



Maryland  
Hospital Association

November 21, 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; effective date change: RIN 0906-AB19 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; (Vol. 83, No. 213, Nov. 2, 2018)***

Dear Captain Pedley:

On behalf of Maryland's 63 hospitals and health systems, we are extremely pleased that the Health Resources and Services Administration (HRSA) has proposed to make January 1, 2019 the compliance effective date for the final rule on 340B drug ceiling prices and civil monetary penalties (CMPs) for drug companies that intentionally overcharge 340B providers. The final rule is critically important for 340B participating hospitals, and the repeated and lengthy previous delays in making the final rule effective have significantly prejudiced Maryland's hospitals and, by extension, their low-income patients whom Congress intended to benefit from the 340B program.

About half of Maryland's hospitals rely on the 340B program to keep outpatient drug prices low and support programs for low-income patients. Further delay to publishing the rule, may reduce access to health care and limit resources needed to serve vulnerable populations as the 340B program provides resources for many uninsured and low-income patients. Hospital savings from the program are reinvested in other programs that reduce potentially avoidable utilization and improve outcomes.

**To help our hospitals continue to support these populations, we urge HRSA to publish the final rule in time to meet the January 1 deadline.**

The final rule requires that the Department of Health and Human Services (HHS) make pricing information available to 340B hospitals and other participating providers online through a secure website. **We believe it is equally important for the website to be published as soon as possible after January 1 because the website is essential for effective enforcement of the 340B program.**

HRSA proposes a January 1 compliance effective date for the final rule that it previously issued on January 5, 2017 with an original 60-day effective date. HRSA issued the final rule after soliciting comments three times, once to an advanced notice of proposed rulemaking and twice to a proposed rule. Moreover, at the time the rule was issued, HRSA expressly found that the 60-day compliance timeframe “provides manufacturers sufficient time to adjust systems and update their policies and procedures.” By now, HRSA has given drug companies almost an additional 18 months to come into compliance. Ensuring that the January 1 compliance effective date does not waiver would offer greater assurances to our member hospitals and other 340B providers that they will receive the savings from drug company discounts that they are entitled to and that Congress provided to support critical health care services in communities with underserved populations that could not otherwise afford services.

**Implementation of the ceiling price methodology and the “penny pricing policy” directly addresses longstanding problems identified with accuracy of required 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 HHS’s 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.

In addition, “penny pricing policy,” an exception to the ceiling price methodology, discourages manufacturers from raising prices faster than inflation. This inflation penalty applies when the calculation of the drug discount results in a ceiling price of zero and entails imputing a ceiling price of \$0.01 for the relevant drug product. The policy, although in place for many years, has not been applied consistently by drug companies and, as the OIG report demonstrates, the largest overpayments by 340B hospitals have resulted from inappropriate handling of ceiling prices that should have been discounted because of the inflation penalty. The 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.”

Promptly enforcing these final rule provisions is valuable in bringing drug companies into compliance and ensuring that 340B providers like our hospital 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 the 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.” 42

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U.S.C. § 256b(d)(1)(A). The incentives of CMPs should encourage drug companies from charging too much for covered drugs. Making the final rule's CMPs' provision effective 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 January 1.** 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.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Brett McCone". The signature is fluid and cursive, with the first name "Brett" being more prominent than the last name "McCone".

Brett McCone  
Vice President  
Maryland Hospital Association