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October 30, 2020

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor, and Pensions Committee
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee
2185 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Alexander and Ranking Member Walden:

On behalf of the AAMC (Association of American Medical Colleges), I would like to thank you for the opportunity to provide feedback on the 340B Drug Pricing Program. The AAMC strongly supports the 340B program and looks forward to working with your offices to maintain and build upon the program's success. We believe the program works well to help safety-net hospitals provide vulnerable patients and communities with access to critical health care services and that no legislative changes are needed. However, we continue to urge Congress to use its oversight function to ensure that the Department of Health and Human Services (HHS) uses its authority to make sure that pharmaceutical manufacturers comply with current law and do not undermine the program. Specifically, we are deeply troubled by recent actions from manufacturers to refuse to offer 340B pricing on eligible drugs at community pharmacies and an effort to change the 340B program from a discount program to a rebate.

The AAMC is a not-for-profit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

AAMC member teaching hospitals, many of which are safety-net providers that participate in the 340B program, represent only 5% of all inpatient U.S. hospitals but provide 27% of all Medicaid inpatient days, 22% of all Medicare inpatient days, and 34% of all charity care costs. In addition, these hospitals provide 23% of inpatient psychiatric unit beds, 25% of the nation's medical and surgical intensive care beds, 36% of cardiac intensive care beds, 61% of pediatric intensive care beds, and are home to 69% of all Level 1 Trauma Centers.

The 340B Program Provides Vital Support to Patients

Congress created the 340B program over 25 years ago to allow eligible safety-net hospitals and other providers (known as "covered entities") to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services."[1] There is no cost to taxpayers since the program allows these covered entities to leverage discounts from pharmaceutical companies to provide their communities with access to care they otherwise may not have received.

Consistent with the intent of the program, these safety-net providers invest their savings from the 340B program in a wide variety of programs to meet the needs of their local communities and help patients. AAMC-member teaching hospitals that participate in the 340B program use their savings to create and sustain critical programs that otherwise might not be financially possible, including:

- Providing free or substantially discounted prescription drugs to uninsured or low-income patients
- Improving access to specialized care previously unavailable in underserved areas
- Establishing and improving neighborhood clinics
- Bringing mobile units to communities with no local primary care provider or pharmacy
- Creating multidisciplinary clinics to treat substance use and mental health disorders
- Providing medical care to children in foster care

The 340B program is a relatively small program but it is a lifeline for many safety-net hospitals that treat the most vulnerable and complex patients. Hospitals that participate in the 340B program treat significantly more Medicaid and low-income patients than non-340B hospitals and are more likely to provide "essential community services" like burn and trauma care that are often financially unprofitable due to low reimbursement rates.[2]

Clarifications About the 340B Program

Your statement raises several misperceptions about the 340B program, including oversight, the size of the program, and the use of community pharmacies that we would like to clarify below.

HRSA Maintains Strong Program Integrity

The AAMC supports the Health Resources and Services Administration's (HRSA) efforts to oversee the 340B program. In order to maintain program integrity and compliance, HRSA already has extensive reporting measures in place and has recently enhanced its oversight of covered entities and drug manufacturers. To participate and remain in the program, covered entities must undertake an initial certification process to demonstrate that they serve a disproportionate share of underserved patients, recertify annually, and have mechanisms in place

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

[2] Dobson DaVanzo. The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients. 2020. https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FIN AL_.pdf

to prevent duplicate discounts and diversion to ineligible patients. HRSA also conducts random audits and posts the findings on its public website. Many hospitals go beyond these requirements and invest additional resources and staff to ensure continued compliance. Additionally, beginning in 2019, HRSA began enforcing penalties on manufacturers that knowingly and intentionally overcharge 340B providers.

Program Growth is Due to the Congressional Expansion of the Program and Rising Drug Costs

Due to the success of the 340B program to help safety-net providers and their vulnerable patients, Congress has expanded the program. Under the Affordable Care Act, additional covered entities became eligible to participate in the 340B program, including critical access hospitals, rural referral centers, sole community hospitals, and free-standing cancer hospitals. In 2016, there were 2,399 hospitals participating in the 340B program with 62% of these hospitals located in rural areas. Of those participating rural hospitals, 93% are critical access hospitals.[3] Many of these providers care for the neediest patients in their communities and the discounts from the 340B program are what enable them to remain open and reach more individuals who may not otherwise have access to care.

Additionally, growth in 340B sales is directly tied to the significant increase in drug prices charged by manufacturers. Even during the coronavirus pandemic, drug manufacturers have instituted more than 800 price increases in 2020, with brand name drugs seeing the highest price increases.[4] As drug prices rise, so do the corresponding discounts received by covered entities. According to the Centers for Medicare and Medicaid Services Office of the Actuary, drug spending has increased from $258 billion in 2013 to an estimated $359 billion in 2020. These numbers are projected to increase over the next decade.[5] At the same time, the largest 25 drug manufacturers have reported annual profit margins between 15-20%.[6] Fortunately, the 340B program remains an important tool to help safety-net providers in both rural and urban communities combat high drug prices.

Community Pharmacies Expand Resources to Low-Income Patients

As you note in your letter, community pharmacies (also referred to as "contract pharmacies") serve an important role in improving access to prescription drugs. HRSA expanded the use of community pharmacies to address obstacles – including transportation barriers – that some patients face around the ability to access locations to fill their prescriptions. These community pharmacies allow patients to receive their medication at a location that is most convenient for

[3] National Rural Health Association Policy Brief. Utilization of the 340B Drug Pricing Program in Rural Practices Policy Paper. 2019. https://www.ruralhealthweb.org/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/2019-NRHA-Policy-Paper-Utilization-of-the-340B-Drug-Pricing-Program-in-Rural-Practices.pdf.
[4] Good Rx. Prices for Prescription Drugs Rise Faster than Prices for Any Other Medical Good or Service. September 17, 2020. https://www.goodrx.com/blog/july-drug-price-hikes-2020/.
[5] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Prescription Drug Pricing, May 2020. https://aspe.hhs.gov/system/files/aspe-files/263451/2020-drug-pricing-report-congress-final.pdf.
[6] U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." https://www.gao.gov/assets/690/688472.pdf.

them, which is especially important in underserved and rural areas where access to care may be limited.

To ensure compliance, HRSA reviews these arrangements for child sites as part of its standard auditing protocol. All covered entities are required to maintain auditable records and are expected to conduct annual audits of contract pharmacies that are performed by an independent auditor. Additionally, HRSA can audit covered entities and enforce sanctions if these covered entities are out of compliance. If HRSA finds a covered entity providing no oversight of its contract pharmacy arrangement, this is a violation of program requirements and HRSA will no longer permit the participation of that contract pharmacy arrangement.

The AAMC is particularly concerned about the recent actions taken by several major drug manufacturers to undermine the 340B program by not offering 340B pricing for eligible drugs that are dispensed at community pharmacies. These actions are contrary to the intent of the 340B program and will reduce access to care for patients and communities who depend on services provided through 340B savings.

The 340B statute clearly requires that manufacturers that participate in the Medicaid program must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price."[7] There are no provisions in the statute that allow manufacturers to set conditions or deny 340B pricing to eligible hospitals.

These actions by the drug manufacturers violate the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their 340B drugs to eligible providers. The AAMC has joined other providers in calling on HHS to use its authority to address this issue and require that these manufacturers comply with the law to ensure that 340B drugs are available and accessible to vulnerable patients and communities.

We also appreciate the bipartisan letters in both the House and Senate that raised significant concerns about this issue and call on HHS Secretary Azar to immediately address these actions.

Thank you again for the opportunity to provide feedback in support of the 340B program. Please feel free to let contact me (kfisher@aamc.org) or Len Marquez (lmarquez@aamc.org), Sr. Director, Government Relations, if you have any questions or would like additional information.

Thank you,

Karen Fisher, JD
AAMC Chief Public Policy Officer

[7] 42 U.S.C. 256b(a)(1)