340B UPDATE: TRUMP ADMINISTRATION WITHDRAWS OMNIBUS GUIDANCE, DELAYS FINAL RULE ON 340B DRUG PRICING AND CMPS

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Health Care Alert

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The new administration has had an immediate impact on the federal 340B Drug Discount Program ("340B Program") with two significant developments in the first days since President Trump took office: (1) the withdrawal of the final 340B Program Omnibus Guidance, which was pending before the White House Office of Management and Budget ("OMB"); and (2) an expected delay in the effective date of the final rule issued by the Health Resources and Services Administration ("HRSA") on 340B drug pricing and civil monetary penalties ("CMPs") for drug manufacturers.

Our prior alert on the 340B Omnibus Guidance can be found here. Our recent alert on the HRSA final rule relating to 340B drug pricing and manufacturer penalties can be found here.

340B OMNIBUS GUIDANCE WITHDRAWN

On January 30, 2017, the OMB website officially designated the Omnibus Guidance as withdrawn, indicating it has been sent back to the Department of Health and Human Services ("HHS"). As discussed in our prior alert, HRSA issued a proposed version of the Omnibus Guidance in August 2015 that was sweeping in its scope, including a new definition of who is considered a patient of a covered entity for purposes of the 340B Program. The proposal was controversial and drew strong reactions from stakeholders — particularly safety net providers dependent on the 340B Program to provide enhanced services to low-income individuals — who expressed concern that the Omnibus Guidance would dramatically scale back the 340B Program.

HRSA submitted a final version of the Omnibus Guidance to OMB last year, where it remained through the end of President Barack Obama's term. The withdrawal of the 340B Omnibus Guidance from OMB on January 30 likely stems from the Trump administration's January 20 Memorandum directing agencies to immediately withdraw regulations that were pending before OMB but had not yet been published in the Federal Register.[1]

At this point, the 340B Omnibus Guidance is unlikely to resurface in its prior form, given that the Trump administration was not expected to finalize many policies developed by the Obama administration even in the absence of the Memorandum. However, the official withdrawal of the Omnibus Guidance gives HRSA the opportunity to send new guidance to OMB or take other action consistent with the new administration's position on the 340B Program. Moreover, in deciding whether and how to proceed on the 340B Program, HRSA must also weigh the Trump administration's recent Executive Order requiring that for every new regulation issued, two existing regulations be repealed, adding further complexity to the issue.[2]

EFFECTIVE DATE OF 340B PRICING AND CMP FINAL RULE DELAYED

The Memorandum discussed above will also likely result in a delay of the effective date of HRSA's recently finalized rule on 340B drug pricing calculations and CMPs for drug manufacturers. Although the final rule was published in the Federal Register on January 5, 2017,[3] the Trump administration's Memorandum directs agencies to delay already-published regulations if they have not yet gone into effect. In particular, the Memorandum directs agencies as follows:

> 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.[4]

Given the final rule's original effective date of March 6, 2017, the Memorandum indicates it will not take effect until 60 days after January 20 — i.e., until March 21, 2017. With that said, even in the absence of the Memorandum, HRSA did not intend to begin enforcing the final rule until April 1, 2017 (to align with the 340B Program's quarterly enrollment and participation schedule),[5] so the delay may not have a material impact on 340B compliance. Nevertheless, HRSA may decide to delay the final rule further through notice-and-comment rulemaking, as suggested by the Memorandum. With the above noted, as of the date of this publication, the HRSA 340B Program website continues to state that the final rule will be effective on March 6, 2017.[6]

CONCLUSION

The first days of the Trump administration have already had a tangible impact on the 340B Program, with the withdrawal of the 340B Program Omnibus Guidance, in particular, being significant news for covered entities, drug manufacturers, and pharmacies. However, the administration's actions have also raised numerous questions about the future of the 340B Program and the direction that HRSA intends to take during the course of President Trump's tenure. Accordingly, all 340B stakeholders should stay up to date as the administration's policies take shape.

Notes:

[1] *See* 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"). Notably, as used in the Memorandum, the term "regulation" includes any "guidance document" as defined in Section 3(g) of Executive Order 12,866, as it existed when Executive Order 13,422 was in effect. Executive Order 13,422 defines "guidance document" as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue." Exec. Order 13,422, 72 Fed. Reg. 2,763 (Jan. 23, 2007), https://www.gpo.gov/fdsys/pkg/FR-2007-01-23/pdf/07-293.pdf.

[2] Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-

controlling. The Executive Order generally applies to any "regulation" or "rule," meaning "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency." According to the Office of Information and Regulatory Affairs, "New significant guidance or interpretive documents will be addressed on a case-by-case basis." Memorandum: Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, Titled "Reducing Regulation and Controlling Regulatory Costs" (Feb. 2, 2017), https://www.whitehouse.gov/the-press-office/2017/02/02/interim-guidance-implementing-section-2-executive-order-january-30-2017.

[3] 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.

[4] Memorandum, 82 Fed. Reg. 8,346. The Memorandum goes on to suggest that agencies consider proposing further notice-and-comment rulemaking with respect to such regulations. Following the delay, no further action should be taken with respect to regulations that raise no substantial question of law or policy — but for those that do raise such questions, agencies should notify OMB and take further appropriate action in consultation with the OMB Director. *Id.*

[5] 82 Fed. Reg. at 1,211.

[6] HRSA, 340B Drug Pricing Program, https://www.hrsa.gov/opa/ (accessed Feb. 6, 2017).

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