340B HEALTH

Submitted via regulations.gov

January 30, 2023

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

On behalf of our over 1,400 members hospitals that participate in 340B, we are 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. We submit these comments to express support and concerns regarding the issues addressed below.

1. **We support HRSA's removing "eligibility" as a basis for manufacturer claims and urge HRSA to retain clarification that overcharge claims include the refusal to sell or conditioning the sale of 340B-priced drugs.**

The proposed regulation at § 10.21(a) states that the ADR process is limited to "claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug; and claims by a manufacturer, after it has conducted an audit of a covered entity, that the covered entity has violated the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity." HRSA is soliciting comments on whether there may be appropriate claims limitations regarding the ADR process.

We support HRSA's proposal to remove language from the 2020 final rule stating that manufacturers could bring claims related to a covered entity's eligibility. The 340B statute restricts manufacturer ADR claims to violations of subsections (a)(5)(A) or (a)(5)(B). Subsection (a)(5)(A) concerns duplicate discounts, while subsection (a)(5)(B) concerns diversion. By expressly referencing subsections (a)(5)(A) and (a)(5)(B), the statute forecloses other types of manufacturer claims. HRSA's proposal is thus compelled by the statute. The statute does not permit the ADR to address eligibility claims, and is strictly limited to diversion, Medicaid duplicate discounts, and overcharges.

We urge HRSA to reinstate language that was included in the 2020 final rule making clear that covered entities may bring an overcharge claim in situations where a manufacturer has limited the covered 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. Current manufacturer policies cutting off or conditioning access to 340B pricing

for contract pharmacy demonstrates that these types of overcharges can have a substantial negative financial impact on covered entities. It is appropriate for an ADR panel to consider these claims because such claims would be based on a violation of a manufacturer's 340B statutory obligation to provide the 340B price.

2. HRSA should make clear that duplicate discount claims involving Medicaid Managed care cannot be heard by the ADR.

The 340B statute permits the ADR to hear claims from manufacturers related to subsection (a)(5)(A). That section, which is titled "prohibiting duplicate discounts," prevents manufacturers from paying 340B discounts on drugs that are eligible for Medicaid rebates.[1] At the time of exactment, manufacturers were required to pay rebates on drugs dispensed to Medicaid patients unless that drug was paid by a Medicaid managed care organization (MCO).[2] In 2010, as part of the Affordable Care Act (ACA), Congress directed states to collect rebates on Medicaid MCO drugs, and specifically excluded 340B drugs from being subject to this new rebate requirement.[3] Notably, Congress did not amend the duplicate discount provisions of the 340B statute to require that subsection (a)(5)(A) apply to all Medicaid drug claims, even those that are not eligible for a rebate. Thus, these claims are not subject to the ADR process.

Because federal law puts the onus on states to avoid obtaining rebates on Medicaid MCO 340B claims, it is the state, not the federal government, that has the authority to ensure compliance with that provision. States may impose and enforce requirements on covered entities relating to identifying claims, but enforcement of state rules is not permitted under the 340B statute, so such enforcement cannot be part of ADR.

We firmly support efforts to ensure that manufacturers do not pay a 340B discount and a Medicaid rebate on the same drug, and we support having all stakeholders working to ensure that this does not occur. Issues relating to Medicaid MCO claims, however, simply cannot be heard by ADR panels.

3. ADR panels should not consider allegations of duplicate discounts unless the manufacturer provides evidence that a rebate was paid on a 340B drug claim.

We request that HRSA exclude from potential ADR claims circumstances when a manufacturer did not pay a rebate to the state Medicaid agency for the drug. The manufacturer should be required to show evidence from the state Medicaid agency that the agency received a rebate, and the manufacturer should be required to submit that documentation with its claim as a

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[1] 42 U.S.C. § 256(a)(5)(A).

[2] See Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, § 4401 104 Stat. 1388, 1388-143 to -159. This is the subject to the mechanism described above, whereby a state may not collect a rebate covered outpatient drugs purchased at the 340B price.

[3] "[C]overed outpatient drugs **are not subject to the requirements of this section** [i.e., not subject to a rebate] if such drugs are . . . (A) dispensed by health maintenance organizations including Medicaid managed care organizations [(MCOs)]. . . and (B) subject to discounts under section 340B of the Public Health Service Act." Patient Protection and Affordable Care Act, Pub. L. 111-148, §2501(c), 124 Stat. 119, 308 (2010). 42 U.S.C. § 1396r-8(j)(1) (emphasis added). To ensure that states have the data needed to avoid rebates on 340B Medicaid MCO claims, Congress amended statutory contracting rules for MCOs to require MCOs to exclude National Drug Codes for 340B drugs from the reports they provide to states. 42 U.S.C. § 1396b(m)(2)(A)(xiii). The Centers for Medicare and Medicaid Services (CMS) issued a final regulation in May 2016 to implement this statutory requirement. 81 Fed. Reg. 27,498 (May 6, 2016). The regulation mandates that states contractually require Medicaid MCOs to identify and exclude 340B claims from the utilization reports they provide for purposes of requesting Medicaid rebates, or require covered entities to submit 340B claims data directly to the state instead of MCOs. *Id*. at 27,546–49; codified at 42 C.F.R. § 438.3(s)(3).

condition for HRSA to approve the sufficiency of the alleged duplicate discount claim. Covered entities should not be required to repay 340B discounts to manufacturers if the manufacturer has not, in fact, paid a duplicate discount. The only entity that can definitively verify whether a state Medicaid agency received a rebate for a drug is the state Medicaid agency. The manufacturer should bear the burden to show evidence from the state Medicaid agency confirming that it received rebates on the drugs at issue.

4. HRSA should not permit suspension of ADR claims that relate to an issue pending in federal court.

We oppose HRSA's proposal to suspend ADR claims that relate to an issue pending in federal court. As demonstrated by the current contract pharmacy litigation, challenges to a government action are not necessarily determined by a single federal court. ADR panel decisions regarding claims could be filed in many different federal courts, and each court could reach a different outcome. Suspending a claim because the issue is before a single federal court prevents covered entities from promptly pursuing claims in their own jurisdictions, as they have a right to do under the 340B statute. In addition, federal law governing legal challenges of final agency actions provides the challenging party a choice of venues.[4] Thus, an issue relevant to an ADR proceeding may be pending in several district courts, and the decisions of those courts may diverge and not achieve a final consistent resolution of the issue. Since the ADR process is the sole avenue for covered entities to challenge drug companies' unlawful behavior, a significant delay in moving forward with a claim could be devastating for a covered entity and prevent it from making its arguments on how the issue applies to the facts in its situation.

We urge HRSA to revise this provision to allow suspension of a claim only if requested by the party bringing the claim. In that situation, the covered entity is deciding to delay its right to pursue a claim, rather than the government taking that right away. A similar policy is currently in use by the Provider Reimbursement Review Board (PRRB), a Department of Health and Human Services (HHS) administrative adjudicative body.[5] If HRSA moves forward with the policy to suspend claims despite our strong concerns, at the very least HRSA should elaborate on the factors used to determine whether the issues are similar, including defining "similar" to ensure suspension is not overly broad.

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[4] Federal district courts have jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. This type of jurisdiction is known as federal question jurisdiction and provides the basis for district court jurisdiction over actions for judicial review of final agency action under the Administrative Procedure Act (APA) when jurisdiction is not provided under a separate statute, such as the Medicare statute. The related general venue statute, 28 U.S.C. § 1391, provides that a civil action, "in which a defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, or the United States,"may be brought, "except as otherwise provided by law," in any judicial district in which a defendant resides, "a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated," or the plaintiff resides where no real property is involved. 28 U.S.C. § 1391(e)(1). This general venue statute allows a plaintiff challenging a final agency action the option of pursuing its challenge in the district court where the plaintiff is located, which means that agency decisions involving similar issues, but different parties may be challenged and litigated in different district courts.

[5] Under the PRRB's rules, a party to the appeal may request that the appeal be held in abeyance, which "suspends action on an appeal until specified events occur or conditions are met." If the request is based on final disposition of another pending case, the party must explain why the pending case is relevant and provide the case caption, the case number, the court where the case is pending, and the status of the case. See Provider Reimbursement Review Board (PRRB) Rule 39, https://www.cms.gov/files/document/current-prrb-rules-v-31-board-order-no-2-november-1-2021.pdf.

Parties should also be permitted to challenge HRSA's decision to suspend a claim. We recommend that the ADR panel provide the parties notice and an opportunity to weigh in on the issue. This would create an administrative record that could be reviewed by a federal court if the claimant decides to appeal the ADR panel's decision to suspend. An ADR panel's decision to suspend a claim should constitute final agency action that can be challenged in federal court.

6. We support proposed changes that would limit conflicts of interest of ADR panelists.

We support HRSA's proposal to remove representatives of Centers for Medicare and Medicaid Services (CMS) from ADR panels, as we believe their participation would have created potential conflicts of interest.

CMS has a fiduciary duty to the Medicare Trust Fund and to the impact proposals may have on Medicaid spending. These duties could conflict with 340B in several areas, such as Medicaid rebates, interpretation of covered outpatient drug, and implementation of the Inflation Reduction Act, to name a few. Such conflicts of interest are not appropriate for members of the ADR panel, which requires objectivity.

We support CMS' removal from ADR panels and request CMS not be considered for ADR panels if HRSA expands potential panelists to professionals outside of OPA in the final rule. We urge to consider a panelist from the HHS Office of General Counsel, as such representatives have additional experience with legal statutory interpretation and Administrative Procedure Act (APA) rules, which could be helpful for the matters that would be considered by the ADR panel.

7. We support proposed changes that would improve access to the ADR process.

We appreciate HRSA's proposal to eliminate the $25,000 minimum claim threshold and use of the Federal Rules of Evidence (FRE) and Federal Rules of Civil Procedure (FRCP) in ADR proceedings. Removing these requirements increases access to the ADR for safety-net providers with limited resources. About half of 340B hospitals are critical access hospitals (CAHs), the majority of which serve rural communities. Since 2005, more than 184 rural hospitals have closed, and many remain vulnerable to closure.[6] 74 percent of CAHs have reported needing 340B savings to keep their hospital doors open.[7]

COVID-19 and manufacturer restrictions on community and specialty contract pharmacies have further strained hospitals. 340B disproportionate share hospitals (DSH) saw a significant decline in operating margins from -3.5% in FY 2019 to -6.1% in FY 2020.[8] Hospitals continue to experience growing financial losses from drug companies' unlawful 340B restrictions, with

[6] The Cecil G. Sheps Center for Health Services Research, Rural Hospital Closures, https://www.shepscenter.unc.edu/programs-projects/ruralhealth/rural-hospital-closures/.
[7] 340B Health, 2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on Hospitals (2021), www.340bhealth.org/2021survey.
[8] Dobson DaVanzo, 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress (2022), https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf.

median annualized 340B hospital losses more than doubling since the end of 2021.[9] Hospitals cannot consistently incur financial losses and continue to provide essential services, making 340B program savings critical to the continued existence of DSH hospitals. Financially constrained providers may not have resources to hire an attorney to help navigate the complicated FRE and FRCP. Twenty-five thousand dollars can create significant financial burdens for providers with limited resources. We support HRSA's proposed procedural changes that remove hurdles to bringing claims that could result in the ADR process being inaccessible to many providers.

8. **To ensure that HRSA's proposed 3-year statute of limitations is fair, we ask the agency to clarify that the time limit for an overcharge claim could begin on a date a manufacturer issues or should have issued a price restatement.**

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. Using a different starting point protects covered entities from manufacturer overcharges that occur before a covered entity could reasonably know that an overcharge occurred. For example, the drug companies Wyeth and Pfizer agreed to pay $784.6 million for knowingly reporting to the government false and fraudulent best price data on two of its proton pump inhibitors.[10] The overcharges occurred between 2001 and 2006, but the settlement agreement was not released until April 27, 2016. Beginning the 3-year limitation period as proposed in these circumstances protects covered entities' right to pursue overcharges claims using ADR and should not cause any hardship to manufacturers because each manufacturer is required to retain for ten years any records supporting its calculations of AMP, best price, customary prompt payment discounts, and nominal prices.

9. **HRSA should implement several requirements for ADR panel decisions that will ensure the ADR process is fair and expeditious.**

We propose several changes to the proposed rule that will create transparency, fairness, and efficiency in the ADR process. We support HRSA making ADR panel decisions non-precedential and support ADR panel decisions following current HRSA 340B policies to allow greater consistency. We recommend ADR panels adhere to a 120-day decision-making timeframe and

[9] 340B Health, Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patient (May 2022), https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf.
[10] U.S. Department of Justice, Wyeth and Pfizer Agree to Pay $784.6 Million to Resolve Lawsuit Alleging That Wyeth Underpaid Drug Rebates to Medicaid (Apr. 2016), https://www.justice.gov/opa/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug-rebates.

urge HRSA to require written ADR panel decisions explaining the reasoning for the decision. HRSA should make decisions or a detailed summary of decisions publicly available to educate stakeholders. HRSA should clarify that the APA will govern judicial challenges to ADR panel decisions.

a. We support HRSA making ADR panel decisions non-precedential.

Nothing in the ADR allows binding decisions on non-parties. We support HRSA excluding from the proposed rule language in the 2020 final rule indicating that ADR panels are precedential. By making ADR panel decisions 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. The 340B statute clearly states that ADR panel decisions are "binding upon the parties involved," not to non-parties in the future. The 340B law contains no language suggesting decisions should be precedential so as to bind other parties in other cases.

The statutory language is consistent with the law's legislative history. The inclusion of provisions in the ACA to create a 340B ADR process followed calls for an ADR process during a 2005 hearing of the House Energy and Commerce Committee's Oversight and Investigations Subcommittee. The hearing witnesses called for an ADR process to resolve disputes between specific parties.[11] There is no indication that they were seeking the establishment of a new body to develop broad 340B policies through precedential decisions.[12]

b. ADR panel decisions should be published.

HRSA should post on its website entire decisions or at least decision summaries omitting party names. The PRRB appeals process provides a good example for publishing decisions, as CMS publishes both PRRB and CMS Administrator decisions on the agency's website.[13] Publishing ADR panel decisions or the rationale for these decisions could help to educate stakeholders on HRSA policies and expectations.

ADR panels should also provide detailed decisions. We request that HRSA, consistent with the APA, require ADR panel decisions to include a "statement of findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the

[11] Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, Hearing Before the Subcomm. on Oversight and Investigations of the H. Committee on Energy and Commerce, 109th Cong., H. Hrg. 109-108 (2006), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG109hhrg30139.pdf.

[12] For example, the Public Hospital Pharmacy Coalition (PHPC) recommended the "institution of an administrative process to resolve disputes between covered entities and manufacturers relating to 340B prices and purchases that culminates in a final and judicially reviewable agency decision." The PHPC called for an ADR process "through which covered entity and manufacturer contentions and evidence of a 340B price dispute would be reviewed and adjudicated by a federal agency decisionmaker, who issues a final agency decision respecting the controversy. Formal, duly promulgated regulations would be the preferable means of defining and establishing such procedures, so that the agency's decision pursuant to the process would have legally binding effect on the parties in the absence of further review by a court." Id. at 48-49 (testimony of William von Oehsen).

[13] PRRB decisions dating back to August 27, 1997 are available on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/List-of-PRRB-Decisions. PRRB decisions regarding jurisdiction over an appeal, dating back to August 2013, are available on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/List-of-PRRB-Jurisdictional-Decisions. CMS Administrator decisions upon review of a PRRB decision, and declinations of review by the CMS Administrator, dating back to December 19, 2002, are available on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/OAA-Decisions.

record."[14] These details will inform the parties of the basis for the ADR panel's decision, provide for effective judicial review of the decision, and help stakeholders better understand HRSA's rules and compliance expectations.

c. We recommend the final rule provide ADR panels 120 days to submit final decisions.

Both the current ADR process and the proposed rule do not include a time limit for ADR panel decisions. Our comments on the 2016 proposed rule outlined our concerns about not having a deadline for ADR panel decisions. We recommended that the ADR panel be required to submit a draft ADR panel decision to the parties within 120-days after briefing has concluded and a final decision to the parties within 30-days after the end of the period for the parties to review the draft decision and provide input.[15] HRSA commented on this issue in that 45 days was too short a period. We recommend that HRSA revisit our proposal and require ADR panels to submit final decisions to parties within a 120-day timeframe. This is a reasonable timeframe that is longer than the 90-day timeframe that Medicare administrative law judges are subjected to for Medicare claims appeals.[16] We also request HRSA clarify that, if an ADR panel does not issue a decision within 120-days, a claimant can bypass the ADR process and proceed to federal court.

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Thank you for considering our comments.

Sincerely,

Maureen Testoni
President and CEO

[14] 5 U.S.C. § 557(c)(3)(A).
[15] Comments on Proposed Rule, 340B Drug Pricing Program; Administrative Dispute Resolution Proposed Rule, 81 Fed. Reg. 53,381 (Aug. 12, 2016), https://www.340bhealth.org/files/Joint_ADR_Proposed_Rule_Comments-Final-10.11.16.pdf.
[16] 42 C.F.R. § 405.1016.