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January 27, 2023

Ms. Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Attention: Office of Pharmacy Affairs
5600 Fishers Lane
Rockville, MD 20857

Re: 340B Drug Pricing Program; Administrative Dispute Resolution (HHS Docket No. HRSA-2021-0004) (RIN 0906-AB28)

Dear Administrator Johnson:

The Association of American Medical Colleges (AAMC or the Association) welcomes the opportunity to submit comments on the proposed rule entitled “340B Drug Pricing Program; Administrative Dispute Resolution” 87 *Fed. Reg.* 73516 (November 30, 2022) issued by the Health Resources and Services Administration’s (HRSA or the Agency).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 157 accredited U.S. medical schools; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and nearly 80 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC’s U.S. membership and expanded its reach to international academic health centers.

The 340B Drug Pricing Program (340B Program) was created to allow certain safety-net hospitals and other providers (known as covered entities) that serve low-income, vulnerable patients to purchase covered outpatient drugs at a discount from drug manufacturers to help “stretch scarce Federal resources”¹ and expand services to these patients. Only hospitals that treat a significant share of vulnerable patients can qualify for the 340B Program. At no cost to taxpayers, the 340B Program allows safety-net providers to utilize the savings under the Program

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

to provide access to programs and services for their communities, including low-income, rural, and other underserved patients. In the decades of the Program's existence, the savings produced by the 340B Program have become essential to hospitals and other covered entities as they struggle to meet the needs of their communities and patients they serve.

The 340B Program is an important program for safety-net providers and must be safeguarded. The savings generated by the Program allow these often financially challenged providers to expand services to vulnerable populations, as the statute directs. Unfortunately, the 340B Program has been unjustly targeted as a driver of high drug prices; this is not true. Drug manufacturers set prices for drugs and often increase these prices significantly, year over year.

The Association supports the administrative dispute resolution (ADR) process as an avenue for covered entities to resolve certain disputes with drug manufacturers. We agree that the decisions of the ADR Panel should be binding on the parties; however, decisions should not be precedential. The proposed rule states that covered entities and drug manufacturers should make good faith efforts to resolve disputes. While we agree covered entities and drug manufacturers should attempt good faith efforts to resolve disputes, these efforts should not have to be exhaustive before filing a claim with the ADR Panel. Covered entities should not have to expend resources if drug manufacturers appear unwilling to participate in efforts to resolve disputes.

The comments below respond to proposals addressed in the proposed rule.

PROPOSAL: ESTABLISH A MORE ACCESSIBLE 340B ADR PROCESS

In response to comments received on previous proposed rules on the ADR process, this proposed rule seeks to establish an ADR process that is more accessible, administratively feasible, and timely. (p. 73517). The AAMC supports this goal. We applaud the Agency's acknowledgement of the significant resources that could be required to submit a claim to the ADR. Safety-net providers struggle financially and having to divert scarce resources to engage in the ADR process is often not feasible. Therefore, if a manufacturer overcharges a covered entity and does not engage in efforts to resolve the dispute, limited resources may prohibit a covered entity from submitting a claim to the ADR process. We support simplifying the process to submit ADR claims to allow all covered entities the opportunity to submit a claim.

HRSA also proposes to remove a minimum financial threshold to be able to submit a claim. The Agency previously finalized a proposal to require a minimum threshold of \$25,000 for a covered entity to submit a claim to the ADR Panel. As the proposed rule acknowledges, some covered entities are "small, community-based organizations with limited means." (p. 73517). The Association supports this proposal and urges HRSA to finalize the proposal to not require a minimum threshold to access the ADR process.

PROPOSAL: INCLUDE SUBJECT-MATTER EXPERTS ON 340B ADR PANEL

The AAMC supports having a dedicated panel of Federal experts to review claims submitted by covered entities and manufacturers. Expertise in the subject matter is essential to ensuring that the parties reach a fair resolution that correctly reflects the requirements of the 340B Program. We support the proposal that 340B ADR Panel members have specific knowledge of the authorizing statute and 340B Program operational processes. (p. 73517). We agree that including 340B Program subject matter experts on the 340B ADR Panel would be beneficial in facilitating disputes between covered entities and manufacturers. The AAMC suggests that names and resumes, or the equivalent, of all individuals selected to serve on the 340B ADR Panel be made publicly available on the HRSA website and updated at least annually.

HRSA is also proposing that the 340B ADR Panel consist of staff from the HRSA Office of Pharmacy Affairs (OPA). While the Association supports the inclusion of individuals who have significant working knowledge and experience related to the 340B Program we ask HRSA to consider the inclusion of other HRSA staff that also focus on 340B-related issues such as those who work with 340B grantees. This would have the advantage of providing a perspective on the 340B Program from staff who do not directly work on enforcement issues. We support the proposal to require OPA 340B ADR Panel members and OPA staff with specific ADR duties to undergo additional screening prior to reviewing ADR claims and to prohibit them from reviewing a claim where a potential conflict of interest may exist. (p. 73519).

PROPOSAL: PARTIES MUST ENGAGE IN GOOD FAITH EFFORTS TO RESOLVE DISPUTES

Under this new proposal, HRSA expects that covered entities and manufacturers work in good faith to resolve disputes prior to initiating an ADR claim. The proposed rule notes that the parties should engage in and *exhaust* good faith efforts to resolve disputes prior to entering into the ADR process. (p. 73516). (emphasis added). The AAMC supports the goal of resolving disputes without having to engage in the ADR process. And while we agree that efforts should be made to resolve any disputes prior to entering into the ADR process, we ask the Agency to clarify its interpretation of when good faith efforts “have been exhausted and fail.” (p. 73516). As the proposed rule acknowledges, many covered entities do not have resources that can be redirected to engage in the ADR process and if not clarified, any attempts to resolve disputes could be unnecessarily prolonged. It is important to ensure that the process does not provide an incentive for one party to claim that all efforts have yet to be exhausted as a way to delay the initiation of the ADR process.

The proposed rule seeks comment on the types of documentation covered entities should submit as part of their ADR claims reflecting good faith efforts to resolve the dispute with the drug manufacturer, such as communication records. (p. 73520-21). Documentation of good faith efforts to support covered entities claims to the ADR Panel should not be burdensome. Documented communication such as emails showing the covered entity’s attempts to discuss and resolve disputes with the manufacturer should be sufficient evidence of a good faith effort to resolve the dispute. For example, multiple emails addressing the dispute to a drug manufacturer that go unanswered should suffice. A minimum threshold of attempts should not be required

between parties. However, both covered entities and manufacturers should make more than one attempt to contact the other.

HRSA also proposes that if a manufacturer fails to respond or fully respond to a covered entity's information or document request, the ADR Panel may draw an adverse inference and proceed with the facts that have already been established in the proceeding. Further, the proposed rule notes that such adverse inference could include holding facts to those already established or precluding a party from contesting a particular issue. (p. 73522). We support the ADR Panel moving forward with a resolution in favor of the covered entity's ADR claim if it is apparent that a drug manufacturer has not engaged in the ADR process.

Finally, we urge HRSA to establish a timeline for the ADR panel's decisions. The proposed rule does not specify when decisions will be rendered by the ADR panel. We believe that ADR panel decisions should be rendered within six months but no later than one year of claim submission. Without a specified timeline for a resolution on ADR claims, 340B covered entities could be forced to wait indefinitely on claims of overcharging by drug manufacturers. Delays would further exacerbate 340B hospitals financial challenges.

PROPOSAL: ALIGN ADR PROCESS WITH 340B STATUTE PROVISIONS – DIVERSION, DUPLICATE DISCOUNTS, OVERCHARGES

The proposed rule states that HRSA considers the ADR process to be an administrative process and will be limited to disputes related to overcharges, diversion, or duplicate discounts. (p. 73516). We urge HRSA to clarify that claims can be brought to the ADR process in response to drug manufacturers' refusal to provide 340B pricing to certain covered entities and their community and specialty pharmacies or when manufacturers impose restrictions not required by the statute to receive 340B pricing. Drug manufacturers have recently shown they will defy the statutory requirements of the 340B Program by refusing to provide 340B pricing to hospitals for drugs distributed through partnerships with community pharmacies thus limiting patients' access to medically necessary prescription drugs. We understand the reluctance of HRSA to use the ADR process to cover disputes that currently are subject to litigation, such as those related to community pharmacies. However, covered entities should be able to bring these issues to the ADR process prior to any litigation.

PROPOSAL: RECONSIDERATION PROCESS FOR ADR PANEL DECISIONS

The proposed rule acknowledges that parties may be dissatisfied with the ADR Panel's decisions. HRSA is therefore proposing an administrative reconsideration of the Panel's decision by a dissatisfied party. The party requesting the reconsideration must do so in writing within 20 business days. In addition, the HRSA Administrator has the discretion to initiate a reconsideration if no request is received by the parties. (p. 73523). The Association supports the proposal. We ask that HRSA clarify the timeline for a decision of a reconsideration.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with HRSA on any of the comments discussed in this letter or other topics that involve the academic medicine community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at mmullaney@aamc.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Jaffery', with a stylized flourish at the end.

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief, Health Care Affairs

Cc: David Skorton, M.D.
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