



Action Alert

November 8, 2018

AHA Model Comment Letter on HRSA Proposed Rule on the Change in Effective Date for 340B Ceiling Price and Manufacturer CMPs

Use AHA model letter to submit your comments by Nov. 23

Facing deadlines for responding to the lawsuit brought by the AHA, Association of American Medical Colleges, America's Essential Hospitals, 340B Health and three hospital systems, the Health Resources and Services Administration proposes a Jan. 1 compliance date for its final rule on 340B drug ceiling prices and civil monetary penalties for manufacturers. The final rule describes how ceiling prices must be calculated and allows the federal government to levy CMPs against drug companies that intentionally overcharge 340B providers.

AHA is pleased that, in response to our lawsuit, HRSA on Nov. 2 proposed the regulation to change the effective and compliance date. Our lawsuit to make the final rule effective immediately continues, and the recent court ruling denying the government request to stay the lawsuit pending the agency's Nov. 2 rulemaking on the effective date puts more pressure on the Department of Health and Human Services to stick to that Jan. 1 deadline. Nevertheless, it is imperative that all 340B hospitals submit comments to HRSA urging the agency to publish the final rule in time to meet the Jan. 1 deadline.

AHA has developed a short model comment letter that you can use in crafting your own letter. [Please click here to download our model comments](#). All comments must be received on or before Nov. 23.

Detailed instructions on submitting the letter follow.

To send electronically: go to <http://www.regulations.gov>. Follow the "Submit a Comment" instructions. **This is the preferred method for the submission of comments.**

To send U.S. mail: see link to instructions on submitting comments below. Please allow sufficient time for mailed comments to be received before the close of the comment period.

E-mail: 340BCMPNPRM@hrsa.gov. Include 0906-AB19 in the subject line of the message.

For complete instructions on submitting comments, see the Addresses section of the Notice of Proposed Rulemaking at <https://www.gpo.gov/fdsys/pkg/FR-2018-11-02/pdf/2018-24057.pdf>. Please submit your comments in only one of the ways described to minimize the receipt of duplicate submissions.

All submitted comments will be available to the public in their entirety. Please do not submit commercial confidential information or personal identifying information that you do not want in the public domain.