MHA Michigan Health & Hospital Association | Leading Healthcare

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 the Michigan Health and Hospital Association (MHA), we appreciate 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. The ADR process is critical to ensuring the integrity of the 340B program. **Our comments primarily focus on two areas:**

(1) using the ADR process as a forum for addressing drug manufacturer overcharges through 340B arrangements with community and specialty pharmacies, and
(2) establishing an appropriate deadline for ADR panel decisions.

As federal law requires, the ADR process establishes a formal way to resolve disputed claims between 340B providers and drug manufacturers. For example, the ADR process is intended to adjudicate disputes that arise when a drug manufacturer overcharges a 340B entity for covered drugs. For nearly three years, in clear violation of the law and with no abatement on the horizon, drug manufacturers have restricted, and in some instances denied, 340B hospitals' access to the statutorily required 340B price for drugs purchased through established arrangements with community and specialty pharmacies. These federally authorized arrangements between 340B hospitals and community and specialty pharmacies improve access by allowing both hospitals and pharmacies to coordinate care and ensure that drugs needed by the patients treated by 340B hospitals are available at their local pharmacies. According to the American Hospital Association's survey data, these unlawful actions by drug manufacturers resulted in 340B Critical Access Hospitals experiencing average annualized losses of approximately $507,000 and 340B Disproportionate Share Hospitals losing an average of approximately $2.96 million.

Over half of Michigan hospitals participate in the 340B Drug Pricing Program and rely on these funds to ensure hospitals and healthcare provider can continue providing access to care in their communities. . Hospitals use the savings from the 340B program to provide access to quality healthcare and high-cost drug therapies, essential cancer treatments, prescription drugs and other medications to uninsured patients and those who have inadequate insurance. These discounts from pharmaceutical manufacturers are more vital than ever as hospitals continue to face dire staffing shortages and unprecedented inflationary cost increases due to the pandemic. Hospitals rely on these savings for providing services that directly impact the quality of life Michigan residents.

Given the significant financial and operational challenges resulting from these unlawful actions, the MHA urges HRSA to explicitly state in the final rule that the ADR process is an available forum for all affected 340B hospitals to seek redress from these restrictions targeted to community and specialty pharmacies. We also continue to strongly support HRSA's efforts outside of the ADR process to enforce the law and restrict drug manufacturers' unlawful actions. Together, we believe these two tracks will help ensure that drug manufacturers offer 340B discount pricing through community and specialty pharmacy arrangements as the law requires.

As a procedural matter, the MHA urges that HRSA establish a deadline by which the ADR panels should render decisions since the proposed rule does not specify one. Absent a specific timeline 340B providers could be forced to wait indefinitely for a resolution on claims of overcharging by drug manufacturers. These delays would further compound the financial impact of overcharging on hospitals and would undermine the utility of the process to seek relief in such cases. 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.

We have additional comments that will be useful as the agency finalizes the rule:

1) **We support the proposal to allow both parties (340B providers and drug manufacturers) the opportunity, if dissatisfied, to challenge an ADR decision through the establishment of a reconsideration process. In addition, we support allowing both parties the ability to further remedy the issue through the federal court system if a satisfactory reconsideration is not reached.**
2) **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 while also reducing the burden on providers since the process would not require significant resources or legal expertise.**

In conclusion, we appreciate HRSA's efforts to operationalize 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 the 340B program continues to provide access to needed services for patients across Michigan. We believe our suggested changes will have a positive impact on 340B hospitals and the vulnerable patients they serve.

Sincerely,

Kaitlyn Jaskolski
Health Finance Manager