340B UPDATE: HRSA DELAYS FINAL RULE ON 340B PRICING AND MANUFACTURER CMPS YET AGAIN

Date: 23 August 2017

U.S. Health Care Alert

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Update: On September 29, 2017, HRSA officially delayed the final rules discussed below until July 1, 2018, and re-iterated its intent to engage in further rulemaking. See 82 Fed. Reg. 45,511 (Sept. 29, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-09-29/pdf/2017-20911.pdf.

On August 21, 2017, the Health Resources and Services Administration ("HRSA") published a Notice of Proposed Rulemaking to further delay the effective date of final rules on drug pricing calculations and civil monetary penalties ("CMPs") for manufacturers that knowingly and intentionally overcharge covered entities under the 340B Drug Pricing Program ("340B Program") until July 1, 2018.[1] HRSA also noted that it "intends to engage in additional rulemaking on these issues."[2] While President Trump has previously expressed negative views regarding pharmaceutical industry pricing,[3] the proposed delay appears to be intended to potentially pull back on some of the obligations in the final rules on drug manufacturers. Accordingly, 340B Program stakeholders should not only review the impact of the delayed effective date, but should also consider any other concerns within the final rules and consider raising issues with regulators through public comments.

BACKGROUND

As discussed in previous K&L Gates 340B Updates (see here, here, and here), the Trump administration issued a Memorandum on January 20, 2017, directing federal agencies to temporarily postpone the effective date of certain regulations issued by the Obama administration that had been published in the Federal Register but had not yet taken effect.[4] As a result, HRSA delayed until March 21, 2017, the effective date of the final rules under the 340B Program on ceiling price calculations and manufacturer CMPs, which were authorized under the Patient Protection and Affordable Care Act ("ACA").[5] HRSA later delayed the effective date of the final rules until May 22, 2017,[6] and then until October 1, 2017.[7] The delay until October was designed to align the effective date with HRSA's quarterly 340B Program enrollment and participation schedule, as well as "mitigate implementation concerns" and "enhance program integrity."

FURTHER DELAY

HRSA is now proposing to delay the effective date until July 1, 2018, while it "continues to examine important substantive issues" covered under the final rules. HRSA notes that this is consistent with the administration's Memorandum, which generally authorizes agencies to delay regulations to consider "substantial questions of fact, law and policy." HRSA notes, "Requiring manufacturers to make targeted and potentially costly changes to pricing

systems and business procedures in order to comply with a rule that is under further consideration and for which substantive questions have been raised would be disruptive." Further, HRSA notes that the Trump administration issued an Executive Order early this year that specifically calls for agencies to use all authority and discretion to delay certain provisions or requirements under the ACA.[8]

Notably, HRSA also states that it needs more time to fully consider previous objections to the final rules, and states, "HHS intends to engage in additional rulemaking on these issues." Accordingly, HRSA encourages all 340B Program stakeholders to comment. Public comments are due by September 20, 2017.

Given HRSA's apparent intent to not only delay but reexamine the substantive provisions of the final rule and the Trump administration's ongoing activities related to numerous 340B Program proposals, engagement with decision makers is critical for those hoping to impact policy outcomes in the months ahead.

Notes:

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 39,553 (July 21, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-08-21/pdf/2017-17633.pdf.

[2] *Id.* at 39,554.

[3] *See, e.g.*, Carolyn Y. Johnson, WASH. POST, *Trump on Drug Prices: Pharma Companies are "Getting Away with Murder*," Jan. 11, 2017, https://www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/.

[4] 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").

[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] 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.

[7] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 22,893 (May 19, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-05-19/pdf/2017-10149.pdf.

[8] Exec. Order 13765, Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 Fed. Reg. 8,351 (Jan. 24, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-01-24/pdf/2017-01799.pdf.

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