Opening Statement
Health Subcommittee Hearing "Examining the 340B Drug Pricing Program"
Rep. Gene Green
March 24, 2015

Good morning and thank you all for being here today. And thank you to our witnesses for coming here to testify.

As we know, the 340B drug pricing program was created by Congress to help safety-net providers care for their most vulnerable patients and afford drugs that would otherwise be out of reach.

Since its inception in 1992, stakeholders and policymakers have been discussing and debating the intended purpose and appropriate scope of the 340B program.

I thank the Chairman for having this hearing today to examine this critical program and the role that it continues to play in our health care system.

It was the hope of policymakers when designing 340B that lower drug prices would enable safety net providers to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services through these savings.

The law does not specify how savings incurred from 340B discounts must be used by covered entities, a point that has been brought up by both opponents and proponents of the program.

Yet, a GAO study in 2011 confirmed that at large, covered entities use these savings to provide more care to more patients, including medications that would otherwise be unaffordable to those they serve.

For example, Harris Health system, which primarily serves the indigent population of Harris County, Texas, saves approximately $17 million a year through participating in 340B Drug Program.

Harris Health uses savings from the program on patient care services, which include costs of treatment, administration and management of services and facilities, and improving access to quality health care for our community.

Harris Health system, like other safety-net hospitals across the country, provides access to cost-effective, quality health care delivered to all residents of Harris County, regardless of their ability to pay.

There is always more patient need than they will have the capacity to provide, and the community's access to care depends upon the contribution of every possible source of funding, such as the 340B Drug Program.

I cannot underscore enough how important the 340B program continues to be to hospitals and other entities that provide care to underserved patients in every district across the country.

It is a key part of a multipronged approach to provide all individuals with access to quality care.

With that said, the program has grown significantly, and oversight is appropriate to ensure it is working properly.

Since 1992, the 340B program has expanded significantly, both *directly*, due to new categories of covered entities, and *indirectly*, due to broader eligibility criteria for existing categories.

According to GAO, the number of 340B covered entity sites has doubled in a little over 10 years, to more than 16,500 sites.

Similarly, the number of contract pharmacy agreements has expanded dramatically over the last decade, particularly since April 2010 when 340B entities were allowed to contact with multiple pharmacies.

A 2011 GAO study found that the Health Resources and Services Administration or "HRSA" oversight of 340B was quote "inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements."

HRSA has taken great steps to implement recommendations made by GAO in its 2011 study, including conducting selective audits and clarifying 340B non-discrimination policy.

But additional administrative action and potentially, additional authorities, may be needed for HRSA to conduct proper oversight of such a large and important program.

I understand HRSA has been working to establish a formal set of regulations to standardize the definition of an eligible patient, compliance requirements for contract pharmacy agreements, clarify hospital eligibility criteria, and the eligibility of off-site facilities.

Steps, such as updating HRSA guidance on the definition of a patient, could address challenges that arise from different interpretations of the current guidance.

This will further program integrity efforts, and make certain that the 340B program is achieving its intended outcomes and maintains its long-term viability.

Congress should let HRSA release this guidance and analyze its impact before making changes to the 340B program that could harm safety-net hospitals and their vulnerable patients.

I know HRSA strives to achieve the best outcomes for those they serve.

The agency does great work to fulfill its mission of improving access to health care services for people who are medically underserved.

As we examine the 340B program and oversight efforts during today’s hearing, it is important to remember that for 23 years, 340B's mission has been to lower drug costs for safety-net providers so they can provide more comprehensive services and reach more individuals.

The program enables providers to decide how to best serve their communities through obtaining and leveraging savings from manufacturers so more patients can receive more care in our communities.

I thank the agency for its continued efforts to implement and oversee 340B program, and GAO and OIG for their work on this issue.

I look forward to hearing more about the status of oversight measures and the 340B program at large during today's hearing.

Thank you and I yield back.