and clinics.

Some of the time, the 340B discount is passed directly to the patient as a lower priced drug. Other times, the hospital or clinic uses the savings to provide other services to patients, like the programs Methodist, Saint Thomas, and Erlanger run. In other words, the savings are used in many different ways.

Arguably, all these uses, and others, fit into the broad language Congress wrote when it created the 340B Program in 1992, 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.”

But, as we learned at our two previous hearings on the Program, there is no consistent data that show how hospitals and clinics are spending the money they save through the 340B Program.

Data is necessary to demonstrate the value of the 340B Program, and Congress cannot evaluate the Program, conduct oversight, or consider changes to improve the Program without more information.

There has been a lot of bipartisan interest. I mentioned Senator Kaine’s role in suggesting that we hear from the Health Resources and Services Administration—we will call that HRSA today—which oversees the 340B Program. Today’s hearing is an opportunity to hear from HRSA on whether they need more authority to collect data and properly oversee the Program.

At our previous hearings, we have heard that the reason we do not have much data is because HRSA may not have the authority to collect data and conduct oversight of the Program.

We heard explicitly from two Government watchdogs—the Government Accountability Office and the Office of the Inspector General at the Department of Health and Human Services—at our last hearing that HRSA needs more authority to properly oversee the 340B Program.

Right now, HRSA has clear authority to determine if hospitals, clinics, and drug companies are eligible to participate in the Program. However, we have heard it is unclear if HRSA has the statutory authority to oversee other aspects of the 340B Program, for example, defining what patients may benefit from in the 340B Program.

Today, I would like to hear directly from the agency in charge of the 340B Program. What data is being collected? What data is missing?

For example, according to HRSA itself, the agency only has data on about 90 percent of drugs sold through the 340B Program.

What oversight is being conducted on the 340B Program and are these oversight activities effective?

For example, HRSA currently conducts audits to determine hospital and clinic eligibility, but we have heard these audits are inconsistent.

One Tennessee hospital shared with me that it was asked to provide information during an audit that was based on draft guidance that was never made final. To satisfy the unexpected request, the hospital was forced to do additional work at additional expense.

Does HRSA need more authority to collect data or provide more oversight? And is HRSA using its existing authority properly?

As I mentioned, we heard at our last hearing HRSA does not have, quote, “broad rulemaking authority” over the 340B Program. On the other hand, HRSA may not be using its clear, existing authority.

For example, earlier this month, HRSA delayed for the fifth time a rule to ensure drug companies are properly participating in the 340B Program. Why is HRSA not using this existing authority to ensure drug companies are participating properly in the 340B Program?

Congress cannot make the 340B Program work better for patients and hospitals if we do not have accurate and complete information about how the program works.

I look forward to hearing from our witness with the Health Resources and Services Administration today, and our other Committee Members about what Congress can do to evaluate the 340B Program, measure the Program’s performance, and ensure that the agency responsible for the Program is conducting proper oversight.

Senator Murray.

#### OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you, Mr. Chairman.

Thank you to our witness for joining us today.

Before we get into the topic of today’s hearing, I want to make one brief comment on another issue that is on the minds of many this morning. I know this is not your jurisdiction, but I hope you will pass this along to Secretary Azar.

What President Trump is doing at the southern border right now with the support of so many others in this Administration, including at HHS, is appalling: separating children from their parents, tearing babies away from breastfeeding moms, ripping these families apart. This is what people across the country are seeing happening in their country’s name.

It is a deliberate choice being made by President Trump and this Administration, and it needs to stop. President Trump can end this right now, on his own, and he should not point fingers and he should not wait any longer.

Captain Pedley, I do not know if you support this policy or not, and you should feel free to weigh-in, if you would like, but I could not let this hearing begin without passing my thoughts on this along. I am hoping you will take them back with you and help your bosses understand that this is not acceptable, especially because I asked Secretary Azar last week to tell me what is being done to, at least at the minimum, ensure that parents know where their children are, whether they are safe, and whether they will see them again. And he has not yet gotten me back that information.

People across this country are going to keep paying attention to this. They are going to continue demanding action. And they are going to hold President Trump, and his Administration, accountable.

Now today, I want to say I am glad we are going to continue our conversation about the 340B Program. It helps so many safety net

providers stretch their resources to serve vulnerable families and how we can help to strengthen it.

340B provides critical drug savings to providers to take on the burden of serving our communities with the greatest needs and fewest resources. It works by requiring pharmaceutical companies to discount their prices for these care providers who can then use those savings to, as the original congressional report puts it, and I quote, “Stretch scarce Federal resources and provide more comprehensive services.”

At our previous hearings on 340B, I have shared stories from care providers across my home State of Washington who are putting their 340B savings to good use. I have shared stories from Seattle, and Spokane, and Sequim, and Olympia, and Walla Walla, and Monroe, and many more.

I have shared stories about:

Programs that serve cancer patients;

Programs that serve homeless and low income communities;

Programs in our rural communities, and stories about countless patients who got the medications they needed, but would not have been able to afford them if their provider had not been able to discount them.

While I have already shared so many great stories from across my state about the good work providers have been able to do with their 340B savings, I have a lot more.

Stories from the very tip of the Olympic Peninsula, where Olympic Medical Center uses those 340B savings to provide discounted care in a community with many seniors and low income patients.

Stories from Providence St. Peter Hospital in Olympia and Providence Centralia Hospital, where they have used these savings to provide thousands of free and discounted prescriptions every year; and lower-cost chemotherapy services, including support and counseling, for patients receiving treatment.

It is clear many providers, in Washington State and across the country, are using these savings to make sure that even with few resources they can do a lot of good.

We should take steps to strengthen 340B by providing more accountability and transparency for everyone in the system. We should be confident entities are using their 340B savings appropriately and pharmaceutical manufacturers are providing 340B discounts fairly.

Unfortunately, instead of working in good faith to make this system stronger, President Trump has worked to sabotage it by repeatedly stalling measures to provide accountability and clarity, severely cutting funds to 340B recipients, and even suggesting 340B discounts somehow contribute to high drug prices.

When the Health Resources and Services Administration, HRSA, drafted a rule to make sure drug companies played by the rules and gave the discounts required by the law, the Trump administration sabotaged it by delaying the rule. Not once, not twice, but five times.

When HRSA drafted its so-called “mega-guidance,” which would have provided more clarity for the Program, the Trump administration walked away from the table with stakeholders who wanted to



find resolution on these issues, and sabotaged the process by withdrawing the guidance completely.

I am particularly interested to hear what our witness today thinks of these efforts.

While President Trump seems entirely uninterested in allowing oversight and guidance of this Program, unfortunately, he has shown an interest in cutting it.

The Centers for Medicare and Medicaid Services have traditionally reimbursed 340B-eligible care providers at market price, just like everyone else, but the Trump administration is working to sabotage the Program by slashing those reimbursements by nearly 30 percent for drugs. That dramatic cut is already hurting many of these care providers and the families that rely on them.

President Trump has talked a lot about lowering drug prices—in crowds, and in his tweets, and in his deeply underwhelming blueprint—but instead of putting forward proposals to actually strengthen or expand 340B, the blueprint characterizes 340B as, quote, “a business challenge,” that contributes to, quote, “downward pressure on revenues” of drug companies.

No mention of the real pressures low income patients and families face. No mention of the great work being done by safety net providers keeping people healthy and delivering care close to home.

The Administration’s suggestion that this Program, which makes companies lower their prices, is actually a barrier keeping companies from lowering their prices contradicts itself. It also contradicts what we saw after Republicans jammed through their partisan tax bill; companies spent that major giveaway on massive stock buybacks, not on lowering prices.

This blueprint speaks loudly about the President’s promises. His Administration’s actions to sabotage 340B, which actually helps make drugs more affordable, are moving us in exactly the wrong direction. Instead of walking away from this Program, we should strengthen it, so providers in Washington State and nationwide can continue to use it to stretch their resources, support struggling families, and reach vulnerable communities.

We do need to look at every part of the 340B system for ways to make sure it is accountable enough to fulfill its intent and solid enough to continue serving our communities for generations to come. These hearings are a great opportunity to do that.

I look forward to seeing what today’s witness has to offer to this conversation.

Thank you.

The CHAIRMAN. Thank you, Senator Murray.

I am pleased to welcome Captain Krista Pedley to today’s hearing, and I thank her for taking the time to be here.

Captain Pedley is the Director of the Office of Pharmacy Affairs at the Health Resources and Services Administration—which we are calling HRSA today—the Office which administers and oversees the 340B Drug Pricing Program.

Before joining HRSA’s Office of Pharmacy Affairs, Captain Pedley served in the Food and Drug Administration’s Office of Generic Drugs and in the Department of Health and Human Services Office of the Secretary.

She began her career as a pharmacist with the United States Public Health Service. In conversation with her before the hearing, I believe she said she has been at her current job 8 years and with HRSA for 11 years.

We look forward to her expertise.

Welcome, again, Captain Pedley. If you could summarize your comments in about 5 minutes, then we will take questions from Senators.

**STATEMENT OF CAPTAIN KRISTA M. PEDLEY, PHARM.D., M.S.,  
DIRECTOR, OFFICE OF PHARMACY AFFAIRS, HEALTHCARE  
SYSTEMS BUREAU, HEALTH RESOURCES AND SERVICES AD-  
MINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN  
SERVICES, ROCKVILLE, MARYLAND**

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

I appreciate the opportunity to appear before you today to discuss the 340B Program.

HRSA shares the commitment to the effective oversight and integrity of the Program, and today, I will provide an overview of the steps we have taken to strengthen those efforts.

The Program was authorized in 1992 to stretch scarce Federal resources by reducing the cost of covered outpatient drugs to 340B eligible entities. Approximately 12,850 entities and over 30,000 associated sites currently participate, in addition to 600 manufacturers.

We appreciate the work done by the HHS Office of Inspector General and the Government Accountability Office to provide recommendations on strengthening safeguards, which inform our activities across all HRSA programs.

HRSA has worked to address the majority of these recommendations through systematic efforts to improve the Program. However, the 340B statute does not provide sufficient authority to effectively implement some of the recommendations that remain open.

We continue to welcome feedback from our stakeholder community, Members of Congress, the GAO, and OIG to help strengthen our operations and oversight.

The President's Fiscal Year 2019 budget includes a proposal to increase transparency and accountability in the Program in two specific ways.

First, by ensuring that the benefits of the programs are used to help low income, uninsured patients.

Second, to amend the statute to provide explicit, general rule-making authority in order for the Program to set clear, enforceable standards of Program participation.

The President's budget also proposes to implement a user fee that would be paid by covered entities based on their overall sales.

The user fee revenue would be used to administer the Program, and enhance Program integrity and oversight activities by conducting additional audits of both covered entities and manufacturers, and by improving our I.T. system capabilities.

HRSA works to verify that both covered entities, and manufacturers, comply with Program requirements.

For covered entities, HRSA conducts efforts, such as initial certification, annual recertification, and Program audits. To ensure the transparency of that audit process, we post the summary of our final audit findings, including the names of the covered entities, on our public Website.

As of April 1, 2018, HRSA has completed 981 covered entity audits since it began auditing in 2012, which encompasses nearly 13,000 offsite facilities and nearly 21,000 contract pharmacy locations. In Fiscal Year 2018, HRSA is on track to conduct an additional 200 covered entity audits.

The findings of the audits have varied. Some findings were minor in nature, requiring basic corrections to their 340B record, while other audits found diversion, either through ineligible providers or ineligible sites.

Through findings in the audits, HRSA developed educational tools and resources for all stakeholders to improve overall Program integrity.

HRSA is also actively engaged in manufacturer oversight. Manufacturers have one core, statutory obligation in the 340B Program, which is to offer a price that does not exceed the statutory 340B ceiling price to covered entities. HRSA's oversight efforts of manufacturers center on this key obligation.

To that end, the audit process for manufacturers is the same as the process for covered entities. As of April 1, 2018, HRSA has conducted 12 audits of manufacturers. HRSA also develops guidance and policy releases specific to manufacturer compliance.

HRSA verifies that manufacturers that participate in Medicaid have signed a Pharmaceutical Pricing Agreement, reviews all allegations of manufacturer noncompliance brought to its attention, and requires refunds and credits when a covered entity is overcharged.

The 340B statute specifies the types of entities eligible to participate in the Program, but does not specify how a covered entity may dispense such drugs to its patients.

The diverse nature of eligible entities has resulted in a variety of drug distribution systems. HRSA has issued guidance recognizing covered entity use of contract pharmacies to dispense 340B drugs. The majority, or 73 percent, of covered entities do not contract with these pharmacies.

Contract pharmacies provide access points for eligible patients to obtain 340B drugs. They do not increase the number of eligible patients. HRSA guidance outlines compliance requirements for entities that utilize contract pharmacies, which HRSA reviews as part of its audits.

If a contract pharmacy is found to be out of compliance with Program requirements, HRSA may terminate the contract pharmacy from the Program.

HRSA is committed to strengthening 340B Program integrity efforts and ensuring that its oversight supports the Program's success.

I appreciate the opportunity to testify today and answer any questions you may have.

[The prepared statement of Captain Pedley follows:]

PREPARED STATEMENT OF CAPT. KRISTA M. PEDLEY, PHARMD, MS

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to discuss the Health Resources and Services Administration's (HRSA) efforts to improve the integrity of the 340B Drug Pricing Program (340B Program). HRSA shares the Committee's commitment to the effective oversight and integrity of this program. In my testimony today, I will provide an overview of the steps we have taken to strengthen oversight of the Program.

HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled workforce, and innovative programs. We do this by working to improve health care for people who are geographically isolated or economically or medically vulnerable. HRSA strives to maximize every dollar and seeks to achieve the best outcomes for the populations we serve. Consistent with HRSA's Strategic Plan, we are continuously working to enhance oversight and integrity in all HRSA programs, including the 340B Program.

### **The 340B Drug Pricing Program**

The 340B Program was authorized by the Veterans Health Care Act of 1992. Based on congressional report language,<sup>1</sup> the 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as "covered entities," in order to stretch scarce federal resources. Some examples of covered entities include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, hemophilia treatment centers, and disproportionate share hospitals (DSH). Covered entities must apply to participate in the 340B Program and, once eligibility is verified by HRSA, the entities may begin purchasing drugs at the statutorily defined ceiling price. As of April 1, 2018, approximately 12,850 covered entities and over 30,000 associated sites currently participate in the Program.

Manufacturers participating in Medicaid enter into an agreement with HHS and agree to charge 340B covered entities a price that does not exceed the statutory ceiling price. Over 600 manufacturers participate in the Program.

We appreciate the work done by the Department of Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office (GAO) to highlight potential program integrity vulnerabilities and provide recommendations on strengthening safeguards. HRSA uses these recommendations to inform our program improvement activities across all HRSA programs, including the 340B Program. The GAO made four recommendations from its 2011 study, and HRSA has implemented two recommendations from the study. The remaining two recommendations are open, which direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient. Additionally, earlier OIG 2005 and 2006 reports include 11 recommendations, nine of which HRSA has implemented. The remaining two recommendations specify that HRSA should develop a pricing system to improve the oversight of the 340B Program and to allow entities access to secure pricing data to ensure that they are charged at or below the 340B ceiling price. In addition, the OIG's 2016 report recommended that HRSA clarify guidance to prevent duplicate discounts for Medicaid managed care organization drugs, and this recommendation remains open.

Within our statutory authority, HRSA has worked to address the majority of these recommendations through systematic efforts to improve the 340B Program. The 340B statute does not provide sufficient statutory authority to effectively implement some of the recommendations. We continue to welcome feedback from our stakeholder community, Members of Congress, GAO, and OIG to help strengthen our program operations and oversight.

### **Budget Proposals**

The President's fiscal year 2019 Budget includes a proposal to increase transparency and accountability in the Program, by ensuring that the benefits of the Program are used to help low-income and uninsured patients. The Budget also proposes to amend the statute to provide explicit general regulatory authority in order for the 340B Program to set clear, enforceable standards of program participation, and

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<sup>1</sup> The House Report accompanying the original 340B Program legislation states the following intent: "[i]n 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." H.R. Rep. No. 102-384(II), at 12 (1992).

to require all covered entities to report on the use of program savings. If Congress were to enact the fiscal year 2019 Budget proposal, HRSA would have explicit general rulemaking authority for all aspects of the 340B program, significantly strengthening HRSA's oversight of the 340B Program. Binding and enforceable regulations would dictate specific 340B Program requirements and provide the clarity necessary for participants to be fully compliant, for example on hospital eligibility requirements and the definition of a 340B patient.

The President's Budget also proposes to implement a user fee that would be paid by covered entities. The user fees revenue would be used to administer the Program and enhance program integrity and oversight activities by conducting additional 340B Program audits of covered entities and manufacturers and by improving IT system capabilities.

### **340B Program Integrity**

HRSA places the highest priority on the integrity of the 340B Program and has strengthened oversight of this program. We work to verify that both 340B covered entities and manufacturers comply with 340B Program requirements. We have always worked to achieve program integrity within our authority to provide clarity in important program areas.

We conduct efforts such as initial certification (entity enrollment and validation), annual recertification, and program audits (onsite audit of 340B compliance). When an entity applies for participation in the program, HRSA staff review and validate the applicant's eligibility based on statutory requirements. In addition, through the annual recertification process, covered entities verify that all eligibility information is up to date and attest to compliance. We have been conducting annual recertification for all covered entities over the last several years. Since 2012, there have been steady improvements in recertification efforts by all covered entities in the 340B Program. Based on program requirements and information submitted and verified during the registration and recertification process, HRSA has instituted additional program integrity checks such as quarterly DSH hospital checks, site visits to grantees, and randomized collection of contracts related to contract pharmacy arrangements.

Fiscal year 2018 is our seventh year of covered entity audits. Randomly selected covered entity audits continue to be utilized according to a risk stratification methodology, so that entities with higher risk factors are more likely to be selected for audit. Targeted audits are also performed and may be triggered by reported violations or allegations. HRSA has also re-audited covered entities with earlier violations.

The 340B covered entity audit process begins with a selected covered entity receiving an engagement letter explaining what to expect and how to prepare for the audit. Auditors follow a strict protocol when conducting an audit. After the completion of the audit, the entity receives a final report, and is granted one opportunity for "notice and hearing," by which it can submit a written disagreement addressing any or all of the audit findings. If the entity submits a disagreement, HRSA considers additional points raised, which may result in adjusted findings. The entity is then issued a revised final report, if warranted. If findings were included in the final report, the entity would be required to submit to HRSA a Corrective Action Plan (CAP), which would include repayment to manufacturers for findings of diversion, duplicate discount, and/or violation of the Group Purchasing Organization prohibition.

HRSA is regularly reviewing and updating its processes to improve program integrity. Based on our reviews, we have updated our audit expectations regarding the implementation of a covered entity's CAP. Specifically, as of April 1, 2018, HRSA expects full CAP implementation, including any settlement with manufacturers, to be completed within 6 months of a CAP approval. If covered entities are unable to meet this expectation, they may be subject to termination from the Program. In addition, HRSA may collect additional documentation to demonstrate that the CAP has been implemented, including any applicable repayment to manufacturers. Covered entities may be subject to a re-audit to assess compliance with program requirements, including when audits have identified the same exact finding of non-compliance. A finding of non-compliance in two or more audits, depending on the type of violation, may be considered systematic and egregious, as well as knowing and intentional, which may result in the covered entity being removed from the 340B Program and may also disqualify the covered entity from re-entry into the 340B Program for a reasonable period of time.

To ensure the transparency of the audit process, HRSA posts a summary of final audit findings, including the name of the covered entity, on our public website. As of April 1, 2018, we had completed 981 covered entity audits since we began auditing in 2012, which encompass nearly 13,000 offsite outpatient/offsite facilities and nearly 21,000 contract pharmacy locations. In fiscal year 2018, HRSA is on track to conduct an additional 200 covered entity audits. The findings of the audits have varied. Some findings were minor, requiring basic corrections in the 340B data base (e.g., contact or address information was incorrect). Other audits found diversion, either through ineligible providers or ineligible sites. For audits with findings of a possible duplicate discount violation, the covered entity is required to work with the state to clarify and resolve the issue.

In addition, for instances of noncompliance, covered entities must work in good faith with manufacturers to remedy any repayment owed after the entity determines the scope of noncompliance. Covered entities and manufacturers have access to the necessary data to resolve any repayment, which is a matter between the two parties due to their established business relationship.

Through findings in the audits, HRSA develops educational tools and resources for all 340B stakeholders in order to improve overall program integrity.

In addition to covered entity oversight, we are actively engaged in manufacturer oversight. Manufacturers have one core statutory obligation in the 340B Program, which is to offer a price not to exceed the 340B ceiling price to covered entities. Our oversight efforts of manufacturers center on this key obligation. To that end, the audit process for manufacturers is the same as the process for covered entity audits as outlined above. As of April 1, 2018, HRSA had conducted 12 audits of manufacturers. HRSA also works to ensure manufacturer compliance through development of guidance and policy releases specific to manufacturer compliance. HRSA verifies that manufacturers that participate in Medicaid have signed a pharmaceutical pricing agreement, reviews all allegations of manufacturer noncompliance brought to its attention, and requires refunds and credits when a covered entity is overcharged.

#### **Contract Pharmacy Use in the 340B Program**

The 340B statute specifies the types of entities eligible to participate in the 340B Program, but does not specify how a covered entity may provide or dispense such drugs to its patients. The diverse nature of eligible entity types has resulted in a variety of drug distribution systems. The majority (73 percent) of covered entities do not contract with pharmacies. Of the 27 percent of covered entity organizations utilizing contract pharmacy arrangements, Section 330 health centers represent the largest users of contract pharmacy arrangements, with 73 percent of health centers utilizing one or more contract pharmacies. HRSA notes that contract pharmacies provide access points for eligible patients to obtain 340B drugs; they do not increase the number of eligible patients.

HRSA issued revised guidance in 2010 to further outline compliance requirements for covered entities that utilize contract pharmacies to dispense 340B drugs to their patients and to permit covered entities to utilize more than one contract pharmacy. The guidance states that covered entities are responsible for compliance of the contract pharmacies, and they must ensure against diversion and duplicate discounts, maintain auditable records, and meet all other program requirements. HRSA expects entities to conduct annual audits of their contract pharmacies in order to conduct sufficient oversight. If HRSA determines that a covered entity has not provided adequate oversight, the contract pharmacy arrangement is terminated from the 340B Program.

HRSA conducts audits of covered entities and their contract pharmacy arrangements and has included in the criteria for risk-based audits the number of contract pharmacy arrangements a covered entity utilizes. HRSA verifies that the covered entity and contract pharmacy have entered into a valid, written contract during its audits of 340B covered entities. Entities must demonstrate that they have mechanisms in place to prevent diversion and duplicate discounts. During audits, HRSA also reviews a sample of the records of 340B drugs dispensed at the contract pharmacy and reviews contract pharmacy compliance. During the annual recertification process, covered entities that have arrangements with contract pharmacies must attest that the arrangement complies with all requirements set forth by the 340B Program. If an arrangement is found to be out of compliance with 340B Program requirements, HRSA may terminate the contract pharmacy arrangement from the 340B data base so that manufacturers no longer ship 340B drugs to the pharmacy.

### Conclusion

HRSA is committed to strengthening 340B program integrity efforts and ensuring that our oversight supports the program's success. As I have outlined today, with our multi-faceted strategy, HRSA is employing many effective tools within our authority to maximize our oversight reach and manage compliance in the 340B Program.

I appreciate the opportunity to testify today.

The CHAIRMAN. Thank you, Captain Pedley.

We will now begin a round of questions. As I mentioned earlier, I will be going to the floor shortly to manage the Appropriations bill and Senator Cassidy has agreed to chair the hearing after that.

Senator Murray mentioned what was happening at our border. New enforcement policies have resulted in hundreds of children being separated from their parents. In my view, the Administration should end that new policy immediately and work with Congress, in a bipartisan way, to secure the border, to provide a status for those who are illegally here, and then prevent a humanitarian crisis at the border.

Captain Pedley, you have a lot of experience with the 340B Program, and we have listened to hospitals and clinics talk about how much good it does, but we do not really know how the money is being spent. I spend a lot of my time here pushing back on new Federal regulations and particularly on requiring people across the country to send in information to Washington that nobody is going to read.

But it seems to me that it would be helpful for us to know how hospitals and clinics spend the money they save from discounted drug prices.

Why should we not require that hospitals and clinics tell us how they are using their 340B savings so that we can know how the money is spent?

Captain PEDLEY. HRSA's authority is currently limited as it relates to requiring what the entities do with their savings and requiring they then report that information to HRSA at this time.

We have proposed in the Fiscal Year 2019 budget to require how the entities spend that savings, as you mentioned, to report that information to HRSA, and then to make that information auditable.

We would want to work on a legislative proposal to move in that direction.

The CHAIRMAN. It would take legislations to do that.

Based on your experience, can you think of any reason not to do it? Why should we not ask a hospital, "Tell us how you are spending the money?" Ask a community health center, "Tell us how you are spending the money."

I gave some examples in my opening statement of activities that are not passing along the direct discounted price to an individual, but obviously help people who need help.

Any reason we should not do that?

Captain PEDLEY. The intent of the Program in the last 25 years was for the entities to stretch their resources as far as possible.

As we continue to examine the Program, and as we proposed in the budget, we think it is an important next step move toward de-

fining how the entities use that savings and then require that they report it to HRSA.

It is a very complex issue and would be a shift in how the Program is operated. Currently, the grantees who participate in the Program do have to report their savings under their grant requirements as Program income. So they are currently doing that under the grant authority, but there is not similar—

The CHAIRMAN. Are you talking about the community health centers in that case?

Captain PEDLEY. The community health centers, the Ryan White grantees, the hemophilia treatment centers, for example. Yes.

The CHAIRMAN. You mentioned “define”. There is a difference between our defining how they spend the savings and our asking them to tell us how they spend the savings.

My inclination would be to say as long as we know what they are doing, and it looks to us like it is within the broad goal of the law, that it would be unnecessary for us to write a narrow definition about how hospitals and clinics should spend the money.

Do you see the difference between defining and reporting?

Captain PEDLEY. Based on our experience, and anecdotally what we hear entities report now on what they do with their savings, it is being defined inconsistently across entities whether the savings is just based on the upfront discount on the product.

Are they also including what they receive via reimbursement from insurance companies? Are they considering the compliance costs to participate in the Program?

I do think in order to receive consistent information that we can then evaluate, it would be important to define the term.

The CHAIRMAN. What do you mean by “define”? Tell them there are only a limited number of things they can do?

Captain PEDLEY. I think we need to define how they—

Again, are they considering just the upfront discount and their cost that they receive from insurance companies when they end up with a number on what they are saving?

Then to define, “What are you allowed to do with that savings to benefit patients?” which could also be very diverse in nature and we would need to think through.

We would want to work with you on also considering the diverse nature of entities that participate in the Program. There are very small clinics to the very large hospitals, so they may be doing very different things at their clinics related to how they are benefiting their patients.

The CHAIRMAN. I think the fear of the hospitals in any event, maybe the community health centers too, is that if we ask them to tell us how they are doing that we will tell them what to do.

I do not see any reason why, at least to start with, we need to say to a hospital, “You may only do A, B, and C,” beyond what we have already said.

What I would like to see is to say to the hospital, “Tell us how you are spending the money and how you think it fits this broad goal that Congress established in 1992?”

Can you give us specifically, either in writing after this or in other conversations with Senators, what authorities you need to ensure you can properly oversee the 340B Program?



My time is about up. I only have 25 seconds, but if you want to give me 20 seconds' worth, that would be good.

Captain PEDLEY. HRSA has outlined in the budget, in addition to the requirement around how entities use the savings, that HRSA needs general rulemaking authority in the Program to appropriately and clearly define how entities should comply with requirements. So that is definitely an area that HRSA needs authority in.

The CHAIRMAN. Thank you. If you would like to expand on that following the hearing, that would be helpful.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman.

The 340B Drug Pricing Program actually allows our safety net providers to stretch limited resources to help vulnerable patients and communities. Over the last three hearings we have had here, we have heard a lot about the need for changes and limitations to the Program.

But I am, frankly, skeptical this is not just a tactic by the Program's opponents from the playbook they have been using against 340B, actually, for years.

For example, the ACA expanded the 340B to more hospitals, like rural and cancer hospitals, but did not allow them to receive a 340B discount on drugs for rare diseases called the orphan drugs.

But Congress intended, actually, to apply that exemption to the treatment of a rare disease, not when a drug that is sometimes used to treat a rare disease is being prescribed for more common conditions like arthritis.

The Obama administration issued a rule actually implementing that provision.

What happened to that rule?

Captain PEDLEY. HRSA did issue a rule to further define that new requirement in the statute around orphan drugs. It was published in a manner whereby the hospitals could not purchase orphan drugs when they were specifically used for their rare disease indication, but that they could purchase those orphan drugs if they were used for their common use.

HRSA and HHS were sued based on that regulation. The courts overruled the interpretation by HRSA that was beyond the plain meaning of the statute. Therefore, we had to withdraw that rule and currently, those hospitals cannot purchase orphan drugs in the Program regardless of the indication, whether it is for the disease or the common use.

Senator MURRAY. That is exactly right.

PhRMA, which represents big drug companies, sued the Government and demanded these drugs be carved out of the 340B Program even if they were not being used to actually treat a rare disease.

Now, our rural and cancer hospitals cannot get discounted prices on many of these big, blockbuster drugs because one of their many uses happens to be treatment of a rare disease. That lawsuit has real costs.

Olympic Medical Center reported that of the over \$12.2 million it spent on prescription drugs in 2017, about half of it was on orphan drugs.

Samaritan Hospital spent over one-third of its operating margin on orphan drugs.

Grays Harbor Community Hospital told us it lost about one quarter of a million dollars on purchasing just one blockbuster drug, Remicade, which has numerous non-orphan indications.

That is what happened to that rule.

Now, the Affordable Care Act also requires regulations to make sure drug companies were charging the appropriate amount or ceiling price for 340B drugs and to hold them accountable for overcharging.

Captain Pedley, when was that regulation finalized?

Captain PEDLEY. That rule was finalized in January 2017 and it currently has an effective date of July 1, 2019.

Senator MURRAY. How many times has the Trump administration delayed the rule?

Captain PEDLEY. The rule has been delayed five times.

Senator MURRAY. Correct. And did the Affordable Care Act also require HRSA to establish a system that listed the ceiling prices for drugs so that providers would know if they were overcharged?

Captain PEDLEY. The statute did require HRSA to develop a secure Web portal to display those ceiling prices to covered entities.

Senator MURRAY. Why has that not been launched?

Captain PEDLEY. HRSA received money in Fiscal Year 2014 to begin the development of that pricing system. We have been in the development and in that process we recognized other of our systems needed to be updated because of security reasons because they feed that system. We have gone through that process and that system was released to the public last fall.

The pricing system is currently available for internal use by HRSA based on data we receive from CMS. However, that system will not be released to the public until the rule that is finalized and in effect as it relates to how prices are calculated.

Senator MURRAY. Right. So because of the delay from the Administration, we do not have now clear rules of the road for what companies are supposed to charge. There are no penalties for overcharging and there is no transparency to know if you are being overcharged.

It sounds a lot to me like the drug companies right now do not have a lot of accountability and I think we need to address that.

I will save my final question for the next round.

The CHAIRMAN. Thank you, Senator Murray.

Senator Cassidy will now chair the hearing, since I am going over to manage the Appropriations bill.

Captain Pedley, thank you for coming.

We will go to Senator Isakson for the next questions.

Senator ISAKSON. Thank you, Mr. Chairman.

Captain, thank you for being here and thank you for your service to HRSA and the country.

Is it correct that the 340B benefit goes to the facility in which the patient is treated, not to the patient?

Captain PEDLEY. The intent was for the covered entity, or the hospital and clinic, to save on these covered outpatient drugs. Yes.

Senator ISAKSON. If I am an eligible patient, due to my poverty or due to my qualifications, and I go to a facility that does not get

the 340B Program, then I do not get the benefit of the 340B discount.

Is that correct?

Captain PEDLEY. You may. It depends on the entity's policies around how they would then use those savings and provide the discounts to certain patients.

But it is not required under the statute currently that they do so.

Senator ISAKSON. Now, this might be a dumb question, because I have not followed this issue that closely, but there have been a number of comments. I know Senator Murray made the comment, and it was a very good one, about telling us where the discounts have gone, what they are doing with the savings in the hospitals and the institutions that are getting the money.

Is that correct, Senator Murray?

Senator MURRAY: [Nods affirmatively.]

Senator ISAKSON. Why can we not get that information now? Or, have we tried to get that information now? Is there any suspicion on your part that if a facility is getting 340B discounts are, in fact, giving us the information we need to know where that discount is going or if we have the chance to get that information?

Captain PEDLEY. The 340B statute is specific to allow HRSA to oversee the Program as it relates to whether they are following Program requirements, such as only providing drugs to the patients and other matters.

It does not address the issue related to what they do with their savings.

Senator ISAKSON. You said, I think in answer to a question previously or in your testimony, that you needed statutory authority to do that.

Is that right?

Captain PEDLEY. That is correct.

Senator ISAKSON. Okay. If you could write that statute, what would you tell the covered hospitals to do or facilities to do when they reported?

Captain PEDLEY. The President's budget outlines that HRSA wants to work very closely with the stakeholders and with the Congress to be able to define how they use the savings, how it would be reported to HRSA.

It is a very complex matter that we would need to think through a lot of different things as it relates to the types of entities that participate; the possible burden it would create for these entities to both track and report that information.

We would want to work with you all on that proposal.

Senator ISAKSON. It is a sticky wicket, as we used to say about some things in business. The devil is in the details in terms of how do you determine exactly where it is going, and whether it is going where you would have liked for it to have gone or it should have gone, and a very complex system to put together.

Most of the time when we try to provide a benefit to anybody to determine where that benefit went, in terms of a savings after they realized that savings, is very difficult to determine because it depends on the entity and how they use the money.

Did we ever anticipate in the legislation or have we ever directed in the legislation in any way for the hospitals or facilities to use it solely to benefit lowering the costs to indigent patients or patients who otherwise qualify for 340B?

Captain PEDLEY. That is not a part of the current statute.

Senator ISAKSON. Would that be the type of thing you would like to see if HRSA was called upon to do it?

Captain PEDLEY. I think as we would work on the legislative proposal, those are the types of things we would need to think about before we look at any type of legislation.

Senator ISAKSON. If you were me—and you are certainly not, you are lot prettier than I am, so you are not me in many ways—but if you were me, and you could ask that one question of the beneficiaries of the 340B Program or the hospitals and facilities that get the benefit to disclose to us, what would it be that you would ask for?

Captain PEDLEY. I think it is important that the entities are using the savings in alignment with the intent of the statute. That they are stretching their scarce resources as far as possible to provide more care to more patients, and what that looks like for them at their entity.

Senator ISAKSON. One last question. In your experience with HRSA, is there any situation you know of, any audit or otherwise in the governing responsibility HRSA has that you have punished, penalized, or otherwise fined a company that got 340B benefits and then were using it in a way you did not like?

Captain PEDLEY. We currently conduct the audits of the covered entities and we audit them for a couple of different things, but the major items are around diversion of drugs to patients who do not meet what is called our patient definition, which is in the guidance. So they do not meet the certain criteria in that guidance, and we have found that in our audits.

Another matter that we find, that is also statutory, is that the entity is prohibited from providing a 340B drug to a Medicaid patient and the state also getting a rebate on that same drug. It is known as a duplicate discount.

We also find that in our audits as well, and when we do, we post that information on our Website. The covered entities are required to submit a corrective action plan and repay the manufacturers accordingly.

Senator ISAKSON. Yes, that is known as “working the system,” and I think that is what some of them have done, to work the system, to try and take advantage of the discount.

Thank you very much for your service.

Thank you, Mr. Chairman.

Senator CASSIDY [presiding]. Senator Casey. Not here.

Senator KAINE.

Senator KAINE. Thank you.

I want to just begin and thank the Chairman and Ranking Member for your strong statements at the beginning of this hearing about the problem on the border with the family separation.

I have a particular feeling about this because I worked as a missionary in Honduras in 1980 and 1981, and a lot of the children and families who are coming to the southern border of the United

States are coming from Honduras. Because I am still very connected there, I know why they are coming.

They live in neighborhoods in a very, very poor country whose institutions have been completely corrupted by something in the compass of this Committee; the sad reality of Americans' desire to buy illegal drugs.

If we buy illegal drugs that are manufactured in Mexico or Columbia, as those drugs transit south to north, the dollars that Americans pay to buy illegal drugs transit north to south and they go into these countries that are so poor. They corrupt police departments, judiciaries. They create gang wars.

Children in these neighborhoods in towns like El Progreso where I worked, they do not want to leave their country. They do not want to leave their home and their parents do not either, but if you have to choose between your child getting killed in the cross-fire of a gun war or some chance that they might have a better life somewhere else, you make that very, very wrenching decision.

These Hondurans, or Salvadorans, or Guatemalans are coming to the border. They generally come in one of two ways. They come many not to break the law, but to seek refuge under the laws of this country. They are not lawbreakers. They are trying to apply. They may or may not be granted asylum or refugee status, but they are trying to comply with American laws.

There should not be a penalty separating families for trying to avail yourself of asylum laws of this country. And yes, some come and their parents bring them over the border illegally and that is a misdemeanor. But nowhere else in our system in this country do we take children away from parents who are charged with a misdemeanor. And so, this policy, that is a completely invented policy of this Administration, is just absolutely heartless.

A couple days before Father's Day, this article appeared in "The New York Times." "Honduran Man Kills Himself After Being Separated From Family at U.S. Border." He crossed into the United States with a wife and a 3-year-old, and as they were separated, was so distraught that he killed himself, hung himself in his jail cell.

We talk about the effect upon children of the separation. What about the effect upon parents losing their children?

To Senator Murray and Senator Alexander, who is now on the floor, thank you for stating strongly the need that we should act in accord with our values and our laws, and support families.

This is an important hearing, but the urgency of this issue compels a congressional urgency in providing a fix. If the President will not do it, we have to. We are not the Article Two-and-a-Half Branch. We do not have to wait around. We are the Article One Branch and we should act like it.

With respect to the HRSA hearing, Captain Pedley, I appreciate your testimony. I just have a couple of questions.

You talk about audits. The vast number of audits of providers, and you indicate what some of those audits have shown. You also indicate that there were 12 audits of manufacturers.

What are you finding as you audit manufacturers' compliance?

Captain PEDLEY. For the manufacturer audits, HRSA monitors the one core obligation as part of the statute, which is to ensure the manufacturers are charging at, or below, the 340B ceiling price.

To date, we have not had any findings in the manufacturer audits around that one core obligation. We do post that information on our public Website, both stating the name of the manufacturer that was audited and any findings, if there are any.

Senator KAINE. There was testimony last year at the House Energy and Commerce Committee about re-audits of providers that resulted in some repayments to manufacturers.

Have you done re-audits of manufacturers?

Captain PEDLEY. We have not. The standard on the covered entity side is that we would re-audit a portion of covered entities that had problems in their first audit that required repayment, and we would then re-audit a certain portion of those.

We apply the same standard on the manufacturer side. However, we did not have any findings yet in any of those reports, so we have not re-audited any manufacturers.

Senator KAINE. What is the rationale for the repeated delay in the draft guidance that would have clarified standards around 340B and imposed fines on manufacturers that did not offer the correct discounts?

Captain PEDLEY. The ceiling price and civil monetary penalty regulation, that has been delayed to July 1, 2019, is an important rule.

It has been delayed in order to allow for a more deliberative process in the context of the broader drug pricing strategy that is being discussed at the Department. Therefore, it would be premature to put that rule into effect at this time as there are broader discussions, not only around the 340B Program, but drug pricing in general.

That is why that has been delayed.

Senator KAINE. Thank you.

Thank you, Mr. Chairman.

Senator CASSIDY. Senator Hassan.

Senator HASSAN. Thank you very much, Senator Cassidy and to Ranking Member Murray, thank you as well.

Captain, good morning. Thank you for being here and thank you for your service.

I will just echo what the Ranking Member, and the Chairman, and now Senator Kaine have said, to ask you to please express the most urgent concern from me, as well as all of our colleagues who are speaking up, about this Administration's policy at our border.

Early in May, I visited Mexican officials in Mexico City to talk about the opioid crisis and how we could work together because, as you may know, New Hampshire, my home state, has one of the highest mortality rates because of the opioid epidemic.

To Senator Kaine's point, the flow of money and weapons from this country to drug cartels south of us is contributing to a level of violence that is unprecedented and is a large driver in the number of people we see coming from places like Guatemala, where I was in the summer of 1974, I think, doing public health work.

It is critical that we address the root causes, but even more critical and more urgent at this time is that we stop separating fami-

lies, stop separating children from their parents. We do not traumatize children to punish parents in the United States of America and we should stop this policy immediately. And I hope very much you will take that back to the Secretary and anyone else in the Administration you talk to.

With that, on this issue, in New Hampshire, we have 13 340B hospitals. These hospitals use 340B as intended. They rely on the Program in order to help them stretch Federal dollars further, so they can help provide benefits to their communities.

I want to share a few examples of how New Hampshire 340B hospitals are using their 340B savings.

Dartmouth-Hitchcock funds substance use recovery coaches in its emergency department. The coaches assist patients experiencing an overdose or substance use disorders to connect them with community programs. The coaches keep in touch with patients long after discharge to ensure that their needs are being met.

Androscoggin Valley Hospital in Berlin, New Hampshire supports their federally Qualified Health Center with a subsidy that otherwise would not be available if not for the additional funds received from the 340B Program.

The hospital and FQHC both support the uninsured and underinsured individuals in their communities with access to primary care and other services. If those went away, then the only access to care would be the hospital emergency department.

Support from the 340B Program also allows Valley Regional Hospital's physician practices in Claremont, New Hampshire to continue to provide needed primary care in the community at the right time and the right place for their patients most in need.

For Valley Regional Hospital, the 340B Program also allows for health care services such as advanced chemotherapy to be provided locally. Otherwise, Valley Regional's patients would have to travel far outside their community for this type of care.

Captain, I know there has been a lot of discussion about greater transparency in the 340B Program. It is my understanding that there are robust auditing requirements currently in place for 340B covered entities.

Can you walk us through the current auditing requirements for hospitals participating in 340B?

Captain PEDLEY. The audit process is one where it is consistent across the board with covered entities. We have a very specific audit protocol that is used onsite when the entities are audited. There is a pre-meeting with the covered entity to ensure they have all the information necessary. They have to produce records to HRSA.

Senator HASSAN. Right.

Captain PEDLEY. They have to produce their drug dispenses to HRSA so that we can sample certain prescriptions to ensure they are meeting the statutory requirements accordingly.

If there are findings related to that audit, a corrective action plan would need to be submitted to HRSA to ensure they are correcting any issues that we find. And any repayment is owed to manufacturers if there are any findings related to a payment and we would follow them and help them through that process.

Senator HASSAN. Okay, thank you.

My time is running short, but I wanted to point out that 340B covered entities are already operating on thin margins, and they are using their 340B savings to benefit their communities and serve more patients.

For them complying with audits and balancing the need to do that with providing necessary services on a very thin margin are a concern, and I hope you all will take that need to balance into consideration.

Lastly, I just wanted to make sure that I understand that HRSA has done only 12 audits of manufacturers compared to 900 hospitals audits.

Is that about right?

Captain PEDLEY. That is correct, but the rates, because there are less manufacturers, we do about 0.8 percent manufacturer audits and about 1.5 percent on the covered entity side.

Senator HASSAN. Okay. That is helpful. I just want to point out that we should not let up on the manufacturers either.

Thank you, and thank you, Mr. Chairman.

Senator CASSIDY. Senator Smith.

Senator SMITH. Thank you, Mr. Chairman, and Ranking Member Murray.

Thank you, Captain, for being here with us today.

I am really grateful that you brought up this terrible situation we are seeing on the border, Senator Murray, and I am very grateful to Senator Alexander for echoing your recognition that we have a humanitarian crisis. I hope that we can resolve this quickly because to use cruelty to children as a deterrent as a public policy of our Government is just so wrong.

I am grateful that we have this chance to talk about the 340B Program because it is so important to hospitals, rural safety net hospitals especially in Minnesota.

In my state, hospitals especially in rural areas are facing big challenges. It includes caring for an increasingly aging population; really on the frontlines of addressing the opioid crisis and drug overdose epidemic; and also really struggling to recruit and retain qualified people to work in the hospital.

I appreciate the questions that have been raised about this delay in enforcement of the manufacturer civil monetary penalties rule. I wonder if you can just give us some sense of when you think we can expect that. I understand that you are holding back as the President's drug blueprint is under consideration, but what does your timing look like, do you think?

Captain PEDLEY. The rule has been finalized and our plan is for the rule to be effective July 1, 2019. As we take another look at the policies contained within that rule as it relates to drug pricing more broadly, and to also look at other 340B policies that intersect with some of the issues in that regulation, so that we can take a more comprehensive look at policy across the board.

Senator SMITH. Well, I would just urge you as you do this—I mean, I am certainly all for accountability in the 340B Program—I urge you to continue to bring accountability to all partners in this effort.

I will also just point out that the GAO identified that the top 25 pharmaceutical companies had an average profit margin of over 20



percent in 2015. I can tell you that the 340B hospitals operating in my state are not looking at that kind of profit margin at all.

I recently was talking with Central Health in central Minnesota and they are using the 340B savings to make sure that sexual assault victims, when they visit their emergency room, are able to immediately start getting preventative HIV treatment. That is a cost of \$3,000 for a 28-day course.

Another great example of what we are doing in Minnesota is the Essentia Health-Ada in northwestern Minnesota, which is using 340B savings to help provide diabetes prevention efforts.

I am concerned that delaying this rule will potentially put a burden on our hospitals. I think it is just so important that we move forward with it.

I would also like to just mention and I would like to get your feedback on this. We have 11 tribal nations in Minnesota, and like the rest of Indian country, they are also dealing with significant health disparities. One of the ways that they can tackle these health disparities is through the benefits that they get through the 340B Program.

Can you tell me about how you are able to work with tribal governments as you think about changes with the 340B Program?

Captain PEDLEY. There are certain tribal organizations that are eligible for the 340B Program. We work with them very closely upon registration into the Program to make sure there is no technical assistance needed as they go through the process necessary to do registration.

We also have an annual recertification process and we ensure they have the education necessary to go through that process so that they are not terminated from the Program because they are not able to, again, recertify.

We also have a lot of different training and education opportunities, not just for tribal, but for other organizations through our prime vendor program. We have a Website that has FAQ's and more information as it relates to how to comply with the Program. So there are a lot of different efforts that we undertake.

We have a specific point of contact in the Office that is able to work with the tribal governments to assist them in any way possible.

Senator SMITH. I think it is so important. Sometimes we forget. It is so important that we have the right level of consultation as changes to programs are being considered.

It sounds like you will commit to me that you will be happy to do that kind of consultation as you move forward with changes to the Program?

Captain PEDLEY. Yes, we will and we will continue the efforts we undertake now to ensure, as well, that they are part of any of our public comment processes. That we reach out to them directly to receive that feedback on how it will impact them specifically.

Senator SMITH. Thank you very much.

Senator CASSIDY. Senator Casey.

Senator CASEY. Thanks so much.

I first wanted to start with a statement. I really appreciate what Senator Murray said at the beginning of her opening statement about the child separation policy. I know that is not the subject of

the hearing, but what is compelling in terms of the arguments against this policy is what we have heard from professionals, doctors across the country.

“The Washington Post” yesterday had an article entitled, “What Separation from Parents Does to Children.” And then in quoting a doctor, Captain Nelson, a pediatrics professor at Harvard Medical School, the effect is, quote, “Catastrophic.”

That is why you have the American Academy of Pediatrics, the American College of Physicians, and the American Psychiatric Association representing a quarter of a million doctors saying end the policy. Not debate. Not have a policy discussion. End it.

I hope the Administration will heed those calls from professionals who do not want to have permanent damage done to thousands of children because of an American policy that was put into place recently.

Captain, thanks for your testimony. I wanted to ask you a couple of questions about hospitals; in particular, one hospital in our state that is affected by some of the interpretations. Let me provide some background.

The GAO has recommended that we reconsider the scope of non-profit hospital eligibility to participate in the 340B Program. It seems to me that different hospitals provide care to uninsured, underinsured, and our seniors in different proportions.

Some have suggested that qualifications to be a 340B hospital should be based on so-called, quote, “charity care,” alone as the sole determinant. But charity care does not tell the entire story.

We know that there are only eight hospitals in the country, only eight, including Temple, the hospital I just referred to, Temple University Hospital in Philadelphia that has over 80 percent of their inpatient caseload comprised of Medicaid, uninsured folks, and Medicare patients. So they are in the unique circumstance.

Hospitals like these have almost no room to shift costs onto higher paying commercial insurers and they operate on very thin or even negative margins. In Temple’s case, they technically do not have a lot of “charity care,” but they have no taxing authority and chronically struggle to make ends meet. Last year, they operated at a loss.

Pennsylvania is also unique because it has no public acute care hospitals. So I have two questions.

Number one, would you agree that it makes sense to assess needy hospitals based upon a broader set of metrics than just “charity care” and legally recognize bad debt? That is question number one.

Question number two, have you looked at the idea of varying the value of the 340B discount based on the relative, uncompensated care burden of different institutions?

Captain PEDLEY. The current statute is very specific around hospitals as it relates to the requirements they must meet and it relies upon the disproportionate share adjustment percentage. Certain hospitals have to meet greater than 11.75 percent; others are greater than 8 percent, for example.

In addition to that metric, they have to be one of three types. They have to have a contract with state or local government. They

have to be owner operated by state government or they have to have governmental powers.

As HRSA registers hospitals that want to come in to the 340B Program, those are the current things we use to evaluate whether they would meet the eligibility requirements for the statute.

If there were changes to be made to those requirements, such as the utilization of charity care, uncompensated care, any of those metrics, a statutory change would need to be made to look at that. We would be happy to serve as a resource to look at any proposals around that.

Again, very complicated issues as you mentioned, but we currently implement the Program according to those standards that I had mentioned.

Senator CASEY. How about on the question of varying the value of the 340B discount based upon the relative uncompensated care burden of different institutions? Any commentary on that?

Captain PEDLEY. That is not something that HRSA has looked at around whether that should be varied based on the type of hospital or level of care that they provide.

Senator CASEY. Okay. We may send you some follow-up on this. Thanks, Captain.

Captain PEDLEY. You are welcome.

Senator CASSIDY. I will take my turn now.

Thank you for being here, Captain.

As you may or may not know, I am a physician. I worked 25 years in a public hospital for the uninsured, similar to what Temple did, except we were really uninsured, Medicaid, poorly insured. And so, I understand very well the importance of 340B.

But I do think it is important to move beyond anecdote, because everyone is quoting articles that quote hospitals in their district. Of course, the hospital has a vested interest in the Program maintaining as it currently is.

Senator Murray, in her opening statement, I think I recall, said that people are alleging that it is actually raising the cost of insurance. But if I recall—

Senator MURRAY. No, I did not.

Senator CASSIDY. I thought you said that. I apologize.

Because it is, and that is not an anecdote as best I can tell. I just want to move beyond the anecdote, if you will.

For example, there is a February 2016 blog published in the "New England Journal of Medicine," from the University of Chicago in which the person speaks about how, "Reports suggest that the original program substantially expanded in recent years to include newly qualified entities, affiliated clinics, certain contract pharmacy arrangements."

It is, "Currently so vast for drugs that are commonly infused or injected into patients by physicians that their prices are probably being driven up for all consumers. As pharmaceutical manufacturers face substantial and expanding demand for discounts on the acquisition prices of these drugs, they can, and do, pass the costs of these discounts on to other payers."

If you have commercial insurance, you are paying more because of 340B. Again, a blog post from the University of Chicago.

Secondly, to point out, there is an article from the “New England Journal of Medicine” which, as the Chairman, I will submit for the record and so approve.

Senator CASSIDY. In which they find that 340B entities are buying physician practices.

They have an overrepresentation of physicians that infuse drugs that the cost has been elevated. Importantly, the poor patients, the Medicaid patients are seen less frequently as a percent of their business than in the non-340B. Counterintuitive, but the more you go into business of providing 340B, proportionally the fewer Medicaid patients you actually see.

Importantly, they also said that the financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality for lower income patients. As a doctor, this means a lot to me.

We have raised the cost of care. There is no improvement in mortality outcomes and indeed, the lower income patient is less likely to be seen. That is incredibly important for us all.

I will also point out another article from “The American Society of Clinical Oncology,” that despite similar—comparing those 340B hospitals—inpatient/outpatient for cancer care, the hospital based care, which is associated with 340B payments is associated with substantially increased costs.

Another article, which I have lost in my mess, but which would say that Medicare patients, under Medicare Part B payments are 10.2 percent higher—again, moving beyond anecdote—10.2 percent higher among the 340B entities because they are using higher cost drugs in a higher cost setting. So I do think it is important that we look at the academic data, which is objective, as we look at all of this.

You mentioned earlier, and just something to mention, Senator Hassan asked how many of the covered entities are audited.

Did I hear you correctly? Only 1.5 percent of covered entities are audited to make sure they are using the Program correctly?

Captain PEDLEY. That is correct.

Senator CASSIDY. Now, also for the record, you just mentioned to Senator Casey the criteria by which someone could become a covered entity.

But if you have someone that meets that criteria who subsequently buys, let us just say, a cosmetic surgery practice in a very rich suburb of that city, and frankly, who do not see any Medicaid, Medicare.

Is that daughter site, so to speak, allowed to benefit from the 340B Program?

Captain PEDLEY. Our standard for eligibility for sites that are offsite of the main hospital, for example, is that those clinics have to be reimbursable on the hospital’s Medicare Cost Report for HRSA to consider them an integral part of the hospital and eligible for the 340B Program.

Senator CASSIDY. If they accomplish that, even though it might have nothing to do with poor folks or not seeing any Medicaid patients whatsoever, indeed, doing cosmetic surgery that they can benefit from the 340B Program, getting the discounted drug, but then charging at the list price for that medication?

Captain PEDLEY. If that site meets our eligibility requirements, then they would be able to participate.

Senator CASSIDY. Again, buy them at a discounted rate, but billing at the normal rate for their cosmetic surgery patient.

Captain PEDLEY. Yes.

Senator CASSIDY. We actually posed that question to CRS, and they gave me the same answer.

I will submit that CRS report for the record.

Senator CASSIDY. I am out of time.

Our next person will be Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

Secretary Azar and President Trump have been making a lot of promises about how drug prices are going to come down as a result of the blueprint that they released this month. They have been boasting about how they are taking on the drug companies.

But Americans have not seen their drug prices come down and when you scratch the surface on the President's tough talk, you find that the Trump plan lets Big Pharma keep jacking up prices and keep raking in profits. Part of the Trump blueprint involves changes to the 340B Program and that is the part that we are digging into today.

Captain Pedley, you run the 340B Program, and just so we are all on the same page, this is a Federal program that requires drug companies to provide discounts on drugs purchased by eligible hospitals and clinics.

Is that right?

Captain PEDLEY. That is correct.

Senator WARREN. Thank you.

Now, the President's drug pricing blueprint suggests that the 340B Program, a drug discount program, is causing high drug prices. The plan asks for input on whether the 340B Program has, quote, "Caused cross subsidization by increasing list prices applicable in the commercial sector."

This is a bizarre question. Apparently, the argument is that right now, we are being too hard on the giant drug companies by forcing them to provide discounts to help children with cancer get treatment.

We are asked to believe that these discounts, which total less than 2 percent of the entire U.S. drug market, leave drug companies with no choice except to raise their prices for everyone else so that they do not have to take a penny out of the billions of dollars in profits that they rake in every year.

Captain Pedley, I am trying to make sense of what the Trump blueprint is proposing here.

If Congress were to reduce the number of discounts that the drug companies have to provide, does HRSA expect them to turn around and reduce prices for everyone else out of the goodness of their hearts?

Captain PEDLEY. HRSA's role is to implement the Program according to the statute.

We work closely with the Department on all 340B policy matters, in addition to what is in the blueprint, and the questions that were asked related to the 340B Program so that a more comprehensive

look could be taken across the board for not only the 340B Program, but all of the other measures that are part of that Program.

Senator WARREN. Okay. I will take that as a no.

Here is what it looks like to me. It looks like the Administration is trying hard to dig up some excuse to let drug companies charge hospitals and clinics more for their drugs, and that is exactly the opposite of what President Trump promised when he was a candidate. It is also bad policy.

It is not the only way that this Administration is trying to let Big Pharma off the hook.

Eight years ago, Congress gave HRSA the authority to impose fines on drug companies that knowingly and intentionally overcharged health care providers in the 340B Program.

The rule that implements these fines was finalized in January 2017. That is almost a year and a half ago. But as we have heard from the Inspector General at our last 340B meeting, HRSA still has not implemented it.

Captain Pedley, HRSA has delayed this rule five separate times since 2017.

Why will this Administration not penalize drug companies that break the law by overcharging for their drugs?

Captain PEDLEY. HRSA does monitor manufacturer compliance and when there is an overcharge, they are required to refund covered entities accordingly.

The rule that you mention is specific to defining how to calculate that price when the manufacturer knowingly and intentionally overcharges a covered entity. We are in the process of looking at the policies within that rule in the broader context of drug pricing. It is currently set to be effective July 1, 2019.

Senator WARREN. You just keep delaying the rule that would do exactly what it is we are asking people to do.

I appreciate the work that everyone at HRSA does to implement the 340B Program, but if the President is truly worried about the connection between high drug prices and the 340B Program, he could forget his blueprint and simply implement the law that Congress wrote to make sure the drug companies do not cheat on their discounts.

It is already available to us in the law. We do not have to change the Program.

Thank you.

Senator CASSIDY. Senator Murphy.

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

We were talking about the difference between anecdote and data. There are enormous amounts of data to show very clearly that hospitals that take part in the 340B Program are actually providing much more charity care, much more uncompensated care than hospitals that do not.

A recent study, for instance, found that 340B hospitals provide 53 percent more uncompensated and unreimbursed care than non-340B hospitals, and that low income patients make up approximately 42 percent of 340B hospitals' patient load compared with about 27 percent for non-340B.

Go back a couple of years ago to a 2015 GAO report which found maybe not as impressive numbers, but similar numbers. The GAO

found that 340B hospitals generally provide a lot more charity care. 340B hospitals had uncompensated care levels that are 23 percent higher than non-340B hospitals and charity care levels that were 62 percent higher.

That is some pretty compelling data to tell us that we might be trying to find a problem that does not exist at the acuity levels that might be suggested by this hearing.

Let me just ask you, Captain Pedley, a simple question. One of the things you have been talking about here today is increased reporting requirements for these hospitals to prove that they are using the money in the way that is intended. This Administration has made a lot of noise about reducing regulations and paperwork for companies, but here is a proposal to increase the paperwork requirement on hospitals. So I assume it is for a good reason.

What is the evidence we have today, the hard evidence, that we have today that hospitals do not use 340B savings to offset the cost of uncompensated or undercompensated care? Especially when we have a GAO report and other datasets that tell us that they actually are providing higher levels of uncompensated care than non-340B programs?

What is the data that exists today that leads you to propose requiring hospitals to report more?

Captain PEDLEY. The 2011 GAO report does outline how entities are using their savings, and have shown that the entities do put that money back into ensuring that patients and their programs can expand based on the 340B Program.

HRSA has no data related to how they use their savings because we do not have the authority to both define or collect that information. So HRSA does not have any specific data as it relates to that element.

Senator MURPHY. Then, you could ask for data on anything, but are you suggesting that you do not have any data today or any hard information to suggest that there is a problem? That, in fact, you have data to the contrary. You have data from the 2011 report suggesting that they do put the money into increase some uncompensated care.

Normally, when you ask for reports, it is because you have some evidence that there is a problem that you need to identify with increased information.

But you are saying here that you do not have evidence that there is a problem. And, in fact, the evidence you do have is that they are putting money back into care for uncompensated populations.

Captain PEDLEY. HRSA has proposed in the budget to take it to that next step to ensure that they are using the money to benefit patients, especially those that are low income and underinsured. We think that is an important next step to take so that we can ensure that the intent of the Program is being served accordingly.

Senator MURPHY. However, the impression when you were asking for that is that there is an existing problem. And so, again, you do not know that there is an existing problem you are trying to solve.

When we spend an entire hearing talking about the need to get this data, it suggests it is because we have evidence of a problem.

But again, we do not have that evidence today. You may get it in the data that is being submitted, but you do not have it today.

Captain PEDLEY. HRSA does not have data as it relates to savings.

Senator MURPHY. Mr. Chairman, I think one of our frustrations in this Administration is that there is often an attempt to try to find a solution for a problem that does not exist.

We are going through this battle over work requirements for Medicaid imagining that there are scores of Medicaid recipients who are scoff laws, able to work, not working when the reality is very different.

Similarly, I worry that we are creating an impression that these hospitals are providing less uncompensated care, less charity care when they are, in fact, providing much more charity care. We have testimony today that suggests there is no evidence that HRSA holds currently to suggest that there is a problem necessary of solving.

I appreciate the time. Thank you, Mr. Chairman.

Senator CASSIDY. I will point out that the GAO study you reported is entitled, "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals." One quote, "Twelve percent of the 340B DSH hospitals were among the hospitals that reported providing the lowest amounts of charity care across all hospitals in the GAO's analysis."

A more complete rendering of that article would suggest there might be.

That said, I think it is Senator Jones.

Senator JONES. Thank you, Mr. Chairman.

Let me, before I begin, Captain Pedley, let me also add to the growing chorus of folks thanking the Ranking Member and Chairman Alexander for their comments concerning what is happening on the border.

I know a little bit about prosecutions and in this country, there is something known as prosecutorial discretion, which this Department of Justice seems to be putting in a lockbox somewhere and not adhering to.

But prosecutorial discretion will give a prosecutor the means to either take a case and go to the most extreme way or go to a much more lenient way. How that prosecutor's office does that is a matter of policy, not a matter of law. They can flip a switch. They can send a memo. They can send a phone call and it will change immediately.

The second thing is the Attorney General should know better than to simply compare what is going on, on the border with people in this country who are sent to prison.

When someone goes to prison in this country, we do not send their children to prison with them or in a separate prison. We do not do that. Moreover, we have in this country a support system for the kids who are left behind. There are churches. There are family services. There are state run services. So to compare that is just disingenuous.

The Attorney General is a former U.S. attorney. He is a prosecutor. He should know better than to make those statements and have the American public believe that.



I will get off of that soapbox and back to the issue at hand, Captain, and I appreciate your service to this country, both in your position at HHS as well as the military. So thank you for that.

The President's budget is calling for user fees for covered entities to administer the Program.

How much would these user fees cost each of the covered entities in order to continue their participation?

Captain PEDLEY. The proposal is 0.1 percent of their purchases under the Program. So \$1 for every \$1,000 they spend under the Program.

Senator JONES. All right. So it is not going to be too burdensome for a covered entity.

But will that be enough to help cover the administrative costs of implementing the Program, do you think?

Captain PEDLEY. HRSA believes that amount would be able to cover costs and enhance the efforts we are already undertaking on both the covered entity and the manufacturer side to ensure they are meeting the Program requirements.

Senator JONES. I would not want to see costs increase, those user fees increase because that will take away money from those entities that are doing the right thing in providing services, or the discounts, or whatever. So \$1 for every \$1,000 we could probably live with.

But I want to talk a little bit about the impact of the Program to rural health, which is something I am especially interested in.

In Alabama, we have been losing hospitals left and right, 12 in just the last few years in our rural areas. We have some 35, I think, entities that are covered and about 28 of those have negative margins. So I want to make sure that this Program stays sound to make sure.

Can you just, for the record here, talk about the effects for the rural hospitals? What would be the effect if we take away this Program from our rural hospitals and our covered entities?

Captain PEDLEY. The law was amended in 2010 to add many new rural types of hospitals to participate in the Program. Prior to that, the rural hospitals were not eligible.

But since that time, we have enrolled many of those rural hospitals into the Program whereby they can now benefit from the discounts that are offered that are required by the manufacturer so they can have that savings for their patients and their communities.

Senator JONES. All right. I know this has been asked, but is it your position that in order to be more transparent and require these covered entities to show how they are spending the money, that is going to take legislation?

Is there not rulemaking ability at HHS to require some more transparency? Because I think everybody wants to make sure there is transparency and that the moneys are going and being spent the way they should be. Does HHS not have that authority? I know you do a lot of things. This Administration is doing a lot of things without talking to the Congress about it.

Do you not have that authority to require something along those lines?

Captain PEDLEY. HRSA does not currently have that authority under the 340B Program to either require what they do with that savings, or to audit, or to receive, or collect that information.

Senator JONES. All right.

Captain PEDLEY. Statutory change would be necessary.

Senator JONES. Okay. Mr. Chairman, I am running out. We may have some additional questions for the record.

Senator JONES. Thank you. Thank you, Captain Pedley.

Senator CASSIDY. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman, and Ranking Member.

I want to begin, as I have in each of these hearings on the 340B Program, by sharing a couple of stories from my home State of Wisconsin to underscore the benefit of the 340B Program that it provides to hospitals, patients, and our communities.

Door County Medical Center is a critical access hospital in northeast Wisconsin and it has relied on its savings from the 340B Program to expand its dental clinic to serve uninsured and Medicaid-eligible adults and children full time.

Previously, the dental clinic could only serve these vulnerable patients on a very, very limited basis which, of course, impacted their overall health.

Last hearing on this topic, I shared a concern of one of Wisconsin's 340B hospitals. This hospital regularly faces instances when drug companies refused to provide them with the 340B price of a drug, but do allow them to purchase the drug at whole cost. These drug manufacturers typically claim the drug is in short supply, but only at the 340B price or they provide no excuse at all.

Dr. Draper from the GAO told me to speak to you about this noting that this was a problem the GAO identified in earlier reports, but that it should no longer be happening according to HRSA's updated nondiscrimination guidance.

HRSA issued clarified guidance in 2012, but I am concerned that hospitals in Wisconsin continue to experience these problems today.

Captain Pedley, what is HRSA doing to positively resolve these problems when experienced by hospitals? And, does your agency have the authority it needs to prevent manufacturers from unfairly gaming the system in this way?

Captain PEDLEY. We work very closely with covered entities with respect to this issue. We have specific tools they can use to contact HRSA or report to HRSA when they are having any issues related to either not being able to obtain the drug at all or not able to obtain the drug at the 340B price, so that we can further investigate what the issue is.

As we do that, we do allow manufacturers under GAO's recommendation to produce what is called a limited distribution plan for drugs that are in short supply. They submit that information to HRSA and what we look for in those manufacturer plans is to ensure they are treating 340B covered entities the same as their commercial customers when they are limiting that supply.

If it is not the case that they are doing that, we would follow-up with the manufacturer to make sure they are doing so, so that they are complying with the statute.

We want to hear from entities if they are not receiving the 340B price, even though that drug may be available in the market at some other price because there could be an issue there that we would look into.

Senator BALDWIN. Modernizing oversight is also an integral part of strengthening the 340B Program to ensure that it fulfills its purpose. However, any oversight efforts should be balanced and address all Program participants.

HRSA has conducted almost 1,000 audits of 340B entities like hospitals, but has only conducted 12 audits of manufacturers. What is more, the agency has issued numerous compliance improvement documents, guides, and Webinars for hospitals, but there are no similar public compliance Webinars or guides for manufacturers. I continue to hear concerns from hospitals in Wisconsin that this uneven playing field persists.

Can you describe HRSA's plans to issue more compliance measures or create more resources, such as Webinars, to encourage manufacturers to play a larger role in ensuring the integrity of the 340B Program?

Captain PEDLEY. HRSA's role around manufacturer compliance is multifaceted.

As you mention, we do conduct audits of the manufacturers, but we also do release program guidance documents. We have a lot of educational resources and Webinars, not only through HRSA, but through our contracted prime vendor program to ensure they are also complying with the statute.

What is unique about the manufacturers versus the covered entities is the manufacturers only have one core obligation under the statute, which is to charge the 340B ceiling price, unlike the covered entities, who have a lot of requirements in the statute.

Naturally, the oversight is different when it comes to entities and the education we provide is in greater detail because they have more requirements than what the manufacturers do. But we do everything we can as it relates to the manufacturers.

Senator BALDWIN. Thank you.

Mr. Chairman, I have run out of time, but will submit some follow-up questions. Thank you.

Senator CASSIDY. We will have a second round now. I will start.

Again, moving beyond anecdote, if you will, Senator Murphy quoted a GAO study. I pulled up the summary of that study and I think there are a couple of other things to point out.

Significantly, as we have mentioned, in the articles that I previously quoted, 340B, according to academicians, incentivizes hospitals to prescribe more expensive medication and drives up cost for both commercial and for Medicare programs. That is important.

Medicare is going bankrupt in 8 years and we should be aware of anything which is driving up the costs for the Federal taxpayer, but also for the patient as she is paying a higher co-pay.

All this is important. I am just taking the perspective of what about the patient?

Here we see, though, just to quote specifically. "In 2012, the average per beneficiary spending at a 340B DSH hospital was," and DSH hospitals are 340B's, "Was \$144 compared to approximately

\$60 at a non-340B hospital. The difference did not appear to be explained by the hospital characteristics.”

It goes on to say, “Therefore,” this is GAO, “There is a financial incentive at hospitals participating in the 340B Program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. Unnecessary spending has negative implications, not just for the Medicare program, but for the beneficiary who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs.”

I will also say as a physician, if you give more drugs to somebody, you are more likely to have complications. And if the patient is our primary priority, we should not be overprescribing because we are exposing her to a greater potential for complications. I mean, that is just, bad things happen.

Just to say, that seems to be the same GAO study that Senator Murphy was referring to earlier. So I do think that we have an issue.

The rule that was put out by the Administration, is it not my understanding that rule actually redistributed some of the benefits from the 340B Program to rural hospitals? Are you familiar with that rule, Captain?

Captain PEDLEY. I believe you are referring to the CMS rule—  
Senator CASSIDY. Yes.

Captain PEDLEY.—as it relates. That is a rule under CMS authority and not under HRSA authority.

Senator CASSIDY. Are you familiar with it at all?

Captain PEDLEY. I am familiar with the rule.

Senator CASSIDY. You are familiar.

Captain PEDLEY. [Nonverbal affirmative response.]

Senator CASSIDY. Okay. So Senator Jones was talking about 340B hospitals not doing as well, but it is my understanding that rule redistributed benefits to rural hospitals. It was net neutral in terms of the cost to the Program. But again, it just redistributed so that rural hospitals benefited more.

Is that your understanding as well?

Captain PEDLEY. I am not that closely familiar with the details of the rule.

Senator CASSIDY. Yes.

Captain PEDLEY. But I would be happy to connect you—

Senator CASSIDY. I am fairly confident of that, and so to Senator Jones’ point, that would actually be a benefit of that rule.

Now, you mentioned, and this I do not know the answer to, you mentioned that you audited 1.5 percent of the covered entities and 28 percent of the manufacturers.

What problems have you found among covered entities that we should be concerned about?

Captain PEDLEY. With covered entities, we focus on their statutory requirements as first that they remain eligible in the Program when we audit them.

Senator CASSIDY. You had mentioned that earlier.

What are the issues that you have found? What percent of that 1.5 percent you have audited have had problems?

Captain PEDLEY. In total, based on our audits, about 70 percent of the entities had findings. However, based on how we choose these audits, they are at higher risk for having findings.

For example, we target audit entities that already have known issues and we go in and audit to better understand what is happening on the ground.

Senator CASSIDY. Seventy percent of those whom you audited who are covered entities have issues, but granted, it is a select population.

What about the pharmaceutical companies? What percent? Now, I am asking. I do not know the answer to any of this. What is the percent of pharmaceutical companies that have issues?

By the way, going back to the covered entities, there is going to be a level of severity. There is going to be a grammatical error that you should have put a comma here, not there, and then there are some that are really significant.

Is there any way? Can you give us any kind of sense of whether these are significant issues or not significant issues?

Captain PEDLEY. They do vary across the board from minor data base issues, to diversion of drugs to patients who were not eligible.

About 60 percent of the audits had required repayment to manufacturers. But again, even within that repayment, it might have been one drug that was found versus—

Senator CASSIDY. I am almost out of time.

What about the pharmaceutical companies? What percent of those whom you audited are there problems and what is the severity of the issues?

Captain PEDLEY. We have not found issues in the manufacturer audits. Again, we audit based on that one core obligation to ensure they are charging the ceiling price and we have not found any related to their statutory requirement.

Senator CASSIDY. Got it. Okay. I am out of time and I think now, Senator Murray, would you like to?

Senator MURRAY. Let Senator Kaine proceed.

Senator CASSIDY. Okay.

Senator KAINE. Thank you and thanks again, Captain Pedley.

One question I did not get to, actually a couple.

In your written testimony, we talked about manufacturer audits and we have talked about provider audits. You also mentioned if an arrangement with a contract pharmacy is found to be out of compliance with 340B Program requirements, HRSA may terminate the contract pharmacy arrangement from the data base.

Has that been done with any contract pharmacies to your knowledge?

Captain PEDLEY. We have removed contract pharmacies from the program if the entities are not appropriately overseeing those pharmacies. I do not have the specific numbers in front of me, but I can get them back to you.

Senator KAINE. I will ask that for the record, then.

Let me ask this. Virginia, just in the last month, finally, thank goodness, embraced Medicaid expansion. Four hundred thousand Virginians are going to have the opportunity to have Medicaid who did not have it before. Many of whom will have health insurance

for the first time in their lives because of the action of our state legislature.

I know that HRSA is doing some studies about 340B utilization in states that have expanded Medicaid and those that have not.

What effects, so far, do you know that Medicaid expansion has had on covered entities in states that have expanded Medicaid?

Captain PEDLEY. That is not an area that we have specifically looked at.

Senator KAINE. You are correct. I thought you were doing it, but the GAO is currently examining differences between 340B hospitals in states that have or have not expanded Medicaid.

But you do not have your own sense of that from the vantage point of HRSA?

Captain PEDLEY. No, we do not.

Senator KAINE. Let me just state something to you that my own staff's research uncovered.

Congress expanded the 340B Program in 2010 to allow additional hospitals and other entities to participate in the Program. That was an expansion that was at the same time as part of the Affordable Care Act.

This did result in increased access to care and services to needy patients, but even with the addition of these new covered entities, 340B sales as a percent of total drug sales grew by less than 1 percent between 2012 and 2016. In other words, while the Program has grown and serves more patients, it is not responsible for increased drug costs.

Would you agree with that statement?

Captain PEDLEY. The data we do have is around the sales in the Program and the percent of the market that it represents. In 2017, sales were \$19.2 billion, which represented about 4.3 percent of the prescription drug market.

Senator KAINE. The statement that I read to you generally agrees with the drift of that. That even though the ACA dramatically expanded the number of providers, the increase in cost in this Program, even with that expanded number of providers, has not been significant as a percentage.

Captain PEDLEY. The sales has grown. I have not looked at it specifically related to the percentage of entities that have been added, but that is one of the reasons that the sales have increased.

Senator KAINE. Yes, thank you. Appreciate it.

Senator CASSIDY. Senator Baldwin.

Senator BALDWIN. Thank you.

The city of Milwaukee has recently experienced a large cluster of HIV and syphilis cases that require a robust response from our city leaders and community health stakeholders.

Our AIDS Resource Center is a 340B grantee and also a Ryan White Clinic. The AIDS Resource Center has been able to help address this crisis in real time by extending testing hours and expanding mobile testing capacity thanks to their 340B savings.

But these clinics continue to face increasing burdens with the rise of opioid abuse and related sexually transmitted infections.

In order to ensure that our community providers can meet the challenges related to addressing the opioid epidemic, is HRSA considering changes to its Program income standards to allow for

greater flexibility in how these savings are used by clinics across the country?

In light of the ravaging opioid crisis, are there policy changes that we ought to be considering to help increase our effectiveness in combating the opioid crisis?

Captain PEDLEY. As it relates to Program income, that is actually a requirement under their grant, which is another part of HRSA that oversees their grant requirements as part of how they participate under Ryan White. That is not under the 340B statute or my specific authority.

I would be happy to connect you with the right folks to get you an answer on that, but I would be unable to provide any information on that.

Senator CASSIDY. Senator Murray.

Senator MURRAY. Yes. Captain Pedley, I just wanted to clarify.

How many audits has HRSA conducted on drug manufacturers in the last 5 years?

Captain PEDLEY. Twelve.

Senator MURRAY. Out of 600.

Captain PEDLEY. Correct.

Senator MURRAY. How many on covered entities?

Captain PEDLEY. In total, 981.

Senator MURRAY. Out of 12,000. Correct?

Captain PEDLEY. It is 12,700, I believe.

Senator MURRAY. Safety net providers including their child sites and contract pharmacies are getting audited at almost twice the rate of the drug companies. I just wanted to make that clear.

Mr. Chairman, thank you for doing the hearing.

I just wanted to say, I am really concerned the Administration is cutting back on oversight. They are cutting the Program with a nearly 30 percent reduction in payments to 340B hospitals this January and they are suggesting in their recent drug pricing blueprint that this crucial discount program is responsible for high drug prices, which does not make sense to me.

Integrity, transparency, accountability are critical to any program, and I believe that we can strengthen the 340B Program by increasing accountability for drug companies that currently have very little. We should focus on that and not on efforts to rollback the 340B Program that provides help for patients and families across the country.

Thank you, Mr. Chairman.

Senator CASSIDY. The hearing record will remain open for 10 days. Members may submit additional information for the record within that time, if they wish.

Senator CASSIDY. Thank you for being here today.

Captain, thank you very much.

The Committee stands adjourned.

[Whereupon, at 11:41 a.m., the hearing was adjourned.]