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January 30, 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 more than 200 hospital and health system members, with more than 40 individual hospitals participating in the 340B program, the Florida Hospital Association is grateful for 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 largely focus on two important 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 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 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 cared for

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by 340B hospitals are available to them at their local pharmacies. For example, according to the American Hospital Association's 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.

Given the significant financial and operational challenges resulting from these unlawful actions, we urge HRSA to explicitly state in its final rule that the ADR process is an available forum for affected 340B hospitals like our members 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, these two tracks should help ensure that drug manufacturers offer 340B discount pricing through community and specialty pharmacy arrangements just as the law requires.

As a procedural matter, we also strongly recommend that HRSA establish a deadline by which the ADR panels should render decisions. The proposed rule does not include a timeline, and without one, 340B providers could be forced to wait indefinitely for a resolution on claims of overcharging by drug manufacturers. Such delays would compound the financial impact of such overcharging on our 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 finalized 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 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.**
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 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.**

In conclusion, FHA appreciates 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 that the 340B program continues to provide access to needed services for patients in our community and communities across the country. If you have any questions please do not hesitate to contact me or Michael Williams at mwilliams@fha.org.

Sincerely,

Mary C. Mayhew
President and CEO
Florida Hospital Association