

May 22, 2018

Capt. Krista Pedley  
Director  
Office of Pharmacy Affairs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane  
Mail Stop 08W05A  
Rockville, MD 20857

**Re: RIN 0906–AB18 - Comments on Notice of Proposed Rulemaking; Further Delay of Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (submitted via Federal eRulemaking Portal: <http://regulations.gov>)**

Dear Capt. Pedley:

On behalf of the thousands of hospitals enrolled in the 340B federal drug discount program, the American Hospital Association, the Association of American Medical Colleges, the Catholic Health Association of the United States, America’s Essential Hospitals, the Children’s Hospital Association, and 340B Health respectfully submit these comments in response to the Notice of Proposed Rulemaking published in the Federal Register on May 7, 2018.<sup>1</sup> The notice proposes a fifth delay, to July 1, 2019, of the effective date of a Final Rule promulgating regulations for the 340B ceiling price and manufacturer civil monetary penalties (CMPs).<sup>2</sup> We *strongly* oppose any additional delay of the Final Rule because doing so will harm hospitals and their patients. The Department of Health and Human Services (HHS) should implement the rule immediately to protect hospitals and other 340B covered entities from manufacturer overcharges that undermine the program’s purpose.

Effective enforcement of manufacturers’ pricing obligations is key to the success of the 340B program, which is intended to allow covered entities to access drugs at a more affordable price so that they can “reach[] more . . . patients” and furnish “more comprehensive services.”<sup>3</sup> To qualify for the program, hospitals must demonstrate that they serve a high level of low-income patients or serve patients in remote rural areas. In 2015 alone, 340B hospitals provided \$23.8 billion in uncompensated care<sup>4</sup> and \$51.7 billion<sup>5</sup> in total benefits to their communities. Hospitals were able to provide these benefits despite significant fiscal pressures.

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<sup>1</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 20,008 (May 7, 2018).

<sup>2</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) (the “Final Rule”).

<sup>3</sup> H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

<sup>4</sup> AHA 2015 Annual Survey Data

<sup>5</sup> AHA 340B Community Benefit Analysis, March 2018, accessed at <https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf>.

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Manufacturer overcharges have long plagued the 340B program. The HHS Office of Inspector General (OIG) has issued multiple reports finding high rates of 340B overcharges by manufacturers, including violations of HRSA's penny pricing policy. There continue to be settlements between the federal government and manufacturers that include repayments to providers for 340B overcharges.

Providers have no significant remedies available to address manufacturer overcharges. They cannot audit manufacturers or sue companies in court. Manufacturers can decide not to participate in the 340B program's current voluntary dispute resolution process, and a proposal to make the process mandatory has been withdrawn. Providers cannot even check that they are being charged the right price. In 2010, Congress mandated that providers be given access to 340B ceiling prices, but HHS has not provided that access over eight years later. At a recent Senate Health, Education, Labor and Pensions Committee hearing, the OIG called for increased 340B ceiling price transparency, so covered entities can ensure they are paying the correct amount for 340B drugs.

Given that there is every reason to believe that the problem of 340B overcharges continues, it is inappropriate to postpone this rule. HHS's interest in conducting additional rulemaking is not a sufficient reason to not enforce current law, especially one that is so vital to the nation's safety net.

We believe that the Final Rule is crucial to codify important 340B policies and to ensure that manufacturers comply with 340B program requirements. We urge HHS to implement the Final Rule immediately. We thank HHS for the opportunity to comment on the proposed delay. If you have any questions or need additional information, please do not hesitate to reach out to any of the individuals in the attached list of organizational contacts.

Sincerely,

American Hospital Association  
Association of American Medical Colleges  
Catholic Health Association of the United States  
America's Essential Hospitals  
Children's Hospital Association  
340B Health