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# THE 340B COALITION

November 20, 2018

Captain Krista Pedley  
Director, Office of Pharmacy Affairs  
Health Resources and Services Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

***RE: RIN 0906-AB19: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation***

Dear Captain Pedley:

On behalf of the undersigned organizations, we write in strong support of the proposed rule to cease any further delay of the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation and change the effective date from July 1, 2019 to January 1, 2019.

340B covered entities have long advocated for timely implementation of the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation in order to ensure the effective enforcement of manufacturers' pricing obligations in the 340B program. 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 for 340B overcharges. Timely implementation of this rule is critical given the fact that providers currently have no actionable remedies available to address manufacturer overcharges. They cannot audit manufacturers or sue companies for non-compliance.

Implementation has been postponed five times to date and in its most recent rulemaking delaying the effective date of the January 5, 2017 final rule, HHS stated that the delay was necessary to allow additional time to develop "comprehensive policies to address the rising costs of prescription drugs."<sup>1</sup> We are encouraged to note that in this proposed rule, "the Department no longer believes a delay in the implementation date is necessary."

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<sup>1</sup> 83 FR 25944

On a related issue, we urge the Agency to release the secure website providing access to 340B ceiling prices for all 340B-eligible drugs as quickly as possible. HRSA's recent budget justification for Fiscal Year 2019 stated that database "[i]mplementation is expected once the Civil Monetary Penalty and Ceiling Price calculation regulation has been finalized and any necessary changes to the system have been implemented."<sup>2</sup>

Ensuring that 340B providers have timely access to this ceiling price website is critical to the effective enforcement of the 340B program and will enable providers the ability to verify that they are, in fact, being charged the correct price for 340B drugs.

We appreciate the opportunity to provide these comments and stand ready to assist the Agency with these critical measures moving forward.

Sincerely,

The 340B Coalition

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<sup>2</sup> HHS Fiscal Year 2019 HRSA Justification of Estimates for Appropriations Committees 269, <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf>

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