

340B UPDATE: HRSA ACCELERATES IMPLEMENTATION OF LONG-DELAYED 340B PRICING AND MANUFACTURER PENALTIES RULE

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Health Care Alert

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On October 31, 2018, the U.S. Department of Health and Human Services ("HHS") and the Health Resources and Services Administration ("HRSA") released a notice of proposed rulemaking ("NPRM") which proposes to move up the effective date of a prior rulemaking clarifying ceiling prices for the 340B Drug Discount Program ("340B" or "340B Program") and civil monetary penalties ("CMPs") for manufacturers that knowingly and intentionally overcharge covered entities under the 340B Program. [1] After multiple delays by the administration, the effective date of these rules has been moved up to January 1, 2019, six months earlier than the previously announced effective date of July 1, 2019. Although the administration's prior delays were largely supported by drug manufacturers, as discussed below, the announcement to move up the effective date to January 1, 2019, has been met with praise from organizations representing 340B covered entities.

SUMMARY OF RULE

As described in our prior [alert](#), HRSA originally released a final rule on January 5, 2017, that finalized certain changes to the calculation of 340B pricing ("2017 Final Rule"). [2] Specifically, the 2017 Final Rule clarified how manufacturers should calculate the 340B ceiling price by subtracting the drug's Medicaid "Unit Rebate Amount" from the drug's "Average Manufacturer Price". [3] If a covered entity paid more than the actual 340B ceiling price for the drug during the period when the estimated price was used, the covered entity is entitled to a refund or credit from the manufacturer for those purchases within 120 days of the determination by the manufacturer that an overcharge occurred. Further, the 2017 Final Rule finalized the 340B "penny pricing" policy, under which manufacturers are instructed to charge \$0.01 for 340B drugs when the ceiling price calculation would be zero. [4] HRSA also noted that it planned to issue guidance on operational elements of the 340B ceiling price calculation in future guidance associated with the 340B Program ceiling price reporting system.

Finally, the 2017 Final Rule would implement CMPs of up to \$5,000 per instance for drug manufacturers who knowingly and willfully overcharge covered entities for 340B drugs. [5] Each order by National Drug Code number for a particular drug (i.e., at the package size level but not at the individual product package level) would constitute a single instance of overcharging for purposes of the rule. The 2017 Final Rule also provides commentary on what constitutes "knowingly and intentionally" overcharging and indicated that it would defer to the HHS Office of Inspector General for enforcement.

DELAY IN IMPLEMENTATION

Although the 2017 Final Rule was scheduled to take effect on March 6, 2017, the Trump administration has delayed the implementation of the rule multiple times as part of its broader efforts to delay or rescind regulations that were initially proposed under the Obama administration, as well as its broader efforts to address drug pricing reform (see our prior alerts [here](#), [here](#), and [here](#)). Most recently, HRSA had postponed the effective date of the rulemaking until July 1, 2019, to allow for "necessary time to consider more fully the substantial questions of fact, law, and policy identified by the Department during its review of the rule" and to allow for the administration's consideration of new comprehensive policies to address the rising costs of prescription drugs in government programs, such as Medicare Parts B & D, Medicaid, and the 340B Program. [6]

As discussed in a separate [alert](#), in response to the continued delays, a number of hospital groups have rallied in support of the rule's swift implementation. A group of plaintiffs including the American Hospital Association ("AHA") and 340B Health filed a complaint in the U.S. District Court for the District of Columbia against HHS which argued that the administration's delay is arbitrary and capricious and violates the Administrative Procedure Act and asked the court to order HHS to implement these regulations. In response to the NPRM, AHA issued a statement that it is pleased HHS is proposing the change the effective date and encouraging HHS to stick to the timeframe discussed in the NPRM moving forward. [7]

NEW EFFECTIVE DATE

In the latest NPRM, HHS states that it has now determined that finalizing the 340B ceiling price and manufacturer CMPs rule will not interfere with the development of comprehensive 340B Program policies and therefore believes that a delay is no longer necessary. [8] As such, HHS proposes moving up the effective date of the rule from July 1, 2019, to January 1, 2019.

HHS is accepting comments for 21 days following publication of the NPRM on its proposals and any potential financial or other impacts that covered entities or manufacturers might anticipate with the new effective date. Accordingly, 340B Program stakeholders should not only review the impact of the accelerated effective date, but should also consider any other concerns within the final rule and consider raising issues with regulators through public comments.

NOTES:

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (to be published Nov. 2, 2018), *available at* <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24057.pdf> (hereinafter "NPRM").

[2] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017).

[3] *Id.* at 1,229 (to be codified at 42 C.F.R. § 10.10(a)). In the case of new covered outpatient drugs, the ceiling price may be calculated by subtracting the appropriate rebate percentage from the drug's wholesale acquisition cost.

[4] *Id.* at 1,229 (to be codified at 42 C.F.R. § 10.10(b)).

[5] *Id.* at 1,229-30 (to be codified at 42 C.F.R. § 10.11(a)).

[6] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg.

25,943, 25,944 (June 5, 2018).

[7] AHA, Press Release, AHA Statement on Proposal to Implement 340B Drug Ceiling Price Rule, Oct. 31, 2018, <https://www.aha.org/press-releases/2018-10-31-aha-statement-proposal-implement-340b-drug-ceiling-price-rule>.

[8] NPRM, at 4.

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