

**Chairman Michael C. Burgess, M.D.**  
**Opening Statement**  
**E&C Subcommittee on Health**  
**“Opportunities to Improve the 340B Drug Pricing Program”**  
**July 11, 2018**

*(As prepared for delivery)*

Today, we convene to learn about opportunities to improve the 340B drug pricing program. This hearing builds on previous work by the Energy and Commerce Committee this Congress and last Congress. Our subcommittee and the Oversight and Investigation Subcommittee have held hearings on various aspects of the program over the last several years. The Committee also issued a comprehensive oversight report on the program earlier this year.

As we start, it is important to emphasize that members of this committee each understand the importance of the 340B Program to safety net health care providers and many communities large and small across our nation. The program enjoys strong bipartisan support as it helps many health care providers provide care to vulnerable Americans.

At the same time, it is worth noting that Congress established the 340B Drug Pricing Program over 25 years ago through the enactment of the Veterans Health Care Act of 1992 – that was around the end of the Cold War and birth of the Internet. Surely, we can all agree that our health care system has evolved significantly since that time, and it is reasonable to review how the program is working in today’s health care system.

In many ways, the 340B Program is certainly a success. Yet, at the same time, there are numerous ways in which the program’s current operation raises valid concerns. Multiple reviews by nonpartisan auditors have identified notable challenges with the program’s current operation and oversight.

- For example, we know the Health Resources and Services Administration (HRSA), the agency overseeing the 340B Program, lacks key regulatory authorities.
- Additionally, HRSA has delayed multiple program regulations repeatedly without a compelling and clear rationale.
- We learned that, in 2016, HRSA audited less than two percent of total entities participating in the program.

- There has also been uncertainty about where the savings from this program are going and how certain covered entities may be utilizing the revenue generated from the program.

The newest concern with the program's oversight has been highlighted by the Government Accountability Office. Today we will hear from GAO who recently released a ground-breaking report on contract pharmacies. We all know that the number of contract pharmacies has grown rapidly since HRSA issued guidance in 2010 that allowed covered entities to contract with multiple pharmacies. Since then, the number of pharmacies that covered entities have contracted with has increased from approximately 1,300 to almost 20,000 in 2017.

I think GAO raises a number of serious challenges with HRSA's current oversight of contract pharmacies. I am also troubled by the fact that many covered entities GAO reviewed do not have in place a policy that ensures uninsured, low-income patients are not hit with a big hospital bill for their outpatient drugs. Certainly, concern about high health care costs – drug costs, hospital costs, and other costs – is an ongoing concern. So, I am proud to have a discussion draft today which outlines one possible solution to this issue – to ensure that covered entities stretch resources through 340B while making sure some of the most vulnerable patients see the financial benefit. Overall, I found this an eye-opening report and I hope we will each review it carefully as we seek to ensure the program helps patients effectively.

I appreciate that members approach the 340B program with different backgrounds and from a variety of perspectives. But, I trust we all share the goal of ensuring this federal program operates with integrity, and the program is appropriately transparent and accountable to patients.

Ultimately, today's hearing is an opportunity to engage in a dialogue and exchange ideas about what might be the best way to move forward with improving the accountability and transparency of the 340B Program. In addition to what I anticipate will be a lively debate, we will be evaluating more than a dozen legislative proposals that address some of the concerns members have. These bills – whether drafts to generate discussion, or introduced bills – are members' ideas from both sides of the aisle to improve the 340B Program. I support several of the policies outlined in these bills but have questions on others. We also need to hear from the wide range of stakeholders impacted by this program.

Now, I would like to welcome Debra Draper, Director of Health Care, at GAO to our hearing and thank her in advance for her willingness to testify before us and answer our many questions.

I also want to give a warm Texas welcome to Dr. Frederick Cerise, President and CEO of Parkland Hospital in Dallas, and Dr. Debra Patt, Vice President of Texas Oncology on our next panel. Both Drs. Cerise and Patt will be able to share their unique perspectives on the role the 340B Program has in providing care to their patients. We also welcome Dr. Charles Daniels from California.

Today's hearing promises to offer thought-provoking ideas and insights to inform our next steps to improve the 340B Program. Again, thank you to each of our witnesses for being here, and I look forward to a constructive dialogue today.