



AMERICA'S ESSENTIAL HOSPITALS

May 22, 2018

Krista Pedley
Captain, U.S. Public Health Service
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Ref: RIN 0906-AB18: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

Dear Captain Pedley,

America's Essential Hospitals appreciates the opportunity to comment on the above-mentioned regulation. The Health Resources and Services Administration (HRSA) proposes to further delay—from July 1, 2018, to July 1, 2019—the effective date of a final rule establishing the calculation of ceiling prices under the 340B Drug Pricing Program and imposing civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than this price. This would be the fifth delay of the long-awaited final rule. We strongly urge HRSA to enact the final rule immediately to infuse transparency and accountability in the 340B program and comply with the statutory mandate to implement the rule more than eight years ago.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 325 member hospitals provide a disproportionate share of the nation's uncompensated care and devote approximately half of their inpatient and outpatient care to Medicaid or uninsured patients.¹ Because of the high percentage of low-income patients served by essential hospitals, many member hospitals qualify to participate in the 340B program. Savings from the program have been critical to ensuring that our members can reach more patients and continue to offer vital services, safeguarding access to affordable health care for vulnerable individuals.

¹ Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2015 Annual Member Characteristics Survey. America's Essential Hospitals. June 2017. www.essentialdata.info/. Accessed May 11, 2018.

Access to the 340B program is critical in an age of skyrocketing drug prices. President Trump recently announced policy ideas aimed at lowering drug costs and reducing out-of-pocket costs for patients. The final rule is in alignment with the administration's aim to provide relief and transparency by establishing a more accurate and timely ceiling price calculation for 340B drugs. It also is a significant step in holding drug manufacturers accountable for their participation in the 340B program. Until this final rule is implemented, covered entities remain unprotected from manufacturer overcharges that can further exacerbate the negative effects of high-cost drugs on both the health care system and patients. We urge HRSA to consider the following points before attempting to further delaying this much-needed rule.

1. The final rule is a critical step to ensuring transparency and accountability within the 340B program.

The 340B program was designed to help covered entities stretch scarce federal resources. Yet, the federal government has documented the issue of manufacturer overcharges within program since the mid-2000s, when the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued several reports on the topic. Most notably, the OIG in 2003 investigated 11 prescription drugs produced by five manufacturers and found, in every case, covered entities were overcharged for the drugs.²

Climbing drug costs burden both providers and patients. In fact, the Health Care Cost Institute observed a 24.9 percent cumulative price increase in prescription drugs between 2012 and 2016.³ Within the context of the 340B program, covered entities are blind to overcharges by drug manufacturers and have no means of accessing ceiling price information. The longer the final rule is delayed, the longer covered entities might be overcharged for drugs with few means of identifying or correcting this problem. Congress directed HRSA to promulgate the rule in question to hold accountable drug manufacturers participating in the 340B program. **To drive transparency and accountability, HRSA must implement the final rule immediately.**

2. HRSA must follow the spirit of the law, under existing 340B statute and the Administrative Procedure Act (APA), by implementing the final rule immediately.

In 2010, Congress directed HRSA to establish regulations on manufacturer ceiling prices and civil monetary penalties on manufacturers who knowingly or intentionally overcharge covered entities. With this direction came a clear statutory deadline: HRSA was to promulgate such regulations by September 19, 2010. HRSA continues to ignore the deadline clearly articulated in the 340B statute. This delay is unwarranted.

² Department of Health and Human Services Office of the Inspector General. Pharmaceutical Manufacturers Overcharged 340B-Covered Entities. March 10, 2003. <https://oig.hhs.gov/oas/reports/region6/60100060.pdf>. Accessed May 11, 2018.

³ Health Care Cost Institute. 2016 Health Care Cost and Utilization Report. <http://www.healthcostinstitute.org/report/2016-health-care-cost-utilization-report/>. Accessed May 11, 2018.

HRSA justifies this most recent proposed delay as necessary because HHS is considering other policy changes in the future that might impact the 340B program. There is no reason that a statutory mandate related to one part of the program cannot or should not be implemented because of contemplated changes in other parts of the 340B program or entirely separate Medicaid and Medicare policies. In addition, HRSA apparently has decided to overrule Congress' judgment that civil monetary penalties are needed, dismissing the idea that the rule would bring any benefit that is not already available to covered entities. HRSA does not have the authority to replace Congress' judgment with its own and ignore the requirements of the law. Finally, we refer you to prior comment letters submitted by the 340B Coalition outlining the ways in which the series of delays of the final rule have violated the APA.⁴

The final rule has been thoroughly vetted through notice and comment and to continue delay without good cause is contrary to the intent and clear letter of the law. **We urge the agency to immediately implement the final rule.**

* * * * *

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

⁴ See, e.g., Letter from 340B Coalition to Capt. Krista Pedley, Director, Office of Pharmacy Affairs. Sep. 20, 2017.