340B Coalition Urges HHS to Implement Final Rule Regarding Ceiling Price and Manufacturer Civil Monetary Penalties

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On April 19, 2017 a coalition of hospitals and safety-net providers, known as the 340B Coalition, submitted correspondence urging the government to implement regulations that would subject pharmaceutical manufacturers to civil monetary penalties (CMPs) for overcharging for 340B drugs.

The federal 340B Drug Pricing Program was established in 1992 and is administered by the Health Resources and Services Administration (HRSA), through its Office of Pharmacy Affairs (OPA). The 340B Program mandates that those pharmaceutical manufacturers who wish to participate in the Medicaid program must discount outpatient drugs to certain qualifying healthcare providers, known under the 340B Program as covered entities.

Citing two reports issued by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), the 340B Coalition stated that manufacturer overcharges have "long plagued" the 340B Program. Following these reports, Congress in 2010 revised the 340B statute to, among other things, direct HHS to issue regulations for determining manufacturer ceiling prices and for imposing civil monetary penalties (CMPs) on manufacturers that "knowingly and intentionally" charge covered entities in excess of ceiling prices for covered outpatient drugs.[1] The amended statute requires HHS to promulgate CMP regulations within 180 days from March 23, 2010. HHS failed to meet this deadline. After three rounds of notice and comment, however, HHS issued a final rule on January 5, 2017 with an effective date of March 6, 2017 (the "Final Rule").[2] The agency indicated that it would begin enforcing the Final Rule on April 1, 2017.

On January 20, 2017, however, the Trump administration issued a "Memorandum for the Heads of Executive Departments and Agencies" seeking a "Regulatory Freeze Pending Review." In the Memorandum, agencies were asked, where permitted by law, to delay for 60 days the effective date of regulations that have been published but have yet to go into effect and to consider proposing for notice and comment a rule to further delay the effective date for such regulations beyond such 60-day period. In response, HRSA on March 6, 2016 published a "Final Rule; Correcting Amendment" that delayed the Final Rule until March 21, 2017.[3] On March 20, 2017, the agency issued an Interim Final Rule further delaying the Final Rule until May 22, 2016 and requesting comments regarding an additional delay until October 1, 2017.[4]

This has prompted the 340B Coalition to urge HHS to immediately implement the Final Rule. According to the 340B Coalition, "[a]dequate enforcement of manufacturers' pricing obligations" is essential to allowing covered entities to save money under the 340B Program and thus enable them to provide more comprehensive services to more patients. Thus the 340B Coalition is asking the government to implement the final rule without further delay.

1 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (amending Public Health Service Act § 340B(d), 42 U.S.C. § 256b(d)).
2 *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210 (Jan. 5, 2017).
3 *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date*, 82 Fed. Reg. 12508 (Mar, 6, 2017).
4 *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 14332 (Mar. 20, 2017).

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