American Hospital Association

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May 22, 2018

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: Notice of Proposed Rulemaking; Further Delay of Effective Date: (RIN) 0906–AB18, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; (Vol. 83, No. 88, May 7, 2018)

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) proposed rule that would further delay the effective date for implementing final regulations regarding the 340B Drug Pricing Program ceiling price and drug manufacturers' civil monetary penalties (CMPs) for violations of the ceiling price.

The AHA strongly opposes any further delay of HRSA's final regulation on the 340B ceiling price and CMPs. The agency's rulemaking on these issues began eight years ago, shortly after the passage of the Affordable Care Act (ACA). This process included an advance notice of proposed rulemaking, a notice of proposed rulemaking and a 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 final regulation has been delayed five times. Delaying the implementation of the ceiling price and CMPs an additional year – from July 1, 2018 to July 1, 2019 – is not justified given the exhaustive development process that has occurred. By failing to implement the final rule, drug manufacturers can continue to overcharge 340B hospitals by violating the ceiling price policy without repercussion.

The AHA supports HRSA's decision to codify its "penny pricing policy" to strengthen the agency's oversight of 340B ceiling prices and to discourage

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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. 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 recent increases in drug prices, which have presented remarkable challenges for hospitals and their patients. An AHA 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] Moreover, 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] Therefore, the 340B program is essential in helping eligible hospitals obtain a reduced price for outpatient pharmaceuticals, 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 regulation'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 than 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 regulation 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 overcharging.

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