United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

January 26, 2018

VIA ELECTRONIC COMMUNCIATION

The Honorable Alex Azar
Secretary
The Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

I applaud the Department of Health and Human Services' (HHS) efforts to ensure that beneficiaries have access to high quality, affordable healthcare. The 340B Drug Pricing Program (340B program) is one such Federal program that makes it possible for hospitals to care for uninsured and low-income patients. The program mandates that, to participate in Medicaid, drug manufacturers must provide eligible hospitals and healthcare centers (covered entities) outpatient drugs at discounted prices. However, since the program was enacted in 1992, the healthcare landscape has changed dramatically. As such, I believe it is important to evaluate the purpose and function of this program, particularly the capabilities of the Health Resources and Services Administration (HRSA) to oversee program growth to ensure benefits are being fully realized by the patients the program was intended to serve.

In 2010, the Patient Protection and Affordable Care Act (PPACA) expanded the size and scope of the 340B Program to include children's hospitals, critical access hospitals, free-standing cancer hospitals, rural referral centers, and community hospitals. In addition, hospitals eligible for 340B prior to enactment of PPACA have rapidly increased their number of sites through acquisition of physician practices and other outpatient clinics in recent years. The number of facilities participating in the 340B program now includes 12,148 covered entities and 25,348 associated sites for a total of over 37,496 registered sites. The HHS Office of Inspector General (HHS OIG) and Government Accountability Office (GAO) have identified program growth as an issue of concern for program integrity and accountability. I fully support the 340B program and believe covered entities should continue to receive these benefits so that the most vulnerable and

uninsured have access to otherwise costly outpatient drugs. However, it is important that federal policy and regulation keep pace with these changes.

The 340B program, especially considering the program's recent and rapid growth, has significant impact on other mandatory federal health programs over which the Committee on Finance has exclusive jurisdiction in the Senate. Medicare pays 340B covered entities for certain drugs provided to beneficiaries under Part B. According to the Medicare Payment Advisory Commission (MedPAC), from 2004 to 2013 Medicare payments to 340B entities for Part B drugs increased by over 500 percent, with the proportion of total Part B spending attributed to 340B entities rising from 22 percent to 48 percent during that same period. Medicare Part D prescription drug plans also pay for some 340B drugs. In addition, Medicaid is impacted by the 340B program. Not only are manufacturer discount requirements tied to their Medicaid participation, careful coordination is needed to ensure that only the standard Medicaid drug rebate or the 340B discount is applied.

Program Expansion has Exceeded HRSA's Ability to Oversee Program Integrity

HRSA lacks the necessary regulatory authority to oversee the 340B program. The agency only has the authority to regulate in three areas, which include establishing an alternative dispute resolution process, imposing civil monetary penalties against manufacturers who knowingly overcharge covered entities, and calculating the 340B ceiling price. Even so, it has not fully implemented these regulations. HRSA audits covered entities for program eligibility, duplicate discounts, and diversion. However, HRSA rarely audits manufacturers to ensure compliance with the ceiling price and conducts fewer than 200 audits of covered entities each year. The limited audits HRSA did conduct reveal high-levels of non-compliance by covered entities. This is disconcerting, given that, with relatively few dedicated staff, by 2021 HRSA will be responsible for providing oversight for over $20 billion in drug sales.

In 2015, HRSA attempted to clarify program requirements by issuing a proposed omnibus guidance interpreting statutory requirements for the 340B program in areas where it does not have regulatory authority. However, in January 2017, the agency withdrew the guidance and indicated to GAO that it was working with HHS to determine next steps. With the limited statutory authority and concern that HRSA lacks adequate resources, HHS should consider whether CMS is better suited for 340B program administration, all or in part. Many determinants of 340B eligibility and other operational program details are linked to Medicare and Medicaid program components. CMS has extensive experience directly interacting with hospitals and drug manufacturers, including ensuring they meet participation requirements and conduct audits. Additionally, HHS already works with the Internal Revenue Service (IRS) to report charity care to Congress. This makes HHS more capable of tracking how covered entities use 340B savings.

In order to get a better understanding of how HHS plans to work with HRSA to clarify program requirements, I ask that you answer the following questions:

1. Congress intended the program to allow covered entities "to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] However, healthcare coverage has dramatically changed since creation of the 340B Program. How does HHS intend to move forward this year to address the myriad of issues with the program expressed by covered entities and pharmaceutical manufacturers?

2. What is the current level of coordination between HRSA, CMS, and HHS in the administration of the 340B program?

3. CMS has extensive experience directly interacting with hospitals and drug manufacturers, including ensuring they meet participation requirements and conduct audits. Given that CMS is already tasked with overseeing Medicare and Medicaid, would CMS be better suited to administer the 340B program? If not, why not, and how can CMS and HRSA coordinate better to ensure access to affordable drugs while protecting taxpayer dollars?

4. Does HRSA have the resources or staff to finalize and begin enforcing regulations in each of the areas which it currently has regulatory authority? What other resources can HHS leverage to provide much needed clarity and certainty in the 340B Program? Please provide an update and timeline. If not in 2018, why not?

5. What steps are being taken to ensure that manufacturers are not paying prohibited duplicate discounts, which occur when a pharmaceutical manufacturer pays both a 340B rebate to the covered entity and a 340B rebate to the state Medicaid program?

6. HRSA is developing a system to provide covered entities with access to ceiling price information. Through this secured system, manufacturers will submit 340B pricing information, allowing HRSA to spot check 340B prices and follow-up with manufacturers on pricing errors.

    a. Provide an update and timeline on where HRSA is in this process.
    b. How will HRSA monitor the data to ensure manufacturers are not over charging covered entities for 340B drugs?
    c. If a manufacturer is found noncompliant, how will HRSA follow-up on pricing errors?
    d. If the manufacturer does not fix the pricing error, how does HRSA plan to enforce its authority?
    e. Are there resources within HHS and CMS that can be leveraged to develop and monitor this system? If so, please provide a list of these resources.

It is important that we strive to improve transparency in the 340B program. By doing so, we can ensure that the program operates as Congress intended and that beneficiaries have access

[1] H.R. Rep. 102-384, Pt. 2 (1992).

to high quality, affordable care. As such, I ask that you provide this information to the Committee no later than February 26, 2018. I also ask that you answer the questions on a question by question basis, indicating which questions that you are answering. If you have any questions, please contact [redacted]

Sincerely,

Orrin G. Hatch
Chairman