American Hospital Association

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November 19, 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; 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation: (RIN) 0906–AB19; (Vol. 83, No. 213, November 2, 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 to change the effective date to Jan. 1, 2019 for implementing final regulations regarding both the 340B Drug Pricing Program ceiling price, along with drug manufacturers' civil monetary penalties (CMPs) for violations of the ceiling price, thereby ceasing any further delay. In addition, the final rule requires that HRSA make pricing information available to 340B hospitals and other participating providers online through a secure website.

The AHA supports HRSA's implementation of the final rule, which, we believe, is critically important to the integrity of the 340B program. The repeated and lengthy delays in making the final rule effective have significantly harmed 340B hospitals and the low-income patients they serve, whom Congress intended to benefit from the 340B program. This is why AHA filed suit to assure that the rule would be finalized. The AHA is pleased that the Department of Health and Human Services (HHS) has abandoned its previous schedule and proposed to make the final rule effective on Jan. 1, 2019. **The AHA strongly urges HRSA to meet the Jan. 1**

effective date it has proposed. We also urge that the policy changes made by the final rule, first published in January 2017, remain substantially unchanged. Lastly, we urge HRSA to make the website available as soon as possible after the effective date, and under no circumstances any later than April 1, 2019 insomuch as the website is essential for effective enforcement of the 340B program.

The development process to establish these policies has been exhaustive, and delaying the implementation of the ceiling price and CMPs any further is not justified. HRSA issued a final rule to implement these policies after soliciting comments three times, once to an advanced notice of proposed rulemaking and twice to proposed rules. Therefore, there have been extensive opportunities for stakeholders to provide feedback and ample time for HRSA to consider such feedback. Despite this, since January 2017, the implementation date for the final regulation has been delayed five times. Ensuring that the Jan. 1, 2019 compliance effective date does not waiver would offer greater assurances to hospitals and other 340B providers that they will receive savings from drug company discounts that they are entitled to and that Congress provided for the support of critical health care services in communities with underserved populations that could not otherwise afford services.[1]

Implementation of the ceiling price methodology and the "penny pricing" policy directly addresses longstanding problems identified with accuracy of drug discounts and resulting overcharges that 340B providers continue to experience. The ceiling price, the maximum per-unit price that can be charged to 340B providers for outpatient drugs, is key to the discounts made available under the 340B program. As the HHS Office of Inspector General (OIG) has found, many drug companies fail to accurately provide the required discounts. In its July 2006 report, OIG found that in one month, 14 percent of total purchases made by 70 sampled 340B providers exceeded the 340B ceiling prices, resulting in total overpayments of $3.9 million for the sample of 340B hospitals studied. [2]

The "penny pricing" policy is triggered by the inflation penalty, which is an exception to the ceiling price methodology intended to discourage manufacturers from raising prices faster than inflation. The penny pricing policy applies when the inflation penalty 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. The 2006 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."[3]

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[1] H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).
[2] Dept. of Health and Human Services., OIG, *Review of 340B Prices* (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[3] Ibid.

Promptly enforcing these final rule provisions is valuable in bringing drug companies into compliance and ensuring that 340B providers are able to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" as Congress intended. It also is entirely consistent with the Administration's stated goal of addressing the issue of the rising costs of prescription drugs.

The final rule's CMPs are an important, additional tool to help 340B providers in enforcing the requirements of the 340B statute, as both Congress and OIG concluded. Congress specifically added the CMPs to the law to "improve . . . compliance by manufacturers," and to "prevent overcharges and other violations of the discounted pricing requirements."[4] The threat of CMPs will deter drug companies from charging too much for covered drugs. Implementing the final rule's CMPs' provision would protect 340B providers from manufacturers' overcharging and ensure they have savings from properly calculated discounts to devote to helping their low-income patients.

Congress also determined that making ceiling prices available to 340B providers would assist them in detecting violations of the 340B law, and we urge HRSA to publish the ceiling price website as soon as possible after Jan. 1, 2019. Prompt publication of the website would give 340B providers access to the data needed to determine if they are being overcharged and allow them to bring such discrepancies in drug ceiling prices promptly to HRSA's attention. We believe that HRSA can easily accommodate the prompt posting of ceiling prices. The agency testified at a July 2017 hearing that it had received funding for the information technology system to post ceiling prices in fiscal year 2014 and that the system would be ready in "the coming months."[5] We encourage HRSA to commit to doing so.

Implementing the final regulation by Jan. 1, 2019 and making the ceiling price available via the secure web-based portal are important steps to improving 340B drug pricing transparency. 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 uncover 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.

[4] 42 U.S.C. § 256b(d)(1)(A).
[5] Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcommittee. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Transcript, at 47, 2017 WL 3104702 (Jul. 18, 2017) ("July 2017 340B E&C Oversight Hearing Transcript").

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President