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Krista Pedley, Pharm.D, MS
Captain, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

RE: Proposed Rule: RIN 0906-AA90, 340B Drug Pricing Program; Administrative Dispute Resolution, (Vol. 81, No. 156, August 12, 2016)

Dear Captain Pedley:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations – including 1,860 hospitals that participate in the 340B Drug Pricing Program (340B program), the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed rule that would implement the Affordable Care Act (ACA) provision requiring a binding administrative dispute resolution (ADR) process for the 340B program.

The rapidly increasing price of drugs presents hospitals and their patients with remarkable challenges. For example, the Centers for Medicare & Medicaid Services projects that while drug spending increased 2.5 percent in 2013, it will jump 12.6 percent in 2014 and an additional 8.1 percent in 2015.[1] The 340B program is a critical program that helps eligible hospitals obtain a reduced price for outpatient pharmaceuticals, thereby allowing them to stretch scarce federal resources to expand and improve access to comprehensive health care services for our nation's most vulnerable patients.

While the AHA believes that HRSA's proposed rule to establish an ADR process is an important first step for 340B hospitals and clinics that have been overcharged for drugs purchased through the program, there are several areas where we recommend the rule be amended. Chief among those areas is improving 340B hospitals' access to 340B ceiling price information.

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2015.pdf

In addition to access to 340B ceiling price information, our comments will focus on:

- Claims initiation;
- ADR panel composition;
- ADR panel decisions;
- Information requests; and
- Claims consolidation

ACCESS TO 340B CEILING PRICE INFORMATION AND CLAIMS INITIATION

HRSA's proposed rule would require hospitals to submit 340B drug ceiling price information when initiating a dispute. However, this proposal overlooks the fact that hospitals do not have access to 340B drug ceiling prices. HRSA explains that efforts are underway to develop a system that will grant 340B hospitals access to drug ceiling prices, but until that time, the agency will give the ADR panel the drug ceiling price information to evaluate a hospital's claim.[2] Not having access to the ceiling price puts 340B hospitals at a significant disadvantage because the ceiling price is central to proving that the drug manufacturer overcharged for the drug. If HRSA is able to give the ADR panel the ceiling price information, we do not understand why it would not be able to give 340B hospitals the information. **The AHA recommends that HRSA develop a fast-track process to provide 340B hospitals and other covered entities access to ceiling prices, which would help ensure a level-playing field in the dispute resolution process.**

The proposed rule also would implement the ACA requirement that drug manufacturers can bring forward claims that 340B hospitals or other covered entities violated the prohibitions on diversion to ineligible 340B patients or on Medicaid duplicate discounts. With regard to preventing Medicaid duplicate discounts, the burden has historically been placed on the hospitals. Yet, a duplicate discount occurs when a *manufacturer* provides a 340B drug to a Medicaid patient for which the state Medicaid program will seek a rebate on that same drug. There are situations that arise where the hospital or other covered entity is in compliance with all requirements to prevent the duplicate discount and, yet, the state Medicaid agency does not have the systems in place to verify claims level data to prevent triggering a rebate on a 340B claim. **The AHA recommends that HRSA specifically exclude from being a "violation" those cases in which the hospital or other covered entity is fully compliant with the requirements to prevent duplicate discounts but the state Medicaid agencies do not have the appropriate systems in place to verify 340B claims.**

[2] Federal Register, Vol. 81, No. 156, Friday, August 12, 2016, Proposed Rules p. 53383

ADR PANEL COMPOSITION

The rule proposes that the ADR panel consist of three members and one ex-officio, non-voting member to facilitate the review. The non-voting member would be a member of HRSA's office of pharmacy affairs (OPA); facilitate review and resolution of claims; and ensure adherence to 340B policies and procedures. However, if the non-voting member is intended to provide 340B expertise and professional facilitation skills, there are other options HRSA could consider to fulfill those tasks. For example, the independent federal agency known as the Federal Mediation and Conciliation Service provides dispute resolution services to interested federal agencies. In addition, the Department of Health and Human Services (HHS) has its own Alternative Dispute Resolution Division with trained mediators available to agencies within HHS. With regard to 340B expertise, the ADR panel could seek consults with OPA staff on 340B policy and procedures without having an OPA staff member on the ADR panel. **Given the available resources for mediation services and 340B expertise, HRSA may wish to consider obtaining a non-voting ADR panel member from outside HRSA and have professional mediation training.**

Additionally, the rule proposes that HRSA would choose the three voting ADR panel members from a roster of eligible individuals comprised of federal employees from the Centers for Medicare & Medicaid Services or from the U.S. Department of Veterans Affairs with demonstrated expertise or familiarity with the 340B program. The ADR panel members would be reviewed for potential conflicts of interest, would not be compensated and could be removed for cause. **The AHA supports HRSA's proposals to ensure the integrity of the process by requiring that ADR panel members be screened for conflicts of interest and be removed from the panel for cause. The AHA further recommends that the final rule clarify that HRSA has the flexibility to expand the panel beyond three members to ensure expeditious review of complex 340B claims.**

ADR PANEL DECISIONS

The proposed rule requires that the ADR process establish procedures by which 340B hospitals and other covered entities may discover or obtain information and documents from manufacturers and third parties relevant to their claim. **The AHA supports HRSA's proposal to allow 340B hospitals discovery of information and documentation from manufacturers and other third parties. We believe this would help ensure a process that is transparent and credible.**

In addition, the rule proposes that the 340B ADR panel review the documents submitted and prepare a draft agency decision letter, which would include the panel's findings and conclusions. HRSA proposes that the draft agency decision letter would be sent to all parties, who would have 20 business days to respond. The ADR panel would then prepare and submit its final agency decision; however, the proposed rule fails to specify a deadline for the ADR panel to render its decision. **The AHA recommends that the ADR**

panel be required to issue its final decision no more than 30 days from receipt of comments from the interested parties on the draft decision.

INFORMATION REQUESTS

While the proposed rule allows 340B hospitals and other covered entities to discover information relevant to their claim from drug manufacturers and other third parties, the proposal's procedures for that discovery process would not hold the manufacturer accountable for actually producing the requested information. In some cases, the manufacturer has historical pricing and purchasing data not available to the 340B hospital or other covered entities. If a manufacturer fails to comply with the information request, the ADR panel would simply rely on information contained in the original submitted claim. Given this, there is no incentive for the manufacturer to fully participate in the ADR process. **All parties must be held to the requirements of this ADR process. As such, the AHA recommends that HRSA give the ADR panel authority to issue a finding in favor of the covered entity claim if the manufacturer fails to fulfill such information requests.**

CLAIMS CONSOLIDATION

The proposed rule would implement the ACA requirement to permit the consolidation of multiple claims against the same entity brought by either the covered entities or manufacturers. The rule specifically proposes to allow organizations or associations that represent 340B hospitals or other covered entities to assert claims on behalf of their members. For manufacturers, the proposal would not permit associations or other organizations to assert claims on behalf of their members.

In general, the consolidation of claims would allow for more efficient review. **The AHA supports HRSA's proposal to allow 340B covered entity associations and organizations to assert claims on behalf of their members while prohibiting associations representing manufacturers from asserting claims.** Limiting the assertion of claims to only those organizations and associations representing covered entities is fair and reasonable given the significant resources manufacturers can bring to bear when filing claims without further outside assistance.

The AHA and our 340B member hospitals appreciate the opportunity to share with you our comments regarding the proposed ADR process. We share the common goal of ensuring that the 340B program can continue to help fulfill its original intent of helping hospitals stretch limited resources to expand and improve access to comprehensive health care services to low-income patients. To that end, we believe a well-designed dispute resolution process will help create greater transparency and go a long way to ensure a more balanced marketplace for hospitals and pharmaceutical manufacturers.

Thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Molly Collins Offner, director of policy, at mcollins@aha.org or (202) 626-2326.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President