

340B program: CMP Final Rule effective and implementation date accelerated to January 1, 2019

November 30, 2018

Yesterday, the Health Resources and Services Administration (HRSA) [issued](#) a Final Rule (Final Rule) that **accelerates the effective and implementation date of the 340B Ceiling Price and Civil Monetary Penalties final rule (2017 CMP Final Rule) from July 1, 2019, to January 1, 2019**. The Final Rule was published in the [Federal Register](#) today. HRSA stated that the Department of Health and Human Services (HHS) has determined that making the 2017 CMP Final Rule effective sooner would not interfere with its development of “comprehensive policies to address the rising costs of prescription drugs... in government programs, such as Medicare Parts B & D, Medicaid, and the 340B Program,” and that HHS therefore no longer believes that delaying the effective date is necessary.

HRSA had [issued](#) the Proposed Rule (Proposed Rule) accelerating the effective date of the 2017 CMP Final Rule on November 2, 2018. The Hogan Lovells alert discussing the Proposed Rule, the previous delays in the effective date, and the litigation that was the apparent impetus for the acceleration is available [here](#). HRSA received 136 comments in response to the Proposed Rule.

2017 CMP final rule: The 2017 CMP Final Rule, which addresses the calculation of the 340B ceiling price and the imposition of CMPs on manufacturers that knowingly and intentionally overcharge 340B covered entities, was [published](#) on January 5, 2017. The Hogan Lovells alert reviewing the 2017 CMP Final Rule is available [here](#).

HRSA’s Rationale for Finalizing the 2017 CMP Final Rule and Accelerating the Effective Date: The Final Rule addresses the following comments in explaining the acceleration of the effective date:

- Commenters urged HRSA not to accelerate the effective date and to further delay the 2017 CMP Final Rule until HRSA issues new guidance regarding the ceiling price website. Other commenters asked HRSA to “publish the ceiling price data on a secure website shortly after January 1, 2019.” HRSA noted that “[c]urrent policies under the 340B Program already provide stakeholders with sufficient guidance regarding programmatic compliance.” In addition, HRSA stated that the 340B ceiling price website is forthcoming, with further updates to be posted on HRSA’s website.
- Commenters disagreed that HRSA has “meaningfully responded to comments or considered the full range of comments on the substantive issues in the” 2017 CMP Final Rule. In

response, HRSA stated that it has “decided to change the effective date ... as the [2017 CMP Final Rule] has been subject to extensive public comment,” “[t]he rule is consistent with the 340B statute,” and HRSA “believes that CMPs provide a critical enforcement mechanism ... if manufacturers do not comply with statutory pricing obligations under the 340B Program.”

- Commenters stated that HRSA “has not provided an adequate rationale for its change of view on the need for additional rulemaking and ... has not released information related to the ‘comprehensive policies’ that it has suggested it intends to promulgate.” HRSA reiterated that it does not believe accelerating the effective date of the 2017 CMP Final Rule will undermine the other comprehensive drug pricing policies it is considering. HRSA noted that, given the delays in adopting and implement the 2017 CMP Final Rule, “it would be more efficient for the rule to go into effect and assess the need for further rulemaking and guidance after [it] is in effect.”
- Commenters argued that HRSA had previously stated that “there is no basis for [HRSA] to suddenly move up the effective date by six months and ... no material development that rationally justifies [HRSA’s] change of view on the need for additional rulemaking.” HRSA disagreed, stating that it “has issued several policies related to lowering prescription drug prices, particularly in the Medicare Program,” that it “continues to explore other policy documents,” and that “commenters have not demonstrated that the finalization of the [2017 CMP Final Rule] would interfere with HHS’s development of these comprehensive policies.”
- Commenters urged HRSA to specify that the implementation date of the 2017 CMP Final Rule should be set at April 1, 2019 (even if the effective date is January 1, 2019), similar to the delay in implementation of the CMP Final Rule to April 1, 2017, when it was originally published on January 5, 2017, to give drug manufacturers time to comply with the regulation. In response, HRSA stated that **the effective date and implementation date for the CMP Final Rule will be the same, January 1, 2019.**
- HRSA agreed with commenters that supported the acceleration of the effective date of the 2017 CMP Final Rule “to bring drug companies into compliance” and because “CMPs are an important deterrent to manufacturers who knowingly overcharge entities.”

HRSA also stated that the change in the effective date cannot be economically significant, in part because “the civil penalties envisioned in the [2017 CMP Final Rule] [are] expected to be rare.” HRSA “estimates that the economic impact on small entities and small manufacturers will be minimal and less than 3 percent.”

As always, it is important that you review the proposed rule to identify all issues relevant to your organization. Please feel free to contact our Government Price Reporting team if you have any questions or concerns.

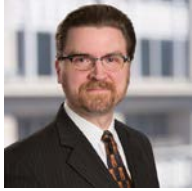
Contacts



Alice Valder Curran
Partner, Washington, D.C.
T +1 202 637 5997
alice.valder.curran@hoganlovells.com



Ken Choe
Partner, Washington, D.C.
T +1 202 637 5675
ken.choe@hoganlovells.com



Christopher H. Schott
Partner, Washington, D.C.
T +1 202 637 5467
christopher.schott@hoganlovells.com



Kathleen A. Peterson
Counsel, Washington, D.C.
T +1 202 637 5810
kathleen.peterson@hoganlovells.com



Margaux J. Hall
Senior Associate, Washington, D.C.
T +1 202 637 5760
margaux.hall@hoganlovells.com



Samantha D. Marshall
Senior Associate, Washington, D.C.
T +1 202 637 3651
samantha.marshall@hoganlovells.com

www.hoganlovells.com

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