OPENING STATEMENT OF THE HONORABLE TIM MURPHY
CHAIRMAN, OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE
"EXAMINING HRSA'S OVERSIGHT OF THE 340B DRUG PRICING PROGRAM."
JULY 18, 2017

Today, the Subcommittee is holding a hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program." The 340B program was created by Congress in 1992 and mandates that drug manufacturers provide outpatient drugs to eligible entities at reduced prices in order for the manufacturers to remain eligible for reimbursements through entitlement programs such as Medicaid and Medicare.

340B program-covered entities are nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs. Federal grantees are eligible for the 340B program by receiving certain federal grants administered by different agencies within HHS. Hospitals eligible for the 340B program include certain Disproportionate Share Hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals.

The Health Resources and Services Administration, or "HRSA," an agency in the U.S. Department of Health and Human Services, is tasked with accepting applications and overseeing covered entities.

HRSA faces several challenges in conducting oversight of the 340B program, one of which is the lack of reporting requirements in the 340B statute. Participating entities save between 25-50 percent of the average wholesale price for covered outpatient drugs, and according to the HHS Office of Inspector General's estimates, covered entities saved $6 billion on drug expenditures in Fiscal Year 2016. However, covered entities are not required to report their annual savings through participation in the program, or how they use the money saved.

For many of these covered entities, those savings are vital to the entity's survival, particularly those that serve a large percentage of indigent patients and operate at a loss each year. Other entities reinvest those savings in patient care, expanding access to patient care by opening centers in rural and underserved areas or passing along the savings to patients by providing discounted drugs. However, as with so many federal programs, there are instances of errors and misuse.

Specialists, oncologists in particular, have told me stories of their grave concerns about the way some entities use the 340B program. For example, one story involves a doctor who referred many uninsured, young breast cancer patients to a 340B hospital to receive cancer treatments, but watched as 16 of those patients

were placed on a waitlist for care, simply waiting for treatment while their cancer progressed from entirely treatable, to potentially life-threatening. According to this doctor, the waitlist was not due to an overall capacity issue. Instead, it was because the hospital simply chose to set a cap on the number of uninsured patients they would treat.

I hope that these instances are outliers – the exception to the rule. The integrity of the 340B program must be protected. HRSA must be able to conduct oversight in a way that allows it to uncover fraud and non-compliance. Indeed, HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements through duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting. Unfortunately, while HRSA has made improvements to their oversight efforts in recent years, the agency simply may not have the resources to adequately safeguard the program.

The program has experienced dramatic growth in recent years, due in part to program expansions in the Patient Protection and Affordable Care Act. At a hearing before the Health Subcommittee in 2015, we learned that from 2001 to 2011, the number of covered entities participating in the program roughly doubled. The most recent data shows that from 2011 to 2017, the number of entities has

nearly quadrupled. HRSA indicates that as of October 2016, 12,148 covered entities were participating in the 340B program.

Despite that growth, HRSA maintains only 22 staff to oversee the 340B program, and conducts roughly 200 audits annually. While HRSA has increased the number of audits conducted annually, which the Committee applauds HRSA for, that number is still dwarfed by the vast number of participating entities and manufacturers. At the current level of annual audits conducted, HRSA is auditing a mere 1.6% of covered entities annually. Further, because HRSA's audits consist of only a sample of drugs within each entity, these audits cover just a fraction of a fraction of the program. Despite that, HRSA's audits have uncovered between 63 and 82 percent of audited entities to be non-compliant with program requirements since 2012. What would more intensive oversight, including additional audits, further reveal?

I thank HRSA for their cooperation in producing audit documents before this hearing in response to the Committee's request last month. We're in the process of reviewing these documents to gain a better understanding of the audit process and may have more follow-up questions at a later date.

I welcome the witnesses appearing before us today and look forward to hearing about HRSA's oversight efforts, the challenges HRSA faces, and how this Committee can best enable HRSA to overcome those challenges.