



October 10, 2016

CAPT Krista Pedley
Director, Office of Pharmacy Affairs
Healthcare Systems Bureau
HRSA
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

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

Dear Director Pedley:

On behalf of our 71 member hospitals, health systems and other health care organizations, the Arizona Hospital and Healthcare Association appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed rule that implements the Affordable Care Act's provision requiring a binding administrative dispute resolution (ADR) process for 340B Drug Pricing covered entities and manufacturers.

AzHHA agrees with HRSA's goal to implement a 340B formal dispute resolution process, and we generally support the process proposed in the rulemaking. This includes:

- Requiring claims be brought within three years of the date of an alleged violation; and
- Permitting associations or organizations of covered entities to file consolidated claims on behalf of their members.

However, we are concerned about a few key elements of the proposed rule. We urge HRSA to amend or clarify these provisions in order to ensure fair dispute 340B resolution between covered entities and manufacturers, as well as clarify some of the requirements. Specifically, we recommend the final rule:

1. Amend the overly-broad 340B experience requirement for voting members of the 340B Panel, and retain the flexibility to appoint an appropriate amount of voting members depending on the complexity of a claim.
2. Increase the timeframe for parties to respond to draft agency decisions before a final agency decision is made.
3. Ensure that the current unavailability of ceiling prices does not preclude covered entities from meeting the documentation requirements for bringing claims of overcharge.

The following outlines our more specific comments on the proposed rule:

1. Panel Composition and Expertise

We believe the final rule should clarify the requisite experience in the 340B Program for panel members. The proposed rule states that HRSA will alternate three voting members for each individual claim from a roster of eligible federal employees with “demonstrated *expertise* or *familiarity*” with the 340B Program. Given the complexity surrounding the 340B Program, ideally each voting member should have *thorough knowledge* of the program in order to ensure a fair outcome.

Additionally, we recommend that HHS retain the flexibility to appoint a requisite number of voting members that is commensurate with the complexity of the claim. Claims brought to the 340B Panel will vary in complexity. We are concerned that particularly complex cases (e.g., those requiring consolidation) will demand considerable time and resources and may necessitate more than three voting members.

2. Draft Agency Decision Response Time Frame

We believe that a longer time frame for parties to respond to draft agency decisions is necessary to facilitate fair, efficient, and timely resolution of claims. We are concerned that given the complexity of the 340B program, the proposed 20 business days provides an insufficient time frame to respond to draft agency decisions. We recommend increasing this time frame, or alternatively, that the 340B ADR panel hear requests for extending this time frame on a case-by-case basis.

3. Insufficient Access to Ceiling Price Information

We are very concerned that our members do not have access to ceiling prices, and will consequently not be able to provide sufficient documents to

demonstrate claims for overcharge. We support HHS's effort to develop a system to verify the ceiling price of 340B drugs and allow covered entities to access this information. However, this system has not been released, and we are currently unaware of an expected date of completion. Because ceiling price information is vital to bringing a 340B claim, we request that HHS and the 340B Panel do not preclude covered entities that lack access to this information from bringing claims of overcharge while HHS's ceiling price verification system is still underway. **Alternatively, we recommend delaying the effective date of the 340B alternative dispute resolution process until HHS's ceiling price verification system has been completed.**

Thank you again for the opportunity to comment on this important rulemaking. Please feel free to contact me if you have any questions.

Sincerely,



Debbie Johnston
Senior Vice President, Policy Development