Opening Statement of Chairman Greg Walden
Subcommittee on Health
"Opportunities to Improve the 340B Drug Pricing Program"
July 11, 2018

(As prepared for delivery)

Thank you, Mr. Chairman, for holding this legislative hearing to examine ideas to improve the 340B Drug Pricing Program (340B Program). Since its creation by Congress more than 25 years ago, the 340B Program has helped provide life-saving medicines at reduced prices to certain safety-net health care providers.

Through this program, many providers have been able to reach more patients – serving more uninsured and underinsured patients due to the savings this program enables. The Health Resources and Services Administration (HRSA) estimates that in 2015, covered entities saved about $6 billion on 340B drugs through their participation in the program.

For some participating health care providers, known as "covered entities," this program and the savings it generates are critical not to just their mission to help patients – but it undergirds their financial viability and their ability to keep their doors open. I've met with hospitals and health centers in rural Oregon, including those in Bend, and Hermiston, and they've told me about how they're using 340B savings to increase access to health care for the underserved.

But it's important to note that a lot has changed since the program's creation. The number of unique hospital organizations participating in the program has nearly quadrupled in just five years – increasing from 3,200 participating hospitals in 2011 to 12,148 in October 2016.

While the actual number of 340B contract pharmacy arrangements is unknown because it is not tracked, GAO has informed us that 1,645 covered entities had a total of 25,481 registered contract pharmacy arrangements. GAO warns this sprawling complex of arrangements increases the likelihood of covered entities being out of compliance with federal law.

GAO's latest report follows others from nonpartisan auditors expressing concerns about a variety of issues that are a challenge to the integrity and accountability of the program. For example, both HHS' Office of the Inspector General and GAO

have identified the lack of a clear definition of a 340B patient as a structural challenge to HRSA having clear rules of the road.

We've also heard serious concerns from stakeholders. Because the 340B Program does not specify how program savings must be utilized by a covered entity, many have questioned whether or not all covered entities are sufficiently transparent with how their participation in the program ultimately benefits patients.

Others suggest this program is need of a tune up—regulations need to be finalized, rules of the road need to be made clearer, audits need to be more comprehensive, and enforcement needs to be more consistent.

There's also the report following the committee's two-year investigation by our own Oversight and Investigations Subcommittee. That report detailed a lack of oversight, reporting requirements, and reliable data.

Earlier this week, HHS Secretary Azar spoke about the department's plans to move forward with finalizing regulations that have been repeatedly delayed. I am encouraged by his comments, but also know there is more HHS should do to improve the oversight and operation of this program.

Our committee has an important responsibility to carefully evaluate a number of ideas from members on both sides of the aisle about how we can improve the 340B Program.

I fully expect that my colleagues will bring different views and ideas forward in examining these bills to strengthen the 340B Program. I hope we will examine the bills from the shared premise that we all want to ensure some of our most vulnerable patients receive the care they need and deserve.

Finally, I would like to highlight one bill in particular, H.R. 6273, a bill I've introduced along with Representative Walters. This bill would require 340B DSH hospitals that have an emergency department to establish a plan for getting victims of sexual assault access to a Sexual Assault Forensic Examiner (SAFE) facility, so they can be properly examined and treated by a qualified health provider.

I'd like to thank our two panels of witnesses for being with us today and for your feedback on the bills before us. There is certainly a lot to discuss, and I look forward to working with my colleagues on both sides of the aisle to strengthen this vital program.