



October 14, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Becerra:

On behalf of the 1,400 Community Health Centers and the 30 million patients they serve, I write to request a meeting with you regarding the 340B Drug Discount Program. As a longstanding champion of Community Health Centers, you know the importance of the 340B program for our patients and operations. We need your guidance and leadership at this critical time to find solutions to the current situation because health centers continue to struggle with unlawful restrictions to contract pharmacy shipments by drug companies.

Under the prior administration, the National Association of Community Health Centers (NACHC) brought a lawsuit against the Department of Health and Human Services for failing to implement the Administrative Dispute Resolution (ADR) rule that was to be implemented in 2010. Because of that lawsuit, the rule was finalized after a decade. NACHC immediately filed claims against multiple drug companies to hold them accountable for these unilateral restrictions. As you know, this is the only legal remedy for health centers with respect to drug manufacturer non-compliance. Yet, inexplicably, the department's ADR panel dismissed our claim against AstraZeneca and Sanofi because of ongoing litigation in which health centers are *not* legally entitled to participate. The ADR panel's ruling stretched a legal doctrine well beyond its proper indications in the name of fairness to manufacturers, but in doing so deprived health centers of due process mandated by Congress. Simply put, we have followed the rules that Congress authorized and the department implemented but continue to be in an untenable situation where health centers and their patients are hurting.

As you mentioned in February 2022, in your remarks at our 2022 Policy & Issues Forum, the 340B program is "integral to the functioning of many of the community health centers we have throughout the country. Without that, it would be very difficult for them to dispense medication to patientsⁱ." Moreover, you said, "we're going to continue to fight because it's the law, at least that's the way we look at it. It's the law and we're going to stand up for that and we hope you'll help us win that battle."ⁱⁱ It is noteworthy that since you made those remarks four additional manufacturers have placed restrictions on shipments to health center contract pharmacies, and the Department of Health and Human Services Office of Inspector General declined to take any enforcement action against drug manufacturers.

Recent data from a NACHC survey underscores the program's importance for health center patients. It found that one-third of respondents estimate that *more than half of their patients* would go without needed medications if they did not have access to 340B discounts. Furthermore, nearly 9 in 10 respondents believe that *at least 10% of their patients* would go without needed medications if they

did not have access to 340B discounts. Nationally, this could translate to 3 million or more patients losing access to prescription drugs due to 340B program restrictions.

I understand that you have called on Congress to provide the department with additional regulatory authority and funding to administer the 340B program. The ADR panel's dismissal of our claim, declining to use clear authority that Congress has already granted to HRSA, leaves us with little choice but to go to Congress. I hope we can count on you and the department to play an active role in driving a meaningful solution for health centers that prioritizes stability for safety-net providers.

Again, thank you for your steadfast support of Community Health Centers and their mission. We look forward to hearing from your office about scheduling an upcoming meeting to discuss these issues further. Should you have any questions, please contact Joe Dunn, NACHC's Senior Vice President for Public Policy and Research, at (703) 244-3799 or by email at jdunn@nachc.org.

Sincerely,



Rachel Gonzales-Hanson
Interim President & Chief Executive Officer

ⁱ 340B Report, HHS Secretary Becerra Pledges to Keep Fighting Against 340B Contract Pharmacy Restrictions "Because it's the Law"—<https://340breport.com/hhs-secretary-becerra-pledges-to-keep-fighting-against-340b-contract-pharmacy-restrictions-because-its-the-law/>

ⁱⁱ Ibid.