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October 27, 2020

Mr. Thomas J. Engels
Administrator
Health Resources and Services Administration
ATTN: Bureau of Primary Care
5600 Fishers Lane
Rockville, MD 20857

Re: Implementation of Executive Order 13937, "Executive Order on Access to Affordable Life-Saving Medications" (RIN-0906-AB25)

Dear Administrator Engels:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to submit comments on the notice of proposed rulemaking (NPRM) entitled "Implementation of Executive Order 13937, 'Executive Order on Access to Affordable Life-Saving Medications,'" 85 *Fed. Reg.* 60748 (September 28, 2020) issued by the Health Resources and Services Administration (HRSA).

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.

As part of the administration's effort to lower drug costs, Executive Order 13937 directs federally qualified health centers (FQHCs) to improve patients' access to insulin and injectable epinephrine. As outlined in the proposed rule, new FQHC grant awardees would be required to establish written practices to make insulin and injectable epinephrine available at or below the 340B price to individuals with low incomes who: (a) have a high cost sharing requirement for either insulin or injectable epinephrine, (b) have a higher unmet deductible, or (c) have no health insurance. (p. 60749).

If finalized, this would be the first time that HRSA has imposed a requirement for 340B covered entities to ensure that patients pay no more than the 340B-discounted price for a drug. We do not believe that any patient should be denied these, or other necessary medications, because of an inability to pay. FQHCs already are required to provide care on a sliding scale basis and

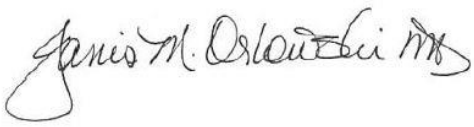
generally have programs available to provide assistance to individuals who cannot afford their medication. If the rule is finalized the major impact would be to restrict funds available to FQHCs to best meet the needs of their communities. We do not believe that was the intent of the 340B Drug Pricing Program (340B Program).

Congress created the 340B Program in 1992 under the Public Health Service Act (PHSA) to support certain safety-net providers that serve low-income, vulnerable patients. At no cost to taxpayers, the program allows these "covered entities" to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

We feel that this proposal is unnecessary. The law clearly states that health centers must ensure that no patient is denied services due to an inability to pay.[2] FQHCs are required to have policies in place to ensure affordable access to health care services. The PHSA Section 330 requirements around the Sliding Fee Discount Schedule (SFDS) state that no patient should be denied services due to the inability to pay and underinsured and uninsured patients with incomes below 200 percent of the Federal Poverty Level may be charged nominal fees for services based on the SFDS.[3] While these requirements do not explicitly apply to drugs, discounts on drugs are frequently included as they are often viewed as part of the services furnished. If a health center elects to provide its patients access to supplies or equipment, including prescription drugs, that are related to, but not included in, the service itself as part of prevailing standards of care, the health center determines how to charge its patients for the supplies or equipment such as using the SFDS to ensure affordability.[4]

Thank you for the opportunity to present our views. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

cc: Ivy Baer

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[1] H.R. Rept. No. 102-384(II), at 12 (1992)
[2] HRSA. Bureau of Primary Health Care. Health Center Program Compliance Manual. August 20, 2018. https://bphc.hrsa.gov/sites/default/files/bphc/programrequirements/pdf/hc-compliance-manual.pdf
[3] NACHC 340B Manual for Health Centers. Section Edition. Revised and Expanded, March 2018.
[4] HRSA. Bureau of Primary Health Care. Health Center Program Compliance Manual. August 20, 2018.