Senate Health, Education, Labor, and Pensions Committee

Hearing on: "Perspectives on the 340B Drug Pricing Program"

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Written Statement for the Record
Submitted by ASHP

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Good morning, and thank you, Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee, for the opportunity to testify today. My name is Joseph Hill, and I am the Director of the Government Relations Division for ASHP, the American Society of Health-System Pharmacists. I am here today to provide ASHP's perspective on the 340B Drug Pricing Program.

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 appreciates the opportunity to provide our views to the Committee on the 340B Drug Pricing Program. ASHP has a longstanding history of support for the 340B drug-pricing program, as many of our members serve as patient care providers in hospitals and health systems that are 340B-eligible and have seen, firsthand, the benefits of the program to the patients they serve.[1] At a time when federal budgets are stretched thin,

[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 "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 340B program in accordance with the intent of the program; (3) further, to advocate for clarification and simplification of the 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 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)

the federal 340B program helps maximize federal resources while providing access to lifesaving medications.

Congress enacted the 340B drug-pricing 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 (disproportionate share hospitals [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]

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further, to educate health-system administrators, risk managers, and pharmacists about the resources (e.g., information technology) required to support 340B program compliance and documentation; (7) further, to encourage communication and education concerning expanded services and access provided by 340B participants to patients in fulfillment of its mission.

[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).

Together, these providers serve tens of millions of uninsured and underinsured people every year.

The increasing shift throughout healthcare toward ambulatory care including more outpatient pharmacy services has contributed to the growth of the 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-pricing program make up a fraction of the nation's total drug expenditures. 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-participating hospitals provide.

Today, the federal 340B program continues to meet Congress' original intent "of enabling these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Access to primary care; behavioral health services; pharmacist-led substance abuse treatment; expanded pharmacy services; provision of naloxone to law enforcement; discounted or free prescription medications; pediatrics; and other services for many uninsured and underinsured are made possible only by the savings realized through the 340B program. In some communities, there would be limited or no access to healthcare services without the financial savings garnered through the 340B program.

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 great importance of program compliance, and we endorse programs that support the covered entities as well as manufacturers. ASHP has partnered with Apexus, HRSA's contracted 340B 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, the largest gathering of pharmacists in the world; our Summer Meetings; and our annual Conference for Pharmacy Leaders. To date, about 30,000 individuals have participated in the 340B University. The goal of these sessions is to educate our members and other stakeholders about the program's requirements as well as to provide a forum to discuss compliance challenges and

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

solutions. These are typically done in panel format, which allows the unique opportunity for covered entities to interface with peers, the faculty, and pharmaceutical wholesaler and manufacturer representatives in live sessions. ASHP believes these programs have had a positive influence on improving compliance within the 340B program.

ASHP remains supportive of the 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 340B program stakeholders to ensure that the requirements of the program are being met and that the program functions as intended.

As we have worked with the committee in the past on a number of important public health issues including drug shortages and compounding, ASHP welcomes the opportunity to be a resource for the committee on this issue, as well as other issues pertaining to the practice of pharmacy or healthcare in general. Again, we thank the committee for the opportunity to provide input.

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