



AMERICA'S ESSENTIAL HOSPITALS

November 20, 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-AB19: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

Dear Captain Pedley,

America's Essential Hospitals appreciates the opportunity to offer its strong support of the above-mentioned proposed rule. The Health Resources and Services Administration (HRSA) proposes to change the effective date—from July 1, 2019, to January 1, 2019—of the January 2017 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 overcharge covered entities. After five delays in the effective date, implementing this long-awaited rule is a critical step in infusing transparency and accountability in the 340B program. We appreciate HRSA's acknowledgment that further delay to review the substance of the January 2017 policy or to consider broader drug pricing issues is unwarranted. We urge HRSA to comply with its statutory mandate to ensure manufacturer compliance by promptly implementing its proposed change in effective date and ensuring effective enforcement by making ceiling price data available on a secure website without delay.

America's Essential Hospitals is the leading 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 320 member hospitals provide a disproportionate share of the nation's uncompensated care and devote three-quarters of their inpatient and outpatient care to uninsured patients and those covered by Medicaid or Medicare.¹ Because of the high percentage of low-income patients served by essential hospitals, most member hospitals qualify to participate in the 340B program. Savings from the program have been critical to ensuring that our members can stretch their scarce

¹ Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. www.essentialdata.info/. Accessed November 7, 2018.

resources to reach more patients and continue to offer vital services, safeguarding access to affordable health care for vulnerable individuals.

1. HRSA should promptly finalize its rule to change the effective date to January 1.

Access to 340B discounts is critical in an age of skyrocketing drug prices. The Health Care Cost Institute observed a 24.9 percent cumulative price increase in prescription drugs between 2012 and 2016.² Climbing drug costs burden both providers and patients. In fact, President Trump has expressed his commitment to lowering drug costs and reducing out-of-pocket costs for patients. This proposal to finally implement the January 2017 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 toward program integrity by holding drug manufacturers accountable for their participation in the 340B 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 (HHS) Office of the Inspector General (OIG) issued several reports on the topic.³ Until this final rule is implemented, it is difficult for covered entities to determine if they are purchasing drugs at the mandated ceiling price. They also remain unprotected from manufacturer overcharges that can exacerbate the negative effects of high-cost drugs on both the health care system and patients.

Congress directed HRSA to promulgate the rule in question in 2010 to hold accountable drug manufacturers participating in the 340B program. The repeated delays in implementation have been unnecessary and inconsistent with the 340B statute. We support HRSA’s conclusion that further delays are unwarranted—the regulations have been “subject to extensive public comment,” the agency already “considered the full range of comments,” and implementing the regulations will not interfere with the administration’s comprehensive drug pricing work.⁴ **We urge HRSA to take the necessary steps to begin enforcing the rule on January 1, 2019.**

2. HRSA should make 340B ceiling price data available to covered entities without further delay.

As part of its statutory mandate, HRSA is required to provide covered entities access to 340B ceiling prices for covered outpatient drugs through a secure website—a critical element in monitoring and enforcing manufacturer compliance. With the January 2017 rule finally in effect, HRSA can verify ceiling price data pursuant to the final policies and make that data available on a ceiling price website, consistent with statements in its

² Health Care Cost Institute. 2016 Health Care Cost and Utilization Report. June 19, 2018. <http://www.healthcostinstitute.org/report/2016-health-care-cost-utilization-report/>. Accessed November 7, 2018.

³ See, e.g., 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 November 7, 2018.

⁴ 83 Fed. Reg. 55135 (November 2, 2018).

most recent budget justification.⁵ **We urge HRSA to operationalize the ceiling price website without additional delays, finally enabling covered entities to access the data in a timely manner and protect themselves and their patients from manufacturer overcharges.**

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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

⁵ HRSA's recent budget justification for fiscal year 2019 stated that database implementation "is expected once the Civil Monetary Penalty and Ceiling Price calculation regulation has been finalized and any necessary changes to the system have been implemented." HHS Fiscal Year 2019 HRSA Justification of Estimates for Appropriations Committees 269. <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf>. Accessed November 16, 2018.