



ADVOCATES FOR
COMMUNITY
HEALTH

January 30, 2023

Michelle Herzog

Acting Deputy Director of Pharmacy Affairs

Health Resources & Services Administration (HRSA)

US Department of Health and Human Services

ATTN: HHS Docket No. HRSA-2022-0001 (HRSA-2021-000X); RIN 0906-AB28

5600 Fishers Lane

Rockville, MD 20857

Re: HHS Docket No. HRSA-2022-0001 (HRSA-2021-000X), RIN 0906-AB28, 340B Drug Pricing Program; Administrative Dispute Resolution

Dear Acting Deputy Director Herzog:

Advocates for Community Health (ACH) is comprised of leading federally qualified health centers (FQHCs) focused on health equity and innovation to drive health care systems, policies, and health programs. Our members serve over two million people and provide high-quality, comprehensive primary health care, mental health services, preventive care, and social services to patients most in need.

The 340B program is a lifeline to our members – it enables health centers to serve more patients at a higher level of complexity than they otherwise could.¹ FQHCs depend on the 340B program to meet their mission and put every dollar received back into the patients they serve.

Unfortunately, the program does not always function as it should. In August 2020, pharmaceutical manufacturers began to deny access to 340B medications at contract pharmacies. To date, nearly twenty pharmaceutical companies have restricted the sale of pharmaceuticals² at contract pharmacies unless the covered entity turns over claims information – a requirement that does not exist in statute or regulation. Many FQHCs do not have the financial resources to provide in-house pharmacy services and rely on contract pharmacies to ensure patients can receive discounted medications without additional barriers. This blatant abuse of power to exploit FQHCs' 340B savings has affected millions of patients' access to life-saving medicines.³ ACH supports the administrative dispute resolution (ADR)

¹ <https://advocatesforcommunityhealth.org/policy-advocacy/340b/>

² <https://www.fiercehealthcare.com/providers/aha-drug-maker-340b-restrictions-are-harming-safety-net-hospitals-financially>

³ https://www.nachc.org/wp-content/uploads/2022/06/NACHC-340B-Health-Center-Report_-June-2022-.pdf

process to protect FQHCs' 340B savings, protect patients' access to life-saving drugs, and ensure pharmaceutical manufacturers can be held accountable for their actions.

Below, we provide our comments on the proposed changes outlined in [HRSA-2021-0004 340B Drug Pricing Program; Administrative Dispute Resolution](#). In summary, our comments specifically address the following:

- **340B ADR Panel:** ACH supports the selection process for members of the review panels. We also urge the agency to consider adding FQHC subject matter experts to the panels.
- **Streamlining the ADR process:** ACH supports making the ADR process more accessible and expeditious.
- **Eliminating the threshold requirements for submitting a claim:** ACH supports eliminating the minimum threshold for making a claim to make the process more accessible to patients.
- **Dismissal of pending claims in federal courts:** ACH opposes this proposal.
- **Proposal of an ADR appeals process:** ACH supports this proposal.

Subsections:

Proposed Changes to Section 10.20 (a) Members of the 340B ADR Panel

Proposal: HHS proposes that the Office of Pharmacy Affairs Director select at least three members for each 340B ADR Panel from a roster of appointed staff to review and make decisions regarding one or more claims filed by covered entities or manufacturers.

- *ACH comment:* ACH supports this provision. However, ACH recommends that HRSA include language requiring a member specifically with FQHC experience or an FQHC subject matter expert to sit on these panels. Especially when it comes to disputed claims, the FQHC perspective is essential to understanding their system and how the 340B program savings are reinvested into patient care. It would be beneficial and equitable for FQHCs to have an expert on these review panels.

Proposed Changes to Section 10.21 (b) Requirements for Filing a Claim

Proposal: HHS is proposing an ADR process that is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion, as outlined in the 340B statute. HHS proposes a more accessible, administratively feasible, and timely process where stakeholders have equal access to the ADR process and can easily understand and participate in it without the expenditure of significant resources or legal expertise.

- *ACH comment:* ACH supports making the ADR process more accessible and expeditious. FQHCs have limited resources to expend outside of patient care. With the complexity of the ADR process, a less formal process would be ideal and a step towards accessibility for FQHCs. ACH urges HHS to continue streamlining this process for more equitable access to the claims process.

Proposal: HHS requests comments on whether to retain the existing minimum threshold, eliminate the minimum threshold, or set a new minimum threshold for submitting a claim to ensure a fair, efficient, and expeditious process.

- **ACH comment:** ACH supports eliminating the minimum threshold for making a claim. The ADR process should be more accessible for patients, and we believe it should not have to have a dollar amount to help a patient cover the cost. Additionally, FQHCs are worried about expiring COVID funding that must be spent by Q1 of 2023. In many cases, this money specifically went towards essential workforce expenses. Coupled with the increase in Medicaid enrollment and the growing need within communities, FQHCs are being put under added financial strain. A minimum threshold only adds another barrier to the ADR process, and ACH urges HHS to eliminate this requirement.

Proposed Changes to Section 10.23 (a) 340B ADR Panel Decision Process

Proposal: HHS is proposing as part of the ADR process that if the ADR Panel determines that a specific issue in a claim is the same as or similar to an issue that is pending in federal court, the ADR Panel will suspend review of the claim until such time the case is no longer pending in federal court.

- *ACH comment:* ACH has concerns with this proposal to suspend pending claims in federal court. While it is an improvement over dismissing the claims as is current practice, existing contract pharmacy claims would still be expected to remain unresolved for the foreseeable future. This change does not provide a recourse for that, and it is the most prominent issue facing covered entities and those most likely to seek a remedy through the ADR process. ACH urges HHS to refrain from implementing this provision to protect FQHCs that utilize contract pharmacies for their patients.

Proposed Changes to Section 10.24 (a) 340B ADR Panel Decision Reconsideration Process

Proposal: HRSA proposes an appeals process that grants the Secretary inherent authority to review and reverse or alter the 340B ADR Panel's decision. Discretionary review by the Secretary would similarly apply to any reconsideration decision upon finalization of this proposed rule. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by a federal court order.

- *ACH comment:* ACH supports this provision to create an appeals process for ADR panel decisions. As HRSA continues to create a more accessible ADR process, granting the Secretary discretionary authority to review and reverse a panel's decision would continue to create equal opportunity for fair decisions. Covered entities and patients deserve the opportunity to appeal an unfair decision, and ACH supports the additional provision outlined in this rule.

Conclusion

The 340B program enables health centers to serve more patients at a higher level of complexity than they otherwise could. Health center use and engagement in the 340B program exemplifies the intent behind its creation: to maximize federal investment and expand care to underserved communities as effectively as possible. ACH thanks the administration for proposing changes to the 340B Administrative Dispute Resolution Process to advance accessibility for FQHCs. For

more information, please contact Stephanie Krenrich, Senior Vice President for Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org.

Sincerely,

Amanda Pears Kelly
Chief Executive Officer