

HRSA delays 340B CMP and Ceiling Price Rule to July 1, 2018 and intends to reopen rulemaking

September 29, 2017

Yesterday, the Health Resources and Services Administration (HRSA) issued a [Final Rule](#) (Final Rule) delaying the effective date and the enforcement date of the [340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Rule](#) (the “CMP and Ceiling Price Final Rule”) from October 1, 2017, until July 1, 2018. ***The Final Rule is effective immediately.***

This Final Rule is the fourth time that HRSA has delayed the effective date of the CMP and Ceiling Price Final Rule. The prior three delays are as follows:

- [March 6, 2017](#): HRSA [delayed](#) the effective date of the CMP and Ceiling Price Final Rule **from March 6, 2017, to March 21, 2017**, following the Trump Administration’s January 20, 2017, [executive memorandum](#) directing agencies to delay any regulations not yet implemented by 60 days from the date of the memorandum.
- [March 20, 2017](#): HRSA issued an [Interim Final Rule](#) (IFR) which further delayed the effective date of the CMP and Ceiling Price Final Rule **until May 22, 2017**, and asked for comment on whether the effective date should be further delayed to October 1, 2017.
- [May 19, 2017](#): HRSA again delayed the effective date, this time **to October 1, 2017**, as part of a final rule [published](#) in the Federal Register on May 19, 2017.

The possibility of an additional, fourth delay was announced on August 17, 2017, when HRSA issued a [proposed rule](#) asking for comments on whether to delay the CMP and Ceiling Price Final Rule again until July 1, 2018, and indicated an interest in potentially revising the CMP and Ceiling Price Final Rule through additional rulemaking. Today’s announcement of this additional delay marks the fourth time that HRSA has delayed the effective and enforcement dates of the CMP and Ceiling Price Final Rule.

HRSA received 97 comments on its proposal to delay the CMP and Ceiling Price Final Rule for the fourth time. These comments included a number of comments on the substance of the CMP and Ceiling Price Final Rule itself, which HRSA did not address as part of the Final Rule. **HRSA did note, however, that it “intends to engage in further rulemaking on issues covered in the [CMP and Ceiling Price Final Rule]” and that the “complexity [of the 340B program] and changing environment warrants further review of the [CMP and Ceiling Price Final Rule].”** Stakeholders therefore should expect HRSA to issue proposed changes to the CMP and Ceiling Price Final Rule in the coming months for notice and comment rulemaking.

HRSA also addressed the following stakeholder comments in the Final Rule:

- In response to comments suggesting that the CMP and Ceiling Price Final Rule should be delayed beyond the proposed July 1, 2018, date to allow sufficient time to reexamine the CMP and Ceiling Price Final Rule, HRSA indicated that it “believes that delaying the effective date to July 1, 2018, provides sufficient time to address these issues and does not believe that a further delay is necessary at this time.”
- HRSA plans to address any concerns that the CMP and Ceiling Price Final Rule is inconsistent with the 340B statute and unnecessarily burdensome on manufacturers as part of its additional rulemaking on the CMP and Ceiling Price Final Rule.
- HRSA agreed with commenters that the delay in the CMP and Ceiling Price Final Rule is consistent with the current administration’s priority of “analyzing final, but not yet effective, regulations, and removing or minimizing unwarranted economic and regulatory burdens related to the Affordable Care Act” consistent with Executive Order 13765.
- In response to comments that the CMP and Ceiling Price Final Rule should be delayed until HRSA “concurrently addresses 340B covered entity compliance obligations and penalties under the 340B statute,” **HRSA indicated that it would “issue separate policy documents for the different areas of the 340B program integrity provisions in the 340B statute and disagrees with the commenters advising [HRSA] to address these issues concurrently.”**
- In response to comments opposing the delay in the CMP and Ceiling Price Final Rule effective date due to concern over manufacturer compliance with 340B program requirements, HRSA stated that it is performing manufacturer oversight in the meantime and that “the delay will provide stakeholders with additional time to come into compliance [with the CMP and Ceiling Price Final Rule] and provide time to consider the substantial questions of fact, law, and policy raised by the rule.”

More information about the CMP Final Rule is available through a Hogan Lovells [Health Alert](#) published on January 9, 2017.

As always, it is important to review the Final Rule in its entirety to ensure you identify all issues relevant to your organization. If you have any questions or would like to discuss these developments, please contact the Hogan Lovells Government Price Reporting team.

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