Paul W. Abramowitz, Pharm.D., Sc.D. (Hon), FASHP
Chief Executive Officer

January 11, 2018

The Honorable Larry Bucshon, M.D.
U.S. House of Representatives
1005 Longworth House Office Building
Washington, DC 20515

The Honorable Scott Peters
U.S. House of Representatives
1122 Longworth House Office Building
Washington, DC 20515

The Honorable Chris Collins
U.S. House of Representatives
1117 Longworth House Office Building
Washington, DC 20515

Dear Representatives Bucshon, Peters, and Collins:

On behalf of ASHP (American Society of Health-System Pharmacists), I am writing in opposition to H.R. 4710, which would impose a two-year ban on new enrollment of Disproportionate Share Hospitals (DSHs) into the 340B Drug Pricing Program. We believe that a wholesale moratorium on new enrollment would potentially harm the nation's most vulnerable patients.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP has a longstanding history of support for the 340B drug-discount program, as many of our members practice in hospitals and health systems that are 340B-eligible and have seen, firsthand, the benefits of the program to the patients they serve.[1] Today, the federal 340B program continues to meet Congress' intent "of enabling these entities to stretch scarce federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services."

[1] ASHP's full policy on the 340B Drug Pricing Program sustainability is as follows: (1) To affirm the intent of the federal drug pricing program (the "federal 340B program") to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; (2) further, to advocate legislation or regulation that would optimize access to the federal 340B program in accordance with the intent of the program; (3) further, to advocate for clarification and simplification of the federal 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; (4) further, to encourage pharmacy leaders to provide appropriate stewardship of the federal 340B program by documenting the expanded services and access created by the program; (5) further, to educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; (6) further, to educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support federal 340B program compliance and documentation; (7) further, to encourage communication and education concerning expanded services and access provided by 340B-eligible participants to patients in fulfillment of its mission.

Congress enacted the 340B drug-discount program 25 years ago with bipartisan support.[2] The program requires pharmaceutical manufacturers participating in the Medicaid or Medicare Part B programs to enter into a pharmaceutical pricing agreement (PPA) with the federal government.[3] The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified safety net providers, known as "covered entities," that serve the nation's most vulnerable patient populations. On several occasions since that time, Congress, ***under the control and support of both parties***, has expanded the program to other hospitals that are part of the nation's safety net. Covered entities include not only hospitals serving many low-income patients (DSHs, rural referral centers, critical access hospitals [CAHs], children's hospitals, and cancer hospitals), but also several other types of safety net providers including federally qualified health centers (FQHCs), state and local health departments, HIV clinics, and hemophilia treatment centers.[4] Together, these providers serve tens of millions of uninsured and underinsured people every year.

The increasing shift at the national level toward ambulatory care and outpatient pharmacy has contributed to the growth of the federal 340B program and has allowed for better access to medications by low-income and uninsured patients. It is important to note that drugs subject to the 340B drug-discount program make up only 5 percent of the nation's total drug spend. Further, the federal 340B program also reduces government expenditures and lessens the burden on taxpayers who would otherwise be responsible for financing the indigent care that federal 340B program hospitals provide. ASHP believes that imposing a moratorium on new enrollment in the program, as proposed in H.R. 4710, is an arbitrary reduction.

H.R. 4710 would require covered entities to report the amount they spend on charitable care; however, the bill fails to recognize that increased services may not solely be considered charitable care. ASHP is concerned that the reporting requirements in the legislation are not properly aligned with how covered entities actually utilize their discounts. Furthermore, the program enables covered entities to serve uninsured and underinsured, making it more difficult to measure charitable care, as it may also apply to underinsured patients.

In September 2011, the Government Accountability Office (GAO) issued a study of the federal 340B program and found that, in large part, the program is operating as originally intended.[5] Specifically, the GAO found that "all covered entities reported using the program in ways consistent with its purpose" and that "all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients." GAO did make several recommendations for improving program oversight and specifically called on the Health Resources and Services Administration (HRSA) to be more proactive in administering the program. As a result, HRSA has significantly increased the number of audits of covered entities to help ensure compliance with program requirements.

ASHP also recognizes the importance of program compliance, and we endorse programs geared to supporting the federal 340B program's participating covered entities as well as manufacturers in managing 340B-compliant

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2 Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b

3 HRSA, Pharmaceutical Pricing Agreement, available at http://www.hrsa.gov/opa/manufacturers/pharmaceuticalpricingagreement.pdf.

4 42 U.S.C. § 256b(a)(4).

5 GAO-11-836: Published: Sep 23, 2011. Publicly Released: Sep 23, 2011.

operations. ASHP has partnered with Apexus, HRSA's contracted federal 340B program prime vendor, to improve compliance through the use of educational training sessions. ASHP continues to collaborate with Apexus to provide training programs, known as the 340B University — at our prominent and widely attended Midyear Clinical Meeting, our Summer Meetings, and our annual Conference for Pharmacy Leaders. The goal of these sessions is to educate stakeholders about the program's requirements as well as to provide a forum to discuss compliance challenges and solutions. These are typically done in panel format, which allows the unique opportunity for covered entities to interface in live sessions with peers, the faculty, and pharmaceutical wholesaler and manufacturer representatives. ASHP believes these programs have had positive influence on improving compliance within the federal 340B program.

ASHP remains supportive of the federal 340B program; we believe it is a critical component for safety-net providers to provide care to uninsured and underinsured patients. Safety net providers are especially critical in our nation's rural areas, where access and ability to pay for care are often compromised. We remain committed to working with HRSA and other federal 340B program stakeholders to ensure that the requirements of the program are being met and that the program functions as intended. Nonetheless, we are concerned that attacks on the program, which may jeopardize the program's existence, are in some cases simply unfounded or based on faulty assumptions.

ASHP looks forward to discussing changes and improvements to H.R. 4710. Please contact me with any questions, or have a member of your team contact Christopher Topoleski, Director of Federal Legislative Affairs, at 301-664-8806 or at ctopoleski@ashp.org.

Sincerely,

Paul W. Abramowitz