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Advancing Health in America

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January 27, 2023

Emeka Egwim, PharmD, RPh LCDR
U.S. Public Health Service Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

RE: HRSA 340B Drug Pricing Program; Administrative Dispute Resolution Proposed Rule, HHS Docket Number: HRSA–2021–000X, Federal Register, Vol. 87, No. 229, Nov. 30, 2022

Dear Dr. Egwim:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including our nearly 2,000 member hospitals that participate in the 340B Drug Pricing Program (340B program), the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed rule regarding the establishment of the 340B Administrative Dispute Resolution (ADR) process. This proposed rule revises the current 340B ADR final rule (December 2020) to better align the ADR process with the statutory requirements first put in place by the Affordable Care Act (ACA). The AHA believes that the ADR process is critical to ensuring the program's integrity and supports HRSA's efforts to make the process more accessible to all 340B providers.

For 30 years, the 340B program has successfully allowed health care providers to stretch scarce federal resources to better serve their patients and communities. As the Supreme Court recently found, the program enables hospitals and healthcare systems to "perform valuable services for low-income and rural communities." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___ (2022) (slip op., at 13).

The program has been especially important in the face of rising drug prices and chronic underpayments from Medicare and Medicaid. A recent report by the Department of Health and Human Services (HHS) found that between July 2021 and July 2022 drug prices increased by an average of 31.6% for over 1,200 drugs — many of which are

used to treat cancer and other chronic conditions.[1] These staggering drug price increases have led to higher expenses for hospitals, compounding an already precarious financial situation due to historic inflation and critical workforce shortages. In fact, compared to pre-pandemic levels in 2019, hospitals experienced a nearly 40% increase in drug expenses per patient.[2] This reality underscores the critical need for the 340B program and a forum like the ADR process to protect 340B entities from drug manufacturer actions that undermine the integrity of the program to the detriment of patient care.

Our comments primarily focus on three key priorities (1) using the ADR process as a forum for addressing drug manufacturer overcharges through 340B hospital arrangements with community and specialty pharmacies, (2) establishing an appropriate deadline for ADR panel decisions, and (3) not suspending ADR review of claims that involve issues pending in federal court.

Drug Manufacturer Overcharges

As federal law requires, the ADR process establishes a formal way to resolve disputed claims by 340B providers and drug manufacturers. For example, the ADR process is intended to adjudicate disputes that arise when a drug manufacturer overcharges a 340B provider for covered drugs. There is no more egregious example of this than the actions drug manufacturers have taken to limit or deny 340B pricing through arrangements with community and specialty pharmacies. For nearly three years, in clear violation of the law and with no abatement on the horizon, several of the largest drug manufacturers have restricted, and in some instances denied, 340B hospitals' access to the statutorily required 340B prices for drugs purchased through established arrangements with community and specialty pharmacies. By intentionally denying or limiting access to the 340B price, these drug manufacturers are forcing hospitals to pay a higher price to acquire these drugs (e.g., wholesale acquisition cost price), representing an overcharge by these drug manufacturers for these covered drugs. According to AHA survey data, these unlawful actions by drug manufacturers have resulted in 340B Critical Access Hospitals experiencing average annualized losses of approximately $507,000 and 340B Disproportionate Share Hospitals approximately $2.96 million.[3] These overcharges jeopardize the ability of 340B hospitals to use these federally-authorized arrangements with community and specialty pharmacies to improve patient access by allowing both hospitals and pharmacies to coordinate care and ensure that drugs needed by the patients cared for by 340B hospitals are available to them at their local pharmacies.

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[1] Price Increases for Prescription Drugs, 2016-2022 | ASPE (hhs.gov)
[2] https://www.kaufmanhall.com/sites/default/files/2022-01/National-Hospital-Flash-Report_Jan2022.pdf
[3] Survey Brief: Drug Companies Reduce Patients' Access to Care by Limiting 340B Community Pharmacies | AHA

Given the significant financial and operational challenges resulting from these unlawful actions, the AHA strongly recommends that HRSA explicitly state in its final rule that the ADR process is an available forum for affected 340B hospitals to seek redress from these restrictions targeted to community and specialty pharmacies.

At the same time, the AHA continues to vigorously support the agency's efforts *outside* of the ADR process, including those by the Office of Inspector General, to enforce the law and penalize drug manufacturers' who intentionally break the law. In particular, the AHA supports HRSA's actions to enforce drug companies' compliance with section 340B(a)(1) of the Public Health Service Act, which requires those companies to sell, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements. To that end, the AHA, along with other national hospital organizations, filed numerous *amici* briefs at the district and appellate court levels where the drug companies have challenged these enforcement efforts. Specifically, we argued that the drug manufacturers "...understate the impact of [their] unlawful polic[ies] on 340B providers and their patients and overstate how reasonable it is to limit access to 340B discounts and to impose conditions found nowhere in the statute."[4] Ultimately, given the scope of drug manufacturers' wrongdoing with respect to contract and specialty pharmacy arrangements, a whole-of-agency effort is needed. Congress has afforded HRSA, OIG, *and the ADR process* the authority necessary to preserve the integrity of the 340B program.

Establishing Timely Deadlines for ADR Decisions

The agency does not set out a timeline for ADR panel decisions in the proposed rule. Without one, 340B providers could be forced to wait indefinitely for a resolution on overcharging claims by drug manufacturers. Such delays would compound the financial impact of such overcharging on 340B hospitals and ultimately undermine the utility of the ADR process to seek relief in such cases. **The AHA therefore strongly recommends that HRSA establish a deadline by which the ADR panels should render decisions. Further we believe that requiring the ADR panel to decide cases within six months and no later than one year of claim submission would ensure that providers get timely relief while balancing the need to conduct a thorough and appropriate review of the claim to ensure program integrity.**

Suspension of Claims Review on Matters Pending in Federal Court

The agency stated in its proposed rule that it is seeking comment on whether to halt review of any ADR claims that involve issues that are identical or similar to issues that

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[4] Amicus Brief: Hospital Groups Urge Appeals Court to Uphold 340B Requirements In Contract Pharmacy Case, AstraZeneca Pharmaceuticals LP v. United States Department of Health and Human Services, June 29, 2022

are pending resolution in federal court. **We strongly urge the agency NOT to suspend the ADR review of any claims that may involve issues pending before the federal court.** As the agency is aware, the judicial process can often take years before a final resolution. In such cases, suspending review of an ADR claim pending resolution in the federal court could render the ADR process toothless and undermine its utility as a forum for 340B providers to seek relief. Further, such a provision in the rule could encourage parties to bring suit in federal court as a way to preemptively undermine or circumvent the ADR process entirely. Therefore, it is important that the ADR process be kept separate of the judicial process, so that timely relief can be sought through the ADR process for both parties involved.

Additional Comments

The following are several additional comments for the agency's consideration as it finalizes the proposed rule:

We support the proposal to allow both parties (340B providers and drug manufacturers) the opportunity, if dissatisfied, to challenge an ADR decision by establishing a reconsideration process. In addition, we support allowing both parties the ability to remedy the issue further through the federal court system if a satisfactory reconsideration is not reached. We believe this will be beneficial to ensure that both parties can exhaust all possible options to seek resolution to their claims. We thank the agency for making this change; it is a significant improvement over the 2020 ADR final rule, which did not permit an opportunity for disputing parties to have the ADR decision reviewed or reconsidered.

We support the agency's proposal to remove a minimum threshold value necessary to bring forth a claim through the ADR process. The 2020 ADR final rule had established a $25,000 minimum claim value before a claim could be filed for consideration by the ADR panel. Removing this threshold is an important step in ensuring that all 340B providers, especially small and rural providers, can seek relief through the ADR process.

We commend the agency's efforts to ensure that the ADR process is more accessible for all 340B providers seeking dispute resolutions. By making the ADR process more administrative rather than trial-like, the process would be more easily understood and the burden on providers will be lowered. Neither significant resources nor legal expertise would be required of providers**,** many of whom are still financially challenged from the ongoing effects of the COVID-19 pandemic, to seek relief through the ADR process.

We support HRSA's proposal to ensure that the ADR panel is comprised of subject matter experts from the Office of Pharmacy Affairs (OPA) knowledgeable about 340B law and regulations. We are mindful, however,

that this could significantly add to the workload of OPA staff. We would encourage that HRSA ensures that OPA is sufficiently staffed to guard against delays in the ADR process that could undermine its success.

We commend the agency in moving away from the policy of the 2020 ADR final rule that established ADR decisions as precedential. We firmly believe that the ADR panel should review each case on its merits as is outlined by the proposed rule. The approach in the 2020 final rule, effectively, allowed the ADR panel to set policy for the 340B program through precedent setting decisions. Setting 340B policy should remain within HRSA's OPA and not with the ADR panel.

In conclusion, the AHA appreciates HRSA's efforts to improve the operationalization of the ADR process and maintain the integrity of the vital 340B program for all stakeholders. We thank the agency for this opportunity to share our comments and look forward to working with you to ensure that the 340B program continues to provide access to needed services for patients in our community and communities across the country.

Please contact me if you have questions or feel free to have a member of your team contact, Molly Collins Offner, AHA's director for policy development, at mcollins@aha.org or Bharath Krishnamurthy, AHA's director for health analytics & policy, at bkrishnamurthy@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President