Chairman Lamar Alexander
U.S. Senate Health, Education, Labor and Pensions Committee
455 Dirksen Senate Office Building
Washington, D.C. 20510

Ranking Member Greg Walden
U.S. House Committee on Energy and Commerce
2185 Rayburn House Office Building
Washington, D.C. 20515

October 30, 2020

Dear Chairman Alexander and Ranking Member Walden:

On behalf of the Alliance for Integrity and Reform of 340B (AIR340B), thank you for the opportunity to share our perspectives on the steps Congress can take to improve the 340B Drug Discount Program and ensure patients always benefit from this safety-net program, especially amid a global pandemic. We appreciate your commitment to strengthening this program.

AIR340B is comprised of patient advocacy groups, clinical care providers, biopharmaceutical innovators, and other stakeholders dedicated to advocating for improvements to the 340B program in ways that ensure patients always benefit. When working as intended, as when it was created nearly three decades ago, 340B can play a vital role as a safety-net program for those who would otherwise lack access to necessary medications.

Our comments and recommendations below are chiefly concerned with identifying areas in which the program can be improved to achieve its purpose – to increase access to discounted medicines to safety-net providers who treat needy patients. This includes clearly defining the eligibility of a 340B patient and addressing 340B-driven hospital consolidation, restricting contract pharmacy arrangements, and establishing clear reporting requirements for disproportionate share (DSH) hospitals. In doing so, we can begin to get the 340B program back on course, so low-income Americans have improved access to medications.

Many of the below recommendations are consistent with previous feedback we have offered over the last six years to various committees. These are consistent with numerous reports from government and non-government entities alike – all of which have sounded the alarm about abuse within the 340B program and highlighted the sad reality that patients are not always the central beneficiaries of the 340B program. In response to your request for information, our full comments and recommendations are outlined below.

What specific steps can Congress take to improve the 340B Drug Discount Program?

1. Clearly Define 340B Patient Eligibility and Address Hospital Consolidation

In 1992, Congress created the 340B Drug Discount Program to support nonprofit entities serving America's most vulnerable or uninsured patients. For decades, hospital and offsite facilities ("child sites") participating in the 340B program have increased substantially[1], and this growth is not matched with increased patient benefits. A consequence of this expansion is decreased program integrity and increased hospital consolidation[2], as 340B has become a vehicle for revenue for large hospital systems instead of an important resource that safety-net entities can rely on to improve patients' access to medications.

Our main goal in reforming the 340B program lies in ensuring needy patients benefit from the manufacturer discounts provided to safety-net covered entities participating in the program. This central aim is difficult to achieve in part because currently, a "patient" under the 340B program is not clearly defined, and the eligibility standards fail to align with congressional intent.

Because the patient definition used within the 340B program is so broad, some covered entities consider any patient eligible for 340B discounts.[3] Simply put, the lack of clearly defined standards by which to identify 340B eligible patients leads to the incorrect assumption that essentially anyone could be eligible for 340B discounts by virtue of receiving health care services at a 340B covered entity. This has led to strong concern that a program established to serve low-income, underinsured, or uninsured patients is being misused to procure discounts for any patient of any facility that happens to be owned by a 340B covered entity. As hospital consolidation continues to add more and more facilities – located in wealthier areas with higher incomes and insured patient populations – to the 340B program, this loose definition of "patient" has allowed covered entities to increase the volume of prescriptions they deem eligible for 340B pricing in order for covered entities to turn a profit[4].

Compounding this issue is the fact that the 340B program uses the in-patient DSH metric to determine hospital eligibility for the outpatient 340B program. Given the lack of or overly broad definition of patient, this hardly comes as a surprise. Sadly, this has led to *The New England Journal of Medicine*, the country's oldest and most prestigious peer-reviewed medical journal, to determine there is no clear evidence that 340B savings are used to expand care for low-income patients.[5] A study published by the Social Science Research Network went further and declared: "It is evident that the ability of people suffering severe economic hardship to afford needed

[1]AIR340B, "340B Facilities and Charity Care," Oct. 2017
[2]Avalere, "Hospital Acquisitions of Physician Practices and the 340B Program," June 2015.
[3] Federal Register. Vol 61, No. 207. October 14, 1996.
[4] Conti M. Rena, and Bach B. Peter. "The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities." Health Affairs, vol. 33, no. 10. Oct. 2014.
[5] Desai, Sunita, and J. Michael McWilliams. "Consequences of the 340B Drug Pricing Program." *New England Journal of Medicine*, vol. 378, no. 6, 2018, pp. 539–548. Feb. 2018.

medicines and medical care, relative to the general population, is negatively correlated with growth in the 340B program."[6] Therefore, it is essential the definition of "patient" be updated in clearer terms with regard to the program. This will also act as a guardrail against abuse within the program by limiting the flow of resources to individuals and entities that do not adhere to the program's core mission, which in turn improves accountability, program integrity, and efficacy.

Profit incentives in the 340B program have also driven hospital consolidation, which often leads to higher costs and worse care for many patients.[7] As DSH hospitals acquire outpatient facilities, even if those facilities are located in wealthy communities, those facilities are able to obtain 340B prices – even if they do not treat uninsured patients. It is not clear these facilities, many of which are spatially distant from the DSH hospital they are associated with, are in fact part of said hospital, which raises questions as to whether they are truly eligible for these discounts. This is another obvious area for improvement of the 340B program, since their eligibility requirements are not spelled out – in fact, these outpatient facilities are not defined or listed under the 340B statute. The 340B program should improve access to medications for low-income patients, not inhibit it, which is why it is critical we address the misaligned program incentives leading to 340B-driven hospital consolidation.

It is clear that patients are not always benefiting from a program created to serve the most vulnerable. **Congress must provide a clearer definition for who qualifies as a 340B-eligible patient and curb the financial incentives driving consolidation within the program via 340B hospitals acquiring community-based physician practices and offsite facilities**, particularly given the substantial increase in health care costs associated with the site of care shifting from physician offices to hospital facilities in the last decade.

2. Restrict Contract Pharmacy Arrangements

Contract pharmacy arrangements have also been a persistent source of concern. Not included in the original statute, for-profit contract pharmacy participation was added through guidance issued by the Health Resources and Services Administration (HRSA) in 1996 and further expanded in 2010, which allowed an unlimited number of contract pharmacies to partner with covered entities to dispense 340B priced drugs. For-profit chain pharmacies took advantage of the expansion, and contract pharmacy participation has grown by 4,228 percent in just the last 10 years.[8] Unfortunately, this exponential growth has not been matched with improved patient access to 340B medicines.

Instead, according to a report by the Government Accountability Office (GAO), the majority of hospitals surveyed noted that 340B discounts were not shared with vulnerable patients when

[6] Levinson, Bruce. "Measuring the Effectiveness of the 340B Program." Social Science Research Network. November 2018.
[7] New England Journal of Medicine, "Changes in Quality of Care after Hospital Mergers and Acquisitions," Jan. 2020
[8] Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program," Oct. 2020.

picking up their prescriptions from contract pharmacies.[9] This finding is of grave concern, especially when another report found that 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B medicines.[10] The Office of the Inspector General also found many of the hospitals required uninsured patients who filled their 340B prescriptions at retail pharmacies to pay full price for their medicines.[11] It is clear the lack of oversight in the 340B program has allowed it to become a revenue stream for for-profit chain pharmacies, and low-income patients are paying the price.

Under current guidance, all covered entities are permitted to contract with multiple outside, for-profit retail pharmacies that share in the profits from the 340B program, and their profits are exorbitant. **Reforms are needed to address the dramatic growth of contract pharmacy arrangements between 340B hospitals and for-profit retail pharmacies.**

3. Establish Clear Reporting Requirements for DSH Hospitals

As a condition of their federal grants, federal grantee providers, such as community health centers, community oncology clinics, and Ryan White AIDS/HIV centers are required to report how savings from the 340B program improve and expand care for their patients. These reporting requirements provide a transparent look into how the patients they serve are benefiting. We believe many federal grantees and qualified health centers serve the goals of the 340B program and provide critical services to vulnerable or uninsured patient communities, and at the same time are held to a higher standard of accountability because of stricter oversight and reporting guidelines.

The same cannot be said for 340B DSH hospitals, which studies show have taken advantage of the program with little benefit to needy patients to show for it.[12] With DSH hospitals making up 80 percent of total 340B drug purchases[13] and contract pharmacy arrangements being a large driver of growth in the program, lack of accountability poses a serious problem for the low-income patients meant to benefit from the program. Implementing strict reporting standards would help close loopholes, disincentivize abuse within the program, and help track if the patient is benefiting, instead of lining the pockets of hospitals and chain pharmacies. **Congress must prioritize the need for clear reporting requirements for all 340B entities, including specific reporting requirements for 340B hospitals.** This will provide much-needed transparency into hospitals' use of the program and help ensure the program serves the vulnerable and uninsured patients it was intended to help.

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[9] Government Accountability Office, "Federal Oversight of Compliance at 340B Contract Pharmacies," June 2018. Needs Improvement
[10] Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program," Oct. 2020.
[11] Office of Inspector General, "Contract Pharmacy Arrangements in the 340B Program." Feb. 2014.
[12] Alliance for Integrity and Reform of 340B, "The Impact of Growth in 340B Contract Pharmacy Arrangements." Oct. 2020.
[13] Berkeley Research Group, "340B Program Sales Forecast: 2016-2021," Dec. 2016

Conclusion

The economic downturn caused by COVID-19 has put families and individuals in precarious financial positions, with many finding themselves unemployed, uninsured or underinsured, and in the midst of challenging times. The role the 340B Drug Discount Program plays as a public health safety-net for our nation's most vulnerable patients is more important now than ever before. Implementing the aforementioned changes to the program will improve long-term sustainability, accountability, transparency, and integrity within the 340B program – thus improving its utility as a public health safety-net program. We encourage Congress to take a deeper look at the 340B program and consider critical legislative changes to benefit patients, the safety-net, and the health care system at large.

Thank you for the opportunity to provide comments on these important issues. Should you have any questions or need more information, please contact Bob Dold at bdold@forbes-tate.com or 202-638-0125.

Sincerely,

Bob Dold
Chairman
Alliance for Integrity and Reform of 340B