



**Association of
American Medical Colleges**
655 K Street, NW, Suite 100, Washington, DC 20001-2399
T 202 828 0400
aamc.org

November 20, 2018

George Sigounas
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted at <http://www.regulations.gov>

RE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 0906-AB19

Dear Administrator Sigounas:

The Association of American Medical Colleges (“the AAMC” or “Association”) welcomes the opportunity to submit this comment letter in response to the notice of proposed rulemaking, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 55135 (November 2, 2018).

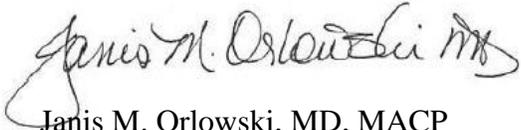
AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and 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 more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Under the Affordable Care Act the Agency was to issue regulations to implement the CMP provision within 180 days (42 USC §256b(d)). After the many years of delays, the AAMC is pleased that the Health Resources and Services Administration (HRSA) proposes changing the effective date of the 340B Drug Pricing Ceiling and Civil Monetary Penalties regulation to January 1, 2019 and fully supports this proposal. The Agency notes that the effective date and the implementation date will be the same. It is essential that the final rule become effective by that date. However, HRSA also must post the drug ceiling prices to allow hospitals to determine that they have been charged correctly by manufacturers for 340B drugs. Without the drug ceiling prices this rule will have no value as there will be no information available on which to

determine whether civil monetary penalties should be imposed. Therefore, the AAMC strongly urges HRSA to begin posting the drug ceiling prices no later than April 1, 2019.

If you need additional information, please contact Ivy Baer, ibaer@aamc.org or 202-828-0499.

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski MD". The signature is written in a cursive style with a large initial "J" and a stylized "M" at the end.

Janis M. Orlowski, MD, MACP
Chief Health Care Officer
Association of American Medical Colleges