



**CALIFORNIA  
HOSPITAL  
ASSOCIATION**

*Providing Leadership in  
Health Policy and Advocacy*

November 20, 2018

Krista Pedley, Pharm.D, MS  
Captain, U.S. Public Health Service  
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:

The California Hospital Association (CHA), on behalf of our more than 400 member hospitals and health systems, appreciates the opportunity to comment on the Health Resources & Services Administration's (HRSA) proposed rule that would make January 1, 2019, the effective date for compliance with the final rule implementing 340B drug ceiling prices and civil monetary penalties (CMPs) for drug companies that intentionally overcharge 340B providers. **The final rule is critically important for the 181 hospitals in California that participate in the 340B program. CHA is extremely pleased with HRSA's proposal to make January 1 the effective date for compliance.**

In addition to enforcing CMPs for drug companies, 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. Congress 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 whether they are being overcharged and allow them to promptly bring such discrepancies to HRSA's attention.

The final rule also established the requirement that a manufacturer charge \$.01 for drugs when the ceiling price calculation equals zero. Known as the "penny pricing policy," this discourages manufacturers from raising prices faster than inflation. The penny pricing policy applies when the calculation of the drug discount results in a ceiling price of zero and entails imputing a ceiling price of \$.01 for the relevant drug product. The policy, although in place for many years, has not been consistently applied by drug companies. A report by the Department of Health and Human Services Office of Inspector General (OIG) 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."<sup>1</sup> The largest overpayments by 340B hospitals have resulted from

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

inappropriate handling of ceiling prices that should have been discounted because of the penny pricing policy.

Promptly enforcing these final rule provisions is valuable in bringing drug companies into compliance and ensuring that 340B hospitals 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 rising prescription drug costs. **For these reasons, we urge HRSA to honor its commitment and publish the final rule in time to meet the January 1 deadline.**

CHA and our 340B member hospitals appreciate the opportunity to offer our support. We share the common goal of ensuring that the 340B program can continue to fulfill its original intent of helping hospitals stretch limited resources to expand and improve access to comprehensive health care services for low-income patients. The increasingly high cost of pharmaceuticals has continued to underscore the 340B program’s importance. Promptly implementing the final rule on 340B drug ceiling prices and CMPs is a crucial step in addressing the rising costs of prescription drugs.

If you have questions, please do not hesitate to contact me at [akeefe@calhospital.org](mailto:akeefe@calhospital.org) or (202) 488-4688, or my colleague Amber Ott, group vice president, data and analytics, at [aott@calhospital.org](mailto:aott@calhospital.org) or (916) 552-7669.

Sincerely,

Alyssa Keefe  
Vice President, Federal Regulatory Affairs