January 30, 2023

Carole Johnson  
Administrator  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

Ref: RIN 0906–AB28: 340B Drug Pricing Program; Administrative Dispute Resolution

Dear Administrator Johnson:

America’s Essential Hospitals appreciates the opportunity to submit comments on the Health Resources and Services Administration’s (HRSA’s) proposed changes to the 340B Drug Pricing Program (340B) administrative dispute resolution (ADR) process in the above-mentioned rule. The 340B program is a key source of support in the patchwork of federal programs on which essential hospitals rely to fulfill their safety net mission. Essential hospitals, which strive to be good stewards of the 340B program, fully support the availability of a robust ADR process to ensure 340B program integrity and transparency.

America’s Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals, most of which are 340B hospitals, provide a disproportionate share of the nation’s uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. They provide state-of-the-art, patient-centered care while operating on margins of 3.2 percent compared with the 7.7 percent margin when accounting for all hospitals nationwide.¹

A disproportionate number of our members’ patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Nearly 8 million people in essential hospital communities have limited access to healthy food, and 15.8 million live below the federal poverty line.² Members of America’s Essential Hospitals have used 340B savings to create programs to tackle these financial and social challenges, as well as to improve health equity—showcasing how indispensable 340B savings are to hospitals operating on narrow margins.

² Ibid.
For example, essential hospitals have used 340B savings to:

- Provide mental health and substance abuse treatment.
- Establish a primary care medical home for low-income, uninsured patients, reducing emergency department (ED) use and increasing medication availability to patients lacking prescription drug coverage.
- Reduce wait times for cancer drugs and improve medication adherence among cancer and HIV patients.
- Establish clinical pharmacy programs, in which pharmacists interact with patients at the bedside and in the ED, ensuring patients understand and adhere to their medication regimen and ultimately reducing excess readmissions.
- Provide meaningful health care access to patients through expanded clinic locations, hours of operation, transportation availability, interpretation services, and patient education not otherwise available in many places.
- Support free clinics in their communities.

The 340B program has enabled essential hospitals to stretch scare federal resources while increasing the availability of lifesaving prescription drugs to low-income patients. Hospitals, patients, and other stakeholders realize the benefits of the 340B program at minimal expense to taxpayers—the lower prices hospitals receive on covered outpatient drugs through 340B are a result of discounts drug manufacturers provide. As HRSA works to preserve the integrity of the 340B program, we urge the agency to consider the needs of the nation’s most underserved patients and the hospitals that care for them by swiftly finalizing an ADR process through which covered entities can ensure manufacturers honor their obligations to provide discounted drugs.

This proposal is a significant step toward program integrity by holding drug manufacturers accountable for their participation in the 340B program and ensuring program integrity. Many of the changes in the proposed rule will make the claims process more accessible for 340B providers seeking to resolve disputes. In recent years, 340B hospitals have been subject to unfair and harmful tactics of drug companies that flout the law and reduce the intended benefits of the program. The federal government has documented the issue of manufacturer overcharges within program since the mid-2000s, when the Department of Health and Human Services Office of the Inspector General issued several reports on the topic.3

Decisions by pharmaceutical manufacturers to withhold 340B-priced drugs from contract pharmacies serve as one example of unlawful and unilateral actions that threaten a valuable tool for essential hospitals to expand their reach into vulnerable populations. If HRSA allows these efforts to proceed, drug manufacturers might continue to take unabated steps to diminish the 340B benefit for essential hospitals and other safety net providers that rely on it to care for under-resourced populations. These unlawful manufacturer actions represent the latest example in a concerning erosion of the 340B benefit and demonstrate the urgent need of an accessible and efficient process to hold manufacturers accountable when participating in 340B.

Further, the finalization of the ADR process is long overdue. The Affordable Care Act, enacted in 2010, required that ADR regulations be promulgated within 180 days of the legislation’s passage. We urge HRSA to operationalize the ADR process without additional delays to ensure program integrity and accountability. It is imperative that

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covered entities can have their claims solved in a timely manner and with less burden so that they can protect themselves and their patients from manufacturer overcharges.

America’s Essential Hospitals and its members are committed to tackling this important topic. We are pleased to offer technical comments on the proposals in the rule and how to improve the ADR process in our joint comment letter with other 340B covered entity organizations.

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America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have any questions, please contact Erin O’Malley, senior director of policy, at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO