STATEMENT OF

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITEE ON OVERSIGHT AND INVESTIGATIONS
U.S. HOUSE OF REPRESENTATIVES

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Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee. My name is CAPT Krista Pedley and I am the Director of the Office of Pharmacy Affairs, within the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the 340B Drug Pricing Program. HRSA shares the Subcommittee's commitment to ensuring the integrity of this program. I will discuss today the steps we have taken to implement key provisions and strengthen oversight of the Program, and some of the current challenges we face in managing the Program.

HRSA focuses on improving access to healthcare services for people who are geographically isolated or economically or medically vulnerable. HRSA strives to maximize every dollar and utilize continuous improvement to achieve the best outcomes for those we serve. To that end, program integrity is essential to 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 disproportionate share hospitals, Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and hemophilia treatment centers. 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. Approximately 12,300 covered entities and 26,000 associated sites participate.

Manufacturers participating in Medicaid enter into an agreement with HHS under which they cannot charge covered entities a price that exceeds the 340B 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 relies on these recommendations to inform our program improvement activities across all HRSA programs, including the 340B Program. Since 2011, GAO and OIG reviews of the 340B Program have resulted in eight recommendations. Two recommendations from GAO's 2011 study which direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient, remain open. The OIG's 2005 and 2006 reports recommended that HRSA 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.

Within our statutory authority, HRSA has worked to address the majority of these recommendations through systematic efforts to improve the 340B Program. We continue to

[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).

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

340B Program Oversight

Since 1992, HRSA has administratively established many requirements of the 340B Program through a series of guidance documents published in the *Federal Register*, typically after notice and comment. In the past few years, HRSA has been undertaking systematic efforts to improve the 340B Program, including proposing new regulations and issuing program guidance. Collectively, these rules and guidance are intended to strengthen the integrity of the 340B Program.

In 2014, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional policy to advance its oversight of covered entities and manufacturers. In May 2014, before HRSA was scheduled to issue the proposed omnibus regulation, the U.S. District Court for the District of Columbia[2] invalidated a 2013 final rule on a provision in the 340B statute related to orphan drugs. HRSA withdrew the proposed omnibus regulation from Office of Management and Budget (OMB) in order to reevaluate the proposed regulation in light of the court's ruling.

On August 12, 2016, HHS issued a notice of proposed rulemaking[3] on the 340B ADR process. On January 5, 2017, HHS promulgated regulations in the *Federal Register*[4] on the calculation of ceiling prices and the imposition of civil monetary penalties for manufacturers, which will become effective October 1, 2017.

In the absence of new regulation on certain issues, HRSA issued a proposed 340B Omnibus Guidance in August 2015.[5] We are working to determine next steps to address these policy issues.

Budget Proposals

The President's FY 2018 Budget commits to developing a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations. HRSA has prioritized rulemaking in areas in which the D.C. District Court has clearly recognized our regulatory authority. Specific legislative authority to conduct rulemaking for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight over, and management of, the 340B Program. In addition, specific regulatory authority would allow HRSA to provide greater clarity and specificity to Program requirements.

[2] *PhRMA v. HHS*, 43 F. Supp. 3d 28 (D.D.C. 2014).
[3] 81 FR 53381(August 12, 2016).
[4] 82 FR 1210(January 5, 2017).
[5] 80 FR 52300, (August 28, 2015).

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 are in compliance 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.

Fiscal year 2017 is our sixth year of covered entity audits. Random audits continue to be selected using 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.

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. HRSA auditors follow a strict protocol when conducting an audit. After the completion of the audit, the entity receives a preliminary 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 Final Report. 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.

To ensure the transparency of the audit process, HRSA posts a summary of final audit findings, including the name of the covered entity, on the Office of Pharmacy Affairs public website. As of June 26, 2017, we have completed 805 covered entity audits since we began auditing in 2012, which encompasses nearly 11,000 offsite outpatient/off-site facilities and nearly 18,000 contract pharmacy locations. In FY 2017, 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.

HRSA re-audits a select number of entities with findings that resulted in repayment to manufacturers. HRSA does not consider covered entities for re-audit until their audit is closed, which does not occur until after the CAP has been fully implemented. This policy is in place to

ensure the covered entity has time to fix the issue and has time to conduct repayment to manufacturers. Therefore, there is some time delay between the first audit and any subsequent re-audit. Through FY 2016, HRSA has re-audited 11 covered entities that were previously audited and had findings that resulted in repayment to manufacturers. HRSA plans to re-audit an additional 10 covered entities in FY 2017. To ensure we conduct a variety of audits in a given fiscal year, HRSA chooses its audits considering many factors, including but not limited to, entities that are eligible for a re-audit.

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. HRSA has the authority to conduct audits of manufacturers with program requirements. The audit process is the same as the process for covered entity audits as outlined above. As of July 1, 2017, HRSA conducted seven audits of manufacturers (one conducted with the assistance of the OIG. HRSA also ensures manufacturer compliance through development of regulations, guidance, and policy releases specific to manufacturer compliance. Additionally, HRSA verifies manufacturers that participate in Medicaid have signed a pharmaceutical pricing agreement, reviews all allegations brought to its attention, and requires refunds and credits when a covered entity is overcharged.

In accordance with the statute, HRSA is required to collect information from manufacturers to verify the accuracy of 340B ceiling prices, and then make ceiling prices available to covered entities.

Contract Pharmacy Use in the 340B Program

The 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. In 1996, HHS issued guidance recognizing covered entity use of contract pharmacy arrangements, which states had permitted, to dispense 340B drugs. The majority (73 percent) of covered entities do not contract with pharmacies. Of the 27 percent of covered entity organizations utilizing contract pharmacy arrangements, community health centers represent the largest users of contract pharmacy arrangements, with 73 percent of community health centers utilizing one or more contract pharmacies.

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 a covered entity is found to not be providing 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 the existence of a contract between a covered entity and contract pharmacy 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 is in compliance 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 them.

Conclusion

HRSA appreciates the work of OIG and GAO to help strengthen the Program. We look forward to continuing our partnership with them as well as with Congress to strengthen program integrity and enforce program requirements, as well as increase transparency on how covered entities use the program to benefit low-income and uninsured patients.