



July 27, 2017

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Murphy and Ranking Member DeGette:

Thank you for the opportunity to submit a letter on behalf of the Association of American Medical Colleges (AAMC) in response to the Energy and Commerce Oversight and Investigations Subcommittee July 18 hearing, “Examining HRSA’s Oversight on the 340B Drug Pricing Program.” The AAMC strongly supports the 340B Program and looks forward to working with Congress and the Administration to ensure the program continues to serve as an effective resource for providing critical services to vulnerable populations across the nation.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 147 accredited U. S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America’s medical schools and teaching hospitals and their nearly 167,000 full-time faculty members, 88,000 medical students, and 124,000 resident physicians.

The AAMC appreciates the Subcommittee’s interest in ensuring the 340B Program can continue to serve as a resource for providing necessary services to underserved populations. Congress created the 340B Program in 1992 to allow certain safety net hospitals and other covered entities to purchase outpatient drugs at a discount from drug manufacturers “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ Under the rules of the 340B Program, pharmaceutical companies are required to sell covered outpatient drugs to covered entities at a reduced price. Given the structure of the program, funds are largely generated through the discounts received from drug manufacturers, which allows the program to be self-sustaining with little federal investment.

¹ H.R. Rept. No. 102-384(II), at 12 (1992)

The 340B Program is critical to major teaching hospitals and the communities they serve. AAMC-member teaching hospitals and their clinical faculty, residents, and students are committed to their mission of expanding access to care for underserved and vulnerable populations. While they only represent five percent of all hospitals, major teaching hospitals account for:

- 33 percent of the country's charity care;
- 23 percent of all hospital inpatient days;
- 24 percent of all Medicaid hospitalizations; and
- 20 percent of all Medicare inpatient days.

Compared with physician offices and other hospitals, major teaching hospitals provide care to a higher proportion of low-income, dual eligible, disabled, and minority patients. As major referral centers with highly specialized expertise, these academic medical centers serve a sicker, more complex, and more vulnerable patient population – patients who often are unable to seek the necessary care elsewhere.

Major teaching hospitals provided \$9.8 billion in uncompensated care in 2015.² These hospitals also operate a variety of programs and provide services that otherwise may not be financially viable without support from the 340B Program, including:

- Free or substantially discounted prescriptions to uninsured or low-income patients;
- Mobile health care units to bring care to those communities that have no local primary care or pharmacy;
- Multidisciplinary clinics offering substance abuse and mental health needs; and
- Transportation support to patients who frequent the emergency room.

In short, at little cost to taxpayers, the discounts from pharmaceutical companies offer safety net hospitals and other eligible providers essential resources to meet the needs of the communities and patients they serve.

The Association appreciates HRSA's efforts to strengthen the 340B Program and to ensure hospitals and other eligible providers comply with program requirements. In order to participate and remain in the program, eligible hospitals must keep 340B database information accurate and up to date, recertify eligibility each year, and prevent diversion to ineligible patients. They are also subject to audits from HRSA, the results of which are made publicly available on HRSA's Office of Pharmacy Affairs website. Hospitals commit a significant amount of resources and staff to ensure they remain compliant with the 340B Program so that they can continue to participate in the program and maintain these critical programs.

The AAMC strongly believes that HRSA oversight is important to ensure that all 340B participants – including covered entities, but also manufacturers – are abiding by the program's strict guidelines and have the opportunity to correct any unintentional violations. The Association continues to stand at the ready to work with policymakers to ensure appropriate program oversight of this important program.

² 2015 American Hospital Association Annual Survey Database

At the same time, the AAMC is concerned about criticisms that have been raised by select stakeholders regarding the 340B Program. For example, critics mistakenly suggest there has been inappropriate growth in the 340B Program. While the amount of spending in the 340B Program has increased in recent years, there are a number of reasonable factors that are driving this growth. For example, the Affordable Care Act significantly expanded the list of entities eligible to participate in the program to include: children's hospitals, freestanding cancer clinics, critical access hospitals, certain sole community hospitals, and rural referral centers starting in 2010. As more covered entities have become eligible for the 340B Program, this has resulted in a commensurate and expected increase in participating entities and in drug spending as participation in the program has grown.

However, while the 340B Program has continued to grow, HRSA estimates that 340B sales are less than three percent of the total U.S. drug market.³ Given how small the 340B Program is relative to the estimated \$457 billion in prescription drug spending in the United States in 2015⁴, the AAMC strongly believes that the 340B Program is not a significant driver of drug spending.

The AAMC is particularly concerned about the recent Centers for Medicare and Medicaid Services (CMS) Outpatient Prospective Payment System (OPPS) 2018 proposed rule, which would penalize 340B hospitals by dramatically cutting Medicare reimbursement to hospitals for outpatient drugs. Currently, Medicare pays the same rate at all hospitals for separately payable, non pass-through drugs – the average sales price (ASP) plus 6 percent. CMS's proposal would reduce this payment to ASP minus 22.5 percent, solely on the basis of a hospital's participation in the 340B Program.

The CMS proposal would negate the longstanding statutory intent of HRSA's 340B Program and severely limit safety net hospitals' abilities to provide needed care and medications to the patients they serve in rural and urban communities across the nation. The AAMC strongly opposes this, which would undermine the 340B Program and will penalize safety net hospitals participating in 340B, severely restricting their ability to sustain vital services and provide needed care to underserved communities.

The AAMC appreciates your continued support of the 340B Drug Pricing Program and looks forward to working with Congress and the Administration toward our mutual objective of strengthening the program so that it continues to provide vital support to hospitals and other health providers as they work to serve vulnerable patients and their communities.

Sincerely,



Karen Fisher, JD
Chief Public Policy Officer

³ Department of Health and Human Services Fiscal Year 2018 Health Resources and Services Administration *Justification of Estimates for Appropriations Committees*, page 244

⁴ U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending*, March 8, 2016