House Energy and Commerce Committee
Subcommittee on Oversight and Investigations
Hearing entitled, "Examining HRSA's Oversight of the 340B Drug Pricing Program"
Questions for the Record
September 26, 2017

The Honorable Tim Murphy

1. **HRSA testified at our July hearing that one of the biggest issues it faces in administering and overseeing the 340B program is the vague definition of patient. In fact, GAO recommended in 2011 that HRSA clarify the definition of a 340B patient, and that recommendation currently remains open. Captain Pedley described HRSA's attempts to tighten the definition of patient, one of the more recent attempts being the August 2015 omnibus guidance, in which HRSA addressed the ambiguity and tried to clarify that definition. HRSA received more than 1,200 comments related to the guidance, some of which were related to the definition of "patient." I am interested in the comments related to the definition of "patient" and how HRSA has taken those comments into consideration.**

    a. **What were the biggest take aways from the comments related to the ambiguous definition of "patient" and how will those comments affect HRSA's approach to clarifying that definition?**

HRSA issued a proposed 340B Omnibus Guidance in August 2015, which addressed key policy issues raised by various stakeholders to assist covered entities and manufacturers in their ability to satisfy 340B Program requirements and expectations, including the definition of a patient. The proposed guidance was open for review and public comment in the *Federal Register.*[1]

Regarding the specific comments HRSA received on the definition of a patient, manufacturers generally supported the revised patient definition. Manufacturer groups also recommended that HRSA limit the term "patient" to the indigent, or those individuals lacking commercial or governmental insurance, or to those who otherwise have no outpatient drug coverage.

Covered entity commenters had concerns about HRSA's authority to define the term patient, that the proposed definition was more restrictive than the 1996 patient definition guidance, and that many of those served by covered entities would no longer qualify as patients. The covered entities also expressed that a "one-size-fits-all" approach to the patient definition did not recognize the unique statutorily mandated structure and goals of certain categories of covered entities. All comments on the 2015 proposed Omnibus Guidance can be found on regulations.gov at https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=HRSA-2015-0002.

    b. **Were there any notable trends that HRSA saw in the comments related to the definition of "patient" and program compliance, such as the issue of drug diversion, that will affect HRSA's work going forward?**

[1] 80 FR 52300 (August 28, 2015)

The comments in the proposed 2015 Omnibus Guidance related to the definition of patient varied; there were no clear trends. HHS is working to determine next steps to address the policy issues included in the proposed Omnibus Guidance, which will inform our efforts to improve program compliance, including with regard to preventing drug diversion.

2. HRSA also testified at our July hearing that it tracked information regarding the growth rate for new child sites compared to new covered entities. On July 17, HRSA's website listed a total of 41,132 registered entities. As of August 4, HRSA's website lists 42,217 total registered entities—an increase of 1,085 registered entities since the hearing.

a. How many of the 1,085 new registered entities are unique covered entities and how many are child-sites?

Currently, HRSA only designates hospital outpatient facilities and health center (and health center look-alikes) service delivery sites as child sites. All other registrations are considered parent sites. During the April 2017 registration period (with a start date of July 1), there were 37 new parent sites and 1,144 new associated/child sites registered under the Program. As of July 1, 2017, 12,470 covered entities and 28,276 associated/child sites participate in the 340B Program for a total of 40,746 registered sites. HRSA tracks this information on a quarterly basis and utilizes information from the previous quarter for our analysis.

b. Overall, is HRSA seeing a faster growth rate for new covered entities or new child-sites?

Since 2010, HRSA has continued to see an increase in both the number of parent and child sites for hospital outpatient facilities and health center sub-grantees, which are deemed child sites in the 340B database. This is due to a variety of factors, including the five new eligible hospital types that were added to the 340B statute in 2010, which increased the total number of hospitals eligible to participate in the program. In addition, for purposes of transparency, HRSA also instituted a new reporting policy in 2012 that required all hospital outpatient services and clinics that use the 340B Program to be listed on the HRSA database. That effort led to a large increase in the number of hospital sites that appeared on the 340B database. Many of those sites had been participating for years, but had not previously been required to register individually. The chart below provides additional information about the growth of 340B parent versus child site participants for hospitals and health centers.

	340B Parent vs. Child Site Participants for Hospitals and Health Centers		
Date	Total Number of Participating Sites	Number of Parent Sites for Hospitals, Health Centers,	Number of Child Sites for Hospitals, Health Centers,

		and Health Center Look- Alikes	and Health Center Look- Alikes
July 2010	14,725	2,063	5,064
July 2011	16,572	2,744	6,135
July 2012	18,561	2,947	7,990
July 2013	22,641	3,190	11,791*
July 2014	26,870	3,318	15,408
July 2015	32,071	3,431	20,233
July 2016	36,914	3,609	24,843
July 2017	40,746	3,726	28,276
Source: Internal Analysis of HRSA 340B Database *In 2012, HRSA instituted a new reporting policy that required all hospital outpatient services and clinics that use the 340B Program to be listed on the HRSA database.			

The Honorable Michael C. Burgess

1. **HRSA has taken specific steps to addressing duplicate discounts by creating the Medicaid Exclusion File (MEF), which providers can use to prevent duplicate discounts in Medicaid fee-for-service. Has HRSA undertaken any efforts to creating a similar MEF for Medicaid Managed Care?**

In December 2014, HRSA clarified that the current mechanism in place to prevent duplicate discounts, the Medicaid Exclusion File (MEF), was specific to Medicaid fee-for-service. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care. HRSA addressed this issue in its 2015 proposed Omnibus Guidance and is working to determine future policy in this area. In the meantime, HRSA is aware that some covered entities are working with managed care organizations (MCOs) and state partners to develop models for the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their states to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs. In addition, HRSA is working closely with the Centers for Medicare & Medicaid Services and other stakeholders to develop possible policy and technical solutions for how covered entities and states can prevent duplicate discounts for 340B drugs dispensed to MCO patients.

2. **Upon delaying HRSA's most recent 340B rule, "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties and Regulations", the agency acknowledged that a delay of the rule was warranted because:**

"objections regarding the timing and challenges of compliance with the [Final Rule]… as well as other objections to the [Final Rule], may not have been adequately considered" such that HRSA should "engage in longer rulemaking" to "adequately consider" stakeholder comments, "consider questions of fact, law, and policy," "consider the regulatory burdens that may be posed," and "ensure that… the implementation of this rule… is coordinated with and takes into consideration overall 340B Program implementation."

a. **However, HRSA has not undertaken any apparent efforts to re-examine these substantive considerations. What is HRSA's plan to ensure that these considerations are reexamined?**

To provide affected parties with sufficient time to make needed changes to facilitate compliance, on May 19, 2017, HRSA issued a final rule, which delayed the effective date until October 1, 2017.[2] HRSA recently proposed a further delay of the final rule's effective date to July 1, 2018, to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking.[3]

The Honorable Frank Pallone, Jr.

1. **The 340B program is a critical component of the safety net. 340B drug discounts allow covered entities—such as community health centers, safety net hospitals, state and local health departments, family planning clinics, and AIDS drug assistance programs—to maximize scarce resources and provide comprehensive health services to vulnerable patients.**

   a. **Can you describe the types of comprehensive services that 340B covered entities provide?**

There are many types of 340B covered entities that provide different services, though the 340B statute itself does not address the types of services that eligible entities provide. For example, HRSA's Health Center Program grantees provide comprehensive primary healthcare services. Health centers also often integrate access to pharmacy, mental health, substance abuse, and oral health services in areas where economic, geographic, or cultural barriers limit access to affordable healthcare services. As another example, HRSA's AIDS Drug Assistance Program (ADAP) grants provide medications to low-income people living with HIV who have limited or no health insurance coverage. ADAP funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments.

2. **Hospitals, clinics, and other 340B covered entities rely on this program to provide essential healthcare services to needy populations. For the 340B program to function as intended, however, we must guarantee an appropriate amount of transparency and adequate oversight of both manufacturers and program participants. One such need for transparency relates to the 340B ceiling price that manufacturers charge covered entities. The Affordable Care Act (ACA) required HHS to share ceiling prices with covered entities, which would allow entities to ensure they are receiving the appropriate price for 340B drugs. HRSA has proposed a web-based system that would allow covered entities to view the 340B ceiling prices.**

   a. **What is the status of this system, and when will it be available for covered entities to access 340B ceiling prices?**

[2] 82 FR 22893 (May 21, 2017)
[3] 82 FR 39553 (Aug. 21, 2017)

Section 340B(d)(1)(B) of the Public Health Service Act requires HRSA to collect information from manufacturers to verify the accuracy of 340B ceiling prices, and then make ceiling prices available to covered entities. With prices for over 40,000 national drug codes, building such a system is extremely complex. Due to the proprietary nature of the pricing data, it is important to ensure that appropriate security safeguards are instituted.

In the process of developing the pricing system, HRSA sought to modernize the registration system database to enhance its functionality and security for both manufacturers and covered entities since the pricing system will interface with the data that is collected through registration. The new system, known as the 340B Office of Pharmacy Affairs Information System (340B OPAIS) will function as one system, and it will have two separate components—a new covered entity registration system and the new secure pricing system.

The new system will be released in a phased approach, beginning with the registration system in mid-September 2017. The pricing component of the new 340B OPAIS will be released at a later date.

3. The Government Accountability Office's (GAO) 2011 report (GA0- 11-836) notes that the ACA established several important program integrity provisions for the 340B Program, and recommended that HRSA take additional steps to improve oversight of the program. In particular, GAO recommended that HRSA conduct selective audits of 340B covered entities for program compliance.

a. How many audits has HRSA conducted to date, and how have these audits been effective in improving program integrity?

Since FY 2012, HRSA has completed 844 audits (as of July 28, 2017), which included review of 11,281 outpatient facilities and 18,851 contract pharmacies. This includes 200 audits that HRSA conducted in FY 2017. HRSA has also taken steps to use audit results to create tools and resources to assist 340B participants in program compliance.