March 9th, 2017

Chairman Lamar Alexander
Senate HELP Committee
455 Dirksen Office Building
Washington, DC 20510

Ranking Member Patty Murray
Senate HELP Committee
154 Russell Senate Office Building
Washington, D.C. 20510

Chairman Greg Walden
House Committee on Energy and Commerce
2185 Rayburn House Office Building
Washington, DC 20515

Ranking Member Frank Pallone
House Committee on Energy and Commerce
237 Cannon House Office Building
Washington, DC 20515

Dear Chairmen and Ranking Members,

As the 115th Congress begins its work, we would like to bring to your attention an important program – the 340B Drug Pricing Program – which we believe is in need of increased oversight. We strongly support the original intent of the program, to help uninsured or otherwise vulnerable patients served by safety net facilities. However, the program needs key reforms to ensure that all 340B facilities meet that goal.

The 340B law, enacted in 1992, requires prescription drug manufacturers to provide discounts on outpatient drugs to specified federally-funded clinics and certain hospitals, known as "covered entities," as a condition of participation in the Medicaid program. In order to qualify as a covered entity, one must either be an organization receiving one of 10 types of federal grants, known as a grantee, or one of six types of non-profit hospitals that meet specified program standards.

Since it was established, the 340B program has grown rapidly, in particular following passage of the Affordable Care Act.[1] According to a report released by the Berkeley Research Group, total sales of drugs through the program have increased from less than $5.9 billion in 2010 to more than an estimated $16 billion in 2016.[2] Without significant reforms, the program is projected to continue to grow and will reach $23 billion in sales at the 340B price by 2021.[3]

About 80 percent of 340B sales are to DSH hospitals,[4] which are not required to use the program to benefit vulnerable or uninsured patients. Unlike grantees, 340B hospitals have no requirements on how they use revenue generated by the "spread" between the price for medicines they charge to patients and their insurers and the discounted 340B prices they pay for the medicines. Hospital eligibility for

[1] The Affordable Care Act allowed 5 new categories of hospitals to participate in the 340B program: critical access hospitals, sole community hospitals, rural referral centers, free-standing children's hospitals, and free-standing cancer hospitals. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2993068/

[2] A. Vandervelde and E. Blalock, "340B Program Sales Forecast 2016-2021," December 2016, located at http://www.thinkbrg.com/media/publication/855_Vandervelde_Blalock_340B_Dec2016_WEB.pdf

[3] *Id.*

[4] C.A. Hatwig, "Apexus Update," Presentation at the 2016 340B Coalition Summer Conference, Washington, DC, July 11-13, 2016.

340B is also not tied to the amount of charity care that a hospital provides. Even though the program is supposed to be geared toward safety net facilities, a recent analysis found more than one-third (37 percent) of 340B hospitals provide charity care that represents less than 1 percent of their total patient costs.[5]

As the program continues to grow without all the necessary standards and oversight, we are concerned that it may lead to perverse financial incentives that fail to take into consideration patient care. These concerns have been echoed by a number of stakeholders and government agencies, including the Government Accountability Office, which in a July 2015 report concluded that Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals than at comparable non-340B hospitals.[6] Reform is needed in several areas. First, a clear definition of a 340B patient is needed for hospitals, which often have only very loose ties to certain patients and providers. Second, hospital eligibility criteria should be changed so that it is tied to true safety net status. Stronger standards are also needed for outpatient clinics purchased by hospitals, which are now often located in much wealthier areas than the 340B hospitals themselves. Last, there should be common-sense limits on the role of for-profit contract pharmacies in the 340B program.[7]

In 2015, for the first time in a decade, the House held a hearing to review the challenges of the 340B program and to begin to consider policy solutions. In that discussion, Rep. Marsha Blackburn's comments captured broad concerns among attending Energy & Commerce Committee members when she stated, "I think the rapid growth in the program has raised concerns, including the adequacy of oversight." We hope the 115th Congress will address these and other program challenges through additional hearings and other actions that support reforming the program so that it is consistent with Congress's original intent. We hope you keep our concerns in mind as the legislative session continues, and we look forward to working together to strengthen the 340B program for the benefit of uninsured, vulnerable patients.

Sincerely,

Alliance for Patient Access
Colon Cancer Alliance
Log Cabin Republicans
National Center for Policy Analysis
National Council of Asian Pacific Islander Physicians
National Hispanic Medical Association
National Medical Association
RetireSafe
The AIDS Institute
The Galen Institute
The National Hispanic Council on Aging (NHCOA)

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[5] Analysis was for the disproportionate share hospitals only. AIR 340B, "Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.

[6] "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" GAO-15-442. Government Accountability Office, July 2015.

[7] R. Conti and P. Bach, "The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities," *Health Aff* October 2014 vol. 33 no. 10 1786-1792.