THE 340B COALITION

Submitted via regulations.gov

January 30, 2023

RE: Comments on Proposed Changes to the 340B Administrative Dispute Resolution (Docket No. HRSA-2021-000X)

The 340B Coalition is writing to provide comments on the Health Resources and Services Administration's (HRSA) notice of proposed rulemaking (NPRM) proposing revisions to the agency's 340B administrative dispute resolution (ADR) process. The 340B Coalition consists of 13 national organizations representing the broad range of safety-net providers and programs that participate in 340B. We submit these comments to express support and concerns regarding the issues addressed below.

We support the following proposed changes from the 2020 Final Rule:

- **Removal of language in the agency's 2020 ADR final rule permitting manufacturers to bring ADR claims related to a covered entity's 340B eligibility and not suggesting, as the agency did in the preamble to the 2020 final rule, that manufacturers are allowed to pursue claims alleging Medicaid managed care duplicate discounts**. Such claims are clearly outside the scope of manufacturer claims permitted by the 340B statute, which limits manufacturers to claims related to diversion and Medicaid fee-for-service duplicate discounts.

- **Removal of staff from the Centers for Medicare and Medicaid Services from ADR panels**, as we believe their participation would have created potential conflicts of interest in several areas, such as Medicaid rebates, Medicare reimbursement for 340B drugs, and implementation of the Inflation Reduction Act.

- **Elimination of the $25,000 minimum claim threshold and use of the Federal Rules of Evidence and Federal Rules of Civil Procedure in ADR proceedings.** Removing these requirements increases access to the ADR for safety-net providers with limited resources.

- **Removal of language indicating that ADR panels are precedential.** By making ADR panel decision precedential, the final rule gave the ADR panel the ability to set and change policy on fundamental program issues, such as who qualifies as a 340B-elgible patient. This role for the ADR panel is inconsistent with the 340B statute and legislative history, as neither supports making ADR panel decisions precedential.

We raise the following concerns and offer recommendations:

- **HRSA should restore language from the 2020 final rule stating a covered entity can bring claims related to a manufacturer limiting the entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price.** When a manufacturer refuses to offer a 340B price for a drug or sets conditions on accessing that price, it necessarily means a covered entity must pay more for the drug than the 340B ceiling price or otherwise incur potentially costly fees to meet the manufacturer's unilaterally imposed conditions, essentially depriving covered entities true access to the statutory price.

- **We oppose HRSA's proposal to suspend ADR claims relating to an issue pending in federal court.** The proposal would significantly delay a covered entity's right to make their arguments in federal court, as well as delay their right to challenge manufacturers' illegal policies and actions in other federal courts.

- **We urge HRSA to revise the 3-year limitation period to ensure fairness for covered entities that have no access to nor right to audit manufacturer actions in setting 340B ceiling prices.** Both the proposed rule and current ADR process require claims to be filed within 3 years of the date of an alleged violation. Because the process for determining the ceiling price is confidential and covered entities have no audit rights, there is no way for covered entities to determine whether the price was calculated lawfully. We urge HRSA to clarify that the 3-year limitation period begins on the date of sale or payment at issue, except in two cases: 1) the manufacturer issues a restatement of the average manufacturer price (AMP), best price, customary prompt pay discounts, nominal prices, or other data that affects the 340B ceiling prices; or 2) the manufacturer should have issued a restatement of any of this data. In the first instance, the 3-year limit should begin on the date that the manufacturer restates the data, and, in the second instance, the 3-year period should begin on the date that the covered entity discovers that the manufacturer should have restated the data.

- **We urge HRSA to publish ADR panel decisions on the agency's website and require panel decisions to include the panel's factual and legal conclusions, including the HRSA policy or policies on which the decision is based.** This will help ensure ADR decisions are consistent with HRSA policies and that 340B stakeholders are able to understand and apply HRSA's rules and compliance expectations.

- **We urge HRSA to establish a timeframe for ADR panel decisions (e.g., 120 days).** This would help ensure that ADR claims are resolved in a timely manner.

Thank you for considering our comments.

Sincerely,

The 340B Coalition

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