

House Energy and Commerce Subcommittee on
Health

Hearing on Examining the 340B Drug Pricing
Program

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Statement for the Record
Submitted by ASHP



pharmacists advancing healthcare®

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The American Society of Health-System Pharmacists (ASHP) respectfully submits the following statement for the record to the House Energy and Commerce Committee's Subcommittee on Health hearing on examining the 340B Drug Pricing Program.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.safemedication.com.

Enacted in 1992, Section 340B of the Public Health Service Act created a drug discount program that enables hospitals, community health centers and other qualified entities to provide care to low-income patients who would otherwise not be able to afford their medications. The 340B program requires drug manufacturers participating in Medicaid or Medicare Part B to offer discounts on covered outpatient drugs purchased by hospitals and other entities that are qualified to receive them based upon the number of low-income or uninsured patients they serve. These covered entities include disproportionate share (DSH) hospitals, rural hospitals, community health centers, HIV clinics, and children's and cancer hospitals. The discounts are then used to help cover the cost of providing care to patients who cannot afford it or don't have health care insurance. Since its creation, ASHP has been a strong supporter of the 340B program, as many of our members practice pharmacy in 340B covered entities and they know firsthand the challenges of caring for the poor.

This program is essential to many hospitals' ability to provide care to uninsured and underinsured patients. The 340B program reduces the burden on taxpayers who would otherwise be footing the cost of providing care to the indigent population. In addition, the 340B program not only is an essential component to provide access to medications, but it also enables caregivers to help those patients use their medications properly. It is important to remember that the discounts received through the program not only enable patient access to free or low-cost medications, but they also help offset the total cost of uncompensated care, which may include critical services such as chemotherapy and HIV treatments. Hospitals serving the poor are more vulnerable to the financial burden of caring for patients who simply cannot afford the care they receive or do not have insurance coverage. Unlike other settings, where insurance coverage or ability to pay may be a requirement for service, covered entities within the 340B program are often the only option for poor or uninsured patients to receive care. Without access to the 340B discounts, many covered entities would be at risk of closing, as they simply would not be able to absorb the cost of providing care to patients who otherwise could not be able to afford it.

When Congress created the program in 1992, the intent was to enable covered entities that serve the poor to obtain discounted medications that would offset the uncompensated care for this population. Overall, ASHP believes that the program is operating as Congress intended. In September 2011, the Government Accountability Office (GAO), issued a study of the 340B program and found that, in large part, the program is operating as originally intended. 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.”ⁱ GAO did make several recommendations for improving program oversight and specifically called on the Health Resources and Services Administration (HRSA) to be more proactive including a recommendation that HRSA increase the number of audits to both covered entities and manufacturers participating in 340B. 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 engage and endorse programs geared to supporting the program’s participating covered entities as well as manufacturers in managing 340B compliant operations. In 2012, ASHP 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 three such training programs, known as the 340B University—two at each of our annual meetings (Midyear Clinical Meeting and our Summer Meetings), and one at our annual Leaders Conference. 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 with peers, the faculty, and pharmaceutical wholesaler and manufacturer representatives in live sessions. ASHP believes these programs have had positive influence on improving compliance within the 340-B program.

As the prime vendor for the 340B program, Apexus also operates a call center for program participants seeking advice or clarification on topics related to drug pricing. In 2014 alone, the call center handled more than 1,500 inquiries per month. Other initiatives include the password-protected prime vendor web site which contains manufacturers’ quarterly ceiling prices provided voluntarily by the manufacturers themselves. If discrepancies are suspected, customers can use a standardized form on the web site to submit that information to HRSA’s Office of Pharmacy Affairs, which in turn can follow up directly with the manufacturer. In addition, Apexus is in the process of creating an online series of educational modules to provide high-level education that stakeholders can watch on demand, which will be made available in fall 2015. In the future, Apexus plans to launch additional in-depth modules that will help manufacturers, wholesalers, and consulting organizations support compliance of 340B program operations.

Conclusion

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. This is especially critical in our nation's rural areas where access and ability to pay for care are often compromised. We also agree with the GAO that overall, the program is operating as originally intended by Congress, but program oversight could improve. Furthermore, ASHP believes that compliance and program integrity are also essential to maintaining the vitality of the program, both for covered entities and drug manufacturers. We remain committed to working with HRSA and other 340B stakeholders to ensure that the requirements of the program are being met and 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 upon faulty assumptions. As we have worked with the Committee in the past on drug shortages and compounding, ASHP welcomes the opportunity to be a resource for the Committee on this issue, as well other issues pertaining to the practice of pharmacy or health care in general. Again, we thank the Committee for the opportunity to provide input.

ⁱ GAO, Drug Pricing: *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept., 2011), at <http://www.gao.gov/assets/330/323702.pdf>.