Howard Brown Health

January 30, 2023

Michelle Herzog
Deputy Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W12
Rockville, MD 20857

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

Deputy Director Herzog,

I am writing on behalf of Howard Brown Health, a federally-qualified health center located in Chicago, IL. Howard Brown is the largest LGBTQ+ health center in the Midwest, serving more than 30,000 patients across eleven clinic locations in Chicago. Howard Brown serves adults and youth in its diverse health and social service delivery system focused around seven major programmatic divisions: primary medical care, behavioral health, research, HIV/STI prevention, youth services, elder services, and community initiatives. As a federally qualified health center, Howard Brown provides services regardless of a patient's ability to pay or insurance status.

As a covered entity participating in the 340B drug discount program, we write to express concerns with the rule proposed by the Health Resources and Services Administration (HRSA) for the 340B program Administrative Dispute Resolution (ADR) process. The rule, proposed on November 30, 2022 (Proposed Rule),[1] would replace the regulations promulgated by HRSA on December 14, 2020 (Current Rule).[2]

The 340B program is critical to our ability to provide comprehensive services to our medically underserved and often uninsured or underinsured patients. The savings and resources we generate by participating in the 340B program allow us to provide the services our patients most need and for which there is no other source of funding. At Howard Brown, 340B savings have helped us to develop and expand our youth development, dental, client assistance, and behavioral health services. As the largest LGBTQ+ health center in the Midwest, our 340B savings have been especially critical for supporting our gender affirming care, HIV case management, and youth housing programs.

[1] 340B Drug Pricing Program; Administrative Dispute Resolution, 87 Fed. Reg. 73,516 (Nov. 30, 2022).
[2] 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (creating 42 C.F.R. Part 10, Subpart C.

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All of these services are critical for the health and well-being of our patients. Like our fellow health centers, we strive to follow all 340B program requirements, and expect the same of all other covered entities and participating drug manufacturers.

For the first 18 years that the 340B program was in operation, we had no way to bring claims directly against drug manufacturers who we believed were overcharging for 340B drugs. Congress rectified that concern in the Affordable Care Act, mandating that HRSA establish an ADR process that would allow covered entities who believe they are being overcharged for covered outpatient drugs to bring a complaint directly against a manufacturer before a decision-making body.[3] The Supreme Court of the United States described the ADR process as the sole remedy for covered entities participating in the 340B program, writing that:

Congress did not respond to the reports of inadequate HRSA enforcement by inviting 340B entities to launch lawsuits in district courts across the country. Instead, in the [Patient Protection and Affordable Care Act], Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities "complaining of overcharges and other violations of the discount pricing requirements" and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the [Administrative Procedure Act].[4]

Thus, the ADR process is covered entities' "proper remedy" to enforce 340B program pricing requirements. It is our only remedy, and we need to be able to access it without unnecessary barriers. With that context, our comments are organized into the following sections. I. Accessibility of the ADR Process; II. Other Recommendations Enhance Entity Access to the ADR process and justice.

I. Accessibility of the ADR Process

We support HRSA's proposals to make the ADR process more accessible. Because the ADR process is our sole venue for bringing complaints against manufacturers, due process requires that the barrier for entry be as low as possible while still allowing HRSA to maintain an efficient and effective process.

[3] 42 U.S.C. § 256b(d)(3).
[4] *Astra USA, Inc. v. Santa Clara Cty.*, 131 S.Ct. 1342, 1350 (2011) (internal citations omitted) (quoting 42 U.S.C. § 256b(d)(3)(A).

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First, we applaud the agency's proposal to remove the minimum threshold of $25,000 at issue in order to bring a claim. As noted in the preamble to the Proposed Rule, parties should be judicious in seeking a hearing before the ADR panel "given the time and resource investment required of the parties involved." We agree that the time and resource investment needed to bring a claim serves as its own threshold, and that neither covered entities nor manufacturers will bring spurious matters before the panel.[5] If a covered entity or covered entity representative chooses to bring a lower value claim, it is likely because the complained of behavior could expand in the future in a way that would be injurious to covered entities. Covered entities should not have to wait until their budgets and services are disrupted to obtain clarity and enforcement. We support the removal of a minimum threshold altogether.

Second, we support HRSA's proposal to make the ADR process less formal and less reliant on the Federal Rules of Evidence and Federal Rules of Civil Procedure.[6] This will make the submission process less formal and more accessible to covered entities acting on their own behalf. Both sets of rules can be highly technical and require the assistance of an attorney to navigate. Covered entities should be able to bring disputes that are primarily factual in nature directly, without the assistance of counsel. We also anticipate that there will be issues that require legal interpretation, and the parties might wish to be represented by counsel when an interpretation of the statute is required. We feel the nature of the dispute rather than the process itself should determine whether legal assistance is required.

Lastly, we appreciate the creation of a reconsideration process, in which the HRSA Administrator can review a decision by an ADR Panel. As HRSA noted, the decision to bring a matter before an ADR Panel requires a significant commitment of time and resources. Appealing an ADR Panel's decision under the Current Rule requires a far greater commitment, as the only mechanism is to seek judicial review of the decision in federal court.

II. Other Recommendations Enhance Entity Access to the ADR Process and Justice

HRSA should reconsider other aspects of the Proposed Rule and to provide meaningful covered entity access to the ADR process and justice. The ADR process should focus on allowing covered entities to have access to a venue to bring overcharge complaints against drug manufacturers. Because covered entities cannot participate in any judicial process to enforce the requirements of the 340B statute, the ADR process and rules should favor easy

[5] *See* Proposed Rule at 73,517.
[6] *Id.*

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access for covered entities. In that spirit, we propose the following changes to the Proposed Rule.

1. **We recommend that HRSA define the word "overcharge" for purposes of the ADR process to include the refusal to sell drugs at 340B pricing or refusal to sell drugs at 340B pricing unless onerous conditions are met.**

The statute directs HRSA to establish the ADR process "for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section…"[7] The term "overcharge" should include an attempt to collect a price in excess of the 340B ceiling price for a covered outpatient, any attempt to cause a drug wholesaler to decline to offer 340B pricing on a covered outpatient drug to a covered entity, and any refusal by a manufacturer to sell a covered outpatient drug at 340B pricing. Further, the covered entity should not be required to make an over-priced purchase to establish that it is being overcharged.

Such a definition would be consistent with the statute. The word "charge" is defined in the context of the sale of goods to mean "to fix or ask as fee or payment" or "to ask payment of (a person)."[8] The words "charge" and "overcharge" do not necessarily include an actual purchase – it is enough to ask. Further, "drugs purchased under this section" must mean "covered outpatient drugs." The definition could not be limited to drugs that the seller classifies as "340B drugs" because any covered outpatient drug for which a manufacturer is asking for (i.e. "charging") more than the 340B ceiling price is not a 340B drug. In the context of a mechanism for challenging overcharges, "drugs purchased under this section" must refer to the type of drugs that can be purchased under Section 340B of the Public Health Service Act – "covered outpatient drugs" generally.

We propose this definition:
Overcharge means (1) to ask for payment in excess of the ceiling price for a covered outpatient drug; or (2) to cause a drug wholesaler to ask a covered entity for payment in excess of the ceiling price for a covered outpatient drug, and includes any refusal to make drugs available for purchase at the ceiling price directly or through a drug wholesaler.

2. **We recommend HRSA allow organizations representing the interests of all covered entities or a class of covered entities to bring combined claims on behalf of all members.**

[7] 42 U.S.C. § 256b(d)(3)(A).
[8] http://www.Merriam-Webster.com/dictionary/charge.

The Proposed Rule should be amended to allow associates to bring claims on behalf of all members, and not just those that individually sign onto a filing. The 340B statute instructs HRSA to create provisions that:

[P]ermit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.[9]

The Proposed Rule limits claims brought by associations and organizations representing covered entities to represent only those covered entities that "consent" to the claim being asserted on their behalf as indicated by individual covered entity signatures.[10]

We believe the Proposed Rule creates limitations that are not found in the statute. The criteria for inclusion in an organizational claim in the statute is merely membership in the organization. We believe that associations should be able to bring claims on behalf of all members, and not just those that affirmatively sign onto the complaint. There is no downside risk to being represented in an overcharge filing – either the filing is successful, and the members receive relief, or it is not and nothing changes. Further, Congress presumably permits covered entities to be represented by associations in overcharge claims because it wanted to allow covered entities (safety net providers) to access the process more easily. Requiring each member of an organization (some of which, like NACHC and 340B Health, having hundreds of members) introduces unnecessary resource and time commitments – to evaluate the filing and decide whether or not to file – and could add significant delay to the filing of claims that are quite time sensitive. We oppose an affirmative "sign-on" requirement for organizational claims.

3. We recommend eliminating the proposed "suspension" of the ADR process when similar claims are being litigated

HRSA is proposing to suspend the ADR process if "a specific issue that would be brought forth in a claim is the same as or similar to an issue that is pending in Federal court…until such time the issue is no longer pending in Federal court." We strongly oppose that provision because we have no way to participate in any litigation relating to similar issues. Congress created the ADR process as covered entities' sole avenue for bringing claims against manufacturers. By suspending the ADR process when an issue is being litigated by

[9] 42 U.S.C. § 256b(d)(3)(B)(vi).
[10] Proposed Rule at 73,526.

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HRSA and manufacturers, HRSA would be essentially silencing the covered entity community with respect to the issue.

Further, allowing the ADR process to proceed would not violate any rights of the agency or manufacturers. Since covered entities cannot be party to any federal litigation involving overcharges, there could not be any argument that covered entities are precluded (or estopped) from bringing a similar claim before an administrative tribunal. The issue has not been litigated by the same parties before. Second, the ADR process would not prejudice the agency in any ongoing court proceedings. If anything, it would allow the agency to provide a more reasoned basis for its position than might already be in the administrative record for the litigation. Just in the last two years, we have seen time and time again that courts have complained that HRSA's reasoning regarding the sale of drugs to covered entities when those drugs will be dispensed by contract pharmacies has been lacking. The ADR process would allow the agency to flesh out its reasoning.

Perhaps most importantly, the 340B statute provides HRSA with enforcement tools in the context of ADR resolution that are less clear in other areas of the statute. In the context of ADR enforcement, HRSA can include "appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process."[11] HRSA should use the powers that Congress delegated to it and not defer to other processes in other venues that could drag on for years.

4. We recommend that HRSA remove the "good faith effort" requirement before filing a claim

We agree that covered entities and manufacturers should always endeavor to resolve overcharge and similar issues in good faith before resorting to the ADR resolution process. We disagree, however, with the requirement that a party show good faith efforts at resolution before bringing an ADR claim. As HRSA noted, bringing an ADR claim requires substantial dedication of time and resources – that alone is a sufficient barrier to entry. We disagree with the need to show good faith efforts at resolution because the act of overcharging a covered entity might not be an act of good faith. If the manufacturer makes a mistake, good faith efforts will be appropriate, and any covered entity would pursue them. If the manufacturer announces a new policy that indicates it will refuse to honor 340B pricing, covered entities should not be required to engage in futile and time-wasting good faith efforts with a party acting in bad faith. The good faith requirement is unnecessary and potentially harmful to claimants. Further, we think a "good faith effort"

[11] 42 U.S.C. § 256b(d)(3)(A).

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prerequisite to filing puts HRSA in the impossible position of determining whether an attempt at resolution was made in "good faith."

Howard Brown Health would like to thank you for this opportunity to present comments on the Proposed Rule. While these are not our only thoughts on the proposed process, we focused on those that increased our ability to access the ADR process in a way that allows health centers and other covered entities to have a meaningful venue to bring overcharge claims against manufacturers that are not honoring their 340B ceiling price obligations. If you have any questions, please contact Tim Wang, Director of Policy and Advocacy, at timothyw@howardbrown.org.

Sincerely,

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