STATEMENT OF

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SUBCOMMITEE ON HEALTH

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Good morning Chairman Pitts, Ranking Member Green and Members of the Subcommittee. I appreciate the opportunity to appear before you today to discuss the history and importance of the 340B Drug Pricing Program, the steps we have taken to strengthen oversight and management of the Program and the challenges we have faced in managing the program.

The Health Resources and Services Administration (HRSA) is the primary Federal agency within the Department of Health and Human Services (HHS) – and across the Federal Government – charged with improving access to health care services for people who are medically underserved because of their economic circumstances, geographic isolation, or serious chronic disease, among other factors. To address these issues, HRSA works through partnerships with states, community-based organizations, academic institutions and programs, health care providers, and others to strengthen our primary care infrastructure, bolster the health care workforce, and achieve health equity. This Subcommittee has a long history of leadership on and engagement in a number of HRSA programs and activities–including the Ryan White Care Act; Community Health Centers; the National Health Service Corps; Children's Hospitals Graduate Medical Education, Maternal, Infant, and Early Childhood Home Visiting; Poison Control Centers; Newborn Screening; and the C.W. Bill Young Cell Transplantation Program–to name a few.

HRSA works continuously to achieve the best outcomes for those that we serve. To that end, program integrity is essential to all HRSA programs, including the 340B Program.

We also strive to improve program performance – not only to deliver the greatest possible impact for the populations we serve – but also to improve how we as an Agency administer Federal resources. This has been an expectation of HRSA under the tenure of the Administrator, Dr. Mary Wakefield, and is also an expectation of HHS Secretary Sylvia Mathews Burwell. As part of this focus, in 2010, HRSA formally launched its "Program Integrity Initiative." Under this approach, we fully integrate program integrity into daily operations and ensure a culture of integrity throughout HRSA programs.

As we work within the Agency to identify and respond to opportunities for continuous improvement, we make every attempt to maximize what we learn from individual programs and apply these lessons learned more broadly.

The 340B Drug Pricing Program

The 340B Program was authorized by the Veterans Health Care Act of 1992. Congressional report language accompanying the bill[1] noted that the program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as "covered

[1] The H. Report for the 340B Program 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."

entities" in order to stretch scarce Federal resources. 340B covered entities are mostly nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs, and hospitals meeting criteria specified in law. Some examples of eligible entities include Federally-Qualified Health Centers (Community Health Centers), Ryan White grantees, hemophilia treatment centers, and critical access hospitals. These covered entities must apply to participate in the program and once eligibility is confirmed by HRSA the entity can then begin purchasing drugs at the statutorily defined price.

In Fiscal Year (FY) 2013, these covered entities saved an estimated $3.8 billion on covered outpatient drugs. Covered entities can only administer or dispense drugs purchased under the 340B program to patients of the covered entity, and 340B drugs can only be administered or dispensed on an outpatient basis.

While the law does not specify how 340B Program savings must be used, covered entities have indicated that they use the savings to provide more care to more patients and provide medications to those who may not otherwise be able to afford them. A 2011 Government Accountability Office (GAO) study confirmed this self-reported data.[2] It found that entities participating in the 340B Program are able to expand the type and volume of care they provide to the most vulnerable patient populations as a result of access to these lower- cost medications.

340B Program Oversight and Administration

Overview

HRSA places the highest priority on the integrity of the 340B Program and has strengthened oversight of this program, particularly in the last four years.

As part of our oversight of the program, HRSA verifies that both 340B-covered entities and manufacturers are in compliance with 340B Program requirements. As a result of our enhanced focus on compliance issues, there has been more attention paid to compliance of program requirements by covered entities, which has resulted in increased self-disclosures and voluntary terminations initiated by the covered entities when requirements were not being met.

In order to augment these efforts, the Congress provided HRSA with an additional $6 million in the Consolidated Appropriations Act for FY 2014. This funding has enabled HRSA to:

- Improve information technology (IT) systems to more effectively track entity and manufacturer compliance;
- Increase the number of audits performed on covered entities and manufacturers in order to ensure compliance; and

[2] *Drug Pricing: Manufacturer Discounts in the 340B Program Shows Benefits, but Federal Oversight Needs Improvements.*

- Hire additional auditors and staff to implement new IT investments for expanded program integrity efforts.

Response to Previous GAO Findings

We have also made progress with recommendations made by the GAO in its 2011 study. We have implemented two recommendations: conducting selective audits, which we have actively done since FY 2012, and clarifying 340B nondiscrimination policy. We issued a clarification on our nondiscrimination policy in 2012. The remaining two recommendations direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient. We plan to address these items in an upcoming omnibus proposed guidance, which will be posted for public comment.

In 2005 and 2006 reports, the HHS Office of the Inspector General (OIG) 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. We expect this pricing system to be operational by late FY 2015.

With respect to these recommendations, we have carefully reviewed the feedback received and where feasible and appropriate found effective ways to address issues that were within our statutory authority. We also continue to welcome feedback from our stakeholder community, Members of the Congress, GAO, and OIG to help strengthen our program operations.

Covered Entity Oversight

HRSA uses a comprehensive, multipronged approach to ensure compliance by covered entities. For example, an entity must apply for participation in the program and recertify annually. Additionally, HRSA conducts risk-based and targeted on-site audits of covered entities. A summary of final audit findings are posted for the public on HRSA's website. In addition to ensuring compliance from the covered entity being audited, the information collected informs the development of educational tools and resources designed to improve overall program integrity. These tools and resources are shared through webinars and in-person trainings and inform technical assistance provided through the Program's call center. In some instances, allegations and self-disclosure reports of non-compliance are reported to HRSA. In these cases, HRSA investigates the allegations of non-compliance and takes corrective action.

Manufacturer Oversight

HRSA also works to ensure manufacturers comply with the statute and offer the 340B ceiling price to covered entities. For example, the statute requires HRSA to verify the accuracy of 340B ceiling prices and make that ceiling price available to covered entities using a secure system. We

expect to operationalize the system to provide pricing information to covered entities by the end of 2015. Additionally, HRSA verifies that manufacturers participating in the Medicaid drug rebate program have signed a pharmaceutical pricing agreement, expects manufacturers to refund covered entities if they are overcharged, and reviews other allegations brought to our attention. HRSA also has statutory authority to audit manufacturers. We are currently developing protocols for conducting additional audits of manufacturers in FY 2015.

Omnibus Proposed Guidance

We were requested to address the process for the forthcoming HRSA omnibus proposed guidance and speak to our rulemaking authority. In 2014, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional clear, enforceable policy to advance our oversight of covered entities and manufacturers. In May 2014, before HRSA was scheduled to issue the omnibus proposed regulation, the U.S. District Court for the District of Columbia issued a ruling addressing a 340B regulation concerning orphan drugs (certain drugs used to treat rare conditions or diseases). The court invalidated the orphan drug regulation, making a finding not on the merits of the policy, but by finding that HHS lacked explicit statutory authority to issue it. In light of this ruling, HRSA withdrew the omnibus proposed regulation from the Office of Management and Budget review.

There are three areas of the 340B statute where HRSA has explicit regulatory authority: calculation of 340B ceiling prices, imposition of manufacturer civil monetary penalties, and implementation of a dispute resolution process. We expect to release this year a Notice of Proposed Rulemaking on manufacturer civil monetary penalties and calculation of the ceiling prices, as well as rule on dispute resolution. We lack explicit regulatory authority for other provisions in the 340B Program statute. HRSA intends to release proposed omnibus guidance for public notice and comment later this year, consider public comments, and finalize the guidance.

Conclusion

Mr. Chairman, we share the goal of ensuring strong oversight of the 340B Program. HRSA will use the full extent of agency authorities in its efforts to ensure the integrity of the 340B Program. As the program and associated responsibilities grow, with support from the Congress, we have strengthened our management and operations to manage this program as effectively and efficiently as possible. Opportunities for enhanced program integrity are outlined in the President's FY 2016 Budget. These proposals would allow HRSA to further implement comprehensive program integrity efforts, including program audits and entity recertification; invest in improvement of the 340B public database, which provides information on covered entities and participating manufacturers to external stakeholders; and increase compliance of manufacturers.

HRSA is fully committed to strengthening 340B program integrity efforts and ensuring that our management and oversight supports the program's continued success. As I've outlined today, with our multi-faceted strategy, we are 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.