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Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

May 21, 2018

CAPT Krista Pedley
Director, Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration (HRSA)
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

RE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, notice of proposed rulemaking; further delay of effective date (RIN 0906-AB18)

Dear Captain Pedley:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the Health Resources and Services Administration's (HRSA's) notice of proposed rulemaking entitled "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" (88 *Fed. Reg.* 20008) that further delays the effective date of the January 5, 2017 final rule (82 *Fed. Reg*. 1210) addressing the calculation of the ceiling price for 340B drugs and the application of civil monetary penalties (CMPs) on drug manufacturers. **The AAMC opposes HRSA's decision to defer the effective date of this final rule to July 1, 2019 and urges HRSA to implement the provisions on July 1, 2018 as is currently required.**

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 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.

The AAMC is dismayed that HRSA is proposing to delay yet again the effective date for the 340B regulation that increases transparency on manufacturers' calculation of the ceiling prices for covered outpatient drugs and imposes civil monetary penalties for pharmaceutical manufacturers that "knowingly and intentionally" charge a covered entity more than the ceiling price. HRSA has delayed the implementation date numerous times, now proposing to further extend the effective date to July 1, 2019. The final rule has gone through extensive rulemaking, including multiple opportunities for stakeholder input and ample time for HRSA to consider such feedback. In the proposed rule, HRSA states, "[W]e do not believe this delay will adversely affect any of the stakeholders in a meaningful way." (p. 20009). As described below, the AAMC strongly disagrees.

The 340B Program Helps Communities

Congress created the 340B program in 1992 under the Public Health Service Act to protect safety-net hospitals from escalating drug prices. The program was designed 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."

The 340B Program is a resounding success. The program offers invaluable services to vulnerable patients and their communities at no cost to taxpayers since the financial support hospitals receive is derived from drug manufacturer discounts. On numerous occasions, the administration has expressed its interest in strengthening the integrity of the 340B program, a goal we share. However, the proposed delay is inconsistent with this objective. The success of the program relies on compliance by all parties, including both covered entities and manufacturers. The further delay of the effective date of this rule means that in cases where manufacturers do not comply there is no remedy, harming the covered entities and their patients.

Ceiling Price Calculation

The 340B Drug Pricing Program allows certain safety-net hospitals and other types of providers (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers. The manufacturers' price of a drug offered to covered entities must not exceed the ceiling price. The ceiling price is calculated using the Medicaid rebate formula and is deducted from the manufacturer's selling price and not paid as a rebate. Currently, covered entities have no ability to verify ceiling prices and therefore have no way of knowing if they are being charged the correct amount for these drugs. Recognizing this shortcoming, the final rule requires drug manufacturers to submit drug pricing information directly into a secure HRSA 340B pricing system designed to calculate and verify 340B ceiling prices. Under the final regulation, covered entities would also have access to this secure database in order to confirm ceiling prices. Continued delay of the final rule inhibits the ability of covered entities to verify whether or not manufacturers' calculations of ceiling prices are correct.

Requiring manufacturers to submit drug pricing information will allow HRSA to exercise its oversight authority over manufacturers' ceiling price calculations. Overcharging by drug manufacturers for covered outpatient drugs under the 340B Program has long been problematic. The HHS Office of Inspector General (OIG) found systematic problems with the accuracy and reliability of ceiling price data. Additionally, OIG noted that HRSA lacked the oversight mechanisms and authority to ensure that 340B covered entities pay at or below the 340B ceiling price.[1] OIG found in a subsequent report that 14 percent of the sampled purchased made by 340B covered entities exceeded the 340B ceiling price.[2] Finally, OIG noted in recent testimony that this lack of transparency leaves "340B providers unable to determine whether they are paying accurate amounts to drug manufacturers."[3] **Implementing the final rule will be a major step in holding drug manufacturers accountable for ensuring covered entities are able to verify the ceiling price and that pricing for covered outpatient drugs does not exceed the 340B ceiling price.** There is no reasonable rationale for delaying its implementation yet again.

Civil Monetary Penalties

The final rule also addresses the imposition of civil monetary penalties on manufacturers that inappropriately charge a covered entity a price for a 340B drug that exceeds the ceiling price. Under the finalized rule, any manufacturer that "knowingly and intentionally" violates the program requirements by

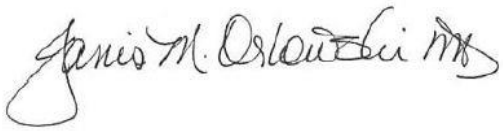
[1] Department of Health and Human Services (HHS) Office of Inspector General (OIG), Pharmaceutical Manufacturers Overcharged 340B-Covered Entities 3 (Mar. 10, 2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[2] HHS OIG, Review of 340B Prices, 10 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[3] Testimony before the United States Senate Committee on Health, Education, Labor, and Pensions. May 15, 2018. https://www.oig.hhs.gov/testimony/docs/2018/maxwell-testimony05152018.pdf

charging a covered entity more than the ceiling price would be subject to a penalty not to exceed $5,000 for each instance of overcharging a covered entity. The AAMC believes that this reasonable requirement is necessary to provide HRSA and the OIG (the entity responsible for applying monetary penalties) with the ability to hold drug manufacturers accountable for drug pricing violations. Its effective date should not be delayed.

Conclusion

The AAMC strongly urges HRSA to implement the final rule without further delay. Thank you for the opportunity to comment on this rule – "340B Drug Pricing Program Ceiling Price and Manufacturer CMP." We would be happy to work with HRSA on any of the issues discussed above, as the 340B Program remains an essential tool that allows our members to provide services to the vulnerable communities they serve. If you questions regarding our comments, please contact Mary Mullaney at mmullaney@aamc.org or 202.909.2084.

Sincerely,



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

cc: Ivy Baer, AAMC
Mary Mullaney, AAMC