STATEMENT OF

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BEFORE THE

U.S. SENATE COMMITTTEE ON HEALTH, EDUCATION, LABOR & PENSIONS

WASHINGTON, D.C.

JUNE 19, 2018

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

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

The 340B Drug Pricing Program

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

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

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

[1] The House Report accompanying the original 340B Program legislation states the following intent: "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

clarify guidance to prevent duplicate discounts for Medicaid managed care organization drugs, and this recommendation remains open.

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

Budget Proposals

The President's FY 2019 Budget includes a proposal to increase transparency and accountability in the Program, by ensuring that the benefits of the Program are used to help low-income and uninsured patients. The Budget also proposes to amend the statute to provide explicit general regulatory authority in order for the 340B Program to set clear, enforceable standards of program participation, and to require all covered entities to report on the use of program savings. If Congress were to enact the FY 2019 Budget proposal, HRSA would have explicit general rulemaking authority for all aspects of the 340B program, significantly strengthening HRSA's oversight of the 340B Program. Binding and enforceable regulations would dictate specific 340B Program requirements and provide the clarity necessary for participants to be fully compliant, for example on hospital eligibility requirements and the definition of a 340B patient.
The President's Budget also proposes to implement a user fee that would be paid by covered entities. The user fees revenue would be used to administer the Program and enhance program integrity and oversight activities by conducting additional 340B Program audits of covered entities and manufacturers and by improving IT system capabilities.

340B Program Integrity

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

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

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

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

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

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

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

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

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

Contract Pharmacy Use in the 340B Program

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

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

HRSA conducts audits of covered entities and their contract pharmacy arrangements and has included in the criteria for risk-based audits the number of contract pharmacy arrangements a covered entity utilizes. HRSA verifies that the covered entity and contract pharmacy have entered into a valid, written contract during its audits of 340B covered entities. Entities must demonstrate that they have mechanisms in place to prevent diversion and duplicate discounts. During audits, HRSA also reviews a sample of the records of 340B drugs dispensed at the contract pharmacy and reviews contract pharmacy compliance. During the annual recertification process, covered entities that have arrangements with contract pharmacies must attest that the arrangement complies with all requirements set forth by the 340B Program. If an arrangement is found to be out of compliance with 340B Program requirements, HRSA may terminate the

contract pharmacy arrangement from the 340B database so that manufacturers no longer ship 340B drugs to the pharmacy.

Conclusion

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

I appreciate the opportunity to testify today.