United States Senate

WASHINGTON, DC 20510

June 16, 2023

To 340B Stakeholders,

Congress created the 340B Drug Discount Program (340B) in 1992 to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services[1]". The 340B program requires that drug manufacturers who participate in Medicaid provide certain non-profit health care providers, hospitals and clinics (covered entities) a discount on outpatient drugs. Since it was created, the program has enjoyed strong bipartisan support in Congress. While the program does not utilize federal taxpayer dollars, federal oversight is necessary to ensure the program functions as intended. We have heard concerns from some stakeholders about ambiguity in the 340B program and the need to strengthen oversight and accountability in the program. We are seeking information from stakeholders on bipartisan policy solutions that would ensure the program has stability and oversight to continue to achieve its original intention of serving eligible patients.

As the health care delivery system has evolved, so too has the 340B program evolved to enable health care providers to offer improved services and care in the communities they serve. More than a decade ago, the Health Resources and Services Administration (HRSA), which administers the 340B program, issued guidance allowing covered entities to dispense drugs through contract pharmacies in the 340B program since many covered entities do not have pharmacies in-house. However, the current 340B statute is silent on the issue, resulting in ambiguity in the treatment of drugs dispensed through contract pharmacies.

In recent years, a number of drug manufacturers have declined to offer 340B discounts on their covered outpatient drugs dispensed at contract pharmacies. We have heard directly from health care providers in our states about the disruption and negative impact these actions have had on hospitals and health centers who serve our constituents. The manufacturers' decisions have resulted in ongoing litigation and enforcement actions. We do not seek to take a position with respect to specific legal questions in ongoing litigation. Instead, we seek to provide 340B hospitals, health centers, and other essential safety-net providers with certainty regarding the allowable use of contract pharmacies. For this reason, we request information from stakeholders regarding potential bipartisan policy solutions to provide certainty and commonsense improvements to the operation and oversight of contract pharmacies in the 340B program.

We also acknowledge that as the 340B program has evolved over the last 30 years, some stakeholders have raised concerns about the need to strengthen program integrity measures in the program to ensure that 340B is serving eligible patients as originally intended. We request information from stakeholders on ways to improve accountability of covered entities in the program and ensure there is appropriate transparency. While duplicate discounts are prohibited by the 340B statute, we understand there is frustration by both covered entities and manufacturers that duplicate discounts continue to occur in the 340B program. We request information from stakeholders on proposals to ensure adequate claims information exists to prevent these duplicate discounts from occurring.

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[1] H.R. Rept. No. 102–384(II), at 12 (1992).

Our goal is to ensure the 340B program has improved integrity and stability, and that it continues to enable eligible health care providers to stretch federal resources to better provide healthcare for the patients they serve. We encourage stakeholders to provide information that will help Congress further the original intent of the program, strengthening the program's ability to support entities serving eligible patients.

We request interested stakeholders submit written responses to this bipartisan request for information no later than July 28, 2023. Responses may be submitted to Bipartisan340BRFI@mail.senate.gov. Our intent is to keep these responses internal and they will not be posted publicly.

1. What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

3. What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

4. What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

5. What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

6. What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

Sincerely,

John Thune
United States Senator

Debbie Stabenow
United States Senator

Shelley Moore Capito
United States Senator

Tammy Baldwin
United States Senator

Jerry Moran
United States Senator

Benjamin L. Cardin
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