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Via Electronic Submission (www.regulations.gov)

October 11, 2016

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

Re: 340B Drug Pricing Program; Administrative Dispute Resolution, RIN 0906-90

Dear Captain. Pedley:

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Health Resources and Services Administration's (HRSA's) *340B Drug Pricing Program; Administrative Dispute Resolution; Notice of Proposed Rulemaking*, 81 Fed. Reg. 53381 (August 12, 2016).

The AAMC is a not-for-profit association representing all 145 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 160,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC is pleased that HRSA, as required by the Affordable Care Act, has proposed an alternative dispute resolution process (ADR) that is limited to the resolution of: (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufactures; and (2) claims by manufacturers, after a manufacturer-conducted audit, that a covered entity has violated the prohibition on diversion to eligible patients or duplicate discounts. The proposed rule will provide covered entities with a process to address manufacturer errors, an important improvement to the 340B Drug Pricing Program. While the Association supports much of the proposed rule, we have several concerns that are described below.

The Purpose of the 340B Program

Congress created the 340B Drug Pricing Program in 1992 to allow certain safety-net hospitals (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers, using the savings "to stretch scarce Federal resources"[1] and expand health care services to

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

vulnerable populations. In the decades of the program's existence, the savings produced by the 340B program have become essential to hospitals as they struggle to meet the needs of the communities and patients they serve in an era of rapidly escalating drug prices. Hospitals use the savings from the 340B program to provide free or low-cost prescription drugs and to expand services and programs to low-income, uninsured patients.

Consistent with the original and continuing intent of the 340B program, AAMC-member teaching hospitals and their clinical faculty, residents, and students are committed to this safety net mission in expanding access to care for underserved and vulnerable patients. While they represent only five percent of all hospitals, major teaching hospitals account for 25 percent of all Medicaid discharges, 18 percent of all Medicare discharges, and 37 percent of the country's charity care. Compared with physician offices and other hospitals, major teaching hospitals provide care to a higher proportion of low-income, dual-eligible, disabled, and minority 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 seek the necessary care elsewhere. The 340B program is critical to these efforts.

AAMC's Concerns with the Proposed Rule

- **Good faith attempts to resolve disputes**. The Association appreciates that in the preamble to the proposed rule HRSA mentions that it **may request** the manufacturer to submit a written summary of attempts to work in good faith to resolve the claims of diversion or duplicate discounts against the covered entity. However, the AAMC suggests that HRSA make the submission of such a summary mandatory and further asks that the Agency review the summary to ensure that the attempts were in good faith before allowing the manufacturer's claim to proceed. To do so, HRSA must provide guidance or a list of factors that it will considering in determining what constitutes a good faith effort.
- **ADR Panel and Conflicts of Interest.** The AAMC supports having a dedicated panel of Federal experts to review the claims. We are pleased that HRSA recognizes the importance of a panel that consists of government officials who have appropriate expertise and also that processes should be put in place to ensure that panel members do not have any conflicts of interest. The AAMC suggests that names and resumes, or the equivalent, of all individual selected to serve as part of the pool of individuals who may be asked to serve on a panel, be made publicly available on the HRSA website. HRSA notes that future guidance will be provided regarding specific procedures for screening members of the panel. The guidance should be developed with input from stakeholders and be available for comment prior to being finalized. We also encourage HRSA to have a non-voting member from HRSA's Office of Pharmacy Affairs (OPA) on each panel to ensure that OPA's experience and expertise with the 340B program are available during the ADR process.
- **Timeframes for responses generally are too short.** The AAMC supports having uniform timeframes for responses in order to minimize confusion and allow all parties ample time to respond to inquiries. The AAMC supports having the party filing the claim

with HSB send written notice to the opposing party within 3 business days of submitting the claim. However, the requirement that an acknowledgement be made by the opposing party within 3 business days is too short. Both manufacturers and covered entities often are large organizations. Should the notification be sent to the incorrect office, it may take some time for the correct office/person to receive it. The party receiving the notification of the filing of a claim should have 10 business days to acknowledge its receipt. While the preamble states that confirmation of the receipt or acknowledgement of receipt [of the claim] must be made within 3 business days, there is no comparable language in the proposed regulatory text at §10.21(d)(2). The AAMC asks that (1) HRSA extend the number of days allowed for an acknowledgement and (2) insert such language into the regulatory text.

HRSA proposes 20 business days for a response to request for additional information by the party filing the claim. The AAMC suggests that 30 business days should be provided.

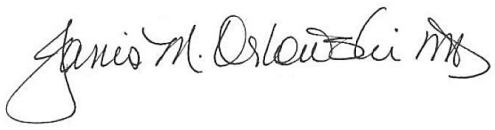
HRSA also proposes that a manufacturer may request one extension of an information request by a covered entity in writing within 15 business days of receipt of the request if the manufacturer is unable to respond by the deadline of 20 business days. The AAMC asks that HRSA limit the extension to no more than an additional 10 business days unless the manufacturer can show cause as to why more time should be provided.

- **A timeframe should be established for the ADR Panel to issue a decision.** HRSA has not proposed a timeframe for the issuance of a decision on the claim. The AAMC suggests that a decision should be issued 30 business days from the date when the submission of all requested information is complete. If the case is especially complex, a process should be established to allow for an additional 15 business days, so that the decision would be issued within 45 business days. This approach would be consistent with Medicare where the deadline for initial determination decisions is 45 days and for redetermination decisions is 60 days.
- **Response to draft agency decision letter.** HRSA proposes that the ADR Panel will send a draft decision letter to all parties and they will have 20 business days to respond. The AAMC suggests that once the responses are received, the Panel have 20 business days to issue the final decision and will, in addition to posting the decision on its website, post the responses received from the parties.
- **Decisions should not be precedential.** The AAMC asks that HRSA state that while the decision will be binding on the parties unless invalidated by an order of a court of competent jurisdiction, that the decision will not have precedential effect as each decision by the ADR Panel is specific to the facts of a particular case.

CONCLUSION

The AAMC appreciates HRSA's efforts to institute an equitable administrative process when disputes arise under the 340B program regarding overcharging, duplicate discounts, or diversion. Should you have any questions, please contact Ivy Baer at ibaer@aamc.org, 202-828-0499 or Mary Mullaney at mmullaney@aamc.org, 202-909-2084.

Sincerely,



Janis M. Orlowksi, MD., MACP
Chief, Health Care Officer

cc: Ivy Baer, AAMC
Mary Mullaney, AAMC