340B UPDATE: TRUMP ADMINISTRATION CALLS FOR NEW LEGISLATION AND REGULATORY AUTHORITY; HRSA DELAYS REGULATIONS ON 340B PRICING & PENALTIES FOR DRUG MANUFACTURERS TO OCTOBER 1, 2017

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Health Care Alert

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Recent developments from the Trump administration relating to the 340B Drug Pricing Program ("340B Program") could have a significant impact on covered entities, drug manufacturers, and others. In particular, the President's recently released budget request calls for new legislation to restrict how covered entities may use the benefits derived from participating in the 340B Program, as well as new authority from Congress to regulate the 340B Program. Meanwhile, the Health Resources and Services Administration ("HRSA") recently delayed again the 340B Program regulations regarding the calculation of drug prices and civil monetary penalties for drug manufacturers.

TRUMP ADMINISTRATION CALLS FOR NEW 340B PROGRAM LEGISLATION AND REGULATORY AUTHORITY

On May 23, 2017, the Trump administration released its fiscal year ("FY") 2018 budget proposal to Congress. The budget is significant in that it signals the administration's policy priorities, and specific proposals and funding levels contained in the budget are often included in appropriations bills or other legislation passed by Congress. In this regard, it is noteworthy that the FY 2018 budget includes specific language on the 340B Program, including a call for new legislation to restrict how covered entities can use the benefits they receive from 340B discounts.

More specifically, HRSA's Congressional Budget Justification includes the following:

> HHS [the Department of Health and Human Services] will work with Congress to develop a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations. This proposal would provide regulatory authority. . . . The FY 2018 Budget Request provides the resources for the 340B Program to educate covered entities participating and prospective sites to comply with statutory requirements. For those covered entities participating in the Program, HRSA will continue to expand its oversight activities, producing a sentinel effect of increased compliance. Data provided by the PVP [HRSA's 340B prime vendor, Apexus] shows education based on oversight measures reduces the risk of

> future compliance issues. Finally, HRSA will conduct audits of manufacturers, which should not only increase compliance, but provide greater insight into the tools and mechanisms used by these companies to comply with 340B statutory requirements and guide future technical assistance.[1]

In the wake of the administration's decision to withdraw HRSA's proposed Omnibus Guidance, it has been unclear what direction HRSA would take on the 340B Program under President Trump. However, the budget proposal indicates that the administration is interested in taking an active role in further regulating the 340B Program moving forward and is particularly focused on enhancing compliance and program integrity, including by working with Congress to develop new legislation to restrict covered entities' use of the 340B Program.

Likewise, several lawmakers in the Republican-controlled Congress have also made clear in public comments that they are considering proposals to change the 340B Program; accordingly, the administration's requests may receive serious consideration.

HRSA DELAYS REGULATIONS ON DRUG PRICING AND MANUFACTURER PENALTIES

In addition, on May 19, 2017, HRSA published a notice in the Federal Register delaying to October 1, 2017, the effective date of regulations under the 340B Program regarding the calculation of drug prices and civil monetary penalties for drug manufacturers that overcharge 340B Program covered entities.[2]

By way of background, HRSA published a final rule on January 5, 2017, that set forth the calculation of 340B ceiling prices and the application of civil monetary penalties to drug manufacturers that sell drugs to 340B covered entities. However, HRSA delayed the regulations as a result of the Trump administration's January 20 Memorandum entitled “Regulatory Freeze Pending Review,” which directed agencies to delay certain regulations that had not yet gone into effect (discussed here), and later issued an interim final rule that delayed the effective date of the regulations to May 22, 2017 (discussed here). After considering public comments, HRSA has now decided to delay the effective date and the enforcement date of the regulations to October 1, 2017, which aligns with HRSA's quarterly 340B Program enrollment and participation schedule. HRSA wrote in the Federal Register that the delay is “necessary to provide adequate time for compliance and to mitigate implementation concerns,” as well as “enhance program integrity.”[3] Notably, HRSA did not withdraw the regulations or indicate that any additional delays would be necessary, suggesting that the administration may not delay the regulations past October 1.

TAKEAWAYS

340B Program stakeholders should continue to monitor activity from Congress and HRSA as the Trump administration's policies regarding the 340B Program continue to take shape.

Notes:

[1] HRSA, HHS, Fiscal Year 2018 Justification of Estimates for Appropriations Committees, https://www.hrsa.gov/about/budget/budgetjustification2018.pdf.

[2] 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.

[3] Id. at 22,894.

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