



Minnesota Hospital Association

2550 University Ave. W., Suite 350-S
St. Paul, MN 55114-1900

phone: (651) 641-1121; fax: (651) 659-1477
toll-free: (800) 462-5393; www.mnhospitals.org

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

Submitted electronically through www.regulations.gov.

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 140 member hospitals and health systems, the Minnesota Hospital Association offers the following comments 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 Drug Pricing program.

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 by 340B hospitals are available to them at their local pharmacies.

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 ours 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.

January 30, 2023

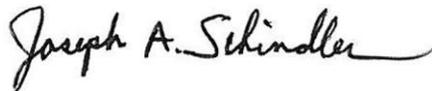
Page 2 of 2

We also 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.

MHA commends 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, 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 that the 340B program continues to provide access to needed services for patients across Minnesota. If you have any questions, please feel free to contact me at (651) 659-1415 or jschindler@mnhospitals.org.

Sincerely,

A handwritten signature in black ink that reads "Joseph A. Schindler". The signature is written in a cursive style with a long, sweeping underline.

Joseph A. Schindler
Vice President, Finance Policy & Analytics