## **PUBLICATION**

## **Trump's Executive Order Targets 340B Drug Pricing Program**

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President Trump issued an Executive Order on April 15, 2025, titled "Lowering Drug Prices by Once Again Putting Americans First," with the express goal of providing Americans and taxpayers access to prescription drugs. One specific program that the Executive Order addressed is the 340B Drug Pricing Program.

Under Section 5 of the Executive Order, President Trump requires HHS to, within 180 days of the date of the Executive Order (April 15, 2025), publish in the Federal Register a plan to conduct a survey to "determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments." Once the study is completed, HHS "shall consider and propose any appropriate adjustments that would align the Medicare payment with the cost of acquisition."

During the first Trump administration, CMS believed that the 340B discounts received by hospitals and other 340B covered entities were too steep and that they were reaping too much of a benefit from the discounts. As a result, CMS drastically cut the 340B payment rates from the Average Sales Price (ASP) *plus* six percent to ASP *minus* 22.5 percent through the 2018 OPPS/ASC Final Rule. In *American Hospital Association v. Becerra*, 596 U.S. 724 (2022), the U.S. Supreme Court ruled that the CMS 340B rate cuts were "unlawful." However, while SCOTUS ruled that the rate decreases were unlawful, it did so because HHS did not first conduct the survey required by the statute. The purpose of Section 5 of this Executive Order is to conduct the survey that is required by the 340B statute and the SCOTUS decision, seemingly to again reduce 340B payments.

The survey is labor-intensive, and if HHS intends to follow the rulemaking process with full notice and comments, it could take as long as two years to complete this process. Further, any reductions in the 340B payments would need to be budget-neutral, which would result in payment increases in other areas.

Although the overall intent of the Executive Order is to benefit and reduce health care costs for patients, the potential 340B price reductions would seem to negate that purpose. The goal of the 340B Program is for covered entities that serve low-income and underserved populations to use the savings resulting from the 340B discounts to reinvest in their organizations to improve current health and wellness programs and create new ones, including outreach programs. Because any significant reduction in 340B payments would likely have a material adverse effect on improving and creating these needed health care programs, we recommend that 340B covered entities take advantage of the notice and comment procedures of the rulemaking process throughout the implementation of this Executive Order. Additionally, 340B covered entities should closely monitor all developments on this, as the White House has shown a propensity to govern by speed and may bypass some or all of the rulemaking process.

For further updates on the Trump administration's proposed and enacted changes to the 340B Program and to stay informed generally about potential changes to the payment mechanism for the 340B Program, please contact Alissa Fleming, Greg Fliszar, Katherine Denney, or any member of the Baker Donelson Health Law team.