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EXAMINING OVERSIGHT REPORTS ON THE 340B DRUG PRICING PROGRAM

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING OVERSIGHT REPORTS ON THE 340B DRUG PRICING PROGRAM

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EXAMINING OVERSIGHT REPORTS ON THE 340B DRUG PRICING PROGRAM

Tuesday, May 15, 2018

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

The Committee met, pursuant to notice, at 10:04 a.m. in room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Good morning.

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

Last Friday, President Trump and Secretary Azar announced a blueprint on drug pricing. It seemed to me that it was sweeping, comprehensive, sophisticated, and appears to me to put patients and taxpayers first.

The Administration is beginning to tell us more about what they have in mind, and in some cases, they are asking for input from the public about some of their objectives. So it may take some time before we know what the specifics of all the proposals are.

Many of their proposals appear to be in the jurisdiction of other committees, but some of the more important pieces will be in the jurisdiction of this Committee including:

More competition for generic drug biosimilars;

Over-the-counter drugs, which this Committee already has taken some steps on, such as the legislation we approved last month to make it easier to get over-the-counter drugs to market by modernizing the outdated monograph system;

Examining the relationship of the list price to what the consumer pays. That should be in our jurisdiction; and,

Policies to prevent drug manufacturers from gaming our current system.

Some of these can be done by administrative action. Others will require legislation. We will be working with the Administration on scheduling a hearing and other ways—such as roundtables or additional briefings with staff and with Members of the Committee—to learn more about their proposals.

The Administration has already started that process. The President announced the proposal on Friday. The Secretary had a bipartisan call for Senators on the same day. The Department has begun briefing staff. We will continue to make sure that Members and staff know as much as we can know about the proposals.

But today's hearing is the second in a series of hearings about the 340B Program. For several months now, this Committee has turned our attention to the high cost of health care. We have held three hearings on the cost of prescription drugs as a part of that, most recently with the National Academies.

Like those hearings, today's hearing is bipartisan, which means Senator Murray and I agreed to it. And the witnesses are bipartisan and we thank you both for coming.

I know Senators have a right to talk about everything from health insurance to football in their 5 minutes, and often do. But I hope we can focus on this unusual opportunity to get some independent evaluation of the 340B Program from the experts we have here today.

Today, I hope we can determine what is the purpose of the Program? Is it fulfilling the purpose? Should there be changes in the law so that the Program can fulfill that purpose?

Senator Murray and I will each have an opening statement, then I will introduce the witnesses, and then we will hear from them. Senators will each have 5 minutes to question the witnesses.

At our first hearing, we heard from hospitals, drug companies, community health centers, and pharmacies. And we learned there is a lack of agreement on the following questions. What is the total amount that Americans spend on prescription drugs? What percent of that spending is subject to the 340B discount? How much do hospitals and clinics save through the 340B discount and on what do they spend those savings?

This lack of agreement on the amount of money, and how the money is spent, makes it hard to properly oversee the Program or to know how much of the savings hospitals and clinics receive from discounted drug prices that are used to reduce the price of drugs and treatments for patients, and how much is spent on other activities.

It very well may be that most are using the savings to benefit low income patients as intended, or it may be that the other activities meet an important public objective, but it is hard to know that until we have more information.

At today's hearing, we will hear from the Government Accountability Office, the GAO, and the Department of Health and Human Services Office of the Inspector General, who have examined and published a number of oversight reports on the 340B Program.

We will have a third hearing, which was suggested by Senator Kaine. We will have that later this year to hear from HRSA, the Health Resources and Services Administration.

On today's hearing, the GAO and the Department of Health and Human Services Office of the Inspector General are nonpartisan Federal watchdogs that issue recommendations on how Federal programs could run better.

In 2011, GAO found that HRSA oversight of the Program was, quote, "inadequate." Saying, "HRSA's oversight is inadequate be-

cause it primarily relies on covered entities' and manufacturers' self-policing; that is, participants ensuring their own compliance with Program requirements."

In 2014, HRSA drafted regulations to define what a patient is.

However, HRSA was sued in 2014 and the courts found HRSA, "Lacked the statutory authority to engage in such rulemaking," limiting what it could do to oversee the Program.

The Inspector General of the Department of Health and Human Services has come to similar conclusions as the GAO, including that oversight of the Program has been inconsistent, and HRSA lacks authority to adequately oversee it.

To improve oversight, the Inspector General recommended that HRSA clarify which patients are eligible to receive 340B drugs, how hospitals and clinics can use contract pharmacies to dispense 340B drugs, and clarify other requirements on eligibility.

Another concern raised by the Inspector General is that states need to have more information about the price and discount of drugs in the Program to properly reimburse through Medicaid. The Inspector General recommended that there be more transparency on the price of 340B drugs to ensure states are making accurate payments.

I hear often that hospitals and clinics are using the 340B Program to benefit low income patients or serve another worthy, public objective. But I would like to hear more about, if HRSA's lack of oversight authority has made it difficult for us to have agreement on a common set of data about the 340B Program on which to make such determinations.

Senator Murray.

STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Chairman Alexander.

I am glad that we are able to continue this discussion about the 340B Program with witnesses from the Government Accountability Office and the Department of Health and Human Services Office of the Inspector General.

I am interested to hear more about how this Program helps so many hospitals and health centers stretch their resources and serve their communities, and how we can strengthen and preserve it. 340B is critical for safety net providers that care for patients and families with the greatest needs and fewest resources.

The Program works by requiring pharmaceutical companies to sell drugs at a lower price to health providers who take on a larger burden by serving vulnerable populations and low income patients.

The congressional intent of this Program is to help providers stretch scarce Federal resources and provide more comprehensive services. In Washington State, they are using their 340B savings to do just that.

Olympic Medical Center uses 340B savings in Sequim, Washington to fund the only full service cancer center on the Olympic Peninsula allowing patients to access treatment close to home and provide treatment regardless of whether patients are able to pay. Without 340B, the Center would operate at a loss and would have to cutback that program.

At Evergreen Health in Monroe, Washington they use 340B savings to fund a program for pregnant women struggling with substance abuse, a primary care center in rural Sultan, and discounted care for those who need it. Without 340B, Evergreen would operate at a loss and have to cut programs.

On the east side of our state, Kootenai Health Center uses 340B to serve rural communities in Washington, Idaho, and Montana. Kootenai's 340B savings support a Level III NICU that helps babies born prematurely and facing health challenges, an E.R. that sees over 50,000 visitors a year, no-cost behavioral health services, and financial support for cancer patients.

It is clear, 340B has helped care providers, who are so essential to their communities, stretch their resources farther than they could otherwise. But that does not mean we cannot also have more clarity in the 340B Program.

We should strengthen the Program and have more accountability and transparency for everyone in our drug system. We should be confident that entities are using their 340B savings appropriately and pharmaceutical manufacturers are providing 340B discounts fairly.

If there is misuse or abuse in the system, we should hold those actors accountable. There have been opportunities, actually, to provide that accountability, but unfortunately, President Trump seems entirely uninterested in actual oversight or Program integrity. He has continued to sabotage efforts to make sure drug companies play by these rules.

The Affordable Care Act gave the Health Resources and Services Administration, HRSA, new authorities to keep the 340B Program accountable. After the Inspector General for the Department of Health and Human Services found many drug companies were overcharging, HRSA drafted a rule to make sure companies were giving the discounts required by the 340B Program.

The Obama administration finalized that rule, but the Trump administration has delayed its implementation over and over. The most recent delay came last week, the same week he gave a speech claiming he was getting tough on drug companies.

When HRSA attempted to provide more clarity for the Program through its so-called "Mega-Guidance," instead of improving that draft and working with stakeholders to develop a path forward, the Trump administration took a giant step back and withdrew that guidance, abandoning the effort completely. They have not just backed away from accountability and clarity for the 340B Program, they have tried to cut it as well.

The 340B eligible providers have traditionally been reimbursed by Medicare at the same rate as everyone else. This year, the Trump administration announced they would unnecessarily and dramatically cut the Program and reimburse 340B hospitals for drugs at a rate nearly 30 percent lower than all other hospitals.

President Trump can talk and tweet about lowering drug prices all he wants, but when his only concrete steps are to holdback rules that would provide accountability and prevent drug companies from overcharging; rollback guidance to clarify how the 340B Discount Program works; and cut resources for providers who are caring for the patients and families least able to afford health care,

he is not going to have a lot of credibility and his promises will not come true.

Even if President Trump does not appreciate the value of the 340B Program, many hospitals across the country, and many of the patients that they help, do. Like the retired social worker in Centralia, Washington who has been fighting melanoma for 7 years. Thanks to the 340B Program, her medication costs $45 a month. Without the Program, it would cost several hundred dollars.

Like a man in Olympia, Washington who lost his health insurance while fighting a very aggressive cancer. Thanks to 340B, he could afford to continue his chemotherapy. Like many patients in struggling communities across the country who fear care might be out of reach or out of their budget, but who have learned a health provider was able to use this 340B savings to stretch its resources far enough to cover them.

There are many stories from my state, and across the country, about how this Program is so important. So I am very glad we have this opportunity to discuss how we make sure 340B remains accountable enough to fulfill its intent and strong enough to continue serving our communities for generations to come.

I look forward to hearing what our witnesses have to say this day. And thank you, Mr. Chairman, for having this hearing.

The CHAIRMAN. Thank you, Senator Murray.

Thanks for your cooperation in scheduling these hearings and the witnesses.

Our two witnesses today are independent witnesses who have focused their time studying the 340B Program. First, we will hear from Ann Maxwell, the Assistant Inspector General for Evaluation and Inspections with the Office of the Inspector General at the Department of Health and Human Services.

She has served that Office for 18 years. In her current role, she conducts national evaluations of healthcare programs to improve program integrity and prevent fraud, waste, and abuse.

Second, Debra Draper is the Health Care Team Director with the Government Accountability Office. Dr. Draper has extensive background in health care finance administration research. In her current role, she focuses on health policy research in Medicare, Medicaid, mental health, and the financing and delivery of health care services.

Welcome, our witnesses. If you each would summarize your remarks in about 5 minutes, then we will go to questions.

Ms. Maxwell, let us begin with you.

STATEMENT OF ANN MAXWELL, ASSISTANT INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Ms. MAXWELL. Good morning, Chairman Alexander, Ranking Member Murray, and other distinguished Members of the Committee.

I am pleased to join you in exploring how to strengthen the 340B Drug Discount Program.

I want to start by thanking you for bringing needed attention to the important role of robust oversight. OIG shares that commitment to oversight and has, over the years, worked to ensure that the 340B Program has the internal controls that would allow us all to feel confident that the Program is operating to best serve the healthcare needs of low income patients.

In the past decade, HRSA has made great strides in improving Program integrity. Long gone are the days when it was difficult to even tell who was in the Program. What remains to be done is to build on that progress and to resolve some longstanding challenges in two key areas.

One, lack of transparency. Two, lack of clarity in Program rules. These challenges compromise the Program's ability to fully deliver the mandated discounts. To overcome these challenges, the OIG has made several recommendations, and I will start with our recommendations to improve transparency.

OIG recommends that HRSA make 340B prices transparent by sharing them with providers and states. This will allow providers and states to verify that they are not being overcharged. Currently, providers have to trust that the drug companies are, in fact, providing the mandated discount.

Similarly, states have to trust that providers are passing along that discount for Medicaid patients. We think there should be an ability to trust, but also verify especially as we have noted instances of overcharging in our work.

Congress did give HRSA the authority to share these prices with providers in 2010. However, 8 years later, HRSA is still working to implement a secure data system to share them. To share the discounted prices with states, HRSA would need more authority.

In addition to pricing information, states need transparency as to which Medicaid claims represent 340B drugs. Even if states gained visibility into 340B prices, as the OIG recommends, Medicaid may still end up overpaying for drugs unless they can identify which claims should be reimbursed at the lower 340B prices.

Transparency into 340B drug claims would also assist states in correctly claiming Medicaid rebates from drug companies. Without it, states may lose out on rebate savings if they misidentify drugs as having already received the 340B discount.

On the other hand, misidentification of 340B drug claims puts drug companies at risk of paying duplicate discounts on the same drug. OIG recommends that HRSA work with CMS to ensure that 340B claims are accurately identified.

The second area needing improvement is to clarify 340B Program rules which, in some cases, have failed to keep up with the evolving complexity of the Program. In particular, OIG work has identified two areas in which program rules, like clarity, are not consistently implemented.

First, HRSA's guidance addresses patient eligibility, but leaves room for interpretation as to which of the patient's prescriptions might be eligible in retail pharmacy settings. In these retail settings, we found that providers, in fact, are making different determinations of what prescriptions are eligible for the 340B discount.

Second, Program guidance does not address how to handle uninsured patients. In our review of retail pharmacies, we found that,

in some instances, uninsured patients were paying out of pocket full price for drugs that had been purchased at steep discounts. HRSA should clarify whether 340B providers must offer discounts to uninsured patients.

To support HRSA's efforts to create clear, enforceable Program rules, we encourage Congress to consider providing HRSA with general regulatory authority over the Program, as their current authority is limited.

I appreciate the opportunity to present OIG's recommendations to improve the 340B Program, greater transparency in 340B prices and claims, along with clear Program rules will ensure that the full benefits of the Program support low income patients who depend on our Nation's health care safety net.

At this time, I am happy to be of assistance, if you have any questions.

Thank you.

[The prepared statement of Ms. Maxwell follows:]

PREPARED STATEMENT OF ANN MAXWELL

Good morning, Chairman Alexander, Ranking Member Murray, and Members of the Committee. I am Ann Maxwell, Assistant Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you to discuss ways to protect the integrity of the 340B Drug Pricing Program (340B program).

OIG reviews have explored various aspects of the 340B program, identified potential vulnerabilities, and offered several recommendations to promote program integrity. Some of the weaknesses we have identified have been addressed through legislation or by the Health Resources and Services Administration (HRSA) directly. However, two long-standing, fundamental vulnerabilities persist, impeding effective program operations and oversight. Specifically, OIG work has identified: (1) a lack of transparency that prevents ensuring that 340B providers are not overpaying pharmaceutical manufacturers and that State Medicaid programs are not overpaying 340B providers; and (2) a lack of clarity regarding program rules that creates uncertainty, resulting in inconsistent program implementation and limited accountability. HRSA has taken some steps toward addressing these concerns, but it has not fully addressed either. My testimony today focuses on the two key improvements OIG recommends to support effective oversight and strengthen the integrity of the 340B program.

OIG Recommends Key Improvements to 340B Program Integrity and Oversight:

- **increase transparency to allow payment accuracy, and**
- **clarify rules to ensure that the program operates as intended.**

THE 340B PROGRAM REQUIRES DRUG MANUFACTURERS TO SELL PRODUCTS AT DISCOUNTED PRICES TO CERTAIN SAFETY-NET HEALTH CARE PROVIDERS

In 1992, Congress established the 340B program to generate savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at discounted prices.[1] A House report, accompanying the original legislation, stated that these savings would "enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] HRSA, which manages the 340B program, reported that total 340B sales in 2016 amounted to approximately $16 billion, or about 3.6 percent of the U.S. drug market.[3]

Pursuant to the Public Health Service Act, drug manufacturers sign a Pharmaceutical Pricing Agreement stipulating that they will charge 340B providers at or

[1] Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.
[2] H.R. Rept. No. 102–384 (Part 2), at 12 (1992) (Conf. Rept.).
[3] HRSA, *Fiscal Year* 2019 *Justification of Estimates for Appropriations Committees*, p. 255. Other stakeholders have produced varying alternative estimates of the size of the 340B program relative to the broader pharmaceutical market.

below specified maximum prices, known as ceiling prices. The manufacturers calculate 340B ceiling prices each quarter by applying a statutorily defined formula to drug pricing data. Due to the proprietary nature of the pricing data used in these calculations, 340B ceiling prices are not made public.

The 340B providers benefiting from these discounted prices include such safety-net providers as community health centers and hospitals that serve a disproportionate number of low-income patients. In 2010, the Affordable Care Act expanded the types of providers eligible to participate in the 340B program to include children's hospitals, critical access hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals. As of January 1, 2018, the 340B program included 12,823 providers and 29,663 associated sites, for a total 42,486 registered sites.[4]

The 340B program intersects with State Medicaid programs in important ways. One way relates to how State Medicaid programs reimburse 340B providers for drugs provided to Medicaid beneficiaries. In February 2016, the Centers for Medicare & Medicaid Services (CMS) clarified that State Medicaid agencies should reimburse providers for drugs purchased under the 340B program at actual acquisition costs and recognized the 340B ceiling price plus a dispensing fee to be an acceptable measure of actual acquisition costs.[5] However, states currently do not have access to the 340B ceiling price as it is protected by confidentiality rules. Another way relates to how states claim Medicaid rebates from drug manufacturers. In general, states are entitled to statutorily defined rebates from manufacturers for covered outpatient drugs. However, "duplicate discounts"—which occur when drug manufacturers pay rebates to State Medicaid agencies on drugs that they sold at the already discounted 340B price—are prohibited by law.[6]

OVERSIGHT OF THE 340B PROGRAM HAS IMPROVED OVER THE YEARS, BUT SOME KEY CHALLENGES PERSIST

Across numerous OIG reviews of the 340B program, our work has identified program integrity vulnerabilities, many of which have been addressed, but others continue to be concerns.[7] Our initial work, released in the early 2000's, found deficiencies in HRSA's oversight of the program. These deficiencies included inaccurate information regarding which providers were eligible for discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices. Systematic monitoring by HRSA was critical, at the time, because confidentiality protections prevented HRSA from sharing the ceiling prices with 340B providers. This lack of transparency left 340B providers unable to determine whether they were paying accurate amounts to drug manufacturers. Further, HRSA lacked the necessary enforcement tools for holding manufacturers accountable.

In the years following OIG's initial work, HRSA took steps to improve oversight of the 340B program and was granted additional oversight authorities. HRSA issued several technical assistance resources to facilitate compliance among manufacturers and 340B providers. For example, HRSA created a training webinar for 340B providers to help them ensure compliance with program requirements to prevent duplicate discounts when working with Medicaid patients. In 2010, legislation directed HRSA to further define standards for calculating 340B ceiling prices and to share those ceiling prices with 340B providers. HRSA was also granted new enforcement tools, including authority to conduct audits of both manufacturers and 340B providers and to impose civil monetary penalties for manufacturers that knowingly and intentionally overcharge 340B providers.[8]

Some of HRSA's efforts to implement its new oversight authorities and clarify program rules through regulations were either unsuccessful or remain unfinished. For example, HRSA developed a proposed omnibus 340B regulation in 2014, but withdrew it prior to publication after a Federal court ruling established limits on HRSA's rulemaking authority for the 340B program. In 2015, HRSA instead issued

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[4] HRSA, *Fiscal Year 2019 Justification of Estimates for Appropriations Committees*, p. 259.

[5] 81 Fed. Reg. 5170, 5317 (February 1, 2016); 42 C.F.R. § 447.518(a)(2).

[6] 42 U.S.C. § 256b(a)(5)(A)(i); 42 U.S.C. § 1396r-8(j)(1).

[7] OIG has issued seven evaluations of the 340B program: (1) *Deficiencies in the 340B Drug Pricing Program's Data base*, OEI–05–02–00071, June 2004; (2) *Deficiencies in Oversight of the 340B Drug Pricing Program*, OEI–05–02–00072, October 2005; (3) *Review of 340B Prices*, OEI–05–02–00073, July 2006; (4) *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI–05–09–00321, June 2011; (5) *Contract Pharmacy Arrangements in the 340B Program*, OEI–05–13–00431, February 2014; (6) *Medicaid Drug Rebate Dispute Resolution Could Be Improved*, OEI–05–11–00580, August 2014; and (7) *State Efforts to Exclude 340B Drugs From Medicaid Managed Care Rebates*, OEI–05–14–00430, June 2016.

[8] Affordable Care Act, Public Law 111–148 § 7102(a).

proposed omnibus 340B guidance that would have addressed a number of OIG and Government Accountability Office recommendations, such as clarifying the definition of a patient.[9] However, HRSA never finalized this guidance, and formally withdrew it in January 2017. HRSA also issued a final regulation on standards for calculating 340B ceiling prices and civil monetary penalties for manufacturers in January 2017.[10] However, HRSA has delayed the effective date of that regulation multiple times, including its most recent proposal to delay the effective date until July 2019, and has indicated that it intends to revisit the substance of the issues involved.[11]

Despite progress in addressing some program vulnerabilities, the steps HRSA has taken do not fully address the long-standing challenges identified by OIG. As such, OIG continues to recommend improving the 340B program by increasing transparency and clarifying program rules. HRSA, CMS, and Congress each have roles in advancing these improvements. These broad areas, and the specific recommendations OIG has made to address each, are explored in detail below.

OIG RECOMMENDS: INCREASING TRANSPARENCY TO ALLOW PAYMENT ACCURACY

Transparency is needed to support payment accuracy in two ways. First, 340B providers and State Medicaid programs need to know the 340B ceiling prices to determine whether they are paying the correct amount. Second, State Medicaid programs need to know which Medicaid claims are associated with 340B drugs to pay 340B providers accurately and ensure that they collect all appropriate drug rebates without subjecting manufacturers to duplicate discounts. The current lack of transparency regarding both 340B prices and Medicaid claims hampers payment accuracy in both of these areas.

The lack of transparency in ceiling prices impedes 340B providers and Medicaid programs from ensuring that they have paid the correct amount for 340B drugs.

Although Congress authorized HRSA to share confidential ceiling prices with 340B providers in 2010, HRSA has not yet done so.[12] HRSA received funding to support this effort in fiscal year 2014. Since then, HRSA has been developing a secure pricing system, which it plans to use as a single point of reference for calculating, verifying, and displaying 340B ceiling prices. According to HRSA's plans, 340B providers will be able to access the system to view 340B ceiling prices and verify that they are paying at or below the posted 340B ceiling price. Manufacturers will also be able to upload their quarterly pricing data and validate their prices with the HRSA-verified 340B ceiling price. HRSA identified this initiative as a priority for fiscal year 2018, and has done so again for fiscal year 2019.[13],[14] Until the system is operational, 340B providers cannot ensure that they are paying the right amount.

The 2010 legislation addressed access to ceiling prices for 340B providers, but it did not address access for State Medicaid agencies. Lack of access to 340B ceiling prices can prevent State Medicaid agencies from effectively enforcing Medicaid payment policies for 340B drugs. OIG found that without access to 340B ceiling prices, states are unable to implement automated, prepayment edits to enforce these policies. Instead, some states conduct labor-intensive and costly audits and post-payment reviews in an attempt to ensure that they have paid 340B providers correctly for 340B drugs. HRSA agreed that ceiling prices should be shared with states, but needs additional statutory authority to do so.[15]

The lack of transparency around which Medicaid claims are associated with 340B drugs hinders states' efforts to correctly apply their 340B payment policies and to claim correct Medicaid rebates from manufacturers.

States also need transparency into which Medicaid claims are associated with 340B drugs to ensure that they make payments in accordance with their payment policies. Even if states can determine *how much* they should be paying 340B providers for 340B drugs, they still may not know *which claims* to reimburse at that rate.

Likewise, knowing which Medicaid claims are associated with 340B drugs is essential for states to correctly and separately claim rebates from manufacturers. If states cannot correctly identify 340B claims, two types of problems may result. One,

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[9] 80 Fed. Reg. 52300 (August 28, 2015).
[10] 20 Fed. Reg. 1210 (January 5, 2017).
[11] 83 Fed. Reg. 20008 (May 7, 2018).
[12] Affordable Care Act, Public Law 111–148 § 7102(a).
[13] HRSA, *Fiscal Year 2018 Justification of Estimates for Appropriations Committees*, p. 245.
[14] HRSA, *Fiscal Year 2019 Justification of Estimates for Appropriations Committees*, p. 258.
[15] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI–05–09–00321, June 2011.

states may inappropriately *include* 340B claims in rebate invoices sent to manufacturers, potentially causing duplicate discount situations. Two, states may inappropriately *exclude* 340B claims and forgo rebates to which they are entitled. In addition, without reliable methods for identifying 340B claims, states may be more likely to have rebate disputes with drug manufacturers, which require additional resources to resolve and may impede or delay rebate payments.

HRSA maintains a tool, the Medicaid Exclusion File, to assist states in identifying providers who have chosen to dispense 340B drugs to Medicaid patients in the fee-for-service program. OIG found that in 2015, states typically used HRSA's Medicaid Exclusion File to identify and exclude 340B claims for the purpose of collecting rebates.[16] However, we found that this provider-level approach may not accurately identify all individual 340B claims, creating a risk of duplicate discounts and forgone rebates. We found that methods that operate at the claim level can improve accuracy in identifying 340B claims and thereby help prevent duplicate discounts and improve collection of rebates. Identifying and excluding 340B claims paid by Medicaid managed care organizations involves additional complications, and claim-level transparency would help address these challenges, too.

To increase transparency, OIG recommends that CMS require states to use claim-level methods to identify 340B claims. CMS did not concur with OIG's recommendation to require the use of claim-level methods to identify 340B claims, stating that it agreed with the importance of claim-level methods but that the statute "does not contemplate" placing such a requirement on State Medicaid agencies. CMS noted that states may develop their own billing instructions in accordance with requirements in the Public Health Services Act. In State Program Release No. 161, CMS informed states about tools they can use to identify 340B claims, including National Council for Prescription Drug Plans Telecommunication Standards that some states have instructed 340B providers to use.

Notably, CMS took steps in late 2017 to increase transparency for 340B claims submitted to Medicare. In its Outpatient Prospective Payment System payment rule for calendar year 2018, CMS began requiring hospitals to use claim-level modifiers when billing for 340B drugs, which was needed to implement its new 340B-specific reimbursement policy.[17]

OIG RECOMMENDS: CLARIFYING RULES TO ENSURE THAT THE 340B PROGRAM OPERATES AS INTENDED

OIG has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements. Contract pharmacies are external pharmacies (often retail pharmacies) that partner with 340B providers to dispense 340B drugs to the providers' patients, and their prevalence is on the rise. These pharmacies typically dispense both 340B drugs on behalf of 340B providers, as well as non–340B drugs. The operations of contract pharmacies are often quite complex, and this complexity has important consequences. In particular, it leads to variation in eligibility determinations across different 340B providers. It also leads to inconsistencies in whether uninsured patients benefit directly from the 340B program. As such, OIG recommends that HRSA clarify rules to address these ambiguities and inconsistencies.

HRSA initiated steps to address OIG's concerns by proposing updates and clarifications that address the patient definition, contract pharmacy arrangements, and other program integrity provisions in its 2015 proposed omnibus 340B guidance. However, HRSA never finalized that proposed guidance. As such, these issues remain unaddressed. To address these issues through rulemaking, HRSA needs additional statutory authority.

HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements.

340B providers are prohibited by law from dispensing 340B drugs to anyone who is not their patient.[18] However, the law does not define what constitutes a "patient." HRSA's official definition of patient eligibility comes from guidance issued before 340B providers were permitted to contract with networks of retail pharmacies. That guidance specifies that an individual is an eligible patient only if he or she has an established relationship with the 340B provider, he or she receives health care serv-

[16] OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI–05–14–00430, June 2016.
[17] 82 Fed. Reg. 59216 (December 14, 2017).
[18] 42 U.S.C. § 256b(a)(5)(B).

ices from the 340B provider, and those services are consistent with the service or range of services for which Federal funding is being granted.[19],[20]

Dispensing a 340B drug to an ineligible patient, which is prohibited by law, is referred to as "diversion." Thus, appropriately determining patient eligibility for 340B drugs is critical to preventing diversion.

Although the law and HRSA guidance focus on 340B eligibility at the patient level, operationally, contract pharmacies determine eligibility at the prescription level. Retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores. To address this reality, many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory. Only later, after dispensing a drug, do these contract pharmacies determine which prescriptions were given to 340B-eligible patients. They then order the appropriate quantity of drugs at 340B prices to replenish their inventory.

To identify which prescriptions were given to 340B-eligible patients, contract pharmacies often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, OIG found wide variation in these eligibility determinations. Different determinations of 340B eligibility appear to stem from the application of the patient definition by 340B providers and their contract pharmacies to a wide variety of prescription-level scenarios.[21] Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.

HRSA's current guidance on patient definition does not account for many of the 340B eligibility decisions that arise in contract pharmacy arrangements. The following example illustrates how contract pharmacy operations have led to different determinations of 340B eligibility in the absence of a clearer patient definition.

Scenario: Nonexclusive physician

A physician practices part time at a 340B provider, but also has a private practice. The physician first sees an individual at the 340B provider. Separately, the physician sees the same individual at his private practice and writes a prescription for that person. The individual fills the prescription at the 340B provider contract pharmacy—even though the prescription was provided at a private practice. Should the patient be considered 340B-eligible?

Whether contract pharmacies determine the prescription in this scenario to be 340B-eligible depends on how they match their dispensing data to information from the 340B provider. One 340B provider in OIG's report noted that it would automatically categorize the prescription in this scenario as 340B-eligible because it uses a list of all prescribers working at the 340B provider to identify 340B-eligible prescriptions. Because the physician in this scenario would be on the prescriber list, the prescription would be categorized as 340B-eligible, even though it was written at the physician's private practice (i.e., it originated outside the 340B provider).

Another 340B provider in OIG's report noted that it would not categorize the prescription in that scenario as 340B-eligible because, although the 340B provider's contract pharmacy also uses a prescriber list to identify 340B-eligible prescriptions, it limits the prescriber list only to those prescribers who work exclusively for the 340B provider. Because the physician in this scenario would not be on the prescriber list (as he does not work exclusively for the 340B provider), the prescription would not be categorized as 340B-eligible.

In its 2015 proposed omnibus guidance, HRSA proposed an update to the patient definition that could have addressed this scenario and many others. The guidance proposed a six-part patient definition, to be applied on a prescription-by-prescription basis, that would have deemed prescriptions to be 340B-eligible only if they resulted from a service (e.g., a physician consultation) provided by a 340B provider. However, HRSA never finalized this guidance, and formally withdrew it in January 2017. HRSA made no public comment as to why the guidance was withdrawn.

Neither the 340B statute nor HRSA guidance addresses whether 340B providers must offer the discounted price to uninsured patients.

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[19] Disproportionate share hospitals (DSHs) are exempt from the requirement that services be consistent with the service or range of services for which Federal funding is being granted. DSHs serve a significantly disproportionate number of low-income patients and receive payments from CMS to cover the costs of providing care to uninsured patients. DSHs are defined in Section 1886(d)(1)(B) of the Social Security Act.

[20] 61 Fed. Reg. 55156, 55157–8 (October 24, 1996).

[21] OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI–05–13–00431, February 2014.

Despite the 340B program's goal of increasing access and providing more comprehensive care, neither the 340B statute nor HRSA guidance speaks to how 340B providers must use savings from the program—nor do they stipulate that the discounted 340B price must be passed on to uninsured patients.

Given this discretion, some 340B providers have chosen to institute extra measures to ensure that uninsured patients benefit through lower drug costs when filling prescriptions at contract pharmacies. If they do not, uninsured patients can pay full price for drugs filled at contract pharmacies and thus not directly benefit from the 340B discount on their prescriptions. Guidance on how the program should apply to uninsured patients in these scenarios should be clarified to ensure that patients are treated consistently across 340B providers and that operations align with the program's intent.

In OIG's 2014 report on 340B contract pharmacy arrangements, we found that a few 340B providers did not offer the discounted price to their uninsured patients at contract pharmacies.[22] These 340B providers' contract pharmacy arrangements would have required additional processes to identify uninsured patients as 340B-eligible because, as previously noted, many contract pharmacies do not know which patients are from the 340B providers when they come to the pharmacy. Not knowing whether the patient is 340B-eligible may not have a financial impact on insured patients, because their costs are often determined by standard copayments stipulated in their insurance plans. For uninsured patients, not knowing whether they are 340B-eligible means that they may be charged the full price for their drugs. Contract pharmacies may later identify uninsured patients' prescriptions as 340B-eligible, but those patients will have paid full price.

CONCLUSION AND SPECIFIC OIG RECOMMENDATIONS

We appreciate the Committee's interest in these important issues. We also appreciate the progress that HRSA has made to improve its oversight of the 340B program. We continue to urge HRSA, in coordination with CMS, to increase transparency and clarify program rules. Within these themes, we have made the following recommendations.

Increase transparency to allow payment accuracy

- HRSA should fully implement its authority to share ceiling prices with 340B providers.
- HRSA should work with CMS to share ceiling prices with State Medicaid agencies.
- CMS should require State Medicaid agencies to use claim-level methods to identify 340B claims and HRSA should update its related guidance.

Clarify rules to ensure that the program operates as intended

- HRSA should clarify the definition of eligible patient.
- HRSA should address whether 340B providers must offer discounted 340B prices to uninsured patients.

HRSA and CMS have both stated that they do not have sufficient statutory authority to carry out most of these recommendations. Therefore, we encourage Congress to consider making statutory changes that would provide HRSA broader regulatory power, as outlined in the fiscal year 2019 President's budget.[23] This would improve program operations and increase clarity in program goals, enabling more effective oversight of this valuable program.

Thank you for the opportunity to testify and participate in the discussion on ways to improve oversight of the 340B program. OIG will continue to work with HRSA, CMS, and Congress to protect the integrity of this program and help ensure that it is efficiently and effectively meeting its intended goals.

SUMMARY OF ANN MAXWELL

The Office of Inspector General (OIG) appreciates the Committee's interest in the important issues raised by our work the 340B program. We also appreciate the progress that the Health Resources and Services Administration (HRSA) has made

[22] OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI–05–13–00431, February 2014.

[23] Office of Management and Budget, *Budget of the U.S. Government for Fiscal Year 2019: An American Budget*. Accessed at *https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf* on May 9, 2018.

to improve its oversight of the 340B program. We continue to urge HRSA, in coordination with the Centers for Medicare & Medicaid Services (CMS), to increase transparency and clarify program rules. Within these themes, we have made the following recommendations.

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Thank you for the opportunity to testify and participate in the discussion on ways to improve oversight of the 340B program. OIG will continue to work with HRSA, CMS, and Congress to protect the integrity of this program and help ensure that it is efficiently and effectively meeting its intended goals.

The CHAIRMAN. Thank you, Ms. Maxwell.

Dr. Draper, welcome.

STATEMENT OF DEBRA A. DRAPER, PH.D., DIRECTOR, HEALTH CARE TEAM, U.S. GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Dr. DRAPER. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee.

Thank you for the opportunity to be here today to discuss the 340B Drug Pricing Program.

The 340B Program was created by statute in 1992 and is administered by HRSA. According to HRSA, the intent of the Program is to enable participating entities, also known as covered entities, to stretch scarce Federal resources to reach more eligible patients and provide more comprehensive services. Participation is voluntary, but there are strong incentives to do so.

Covered entities, such as certain hospitals and federally qualified health centers, can realize substantial savings through 340B drug discounts; reportedly, an estimated 20 to 50 percent of the cost of outpatient drugs and generate revenue to the extent that any reimbursement exceeds the 340B drug price.

For drug manufacturers, 340B Program participation is required to receive Medicaid reimbursement for their outpatient drugs.

Since the 340B Program first became operational in 1993, it has experienced exponential growth in the number of covered entities and contract pharmacies. In 1993, the Program had approximately

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[1] Office of Management and Budget, *Budget of the U.S. Government for Fiscal Year 2019: An American Budget*. Accessed at *https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf* on May 9, 2018.

400 covered entities and by 2017, there were more than 12,000 representing approximately 38,000 covered sites.

Prior to March 2010, only one contract pharmacy was allowed for covered entities without an in-house pharmacy. In March 2010, HRSA lifted that restriction and as a result, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 19,000 at the beginning of 2017 encompassing more than 46,000 arrangements.

In 2011, we reported HRSA's oversight of the 340B Program was inadequate to provide a reasonable assurance that participants were in compliance with Program requirements. As a result of the identified weaknesses, we made four recommendations.

One recommendation was for HRSA to conduct audits of covered entities to ensure compliance with Program requirements. This recommendation was a result of our finding that HRSA primarily relied on participants to self-police and ensure their own compliance.

In 2012, HRSA initiated audits of covered entities and since 2015 has conducted 200 audits annually. This currently represents less than 2 percent of the total number of covered entities participating in the Program. The audits conducted to date have identified instances of noncompliance including the dispensing of 340B drugs to ineligible patients.

A second recommendation was for HRSA to clarify its guidance for cases in which the distribution of drugs is restricted. This recommendation was a result of our finding that in some cases, such as when the supply of a drug is inherently limited, manufacturers may have restricted distribution, but the manner in which they did so was not always clear. HRSA issued updated guidance in 2012 which addressed our recommendation.

The remaining two recommendations were for HRSA to issue more specific guidance on the definition of a patient eligible to receive a drug purchased through the 340B Program and the criteria that households must meet to be eligible to participate.

These recommendations are the result of our findings, but the lack of specificity in the guidance could be interpreted in ways that were not consistent with the Program's intent.

HRSA has attempted, but not succeeded, in addressing these two open recommendations. In 2012, HRSA developed a comprehensive 340B Program regulation, but a court ruling found that its rulemaking authority was limited to specified areas.

In 2015, HRSA issued proposed guidance, but subsequently withdrew plans to finalize it, following the Administration's directive to agencies to withdraw pending regulations and guidance.

More recently, HRSA has indicated that it needs broader regulatory authority for areas such as hospital eligibility.

In summary, while HRSA has taken some steps to improve the integrity in its oversight of the 340B Program, a number of important issues remain including whether the intent of the Program, which was established 25 years ago, is still relevant today given the vastly changed healthcare landscape and 340B Program environment, and continued lack of specificity in Program guidance, most notably, the definition of a patient and hospital eligibility criteria.

Until these issues are resolved, there will continue to be questions about the integrity of the 340B Program and HRSA's ability to provide effective oversight.

Mr. Chairman, this concludes my opening remarks.

I would be happy to answer any questions.

[The prepared statement of Dr. Draper follows:]

GAO Highlights

Highlights of GAO-18-556T, a testimony before the Committee on Health, Education, Labor & Pensions, U.S. Senate

May 15, 2018

DRUG DISCOUNT PROGRAM

Status of Agency Efforts to Improve 340B Program Oversight

Why GAO Did This Study

According to HRSA, the purpose of the 340B Program, which was created in 1992, is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services. Covered entities can provide 340B drugs to eligible patients regardless of income or insurance status and generate revenue by receiving reimbursement from patients' insurance. The program does not specify how this revenue is to be used or whether discounts are to be passed on to patients. The number of participating covered entity sites—currently about 38,000—has almost doubled in the past 5 years and the number of contract pharmacies increased from about 1,300 in 2010 to around 18,700 in 2017. In recent years, questions have been raised regarding oversight of the 340B Program, particularly given the program's growth over time.

In September 2011, GAO identified inadequacies in HRSA's oversight of the 340B Program and made recommendations for improvement. Among other things, this statement describes HRSA actions in response to GAO recommendations to improve its program oversight.

For this statement, GAO obtained information and documentation from HRSA officials about any significant program updates and steps they have taken to implement the 2011 GAO recommendations. More detailed information on the objectives, scope, and methodology can be found in GAO's September 2011 report.

View GAO-18-556T. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

The 340B Drug Pricing Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—eligible clinics, hospitals, and others—in order to have their drugs covered by Medicaid. Covered entities are only allowed to provide 340B drugs to certain eligible patients. Entities dispense 340B drugs through in-house pharmacies or contract pharmacies, which are outside pharmacies entities contract with to dispense drugs on their behalf. The number of contract pharmacies has increased significantly in recent years.

In its September 2011 report, GAO found that the Health Resources and Services Administration's (HRSA) oversight of the 340B Program was inadequate to ensure compliance with program rules, and GAO recommended actions that HRSA should take to improve program integrity, particularly given significant growth in the program in recent years. HRSA has taken steps to address two of GAO's four recommendations:

- **HRSA initiated audits of covered entities**. GAO found that HRSA's oversight of the 340B Program was weak because it primarily relied on covered entities and manufacturers to ensure their own compliance with program requirements and HRSA engaged in few oversight activities. GAO recommended that HRSA conduct audits of covered entities and in fiscal year 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities. HRSA now audits 200 covered entities a year, which is less than 2 percent of entities participating in the 340B Program. Audits conducted to date have identified instances of non-compliance with program requirements, including the dispensing of drugs to ineligible patients. GAO currently has work underway reviewing HRSA's efforts to ensure compliance at contract pharmacies, which includes an examination of HRSA's audits of covered entities.
- **HRSA clarified guidance for manufacturers.** GAO found a lack of specificity in guidance for manufacturers for handling cases in which distribution of drugs is restricted, such as when there is a shortage in drug supply. GAO recommended that HRSA refine its guidance. In May 2012, HRSA clarified its policy for manufacturers that intend to restrict distribution of a drug and provided additional detail on the type of information manufacturers should include in their restricted distribution plans.
- **HRSA has not clarified guidance on two issues.** GAO also found that HRSA guidance on (1) the definition of an eligible patient and (2) hospital eligibility criteria for program participation lacked specificity and recommended that HRSA clarify its guidance. HRSA agreed that clearer guidance was necessary and, in 2015, released proposed guidance that addressed both issues. However, in January 2017, the agency withdrew that guidance in accordance with recent directives to freeze, withdraw, or postpone pending federal guidance. In March 2018, HRSA indicated it was in the process of determining next steps related to guidance on the patient definition, but would need additional authority to further clarify guidance on hospital eligibility; rulemaking authority for the 340B Program was requested in the administration's fiscal year 2019 budget proposal.

Chairman Alexander, Ranking Member Murray, and Members of the Committee:

I am pleased to be here today as you examine the 340B Drug Pricing Program (340B Program), including issues concerning its oversight. The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA), requires drug manufacturers to sell outpatient drugs at discounted prices to eligible clinics, hospitals, and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid.[1] According to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.[2] In recent years, questions have been raised regarding HRSA's oversight of the 340B Program, particularly given growth in the program over time. According to HRSA, as of January 2017, covered entities had more than 38,000 sites participating in the 340B Program—almost double the number reported just 5 years earlier.[3]

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate:

- Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to HRSA. In addition, covered entities can generate 340B revenue. For example, they can purchase drugs at 340B prices for all eligible patients regardless of the patients' income or insurance status and generate revenue, such as by receiving reimbursement from a patient's insurance that may exceed the 340B price paid for the drugs. The 340B Program does not dictate how covered entities should use

[1]42 U.S.C. § 256b.

[2]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

[3]Data represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there were 12,340 unique organizations participating in the program as of January 1, 2017.

this revenue or require that discounts on the drugs be passed on to patients.

- Incentives for participation by drug manufacturers also are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA also requires program participants to meet certain conditions set forth both in law and agency guidance. For example, covered entities are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the entities.[4] Similarly, to help ensure covered entities receive discounts to which they are entitled, HRSA has issued guidance (referred to as "HRSA's nondiscrimination guidance" throughout this statement) prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to non-340B health care providers, such as by imposing minimum purchase requirements or other restrictive conditions.[5]

In a September 2011 report, we identified inadequacies in HRSA's oversight of this program and recommended actions that should be taken to improve oversight and ensure appropriate use of the program.[6] Since then, we have been monitoring HRSA's progress in addressing our recommendations and have testified about this at hearings before the House Committee on Energy and Commerce on March 24, 2015, and July 18, 2017.[7] My statement today will describe HRSA actions in response to GAO recommendations to address (1) weaknesses in oversight of the 340B Program and (2) the lack of clarity in program guidance. The statement will also (3) describe ongoing GAO work regarding the 340B Program and HRSA oversight.

[4]42 U.S.C. § 256b(a)(5)(B).

[5]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

[6]See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Washington, D.C.: September 23, 2011).

[7]See GAO, *Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight*, GAO-15-455T (Washington, D.C.: March 24, 2015) and GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight, GAO-17-749T (Washington, D.C.: July 18, 2017).*

For this statement, we obtained information and documentation from HRSA officials about any significant program updates, and steps they have taken to implement our 2011 recommendations. More detailed information on the objectives, scope, and methodology for our 2011 report can be found in that report.[8] We conducted our work for the 2011 report from September 2010 to September 2011, and updated this work in February and March 2015, in June and July 2017, and again in March 2018. The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program was created following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to state Medicaid agencies.[9] HRSA is responsible for administering and overseeing the 340B Program.

Program Participants

Eligibility for the 340B Program, which is defined in the PHSA, has expanded over time, most recently through the Patient Protection and Affordable Care Act (PPACA), which extended eligibility to additional types of hospitals.[10] Entities generally become eligible by receiving certain federal grants or by being one of six hospital types. Eligible grantees include clinics that offer primary and preventive care services, such as Federally Qualified Health Centers, clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, and AIDS Drug Assistance Programs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to

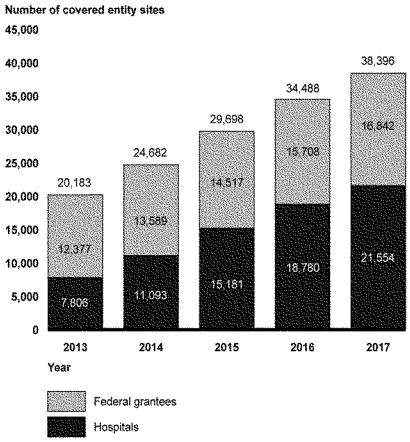
[8]GAO-11-836.

[9]The Medicaid Drug Rebate Program was established through the *Omnibus Budget Reconciliation Act of 1990* and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508 § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

[10]See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

certain low-income individuals. Eligible hospitals include certain children's hospitals, free-standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and general acute care hospitals that serve a disproportionate number of low-income patients, referred to as disproportionate share hospitals (DSH).[11] To become a covered entity and participate in the program, eligible entities must register with HRSA and be approved. Entity participation in the 340B Program has grown over time to include more than 38,000 entity sites, including more than 21,000 hospital sites and nearly 17,000 federal grantee sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2013 to 2017



Source: GAO analysis of Health Resources and Services Administration data. | GAO-18-556T

Note: Numbers are as of January 1 of each year.

[11]Medicare DSH hospitals receive an additional Medicare payment based on their DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

To be eligible for the 340B Program hospitals must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify.[12] Additionally, they must be (1) owned or operated by a state or local government, (2) a public or private nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare.[13]

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B Program and must participate in order to have their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions.

Program Structure, Operation, and Key Requirements

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a participating drug manufacturer may charge covered entities.[14] Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example

- covered entities are prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.[15]
- covered entities are also prohibited from diverting any drug purchased at the 340B price to an individual who does not meet HRSA's definition of a patient. This definition, issued in 1996, outlines three criteria that generally state that diversion occurs when 340B

[12]Critical access hospitals are exempt from this requirement.

[13]According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

[14]Manufacturers may sell a drug at a price that is lower than the ceiling price. As such, covered entities may negotiate prices below the ceiling price.

[15]42 U.S.C. § 256b(a)(5)(A).

discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services.[16] (See table 1 for more information on HRSA's definition of an eligible patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the 340B Program definition of a patient regardless of whether they are low-income, uninsured, or underinsured.

Table 1: Health Resources and Services Administration's (HRSA) Definition of a Patient Eligible for Discounted Drugs under the 340B Program

Criteria for patient eligibility:[a]
1. The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual's health care.
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.[b]
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided.[c]

Source: GAO analysis of HRSA guidance. | GAO-18-556T

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B Program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

[a]These criteria do not apply to AIDS Drug Assistance Programs; rather an individual enrolled in an AIDS Drug Assistance Programs will be considered a patient of that program.

[b]An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

[c]According to HRSA, hospitals are exempt from this requirement. Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the health center program but do not receive federal grants are referred to as look-alikes and are eligible to participate in the 340B Program.

A covered entity typically purchases and dispenses 340B drugs through pharmacies—either through an in-house pharmacy, or through the use of a contract pharmacy arrangement, in which the covered entity contracts with an outside pharmacy to dispense drugs on its behalf. The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance. HRSA's original guidance permitting the use of contract pharmacies limited their use to covered entities that did not have in-house

[16]See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

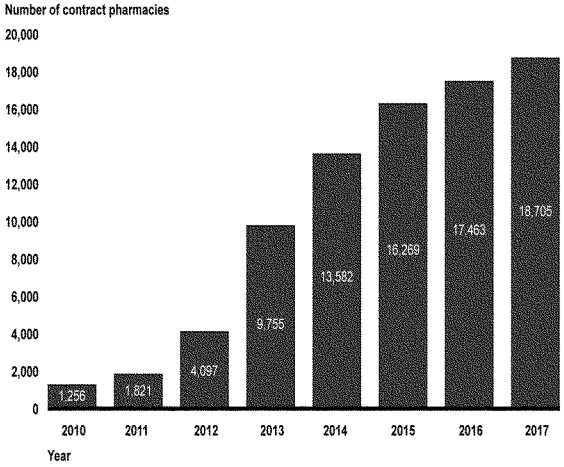
pharmacies and allowed each covered entity to contract with only one outside pharmacy.[17] However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.[18] Since that time, the number of unique contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to around 18,700 in 2017 (see fig. 2); and, according to HRSA data, in 2017, there were more than 46,000 contract pharmacy arrangements.[19] HRSA guidance requires a written contract between the covered entity and each contract pharmacy. Covered entities are responsible for overseeing contract pharmacies to ensure compliance with prohibitions on drug diversion and duplicate discounts. HRSA guidance indicates that covered entities are "expected" to conduct annual independent audits of contract pharmacies, leaving the exact method of ensuring compliance up to the covered entity.

[17]Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996).

[18]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

[19]Contract pharmacies may have arrangements to dispense drugs for more than one entity. HRSA data indicates that there were 46,174 contract pharmacy arrangements—arrangements between a covered entity site and a pharmacy—as of January 1, 2017. However, the total number of contract pharmacy arrangements is likely higher, as HRSA does not require entities to report all arrangements to the agency.

Figure 2: Growth in Contract Pharmacy Participation, 2010 to 2017



Source: Health Resources and Services Administration. | GAO-18-556T

Note: Data represent the number of unique contract pharmacies participating in the program as of January 1 of each year. Contract pharmacies may have arrangements to dispense drugs for more than one entity.

Drug manufacturers also must follow certain 340B Program requirements. For example, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same channels that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the program.

HRSA Has Implemented GAO's Recommendation to Improve Its Oversight of the 340B Program by Conducting Audits

In our September 2011 report, we found that HRSA's oversight of the 340B Program was weak because it primarily relied on covered entities and manufacturers to police themselves and ensure their own compliance with program requirements.[20] Upon enrollment into the program, HRSA requires participants to self-certify that they will comply with applicable 340B Program requirements and any accompanying agency guidance, and expects participants to develop the procedures necessary to ensure and document compliance, informing HRSA if violations occur. HRSA officials told us that covered entities and manufacturers could also monitor each other's compliance with program requirements, but we found that, in practice, participants could face limitations to such an approach.

Beyond relying on participants' self-policing, we also found that HRSA engaged in few activities to oversee the 340B Program and ensure its integrity, which agency officials said was primarily due to funding constraints. Further, although HRSA had the authority to conduct audits of program participants to determine whether program violations had occurred, at the time of our 2011 report, the agency had never conducted such an audit.

In our 2011 report, we concluded that changes in the settings where the 340B Program was used may have heightened the concerns about the inadequate oversight we identified. In the years leading up to our report, the settings where the 340B Program was used had shifted to more contract pharmacies and hospitals than in the past, and that trend has continued in recent years. We concluded that increased use of the 340B Program by contract pharmacies and hospitals may have resulted in a greater risk of drug diversion to ineligible patients, in part because these facilities were more likely to serve patients that did not meet the definition of a patient of the program.

To address these oversight weaknesses, we recommended that the Secretary of HHS instruct the Administrator of HRSA to conduct selective audits of covered entities to deter potential diversion. In response to that recommendation, in fiscal year 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities that is outlined

[20] GAO-11-836.

on its website.[21] HRSA audits include entities that are randomly selected based on risk-based criteria (approximately 90 percent of the audits conducted each year), and entities that are targeted based on information from stakeholders (10 percent of the audits conducted). HRSA currently audits a total of 200 entities per year, which accounts for less than 2 percent of covered entities. (See table 2.)

Table 2: Number and Percent of 340B Covered Entities Audited by the Health Resources and Services Administration (HRSA), fiscal years 2012-2017

Fiscal year	Number of audits	Percent of covered entities audited[a]
2012	**51**	0.5%
2013	**94**	0.9%
2014	**99**	0.9%
2015	**200**	1.7%
2016	**200**	1.7%
2017	**200**	1.6%

Source: HRSA. | GAO-18-556T.

[a]Determined using the number of covered entities as of January 1 of each fiscal year.

As a result of the audits already conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion and the potential for duplicate discounts. The agency has developed a process to address non-compliance through corrective action plans. The results of each year's audits are available on HRSA's website, and we currently have work underway reviewing HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies that includes an examination of HRSA's audits of covered entities.

[21]See https://www.hrsa.gov/opa/programintegrity/index.html, accessed May 2, 2018.

HRSA Implemented One of Three GAO Recommendations to Clarify Program Guidance

In our 2011 report, we found that HRSA's guidance on three key program requirements lacked the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance, and raising concerns that the guidance could be interpreted in ways that were inconsistent with its intent.[22]

First, we found that HRSA's nondiscrimination guidance was not sufficiently specific in detailing practices manufacturers should follow to ensure that drugs were equitably distributed to covered entities and non-340B providers when distribution was restricted.[23] Some stakeholders we interviewed for the 2011 report, such as covered entities, raised concerns about the way certain manufacturers interpreted and complied with the guidance in these cases. We recommended that HRSA further clarify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices in such cases. In response, HRSA issued a program notice in May 2012 that clarified HRSA's policy for manufacturers that intend to restrict distribution of a drug and provided additional detail on the type of information manufacturers should include in such restricted distribution plans.[24]

In addition, we found a lack of specificity in HRSA's guidance on two other issues—the definition of an eligible patient and hospital eligibility for program participation. Specifically, we found that

- HRSA's guidance on the definition of an eligible patient lacked the necessary specificity to clearly define the various situations under which an individual was considered eligible for discounted drugs through the 340B Program. As a result, covered entities could interpret the definition either too broadly or too narrowly. At the time of our report, agency officials told us they recognized the need to provide additional clarity around the definition of an eligible patient, in part because of concerns that some covered entities may have interpreted the definition too broadly to include non-eligible

[22]GAO-11-836.

[23]Restricted distribution may occur when there is a shortage in drug supply or when shortages are anticipated.

[24]HRSA Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012).

individuals, such as those seen by providers who were only loosely affiliated with a covered entity.

- HRSA had not issued guidance specifying the criteria under which hospitals that were not publicly owned or operated could qualify for the 340B Program.[25] For example, we found HRSA guidance lacking on one of the ways hospitals could qualify for the program, namely by executing a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. Specifically, we found that HRSA did not outline any criteria that must be included in such contracts, such as the amount of care a hospital must provide to these low-income individuals, and did not require the hospitals to submit their contracts for review by HRSA.[26] As a result, hospitals with contracts that provided a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not have been what the agency intended.

Given the lack of specificity in these areas, we recommended that HRSA (1) finalize new, more specific guidance on the definition of an eligible patient, and (2) issue guidance to further specify the criteria that hospitals not publicly owned or operated must meet to be eligible for the 340B Program. HRSA agreed with these recommendations and had planned to address them in a comprehensive 340B Program regulation that it submitted to the Office of Management and Budget for review in April 2014. However, HRSA withdrew this proposed regulation in November 2014 following a May 2014 federal district court ruling that the agency had not been granted broad rulemaking authority to carry out all the provisions of the 340B Program.[27] After this ruling, the agency issued a proposed Omnibus Guidance in August 2015 to interpret statutory requirements for the 340B Program in areas where it did not have explicit rulemaking authority, including further specificity on the definition of a patient of a

[25]We use the term "hospitals that are not publicly owned or operated" to refer to public and private nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B Program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B Program.

[26]HRSA officials we interviewed for the September 2011 report told us that contracts were selectively reviewed if further clarification was necessary.

[27]See *Pharm. Research & Mfrs. of Am. v. United States HHS*, No. 13-1501, 2014 U.S. Dist. LEXIS 70894 (D.D.C. May 23, 2014).

covered entity and hospital eligibility for 340B Program participation.[28] However, in January 2017, the agency withdrew the guidance following the administration's January 20 memorandum directing agencies to withdraw or postpone regulations and guidance that had not yet taken effect.[29] In March 2018, HRSA indicated that it was working with HHS to determine next steps regarding the proposed Omnibus Guidance, which included the patient definition, but that it was unable to further clarify guidance on hospital eligibility without additional authority. HRSA also noted that the administration's fiscal year 2019 budget proposal requests rulemaking authority, which, if enacted, would provide the agency with the authority to regulate hospital eligibility for the 340B Program.

GAO Has Ongoing Work Related to the 340B Program

GAO has ongoing work related to 340B contract pharmacies and the characteristics of hospitals participating in the program. Specifically, given the increase in the number of contract pharmacies in the 340B Program and concerns that contract pharmacy arrangements present an increased risk to the integrity of the program, we were asked to review contract pharmacy use under the 340B Program. In our forthcoming report, we plan to

- describe the extent to which covered entities contract with pharmacies to distribute 340B drugs, and the characteristics of these pharmacies;
- describe financial arrangements selected covered entities have with contract pharmacies and third-party administrators related to the administration and dispensing of 340B drugs; [30]
- describe the extent to which selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and
- examine HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies.

[28]See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).

[29]See Memorandum for the Heads of Executive Departments and Agencies, Regulatory Freeze Pending Review, 82 Fed. Reg. 8346 (Jan. 24, 2017).

[30]Third-party administrators are private companies that some covered entities contract with to manage systems for patient eligibility, program finances, and 340B inventory.

In addition, with the growth in the number of hospitals participating in the 340B Program and Medicaid coverage expansions as a result of PPACA, we were asked to review how hospitals that participate in the 340B Program compare to other hospitals. In our forthcoming report, we plan to address

- how hospitals that participate in the 340B Program compare to non-340B hospitals in terms of certain characteristics; and
- how, if at all, the characteristics of 340B and non-340B hospitals changed after state Medicaid coverage was expanded under PPACA.

We expect to issue these reports this summer.

Chairman Alexander, Ranking Member Murray, and Members of the Committee, this concludes my statement. I would be pleased to respond to any questions you may have.

GAO Contacts and Staff Acknowledgments

For further information about this statement, please contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Key contributors to this statement were Michelle Rosenberg, Assistant Director; Amanda Cherrin, Sandra George, and David Lichtenfeld.

The CHAIRMAN. Thank you, Dr. Draper.

We will now begin a 5 minute round of questions.

Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman.

Thanks to both of you for being here.

I was sitting here contemplating what I might ask, realizing, I am so confused. I do not think I am at a point where I can ask a question.

This reminds me of some of the explanations of Government programs that are sometimes so complicated. But you were just talking, Dr. Draper, about determining if we are still carrying out the intent of the original Program. The intent of the original Program was to lower the cost of drugs to in-need patients.

Is that not correct?

Dr. DRAPER. Well, that is not explicitly stated.

Senator ISAKSON. Explicitly state to me what the purpose of the Program was, then.

Dr. DRAPER. Yes. The intent of the Program—and this is also in a House report that accompanied the legislation—was to enable participating entities, also known as covered entities, to stretch scarce, Federal resources to reach more eligible patients and provide more comprehensive services.

Senator ISAKSON. That would be hospitals and providers.

Is that correct?

Dr. DRAPER. Federal grantees like federally qualified health centers.

Senator ISAKSON. I think you said there are 19,000 of them as of this year.

Is that correct?

Dr. DRAPER. Yes, with 46,000 sites.

Senator ISAKSON. The pricing of the pharmaceuticals is done by the pharmaceutical company that sells them to the hospital providers.

Is there a middleman they go through? Do they go through a benefit manager or insurance company, or does it go directly to the hospital?

Dr. DRAPER. Yes, the covered entities, there are certain restrictions on how they go about purchasing the drugs. For example, they cannot use an approved purchasing organization because of some of the issues around the discounts. They can use HRSA's Prime Vendor Program to purchase the drugs.

Senator ISAKSON. There are various ways for them?

Dr. DRAPER. There are various ways that they can acquire the drugs.

Senator ISAKSON. But under the rules, the pricing is the same no matter what in terms from the pharmaceutical company.

Dr. DRAPER. Whatever the list price is from the pharmaceutical company.

Senator ISAKSON. You, or possibly Ms. Maxwell, made a comment about there was not enough transparency to really be sure whether the Program is functioning at optimum intent. I take that meant from the pharmaceutical companies justifying the cost that they are charging.

Is that correct?

Ms. MAXWELL. Yes, our focus on transparency is making sure the full benefits of the Program are realized by the 340B providers as well as states. Right now, they do not have visibility into the prices.

Senator ISAKSON. Tell me real quickly, right now, how do you currently do that?

Ms. MAXWELL. Right now, states and providers do not have visibility into what those prices are. So they simply pay what they are charged.

Senator ISAKSON. That is why you used the term "trust, but verify."

Is that right?

Ms. MAXWELL. Correct.

Senator ISAKSON. It seems like we have a problem in the search of a system to evaluate it, listening to the testimony of both of you. That we really need to be able to trust, but verify the cost that is put in by the company and make sure the providers that have become eligible to make the purchase are qualified and are delivering it to the intended people. That is what it sounds like to me.

We probably need to work on that, Mr. Chairman, as a Committee to help the Program.

I yield back the rest of my time.

The CHAIRMAN. Thank you, Senator Isakson.

Senator Murray.

Senator MURRAY. Both testimonies speak strongly to the greater need for 340B Program integrity. I support the efforts by HRSA to ensure 340B resources are being used to help safety net providers stretch their scarce resources to serve those in the greatest need, as you stated was the goal.

Ms. Maxwell, did the Affordable Care Act require regulations to make sure drug companies were charging the appropriate amount or ceiling price for these drugs and to hold them accountable for overcharging?

Ms. MAXWELL. Yes, it did, and HRSA's authority to regulate that was upheld in court.

Senator MURRAY. Right. And when was that regulation finalized?

Ms. MAXWELL. January 2017.

Senator MURRAY. Why has it not been implemented?

Ms. MAXWELL. Since finalizing that rule in January 2017, HRSA has repeatedly delayed the effective date, as you mentioned, multiple times and most recently has proposed to delay that effective date to July 2019.

Senator MURRAY. Their delay, the Trump delay in continuing to implement that is having an impact.

I noticed that they delayed again last week, the same week, as I said, that the President said he was cracking down on the pharmaceutical industry. So they are not moving forward on this, I would assume.

You would say that, yes?

Ms. MAXWELL. Yes, and in addition to that, the rule delegated enforcement authority to the OIG. And as a result, the OIG has not received any referrals for enforcement authority, and we do not anticipate receiving any until the rule is finalized.

Senator MURRAY. Dr. Draper, your testimony recommends the definition of 340B eligible patient and the criteria for hospitals to be clarified. I believe that needs to be done in a way that strengthens this Program that helps so many patients.

Has HRSA attempted to address the issues of hospital eligibility and patient definition to assure that 340B is being implemented consistently across the country?

Dr. DRAPER. They have not attempted to do it with the 2014 regulation and the guidance that was pulled-back in 2017. So it is still an issue.

I think part of the issue, for example, with the definition of a patient, there are a lot of covered entities that consider that and look at that very narrowly and others look at it very broadly. So you have a wide range of how that is being interpreted.

For the entities that look at it very narrowly, there could be patients who could benefit from the Program that are not getting that service because of the narrow definition of how that hospital, or an entity, is interpreting it.

Senator MURRAY. What happened to the draft guidance?

Dr. DRAPER. It was pulled-back in 2017, based on the Administration's directive to agencies to pullback any pending regulations and guidance.

Senator MURRAY. Instead of working with stakeholders to provide more clarity to that guidance, it was pulled back and the Administration punted it again.

As I said in my opening remarks, I think that is sabotage and it is hindering the efforts to improve transparency and accountability. They cutback the Program, and then argued in last week's drug pricing plan, the Program does not work.

I think that is just not the right approach and I just wanted everybody to understand that is what is happening.

I wanted to ask one more question. Hospitals provide for the community in more ways than simply caring for uninsured patients.

In my state, the University of Washington uses the Program to help support medical care at what they call the 1811 Eastlake Housing Project. That is for individuals who struggle with homelessness and alcohol abuse. That care model helped King County save $4 million by allowing those individuals to avoid the more expensive services like the emergency room.

We heard from some stakeholders that better reporting of hospitals' 340B savings, and the services they provide would reduce the complexity, would increase transparency, and better assure compliance.

From your work on 340B, do you think additional reporting from hospitals in their use of 340B savings is helpful for Program integrity? Anyone?

Ms. MAXWELL. We are very supportive of Program integrity. We think reporting requirements would provide greater transparency, of course.

But in thinking about responsible reporting, we always need to weigh that against the potential provider burden. We also think responsible reporting is most valuable when it is tied to clear program goals.

Senator MURRAY. What would be the best metrics to determine which hospitals are good program stewards?

Ms. MAXWELL. I would not be the person to opine on that. Just from a Program integrity perspective, we find the most value in reporting when it is tied to clear Program goals and rules. And as we have noted here already, this Program lacks some clarity in the intent of the Program.

Senator MURRAY. Dr. Draper, what is a good metric that we should be looking at?

Dr. DRAPER. I think that currently the program does not require any reporting of how revenues are spent. I think anything that enhances the transparency of the Program, I think would enhance the integrity of the Program.

But I also think that is also tied to the issue about what is the real intent of the Program? Because I think there is some ambiguity around what is the actual intent of the Program.

A lot of people think it is a Program for low income people and indirectly, they may benefit, but that is not really explicitly stated in the intent.

Senator MURRAY. Thank you.

The CHAIRMAN. Thanks, Senator Murray.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

According to the Maine Hospital Association, 25 Maine hospitals qualify for the 340B Drug Discount Program, and they receive a collective benefit estimated to be $105 million a year.

Fourteen of those 25 hospitals already have negative operating margins. For some of the other 340B hospitals with positive operating margins, the value of the Program represents the difference between a positive operating margin and a negative one.

At the same time, part of what is driving the narrow hospital margins and losses in Maine is the growth in pharmaceutical spending. Maine hospitals have experienced a 30 percent increase in drug spending over the past 4 years.

I wanted to give you that background because the Hospital Association in Maine has told me that if we were to limit or eliminate the 340B benefit, it would wipeout the positive operating margins for those hospitals that actually are in the black.

Ms. Maxwell, you testified about the lack of transparency to ensure that the 340B providers are not overpaying pharmaceutical manufactures.

What can we do to increase transparency and ensure that overpayments are not occurring?

Ms. MAXWELL. Thanks for that question. It is a really important one and one that speaks to a number of our recommendations around transparency.

We think the best way to provide better transparency is for HRSA to share the 340B ceiling prices directly with providers as well as states.

Senator COLLINS. Is there any reason that HRSA is not doing that now?

Ms. MAXWELL. In terms of providers, HRSA does now currently have the authority that was granted in 2010 with the ACA, but they have not completed their secure data system. My under-

standing is that that is in progress, but it is not completed, and may not be completed until the completion and effective date of the ongoing rules about ceiling price.

In terms of sharing the information with states, that would require more authority from Congress for HRSA to be able to share that.

Senator COLLINS. Thank you.

Ms. MAXWELL. Thank you.

Senator COLLINS. I held a hearing in the Aging Committee last week on the increase in the price of insulin during the past 10 years when it has tripled, despite the fact that insulin has been around since 1921, and granted, there are different modifications. But once again, we ran into this lack of transparency.

The American Diabetes Association did a chart that showed the number of middlemen—including Pharmacy Benefit Managers, wholesalers, distributors, insurers—that are between the manufacturers and the patients, and the fact that rebates and discounts often do not get passed on.

When Senator Isakson was talking about that lack of transparency in the system, and listening to your testimony, I think that that is a major problem in the pharmaceutical network, if you will. And it sounds like it is partly an issue here as well.

Ms. MAXWELL. Indeed.

Senator COLLINS. Thank you, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Collins.

Senator Kaine.

Senator KAINE. Mr. Chairman, I am glad we are having this hearing and look forward to the hearing with HRSA as well.

Thanks to the witnesses for being here.

Ms. Maxwell, first, for you, I want to talk about one of my critical health care providers, the Virginia Commonwealth University. It is the largest safety net hospital in Virginia. It is an urban, Disproportionate Shared teaching Hospital, and it is representative of the hospitals that could be hurt most by recent HHS cuts to reimbursements for 340B drugs.

The 340B savings have allowed them to innovate. They have created a managed care program for the uninsured called Virginia Coordinated Care for the uninsured, or VCC. The program is not insurance coverage, but it is a partnership between VCU and health care providers to treat qualified, uninsured individuals.

When Congress passed the 340B Program, it explained it wanted the Program to stretch Federal resources further and provide more comprehensive services, as Dr. Draper said.

Statements by the OIG and reports were a factor in the nearly 30 percent cut to payments to the 340B hospitals that went into effect in January.

I am looking at one of the reports that the OIG has done, which is a report dated November 2015, entitled, "Part B Payments for 340B Purchased Drugs." I just want to read the conclusion, quote Page 13, "It is important to note that our analysis was entirely financial. We did not examine the effect these changes would have on covered entities' ability to serve their communities."

Just to be clear, the OIG report, this one in particular, did not examine how the cuts would affect urban and teaching hospitals' ability to offer more comprehensive services to their needy patients.

Ms. MAXWELL. That is correct. The focus of the report was to provide an independent analysis of how the savings might be shared across different payers.

We understood that there was a policy conversation happening about the needs to bring down costs in taxpayer-funded Medicare, as well as the need to reinvest in community health centers. And we simply wanted to provide the data to help enable that conversation.

Senator KAINE. I think that is just an important point to make.

For purposes of making the policy decisions that we have to make, we obviously have to grapple with the cost and efficiencies that were the subject of your report. However, we also have to grapple with the consequences to patients of hospitals like VCU of cuts and try to balance those out.

That is a fair statement, is it not?

Ms. MAXWELL. That is actually true.

It is also good to note that big policy changes like this, change the financial equation, and it is possible the hospitals could opt out of 340B altogether.

If they do that, the discounts are lost to all parties.

Senator KAINE. Right.

Ms. MAXWELL. To the hospitals, to Medicare, and to Medicare patients.

Senator KAINE. That would have significant consequences as well.

Dr. Draper, for you, I agree. I think both the Chairman and Ranking Member in their testimony have talked about the need for transparency and oversight to any Government program, including this one.

In your testimony, you report that HRSA has audited 200 covered entities in 2017 to ensure compliance with the Program, which is a fourfold increase over the number of audits that were done in 2014. Given the number of covered entities, that sounds like a good thing to do. Let me ask this question.

How many manufacturers did HRSA audit to ensure they were in compliance with the Program and not overcharging?

Dr. DRAPER. Yes, so according to the HRSA Website, in 2015, they audited one and in each of 2016 and 2017, they audited five. And again, on their Website, they report that they had no findings for the manufacturers. So it is not a systematic process as it is for the covered entities.

Senator KAINE. I would suggest, and I think the Ranking Member got into this a bit in her questions as well, that if we are going to be doing these audits, if we are going to be systematically auditing the providers, we should also be systematically auditing the manufacturers.

Dr. Draper, according to your testimony, the GAO is preparing additional reports on the 340B Program. I just wanted to ask you.

What are the areas that you are examining and when do you think these reports will be ready?

Dr. DRAPER. Sure. We have two reports coming out. They will be coming out this summer. One report is looking at the issue around contract pharmacies. So we are looking at the extent to which covered entities are contracting with contract pharmacies, and some of the characteristics of those pharmacies.

We are also looking at the extent to which discounts are passed on to low income patients or individuals from the 340B Program. We are also looking at HRSA oversight of the Program. We are also going to be delving a little bit more into the audits of the covered entities.

Then the fourth thing that we are looking at is looking at financial arrangements between covered entities and contract pharmacies, as well as with TPA's. TPA's is a whole cottage industry that has evolved around the 340B Program. So that is something that we will be looking at, as well as with the TPA arrangements.

Senator KAINE. Excellent, excellent. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Kaine.

What arrangement? TPA, what does that mean?

Dr. DRAPER. Yes, Third Party Administrator. So a lot of those, they work with 340B covered entities to help set up and manage their 340B Programs.

The CHAIRMAN. Thank you.

Senator Cassidy.

Senator CASSIDY. Just to follow-up on what Senator Kaine said because if, obviously, the Program is being used, as it is to be used, to help those lower income folks, that is a good thing.

But I do want to quote a "New England Journal of Medicine" article in which NYU researchers found that if you look at the provision of cancer care at a 340B Program versus a non–340B Program, there is actually fewer lower income patients in that cancer care.

The 340B Program, which ostensibly is getting this discount to provide more services, statistically is associated with providing fewer services.

There is no significant difference in hospital provision of safety net or inpatient care for low income groups or in mortality among the low income residents of the hospital's local service area. If you will, it is an indictment because, theoretically, this is supposed to——

I have worked in a 340B hospital. Some of them are fantastic and there are patients at the poor folks' hospital, if you will, where I worked that only got medicine because of this Program. But it does seem as if there are some issues with how it is currently being done.

In fact, I noticed that consumer groups are advocating for it. Let me just point out something else.

Last week, Memorial Sloan-Kettering's Drug Pricing Lab reported research, or made the suggestion, that should 340B hospitals be required to provide charity care totaling just 1 percent of their patient revenue, 9 percent of 340B hospitals would no longer be eligible for 340B. That is, if they provided just 1 percent of their revenue for charity care.

Second, I will point out that if you say that the way the business model works is that the more expensive the drug, the greater the

discount. If the hospital is not returning that discount to the payer, to the patient or to the Federal Government, they get a bigger spread with a more expensive drug.

Now, Ms. Maxwell, I think I have seen evidence that the incentive is for the 340B Program to use the more expensive medicine because, again, that increases their spread.

Is that reasonable and do you agree with that?

Ms. MAXWELL. The work of the IG has not touched on that particular issue.

Senator CASSIDY. Let me ask Dr. Draper that.

Ms. MAXWELL. Absolutely.

Dr. DRAPER. We had done a report in 2015 that looked at Medicare Part B drugs and the 340B Program. In that work, we found that the 340B DSH hospitals were generally larger, often teaching hospitals. They tended to have lower overall margins, but higher Medicare margins and we also found that Medicare Part B spending at those hospitals was substantially higher than non-DSH hospitals.

Senator CASSIDY. Medicare Part B, so the interaction between that and 340B is that 340B would cover the infusion drugs given on a Medicare Part B billing. Correct?

Dr. DRAPER. Yes, if it is an outpatient drug.

Senator CASSIDY. When you say that the differential is higher, it implies at least, that they are using more expensive services, or a greater intensity of services for whatever reason, and that would include potentially using more expensive medications.

Dr. DRAPER. Well, it suggests that there may be some financial incentives, unintended incentives for prescribing patterns.

Senator CASSIDY. Now, thank you. You also mentioned that 340B entities tend to be larger hospitals. Last week, researchers from Yale, Penn, Carnegie Mellon, and MIT published a paper that found, among other things, prices at monopoly hospitals are 12 percent higher than in markets with four or more rivals.

Does the current structure of the 340B Program incentivize consolidation?

Dr. DRAPER. We really have not done work on that, so I cannot really address that.

I can tell you that another one of our reports that is coming this summer compares characteristics of 340B hospitals and non–340B hospitals, and also looking at how those characteristics have changed pre-and post-healthcare reform.

Senator CASSIDY. That report is pending.

Dr. DRAPER. Yes, so that will be coming out this summer.

Senator CASSIDY. Okay. And then in 2014, OIG published a report that provided useful insight into where the benefits of the 340B discounts were flowing. The agency found that few of the hospitals you surveyed—this is for you, Ms. Maxwell—few hospitals said they passed the 340B discount back to the uninsured patient.

These are the ones that, it is not Blue Cross, it is the uninsured patient who can hardly afford their medicine to personal insulin, for example, filling prescriptions at the hospital's contract pharmacy.

Given that, in the intervening 3 years, no new guidance or regulation with the goal that the patients are the true beneficiaries of

the Program has been issued, do you have any reason to believe that hospitals have begun to pass these savings back to the uninsured?

Ms. MAXWELL. We worked closely with HRSA and let them know about these situations. So they were able to address them as they thought appropriate. I do not know whether HRSA did, indeed, reach out and talk to these hospitals about their current policies.

Senator CASSIDY. You have no indication either way that hospitals have begun to pass it back to the uninsured or that they have not?

Ms. MAXWELL. That is correct.

Senator CASSIDY. I yield back. Thank you.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Smith.

Senator SMITH. Thank you, Chairman Alexander and Ranking Member Murray, and to our testifiers today.

I want to just start by saying, Senator Isakson, I appreciate your candor in saying it is hard to figure out what is going on with drug prices and who pays what when, and how much, and why. Sometimes I wonder whether that is not by design rather than by accident, to tell you the truth as I struggle to understand this.

This is such an important issue in Minnesota. Senator Collins was talking about drug prices increasing. I think she was talking about overall for hospitals increasing 30 percent, and we wonder why hospitals are struggling to try to make ends meet.

I want to just make sure that what we are talking about in reforms to the 340B Programs do not hurt safety net hospitals, especially in rural areas, and I want to just talk about that for a minute.

I have an example. RiverView Health, a rural Minnesota health system, a 25-bed critical access hospital, recently told me that the 340B Program has enabled them to stay operational. Literally, they would not be there without this as it maintains a Level II trauma center for the region, and also treats an increasing number of people who need mental health services.

They say cutting back on this Program—and I realize that is not specifically what we are talking about here—every penny we spend comes to patient needs. So to Senator Murray's point, this is how we stretch scarce resources.

Ms. Maxwell, could you just tell us a little bit about how you think the proposed changes would affect rural safety net hospitals?

Ms. MAXWELL. Let me make sure I understand your question correctly. Are you talking about the cuts in Part B payments in particular?

Senator SMITH. Yes, exactly. And also, this emphasis on what additional regulatory burden might be placed on small safety net hospitals.

Ms. MAXWELL. Yes, the cuts to Part B are new this year and so, I think it is important to address your issue about how they will actually affect hospitals. We will need to monitor that as the implementation rolls out and see whether or not the redistribution of the savings blunts those cuts in any way.

I think in terms of the regulatory burden, which I think you are also addressing, that also needs to be taken into consideration. Ob-

viously, the Inspector General is all for greater Program integrity and greater transparency.

But we are always cognizant when recommending new reporting requirements of the potential burden on providers to provide that information and how the information will be used to benefit stronger Program integrity.

Senator SMITH. Right. I think this gets me to the question of transparency for whom, and how does it work? Senator Collins got to this a little bit and I also think Senator Murray did.

I am stunned to understand how much drugs are costing, and people do not know.

To the people who are paying for them, it is like saying, "I am going to go and buy a car, but I do not know exactly how much it is costing. I also do not know whether the person standing right next to me is buying the same car and is paying more or less."

Is that not the fundamental problem here?

Ms. MAXWELL. It has been a fundamental issue in the 340B Program almost since its inception, this lack of transparency. It is a significant issue.

Senator SMITH. What is the impact, do you think, of not moving forward on the proposed improvements that the Trump administration has been holding back? What is the impact of that on the prices that people are actually paying, do you think?

Ms. MAXWELL. What I can refer to is a report that we did back in 2005. At that time, we looked and saw that 14 percent of all purchases by 340B entities were, in fact, over the mandated ceiling price.

Senator SMITH. What was that again?

Ms. MAXWELL. In 2005, of the total purchases, 14 percent of them were over the mandated 340B ceiling price, which resulted in $3.9 million in overcharges for that month, which was June 2005. So we do, in fact, have evidence that overcharging has taken place.

Senator SMITH. That was 1 month in 2005.

Ms. MAXWELL. That was 1 month.

Senator SMITH. Well, today's hearing is on the 340B Program, which is, of course, important and plays an important role in making sure that people can get access to prescription drugs and quality healthcare at the same time.

I hope that in this conversation, we do not lose sight of the central problem we have, which is that prescription drug prices are too high and people in my state, and all over the country, are choosing between buying the medicine that they need and other essential parts of their life. I hear these stories all the time in Minnesota.

While I am glad that the President says he wants to tackle these challenges, I hope that we can find some common ground.

I also agree that I do not think the proposals that were laid out last week get at the core problem. I think great evidence of that was the pharmaceutical companies' stock prices went up after the President made this announcement.

At the same time, we have issues with big drug companies, like Novartis, paying Michael Cohen for access to the Administration. These are the issues that, I think, are deeply concerning to people in my state that we have to get to the bottom of.

Thank you.

The CHAIRMAN. Thank you, Senator Smith.

During our first hearing on 340B, it became obvious that among the witnesses, there was some disagreement about statistics, about data.

Let me ask you three or four questions. If you do not have the answer right at hand, maybe you could provide them to me after the hearing.

The Office of the Assistant Secretary for Planning and Evaluation estimated that Americans spent $457 billion on prescription drugs in 2015.

Is that $457 billion accurate for 2015?

Ms. MAXWELL. My understanding, that is accurate for sales.

The CHAIRMAN. For sales.

Well, would you measure it some other way?

Ms. MAXWELL. As opposed to net revenues that would incorporate discounts after the fact.

The CHAIRMAN. Right, Okay, so overall sales.

According to HRSA, of that $457 billion, approximately $12 billion was spent on 340B drugs.

Does that sound correct?

Dr. DRAPER. Yes, I think that is what MedPAC reported as well. That was pre-discount, I believe.

Ms. MAXWELL. Correct. I believe it was $16 billion in 2016 and up to $19 billion in 2017.

The CHAIRMAN. Yes. Well, back on 2015, if it was $12 billion spent on 340B drugs, that was an estimated $6 billion in savings for hospitals and clinics, covered entities, that participate in the Program.

Does the $6 billion figure sound right?

Ms. MAXWELL. It does.

The CHAIRMAN. Yes. So using those numbers, $12 billion out of $457 billion is about 2.6 percent. That would mean that in 2015, the purchase of 340B drugs were about 2.6 percent of the total drug purchases in the country.

Correct?

Ms. MAXWELL. Correct.

The CHAIRMAN. According to HRSA, now, this is looking at the next year, 340B sales were about $16 billion or about 3.6 percent of drug sales in the country; $440 billion in 2016.

Does that sound correct?

Ms. MAXWELL. Yes.

The CHAIRMAN. That would suggest that in 1 year, sales in the 340B Program increased by about 33 percent.

According to the Government Accountability Office, hospitals, clinics, and affiliates—and you testified some to this—participating in the Program nearly doubled from about 20,000 in 2014 to nearly 40,000 in 2017.

Is that correct?

Dr. DRAPER. Yes, over the past 5 years, hospital covered sites increased 175 percent and Federal grantee sites increased about 40 percent. So the growth is really primarily disproportionate in hospital sites.

The CHAIRMAN. Would you both agree that it would be hard for us to do anything else until we clarify the intent of the Program?

Dr. DRAPER. I think clarifying the intent of the Program would go a long way to establishing what the guidance needs to be and it will help create——

Then the guidance needs to happen to create the transparency and enhance it. Right now, there is a lot of ambiguity as to what the Program rules are.

The CHAIRMAN. Ms. Maxwell.

Ms. MAXWELL. I would agree. Clarity in the Program goal, as well as clear Program rules, is the foundation of a strong Program integrity strategy.

The CHAIRMAN. In our previous hearing, it was pretty clear that we could not tell, in all instances, on what the covered entities were spending their money. In other conversations since then, I have had hospitals say to me, "Well, we are glad to tell you."

Is it true that because of the way clinics are supervised that we know more about how they spend their money than we do hospitals? Or is there any reason why we should not ask hospitals and clinics, covered entities, to tell us how they spend this $6 billion?

If it goes to help individual patients reduce the price of a specific drug, that is one thing. If it goes for some other purpose, which it could and does, which may be a worthy purpose, but that is another thing.

Is there any reason not to ask for that information?

Dr. DRAPER. Well, the underlying issue is that it is not a requirement of the Program that entities have to report how they spend their money or what they use the revenue for.

The CHAIRMAN. Yes.

Dr. DRAPER. Now, for some of the Federal grantees, their grant requirements may require them to spend the money in a certain way.

The CHAIRMAN. It does not require that.

Dr. DRAPER. No.

The CHAIRMAN. But it would seem to me we could do a better job of oversight if we knew that.

Dr. DRAPER. I think it is somewhat dependent on the sophistication, probably, of the entity and what type of data systems or other systems they have to put in place to really monitor that.

But I think that it is something that certainly should be explored because I think this is another issue that there will always be questions about the integrity of the Program if that information is not available.

The CHAIRMAN. Yes. Well, we are not clear about the intent of the Program, and if that information is not available, it makes it difficult to oversight.

Dr. DRAPER. I am sorry.

The CHAIRMAN. My time is up.

Dr. DRAPER. I was going to say that people have a lot of interpretations on what the intent of the Program is.

The CHAIRMAN. Yes.

Dr. DRAPER. But that is not consistent with what the stated intent is. I mean, someone gets on a program for low income folks and as I said, it may well be, but that is not explicit in the intent.

I think deciding what the intent of the Program is would go a long way to really helping with creating the necessary guidance and regulations that are needed for the front room.

The CHAIRMAN. Thank you very much.

Well, I have run over my time. Senator Warren is always good about sticking to her time.

Senator Warren.

Senator WARREN. Thank you.

The CHAIRMAN. I have set a bad example.

Senator WARREN. Thank you, Mr. Chairman.

The 340B Program has one basic requirement, that drug companies must provide discounted medications to hospitals and clinics caring for the most vulnerable patients: children with cancer, the uninsured, the underinsured, people with HIV and AIDS.

Federal law specifies the formula used to calculate this discounted price, which is called the ceiling price. In order for the 340B Program to work, the ceiling price calculations need to be done correctly, and there need to be consequences when drug companies break the law and deliberately overcharge for these drugs. So let me start there.

Dr. Draper, in 2011, the GAO raised concerns that the 340B Program, quote, "Primarily relies on self-policing; that is, participants ensuring their own compliance with program requirements."

Tell me, why might it be a problem if a drug company is the only one doing these ceiling price calculations, and no one is able to check its work?

Dr. DRAPER. On the covered entity part, the prices are not available to them, so they do not know really.

The self-policing only works if you have transparency and you have the information that you need to really self-police. The information is not available to the covered entities.

On the other end, too, with drug manufacturers that they may suspect that a covered entity is dispensing drugs to ineligible patients, they have the authority to audit a covered entity, but there are a lot of burdens associated with that, so they rarely do that.

It is both ends and there is just an overall lack of transparency.

Senator WARREN. I get your point, but I just want to start with the premise of just how the Program is set up to begin with because when it comes to these drug companies, if no one can check their work, they could cheat, charge more for drugs, and no one could catch them when they break the law. There is just no way to catch them on this.

Senator Smith started on this issue, so let me ask another part of this.

Ms. Maxwell, the OIG has conducted numerous analyses of 340B prices.

Is there evidence that drug companies have overcharged health care providers in the 340B Programs?

Ms. MAXWELL. Yes, there is evidence.

Senator WARREN. These findings led Congress to include a provision in the Affordable Care Act to crackdown on this behavior.

The ACA required the Government to create a verification system for ceiling prices to make sure hospitals and clinics got refunds if the drug companies overcharged them.

Now, Congress also established fines called Civil Monetary Penalties that drug companies could be charged if they knowingly, and intentionally, overcharged a healthcare provider.

Ms. Maxwell, the OIG is in charge of enforcing the Civil Monetary Penalties.

How many penalties have you assessed to date?

Ms. MAXWELL. To date, we have received no referrals from HRSA, and we do not anticipate receiving them until the rule is made effective, which now is looking like July 2019.

Senator WARREN. There was evidence in earlier studies that drug companies have overcharged health care providers.

Right now, you have not received any referrals, and the reason you have not received any referrals is because the Trump administration has already delayed the implementation of these penalties not once, not twice, not three times, but four separate times since 2017. And just last week, they proposed yet a fifth delay.

When President Trump delivered his big drug pricing speech last week, he said that the 340B Program, a drug discount program, contributes to the problem of higher drug prices. And that is one of the parts of the speech where the drug industry lobbyists must have stood up and cheered because here is the thing.

If the President is truly worried about the connection between high drug prices and the 340B Program, he could start by implementing the law that Congress wrote to actually stop drug companies from cheating on their discounts.

No one should be above the law, and that includes giant drug companies that are raking in profits while complaining about a Program that helps out our most vulnerable patients.

Thank you. I yield with time.

The CHAIRMAN. Thank you for your usual succinctness, Senator Warren.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

I have long worked with a group of bipartisan colleagues in the Senate to protect and strengthen the 340B Program.

In 2013, we called on HHS to consider recommendations from a 2011 GAO report. However, the Administration continues to delay any real action to enhance Program operations for all participants and, instead, has continued to unfairly single out and target hospitals.

Aurora, in downtown Milwaukee, Wisconsin, is one of our 71 hospitals that rely on the 340B Program to care for its uniquely vulnerable population. Aurora estimates that over 8,000 of its patients have undiagnosed hepatitis C with over 37,000 undiagnosed cases in the state.

They have used their 340B savings to develop a screening program and to partner with the city health department, a local Ryan White clinic, and a nearby community health center to improve community health and better address hepatitis C.

Aurora recently shared their frustrations with regular instances where drug companies refused to provide them with the 340B price of a drug. Often, the manufacturer will provide no excuse at all or they will claim that the drug is in short supply. This forces the hos-

pital to buy the needed medication at full cost. At which point, the drug is curiously no longer in short supply.

The GAO recommended that HRSA clarify guidance to prevent drug companies from restricting distribution of drugs at 340B prices. While the agency released clarification, hospitals in Wisconsin continue to experience these problems.

Dr. Draper, what additional work do you plan to do to examine instances where drug manufacturers refuse to provide the 340B price, and what other oversight measures could help address this?

Dr. DRAPER. Yes, we do not currently have work underway or have any planned work related to that. However, that is a HRSA oversight issue and if hospitals are experiencing that, they need to work with HRSA to resolve the issue.

That was something we found in our work that led up to the 2011 report that manufacturers of drugs that were inherently in short supply that they often restricted distribution in a way that was not always clear between 340B and non–340B hospitals.

That is a HRSA oversight and it is a HRSA enforcement issue. I think that the hospitals need to work with HRSA to resolve that issue because that should not be happening in accordance with their updated guidance.

Senator BALDWIN. Many Wisconsin 340B hospitals have also told me about numerous audits that they experienced, not only from their own internal rigorous self-auditing, but also from HRSA audits, as well as audits by the drug companies.

Your agencies have recommended increasing oversight of drug manufacturers including increasing audits, transparency, as well as a dispute resolution process for covered entities to better obtain information from manufacturers.

I am concerned that this uneven playing field between hospitals and drug companies continues to persist, burdening hospitals in the Program.

Dr. Draper and Ms. Maxwell, can you explain why your agencies recommended enhanced drug manufacturer oversight, such as audits? And what gaps remain that the Administration has failed to address?

Ms. MAXWELL. With respect to our work, the gaps that remain are the visibility into the prices. So right now, providers and states do not know what the 340B ceiling prices are. So at this point, they just pay what they are charged and we have evidence from previous work that there are overcharges that occur.

We strongly encourage HRSA to complete the data system, to share the prices with the providers, and also to seek the authority needed to share prices with states.

Dr. DRAPER. Yes, and currently we encourage oversight of all entities participating in the Program, for covered entities, as a result of our recommendations in 2011. HRSA now conducts about 200 audits of covered entities each year.

Earlier, I had talked about that it is not a systematic process for manufacturers. In 2015, they did one manufacturer audit. In each year in 2016 and 2017, they did five.

We would encourage that there is a process to ensure that all participants in the Program are adhering to Program regulations and rules, and that there is greater transparency.

Senator BALDWIN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Baldwin.

I want to thank our two witnesses today for your very helpful comments. You had some questions, which you may want to follow-up on.

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

Our Committee will meet again on Tuesday, May 22 at 10 a.m., for a hearing on, "The Health Care Workforce: Addressing Shortages and Improving Care."

Thank you for being here.

The Committee will stand adjourned.

[Whereupon, at 11:14 a.m., the hearing was adjourned.]

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