

340B UPDATE: HRSA FURTHER DELAYS REGULATIONS ON 340B PRICING & PENALTIES FOR DRUG MANUFACTURERS

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U.S. Health Care Alert

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On March 20, 2017, the Health Resources and Services Administration ("HRSA") published in the Federal Register an Interim Final Rule delaying the effective date of regulations relating to drug pricing and civil monetary penalties for drug manufacturers under the 340B Drug Pricing Program ("340B Program").^[1] Further, commentary in the Interim Final Rule suggests that additional developments on the 340B Program from HRSA may be forthcoming.

BACKGROUND

As discussed in a prior alert, the Trump administration issued a Memorandum on January 20, 2017, directing agencies to, among other things, temporarily postpone the effective date of regulations that had been published in the Federal Register but had not yet taken effect.^[2] In particular:

With respect to regulations that have been published in the [Federal Register] but have not taken effect, as permitted by applicable law, temporarily postpone their effective date for 60 days from the date of this memorandum . . . for the purpose of reviewing questions of fact, law, and policy they raise. Where appropriate and as permitted by applicable law, you should consider proposing for notice and comment a rule to delay the effective date for regulations beyond that 60-day period.^[3]

In addition, the Memorandum advises agencies to consider proposing further notice-and-comment rulemaking with respect to such regulations if they raise substantial questions of law or policy. Although HRSA published a Final Rule on the 340B Program drug pricing and manufacturer penalties prior to the Memorandum on January 5, 2017^[4] (discussed in detail in a prior alert), the regulations had not yet gone into effect at the time the White House issued the Memorandum. Accordingly, HRSA delayed the Final Rule's effective date until March 21, 2017 — 60 days after the Memorandum.^[5] However, HRSA had not intended on enforcing the Final Rule until April 1, 2017, regardless of the delay, meaning the announcement did not have a significant impact on 340B Program compliance.

INTERIM FINAL RULE

On March 20, 2017, HRSA followed up on its initial delay by publishing an Interim Final Rule that further delays the effective date of the 340B Program drug pricing rules and manufacturer penalties until May 22, 2017.

Moreover, HRSA invites comment on whether to delay the effective date to October 1, 2017, which would align the effective date with HRSA's quarterly enrollment and participation schedule under the 340B Program. Consistent with the Trump administration's Memorandum, HRSA indicates that the decision to delay the regulations was made "after further consideration and to provide affected parties sufficient time to make needed changes to facilitate compliance, and because there are substantive questions raised" by the rules issued under the Obama administration.[6]

Notably, in publishing the Interim Final Rule, HRSA states, "HHS 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." [7] In this regard, although the Interim Final Rule does not reference specific forthcoming actions or policies relating to this comment, the statement could signal that further rulemaking or guidance on the 340B Program is under consideration by the Trump administration. It also suggests that an additional delay until October 1, 2017, could be forthcoming, given that this date would better align with the quarterly 340B Program enrollment and participation schedule than a May 22 effective date. As a result, 340B Program-covered entities, manufacturers, and others should continue watching for developments out of HRSA to ensure continued compliance with 340B Program rules.

Notes:

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332 (Mar. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-03-20/pdf/2017-05491.pdf> ("Interim Final Rule").

[2] Memorandum for the Heads of Executive Departments and Agencies; Regulatory Freeze Pending Review, 82 Fed. Reg. 8,346 (Jan. 24, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-01-24/pdf/2017-01766.pdf> ("Memorandum").

[3] *Id.*

[4] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf>.

[5] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date, 82 Fed. Reg. 12,508 (Mar. 6, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-03-06/pdf/2017-04337.pdf>.

[6] Interim Final Rule at 14,333.

[7] *Id.*

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