

340B Program: Ceiling Price and CMP Final Rule Delayed Until May 22—Comments Requested on Possible Further Delay

20 March 2017

On 20 March 2017, the Health Resources and Services Administration (HRSA) published an [Interim Final Rule](#) (IFR) delaying the effective date of the [340B Ceiling Price and Civil Monetary Penalties \(CMP\) Rule](#) (the Final Rule) until 22 May 2017. **The delay is effective immediately.**

HRSA also asked for comments on whether the effective date of the rule should be delayed further, until 1 October 2017. Comments are due on or before 19 April 2017.

As a reminder, the Final Rule¹ established:

- CMPs for manufacturers who knowingly and intentionally charge covered entities more than the ceiling price for a covered outpatient drug.
- A methodology for calculating the 340B ceiling price, including:
 - The codification of HRSA's penny pricing policy, which requires manufacturers to charge \$0.01 for a drug whose ceiling price calculates to less than \$0.01.
 - A ceiling price estimation methodology for new drugs.
- Requirements for refunding covered entities in connection with truing up estimated ceiling prices and revised ceiling prices resulting from routine restatements of CMS Medicaid data.

HRSA published the Final Rule in the Federal Register on 5 January 2017, with an effective date of 6 March 2017. HRSA later [delayed](#) the effective date of the Final Rule to 21 March 2017, consistent with the Trump Administration's 20 January 2017 [executive memorandum](#) (the Memorandum) asking federal agencies to delay the effective date of all rules that had been published, but were not yet effective, by 60 days from the date of the Memorandum.² Under either of these effective dates, HRSA had indicated that it would not begin enforcing the Final Rule until 1 April 2017, the first day of the next calendar quarter. The IFR's delay in the effective date to 22 May 2017 also delays the enforcement of the Final Rule. The IFR states that "enforcement will be correspondingly delayed" but does not address whether enforcement will again be delayed until the first day of the next calendar quarter.

¹See Hogan Lovells previously published [Health Alert](#) discussing the Final Rule.

²See Hogan Lovells previously published [Health Alert](#) discussing the impact of this Memorandum and of other actions of the Trump Administration related to health care.

HRSA cites multiple reasons for delaying the effective date:

- HRSA acknowledges that “it appears that objections regarding the timing and challenges of compliance with the rule . . . , as well as other objections to the rule, may not have been adequately considered, thereby requiring additional time and public comment before the rule goes into effect.”
- It needs more time “to review substantial questions of fact, law, and policy in regulations not currently in effect,” consistent with the Memorandum’s directive to federal agencies.
- HRSA believes that the delay is consistent with the Trump Administration’s 20 January 2017 [Executive Order](#) (the Executive Order), which directs agencies to use all means within their power to delay implementation of the Affordable Care Act (ACA). The requirement for HRSA to establish CMPs was added to the 340B statute by the ACA.
- HRSA wishes to avoid exacerbating the burden on stakeholders while issues with the Final Rule remain unresolved, including the burden of “[r]equiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures to come into compliance with a rule that is itself subject to further agency consideration and for which there are substantive questions raised . . .”
- HRSA “believes that it is important to ensure that this rulemaking—as well as the implementation of this rule—is coordinated with and takes into consideration overall 340B Program implementation.”

As always, it is important that you review the IFR in detail to identify all issues relevant to your organization. Please feel free to contact the Hogan Lovells Government Price Reporting Team below if you have any questions or would like to discuss these developments.

Contacts



Alice Valder Curran

Partner, Washington, D.C.

Tel +1 202 637 5997

alice.valder.curran@hoganlovells.com



Ken Choe

Partner, Washington, D.C.

Tel +1 202 637 5675

ken.choe@hoganlovells.com



Christopher H. Schott

Partner, Washington, D.C.

Tel +1 202 637 5467

christopher.schott@hoganlovells.com



Kathleen A. Peterson

Counsel, Washington, D.C.

Tel +1 202 637 5810

kathleen.peterson@hoganlovells.com



Samantha D. Marshall

Associate, Washington, D.C.

Tel +1 202 637 3651

samantha.marshall@hoganlovells.com

Lacey L. Withington

Associate, Washington, D.C.

Tel +1 202 637 5842

lacey.withington@hoganlovells.com