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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-2021-000X; 340B Drug Pricing Program; Administrative Dispute Resolution; Proposed Rule

Dear Dr. Egwim:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, welcomes the opportunity to comment on the 340B Drug Pricing Program Administrative Dispute Resolution proposed rule.

The 340B Program is intended to enable covered entities *“to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”* Eligible hospitals in New York and across the country leverage savings accessed under 340B to operate programs and services that they might otherwise not be able to offer, such as:

- free or substantially discounted prescriptions to uninsured or low-income patients;
- medication therapy management programs to improve patient care and reduce overall healthcare costs and hospital readmissions;
- mobile units to bring care to rural and other medically underserved communities without local primary care options or pharmacies;
- free oncology services to low-income patients;
- multidisciplinary clinics offering substance use disorder treatment and mental healthcare; and
- transportation for patients who need emergency room services.

The Affordable Care Act requires the HHS secretary to establish and implement a binding ADR process for certain disputes arising under the 340B Program. While HRSA finalized a 340B ADR process in its December 2020 final rule, due to policy and operational challenges with implementation, the agency is soliciting feedback on a new approach.

The following are HANYYS' comments by topic area, which align with those of the American Hospital Association.

## Addressing drug manufacturers' concerns

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 to care by allowing both hospitals and pharmacies to coordinate care and ensure that drugs needed by patients are available to them at their local pharmacies.

**Given the significant financial and operational challenges resulting from these unlawful actions, HANYS aligns with the AHA and urges HRSA to 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.**

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.

### **ADR panel**

The 2020 ADR final rule allows the HHS secretary to establish a 340B ADR board with at least six appointed members and requires that three of those members form a 340B ADR panel to conduct the initial review of claims. In this rule, HHS proposes to revise the 340B ADR panel structure to include subject matter experts, including one ex-officio, non-voting member from the Office of Pharmacy Affairs.

**We support a dedicated 340B ADR panel of experts to review the claims and the inclusion of a non-voting member from HRSA's OPA on each panel to ensure that OPA's program experience and expertise are available during the ADR process.**

**In addition, HANYS aligns with the AHA and strongly recommends that HRSA require the ADR panel to decide cases within six months or no later than one year after claim submission to ensure that providers get timely relief while balancing the need to conduct a thorough and appropriate review of the claim to ensure program integrity.**

Without a timeline, 340B providers could 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 undermine the utility of the process to seek relief in such cases.

### **340B appeals process**

Based on prior comments from the industry, HHS is proposing an appeals or reconsideration process for all parties that are dissatisfied with the 340B ADR panel decision.

**HANYS aligns with the AHA and strongly supports an appeals process for disputed 340B panel decisions and urges the HHS secretary to use their authority to reverse or alter a panel's decision as warranted. In addition, we support allowing both parties to remedy the issue further through the federal court system if a satisfactory reconsideration is not reached.**

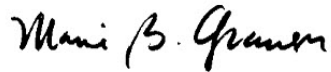
### **Administrative ADR process**

HHS is proposing an ADR process more aligned with the process established in 1996, which was less trial-like and resource-intensive than the current 2020 guidelines.

**HANYS aligns with the AHA and fully supports a less trial-like and resource-intensive ADR process, which would be more easily understood and would place less burden on providers.** 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.

Again, thank you for the opportunity to comment. If you have questions, contact Kevin Krawiecki, vice president, fiscal policy, at [kkrawiec@hanys.org](mailto:kkrawiec@hanys.org) or 518.431.7634.

Sincerely,

A handwritten signature in black ink that reads "Marie B. Grause". The signature is written in a cursive, flowing style.

Marie B. Grause, RN, JD  
President

MBG:lw