

October 11, 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 advance of the Energy and Commerce Oversight and Investigations Subcommittee Oct. 11 hearing, “Examining How Covered Entities Utilize the 340B Drug Pricing Program.” The AAMC strongly supports the 340B Program, which allows safety-net hospitals and other eligible providers to leverage discounts from pharmaceutical companies to provide critical, life-saving services to vulnerable patients at no cost to taxpayers.

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 340B Program Provides Critical Support to Vulnerable Patients

The AAMC appreciates the Subcommittee’s continued interest in ensuring that the 340B Program serves as an effective resource for providing necessary support 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 Savings are generated from the 340B Program because pharmaceutical companies are required to sell the drugs to hospitals at a reduced price if they want to participate in the Medicaid program.

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

At no cost to taxpayers, the 340B Program has been a success. According to the Health Resources and Services Administration (HRSA), which oversees the program, 340B sales are less than three percent of the total U.S. drug market.² Yet, the discounts generated from the program allow safety-net hospitals that treat large numbers of uninsured and underinsured patients to expand health care services and provide critical support to this patient population.

As you will hear from the witnesses at the hearing, hospitals and other eligible providers are using their savings from the 340B Program in a variety of ways to help support their underserved patients. In addition to those examples, major teaching hospitals also operate other programs and provide services that otherwise would not be financially viable without support from the 340B Program, including:

- Free or substantially discounted prescriptions to uninsured or low-income patients;
- Multidisciplinary clinics offering substance abuse and mental health treatment;
- Pharmacist counseling services for medication therapy; and
- Smoking cessation programs to help uninsured and underinsured patients gain access to cessation drugs.

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.

Major teaching hospitals provide care to a higher proportion of low-income, dual eligible, and disabled 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 find the necessary care elsewhere.

Major teaching hospitals provided \$9.8 billion in uncompensated care and 33% of all charity care in 2015.³ In addition, they conduct community health needs assessments to identify and implement strategies to address many of the local health needs in their communities, such as access to medical care, mental health access and treatment, chronic disease management, and social determinants of health.

² Department of Health and Human Services Fiscal Year 2018 Health Resources and Services Administration *Justification of Estimates for Appropriations Committees*, page 244

³ 2015 American Hospital Association Annual Survey Database

Program Integrity Efforts to Strengthen 340B

The Association appreciates HRSA's efforts to strengthen the 340B Program and to ensure that hospitals and other eligible providers, as well as pharmaceutical companies, comply with program requirements. As Captain Krista Pedley, PharmD, director, Office of Pharmacy Affairs, HRSA, highlighted in her testimony during the Subcommittee's July 18 hearing, HRSA continues to strengthen its oversight of the program.⁴ In order to participate and remain in the program, covered entities must go through an initial certification process, recertify for the program annually, prevent diversion to ineligible patients, and are subject to random audits from HRSA. To ensure transparency, HRSA posts a summary of final audit findings on its website. The AAMC strongly believes that HRSA oversight is important to ensure that all 340B participants – including covered entities and manufacturers – are abiding by the program's strict guidelines and have the opportunity to correct any unintentional violations.

In addition to HRSA's oversight, hospitals that participate in the 340B Program invest in their own internal program integrity efforts in order to maintain compliance. Hospitals purchase or create sophisticated software to ensure that 340B drugs are dispensed only to eligible patients. The software electronically checks whether the patient had a qualifying visit and ensures that drugs are purchased at 340B prices and dispensed only when appropriate. Participating hospitals also employ a number of other safeguards to ensure continued compliance, including: internal audits; regular team meetings; targeted chart reviews; drug order verifications; executives serving on oversight committees; a growth in legal, finance, and senior leadership staff time dedicated to program oversight; and other policies.

Opposition to CMS Proposal to Cut Reimbursements to 340B Hospitals

The AAMC, as well as other hospital associations, safety-net hospitals, members of Congress, and an influential advisory panel have opposed the recent Centers for Medicare and Medicaid Services (CMS) Calendar Year 2018 Outpatient Prospective Payment System (OPPS) proposed rule that includes a proposal to dramatically cut the outpatient drug reimbursement rate for hospitals participating in the 340B Program. Currently, Medicare pays for separately payable, non pass-through drugs (i.e. drugs not included in a bundle or vaccines) at the average sales price (ASP) **plus 6%**. CMS proposed to pay disproportionate share hospitals (DSH) for drugs purchased under the 340B Program at ASP **minus 22.5%** beginning in 2018. This is a significant reduction targeted at the subset of hospitals that are the nation's safety net, undermining the purpose and benefits of the 340B Program and crippling the ability of these crucial hospitals to serve vulnerable and low-income patients.

The AAMC's Sept. 11 comment letter to CMS Administrator Verma highlighted that the proposed cuts to one subset of hospitals – those serving the most vulnerable patients – undermine the intent of the 340B Program. In making this proposal, CMS did no independent analysis to understand the impact, which the law requires. The AAMC's own analysis, conducted by Watson Policy Analysis, estimated that this proposal would reduce critical payments to safety-net hospitals by \$1.2 to \$1.6 billion in 2018 alone, far exceeding CMS's own estimated drastic

⁴ Testimony available here: <http://docs.house.gov/meetings/IF/IF02/20170718/106269/HHRG-115-IF02-Wstate-PedleyK-20170718.pdf>

reduction of \$900 million.⁵ The AAMC strongly urges CMS to rescind these proposed Medicare cuts to hospitals that participate in the 340B Program.

Congress has also expressed concern about this proposal. A majority of Congress (228 members of the House of Representatives and 57 members of the Senate) recently sent bipartisan letters to CMS Administrator Verma showing their support for the 340B Program and raising significant concerns about the impact of this proposal on safety-net hospitals and the vulnerable patients they serve.⁶

Additionally, at its Aug. 21 meeting, the CMS Advisory Panel on Hospital Outpatient Payment recommended that CMS not finalize its proposal to revise the payment rate for drugs purchased under the 340B Program and for CMS to collect data to understand the impact of the proposal and assess the regulatory burden associated with the proposed modifier to identify drugs not purchased under the 340B Program.⁷

Conclusion

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 in their communities.

Sincerely,



Karen Fisher, JD
Chief Public Policy Officer

⁵ AAMC Comment Letter on Proposed Rule *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program for Calendar Year 2018*. Available here: <https://www.aamc.org/download/482774/data/aamccommentlettercy2018opps.pdf>

⁶ House of Representatives “Dear Colleague” Letter available here: <https://www.aamc.org/download/483424/data/340bletterfinal.pdf>; Senate “Dear Colleague” Letter available here: <https://www.aamc.org/download/483582/data/340bsenateletterfinal.pdf>

⁷ CMS Advisory Panel on Hospital Outpatient Payment, Aug. 21, 2017: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2017-08-21-Panel-Recommendations.pdf>