

January 30, 2023

Carole Johnson  
Administrator  
Health Resources and Services Administration  
5600 Fishers Lane  
Rockville, MD 20857

**RE: HRSA-2021-000X; 340B Drug Pricing Program; Administrative Dispute Resolution**

**Submitted electronically via regulations.gov.**

Dear Administrator Johnson,

The National Rural Health Association (NRHA) is pleased to offer comments on the Health Resources and Services Administration's (HRSA) proposed rule revising the current 340B administrative dispute resolution (ADR) process.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

We appreciate HRSA's continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

### **III. Summary of the Proposed Regulations**

NRHA thanks HRSA for its proposed revisions to make the ADR process more accessible for the essential safety net providers that participate in the 340B program. NRHA's members benefit greatly from participating in the 340B program and the savings that the program generates. Opening up the ADR process by removing some burdensome requirements ensures that less well-resourced providers can fully utilize all benefits that are part of the 340B program.

#### **Section 10.21: Claims**

##### **Subsection (a): Claims Permitted**

NRHA supports HRSA's proposed language that clarifies that claims submitted to the ADR Panel must be specific to the parties identified in the claims. This clarification aligns the ADR regulations more closely with the statutory language.

##### **Subsection (b): Requirements for Filing a Claim**

NRHA suggests that HRSA retain the proposed 3-year limitation on claims. One potential tweak that would benefit small rural covered entities is an undue hardship exception. Small rural safety net providers may be handling claims independently without outside counsel. The decision to file a claim or to understand that they are entitled to file a claim with the Office of Pharmacy Affairs (OPA) may take a considerable amount of time. Alongside other challenges that a covered entity could be facing, pulling together the needed documentation to file a claim could be burdensome. The ability for

covered entities to apply for an exception to the 3-year time bar on claims would be useful for under resourced entities.

Additionally, NRHA would like HRSA to clarify that when the Panel suspends a claim due to “the same or similar” issue pending in Federal court, this would not affect the parties’ ability to have their claim heard due to the 3-year limitation. Please see “*Section 10.23: 340B ADR Panel decision process*” below for more.

NRHA encourages finalizing the good faith effort proposal to ensure that parties are not unnecessarily engaging the Panel to hear claims that could be settled independently. However, NRHA urges HRSA to provide clarification or a more concrete definition of a “good faith effort,” especially to make clear that this effort should not be overly burdensome. Rural covered entities should not face additional burdens before the ADR process. This would be a helpful addition in the regulatory text or alternatively in guidance documents. HRSA could include examples of good faith effort negotiations to concretely show covered entities and manufacturers what evidence would suffice to prove a good faith effort. This guidance would aid parties in including documentation of a good faith effort in the filing and help parties understand what actions that they must take to resolve the violation independently.

HRSA should also be mindful of the good faith effort requirement and how it interacts with the 3-year time bar. NRHA is concerned that one party may unnecessarily extend good faith negotiations in a way that would threaten the other party’s ability to later file a claim with OPA if the good faith negotiations fall through. For example, a manufacturer that overcharged a covered entity could take advantage of the good faith negotiation requirement and ultimately block the covered entity from timely filing. As referenced earlier in this section, an undue hardship or other exception should be allowed for these situations.

NRHA supports removing the \$25,000 minimum to access the ADR process. A minimum damages amount creates a barrier for some covered entities to receive a remedy. Claims regarding violations less than \$25,000 are still significant for many small, rural covered entities and allowing them to use the ADR process creates a fair and impartial opportunity to recuperate losses and that may impact their bottom line. If HRSA retains a minimum damages amount, NRHA urges HRSA to create an exception or a lower threshold for small, rural covered entities with claims against manufacturers.

### *Section 10.23: 340B ADR Panel decision process*

#### Subsection (a)

NRHA is troubled by the Panel’s proposed authority to suspend a claim if it is “the same or similar” to an issue pending in Federal court. Covered entities should not lose their right to have their claim against a manufacturer heard because of Federal litigation that may last for years. This is especially unfair in instances where a vulnerable safety net provider was overcharged and cannot receive a remedy from the Panel until pending litigation is concluded.

The proposed regulations do not define “same or similar” as it pertains to a case in Federal court. The language in the proposed regulation at § 10.23(a) implies that the Panel has unchecked authority to decide that a claim is the same or similar. Providing a definition or clarification on what “same or similar” means may assuage concerns about parties wrongly losing their ability to engage the ADR process. Additionally, parties must submit their claims for ADR review within 3 years of the alleged violation. NRHA hopes that the Federal litigation bar on claims will not dissuade providers from filing a claim with the OPA and result in the 3-year window closing, thus HRSA should include an exception to the time bar for this situation.

Subsection (b)

Removing the use of the Federal Rules of Civil Procedure (FRCP) and Federal Rules of Evidence (FRE) is another positive step towards making ADR more accessible. Following the FRCP and FRE for the ADR process requires an understanding of the complex rules and how to apply them to the filing, which likely only an attorney can do. Covered entities will find it easier to engage in ADR without using an attorney, which is likely resource intensive for smaller safety net providers.

Reforming ADR to look and function less like a trial or legal proceeding removes some of the unequal distribution of power between covered entities and manufacturers considering that manufacturers are typically more well-resourced and able to use an attorney without significant time or financial strain.

NRHA requests that HRSA include a timeframe for ADR panel decisions at § 10.23(b). Ensuring that parties' claims are decided in a reasonable timeframe will provide certainty and guarantee that parties receive remedies in a timely manner.

Section 10.24: 340B ADR Panel decision reconsideration process.

Subsection (a)

NRHA is supportive of the reconsideration or appeals-like process. We also support the Administrator's authority to initiate a reconsideration of a claim even if parties do not do so.

Subsection (b)

NRHA suggests that HRSA consider a longer timeline for requesting reconsideration. As the proposed provisions attempt to move 340B ADR away from a formal, trial-like process, NRHA believes that parties are less likely to engage legal or outside resources to participate in ADR. With that said, NRHA urges HRSA to give parties up to 30 days to request a reconsideration so that parties are able to (1) determine that they believe reconsideration is necessary, and (2) file the request in a timely manner. For safety net providers in particular, the reconsideration process, if not the entire ADR process, would likely be handled by their own employees and not outside help. A longer timeline would be valuable for short-staffed safety net providers.

Thank you for the chance to offer comments on this proposed rule and for your consideration of our comments. We very much look forward to continuing our work together. If you would like additional information, please contact Alexa McKinley at [amckinley@ruralhealth.us](mailto:amckinley@ruralhealth.us).

Sincerely,



Alan Morgan  
Chief Executive Officer  
National Rural Health Association