

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: RIN 0906-AB19, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Proposed Rule: Effective Date Change; (*Federal Register*, Vol. 83, No. 213, November 2, 2018)

Dear Captain Pedley:

On behalf of our more than 200 member hospitals and nearly 50 health systems, the Illinois Health and Hospital Association (IHA) is taking this opportunity to formally comment on the proposed rule establishing Jan. 1, 2019 as the compliance effective date for the final rule implementing 340B drug ceiling prices and civil monetary penalties (CMPs) for those drug companies that intentionally overcharge 340B providers. Implementing the final rule is critically important for our 340B-eligible hospital members. The previous delays in the effective date have significantly hurt our hospital members and consequently, the communities they serve whom Congress intended to benefit from the 340B program. **We urge HRSA to hold to its commitment and to publish the final rule in time to meet the Jan. 1 deadline.**

The final rule also 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. **IHA believes it is equally important for the website to be published quickly after Jan. 1 because the website is essential for effective enforcement of the 340B program.**

The Health Resources and Services Administration (HRSA) proposed a Jan. 1 compliance effective date for the final rule that it previously issued on Jan. 5, 2017, with an original 60-day effective date. HRSA issued the final rule after soliciting comments three times. Moreover, at the time the rule was issued, the agency expressly found that the 60-day compliance timeframe “provides manufacturers sufficient time to adjust systems and update their policies and procedures.”

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As of this writing, drug companies have had almost 18 months to establish compliance. Ensuring that the Jan. 1 compliance effective date is implemented offers 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 created to support critical healthcare services in communities with underserved populations that could not otherwise afford services.

Implementation of the ceiling price methodology 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 a key component in the determination of 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 providers.

In addition, the "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. Although in place for many years, the policy 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 will bring drug companies into compliance and ensure that our member hospitals are able to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" as Congress intended. Enforcement is entirely consistent with the administration's stated goal of addressing the issue of the rising costs of prescription drugs.

The final rule's civil monetary penalties help enforce the requirements of the 340B statute, as both Congress and the OIG concluded. The threat of CMPs will deter 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.

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Congress also determined that making ceiling prices available to 340B providers would assist them in detecting violations of the 340B law; therefore, we urge HRSA to publish the ceiling price website shortly after Jan. 1. Prompt publication of the website would give 340B hospitals 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.

Captain Pedley, thank you again for the opportunity to comment. If you or your staff has any questions on the comments, they should be addressed to Thomas Jendro, senior director of finance, at 630-276-5516 or tjendro@team-iha.org.

Sincerely,

A.J. Wilhelmi
President & CEO