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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 write on behalf of the AIDS United 340B Working Group (Working Group), a national coalition of 11 Ryan White clinics, some of which are also federally qualified health centers. Each member of the Working Group is a "covered entity" participating in the 340B drug discount program. Members of the Working Group advance health equity across the country by providing HIV prevention and care and other necessary health care and supportive services to the people in communities harmed by systemic barriers. Collectively, Working Group members provide care and services to more than 100,000 people across 11 states and the District of Columbia.

The Working Group writes to share its 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 necessary health care to underserved patients. The savings and resources that result from our participation in the 340B program allow us to provide services our patients need most and for which there is no other source of funding. Also of critical importance, the 340B program directly enables us to help end the HIV epidemic in the United States by allowing us to provide to our patients access to prescriptions like Pre-exposure Prophylaxis, testing, and other holistic care like transportation assistance and food pantries. Without 340B, many HIV service organizations will not be able to operate, meaning that millions of Americans living with and most at-risk of contracting HIV will not have access to needed care.

The ADR process is a relatively new mechanism for covered entities to bring before a decision-making body claims made directly against drug manufacturers alleged to have overcharged for 340B drugs. Before Congress mandated establishment of the ADR process in the Affordable Care Act, covered entities had no

[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.

method to seek recourse against overcharging drug manufacturers. In 2011, the Supreme Court of the United States acknowledged the ADR process as the exclusive remedy for covered entities participating in the 340B program.[3]

The ADR process is covered entities' only remedy to challenge drug manufacturers believed to have overcharged for 340B drugs. The Working Group supports the provisions of the proposed rule that enhance access to the process and strongly opposes other provisions in the proposed rule that, in fact, serve to reduce access to the ADR process.

I. The Working Group supports the provisions in the Proposed Rule that would enhance access to the ADR process.

Because the ADR process is the only mechanism by which covered entities can challenge manufacturers, the ADR process itself must be accessible to covered entities. Some components of the proposed rule do in fact enhance accessibility to the process. We specifically support the proposals to remove the minimum threshold of $25,000 at issue to bring a claim; make the process less formal and less reliant on the Federal Rules of Evidence and Federal Rules of Civil Procedure; and create a reconsideration process.

First, we believe that removing the minimum threshold of $25,000 at issue to bring a claim does not jeopardize the Agency's interest – which we share – in preventing frivolous or illegitimate claims. The preamble to the Proposed Rule seemingly acknowledges that the process of bringing a claim is itself resource and labor intensive. We do not believe an additional dollar threshold adds a meaningful layer of additional protection against baseless claims. Additionally, we agree with the Agency's proposal to make the ADR process less reliant on Federal Rules of Evidence and Civil Procedure. Because the ADR process is the only avenue for defending against an overcharging manufacturer, we believe it should be available to *all* covered entities, not just those that can afford legal representation required to navigate the Federal court system. Lastly, we support the creation of a reconsideration process by which a decision by an ADR Panel may be reviewed by the HRSA Administrator, instead of a federal court per the Current Rule.

II. The Working Group asks HRSA to reconsider provisions in the Proposed Rule that would restrict access to the ADR process.

Because no judicial process is available to covered entities seeking to enforce the requirements of the 340B statute, it is of paramount importance that covered entities easily be able to access the ADR process to seek relief from allegedly overcharging drug manufacturers. The following recommendations seek to maximize access to the ADR process:

1. Permit organizations representing all covered entities or a class of covered entities to bring claims on behalf of all members.

The agency should revise the Proposed Rule to allow associations and organizations to bring claims on behalf of all members, not just those that individually sign onto a filing. The Proposed Rule permits claims brought by associations and organizations representing covered entities to

[3] *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).

represent *only* covered entities that "consent" to the claim being asserted on their behalf as indicated by individual covered entity signatures.[4] The 340B statute itself, however, directs HRSA to:

> [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.[5]

It thus appears that the Proposed Rule creates limitations not included in the statute; the statute permits *any* member of an organization to be included in the organization's claim. We believe that associations and organizations should be permitted to bring claims on behalf of *all* members, not just those that sign onto the complaint.

2. Eliminate the proposal to suspend the ADR process while similar claims are being litigated.

The agency should eliminate proposed language that would suspend the ADR process when an issue included in an ADR claim is the same as or similar to an issue pending in Federal court. This requirement is harmful to covered entities because there is no mechanism for us to participate in litigation relating to similar issues. Rather, our exclusive avenue for bringing claims against manufacturers *is* the ADR process. Pausing the ADR process when an issue is being litigated by HRSA and manufacturers effectively suppresses the covered entity community with respect to the issue. Importantly, allowing the ADR process to continue during litigation in Federal court does not prejudice or harm the rights or legal standing of the agency or manufacturers and also facilitates due process for covered entities.

3. Eliminate the "good faith effort" requirement before a covered entity files a claim.

The agency should eliminate the requirement that a covered entity must demonstrate it has taken good faith efforts to resolve a claim that the manufacturer overcharged for 340B drugs. As covered entities, Working Group members commit to working to resolve potential overcharge claims outside of the ADR process and to invoke the ADR process only when pre-ADR efforts fail and harm continues to occur. The ADR process itself requires an investment of time and resources and should in and of itself act as a filter for frivolous claims.

Importantly, requiring a covered entity to demonstrate it has made a good faith effort at resolution ignores the manufacturer's motive for an alleged overcharge which itself may not be in good faith. It is the position of the Working Group that manufacturer policy changes that refuse to honor 340B pricing are implemented in bad faith.

4. Define "overcharge" to include the refusal to sell drugs at 340B pricing or refusal to sell drugs at 340B pricing unless onerous conditions are met.

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[4] Proposed Rule at 73,526.

[5] 42 U.S.C. § 256b(d)(3)(B)(vi).

The 340B statute requires 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…"[6] We agree with the National Association of Community Health Centers' (NACHC) submission that the term "overcharge" should include an attempt to collect a price in excess of the 340B ceiling price for a covered outpatient drug, any attempt to cause a drug wholesaler to decline to offer to a covered entity 340B pricing on a covered outpatient drug, and any refusal by a manufacturer to sell a covered outpatient drug at 340B pricing. The definition proposed by NACHC is not inconsistent with the 340B statute, which does not require an actual purchase to be made in the context of the terms "charge" and "overcharge". Rather, it is simply enough to ask for payment to be made.

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On behalf of the Working Group's 11 members, thank you for the opportunity to comment on the Proposed Rule. If you have any questions or would like to learn more about our position, please contact Daphne Kackloudis, AIDS United 340B Working Group Facilitator, at dkackloudis@aidsunited.org.

Sincerely,

AIDS United
APLA Health
Crescent Health
DAP Health
Equitas Health
Fenway Health
Howard Brown Health
Legacy Community Health
Los Angeles LGBT Center
San Francisco AIDS Foundation
Vivent Health
Whitman-Walker Health

[6] 42 U.S.C. § 256b(d)(3)(A).