American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

September 20, 2017

Krista Pedley, Pharm.D, MS
Captain, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

***RE: Interim Final Rule Delayed Effective Date: (RIN) 0906–AB11, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; (Vol. 82, No. 60, August 21, 2017)***

Dear Captain Pedley:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) interim final rule that would further delay the effective date for the implementation of the Affordable Care Act (ACA) provision requiring a 340B Drug Pricing Program ceiling price calculation methodology and application of civil monetary penalties (CMPs) for violations of the ceiling price.

**The AHA strongly opposes any further delay of HRSA's final rule on the 340B ceiling price and CMPs.** The agency's rulemaking on these issues began seven years ago, shortly after the passage of the ACA. This process included an advance notice of proposed rulemaking, a notice of proposed rulemaking, a final rule and now an interim final rule. Therefore, there have been extensive opportunities for stakeholders to provide feedback and ample time for HRSA to consider such feedback. Since January 2017, the implementation date for the interim final rule has been delayed three times. Delaying the implementation of the ceiling price and CMPs an additional nine months – from Oct. 1, 2017 to July 1, 2018 – is not justified given the exhaustive development process that has occurred.

**In addition, the AHA reiterates our support for HRSA's decision to codify its "penny pricing policy" to strengthen the agency's oversight of 340B ceiling prices and to**

**discourage manufacturers from raising prices faster than inflation.** This policy is an exception to the ceiling price policy that applies when the calculation results in a ceiling price of zero and entails imputing a ceiling price of $0.01 for the relevant drug product. While this policy has been in place for many years, drug manufacturers have not applied it consistently. Indeed, a Department of Health and Human Services Office of Inspector General (OIG) report found that manufacturers overcharged for more than half of the drugs subject to the penny pricing policy with incorrect charges ranging "anywhere from $1.65 to $1,931 per purchase over the ceiling price."[1] Such practices are particularly troubling given the recent drug price increases that have presented hospitals and their patients with remarkable challenges. The AHA's study on trends in inpatient drug costs shows that hospitals, as large volume purchasers, are often targets for greater drug price increases by pharmaceutical manufacturers.[2] The Centers for Medicare & Medicaid Services projects that prescription drug spending will grow an average of 6.3 percent per year for 2016 through 2025.[3] The 340B program is critical in helping eligible hospitals obtain a reduced price for outpatient pharmaceuticals, thereby allowing them to stretch scarce federal resources to expand and improve access to comprehensive health care services for the nation's most vulnerable patients.

In addition, we support the final rule's enforcement of the ACA's CMPs (not to exceed $5,000 per instance) for drug manufacturers who intentionally charge a 340B hospital or covered entity more that the established ceiling price. This provision provides HRSA and the OIG (the entity responsible for applying monetary penalties) with the means to hold drug manufacturers accountable for drug pricing violations.

**We urge HRSA to implement the final rule without further delay. In addition, we look forward to working with HRSA on further guidance on the 340B ceiling reporting system and how 340B hospitals and covered entities can access ceiling price information to establish instances of manufacturer overcharges.**

Thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Molly Collins Offner, director of policy, at mcollins@aha.org or (202) 626-2326.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

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[1] Dept. of Health and Human Services., OIG, *Review of 340B Prices* (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf

[2] NORC, Trends in Hospital Inpatient Drug Costs: Issues and Challenges, Oct. 2016 www.aha.org/content/16/aha-fah-rx-report.pdf

[3] www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf