

**Opening Statement of Chairman Greg Walden
Subcommittee on Oversight and Investigations
“Examining HRSA’s Oversight of the 340B Drug Pricing Program”
July 18, 2017**

Thank you, Mr. Chairman, for this hearing. This committee has really been ramping up its top-to-bottom oversight of many aspects of our health care system. The subcommittee’s hearing on the 340B drug pricing program and the oversight role of the Health Resources and Services Administration, or HRSA, is part of this broader overview.

Since its creation by Congress in 1992, the 340B drug pricing program has provided life-saving medicines at reduced prices to certain safety-net health care providers. Indeed, this program has helped these providers known as “covered entities” stretch scarce federal dollars as far as possible to better serve uninsured and underinsured patients across the country. HRSA estimated that, in 2015, covered entities saved about \$6 billion on 340B drugs through their participation in the program.

For a variety of reasons, participation by hospitals in the 340B program has grown substantially in recent years. The number of unique hospital organizations

participating in the program has nearly quadrupled from 2011 to 2016—increasing from 3,200 participating hospitals in 2011 to 12,148 in October 2016.

With this program growth, concerns have surfaced about HRSA’s ability to adequately oversee the program. As the witnesses from the HHS Inspector General’s office and GAO will discuss in detail today, HRSA’s oversight of the program has improved in recent years through enhanced authority and resources, but program vulnerabilities still exist. Today, we will examine a number of important programmatic issues:

- First, we want to learn how HRSA’s oversight efforts can best meet the challenge of 340B program growth. While HRSA has made improvements to its oversight efforts in recent years, HRSA’s audit activity has remained at or below 200 annual audits of covered entities since 2012 despite the rapid growth of the program. That’s one reason we are here today – to answer the question: how can HRSA improve its audits to better detect problems or somehow raise the annual number of audits?

- Next, we will focus on the problems already discovered and how HRSA can address them. HRSA’s annual audits reveal a high level of non-compliance with program requirements by covered entities, including the potential for duplicate discounts and diversion of 340B drugs to ineligible patients.
- We will also want to find out how HRSA can be more transparent. Lack of transparency hinders HRSA’s oversight capabilities. While the purpose of the program is to “stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services,” neither the 340B statute nor HRSA guidance explains how 340B providers must use savings from the program.
- Finally, we will discuss how HRSA’s lack of regulatory authority limits the agency’s ability to adequately oversee the program.

The committee has been reviewing HRSA’s oversight of the 340B drug pricing program for over two years, and plans to continue this work after the hearing. As we move forward, it’s also important not to overreact and create unnecessary red tape for providers who are truly using the program to benefit

patients. I've heard from hospitals in rural areas, like those in my district, that use 340B discounts to help beneficiaries in underserved parts of the country. While we do not want to overburden these safety-net providers, we also need robust oversight in the program to determine where these scarce federal dollars are going.

Just last month, the committee sent a letter to HRSA to gain more insight into the audits conducted into the 340B program, and we want to extend our appreciation to HRSA for their timely production of information responsive to our requests. We look forward today to hearing from HRSA about the steps that they have taken to strengthen the program and the challenges they face in their efforts to oversee the program.

I also want to thank the Office of Inspector General at the U.S. Department of Health and Human Services and the Government Accountability Office for being here to discuss their important work on this topic too. We look forward to hearing their recommendations on how to best promote program integrity and improve the program.