

Trump Administration Announces Executive Action Intended to Reshape the Economics of the Prescription Drug Distribution Chain in the United States

AUGUST 4, 2020

On July 24, 2020, one day after Department of Health and Human Services (HHS) Secretary Alex Azar renewed the COVID-19 public health emergency declaration for an additional 90 days, President Trump announced a series of three executive orders and one anticipated executive order aimed at addressing the perception of high-cost prescription drugs in the United States.

Two of the announced orders would obligate certain clinics to pass along 340B program discounts to patients and effectively eliminate the Anti-Kickback Statute's safe harbor for drug manufacturer rebates specifically offered to pharmacy benefits managers (PBMs). The Administration's public advocacy of these goals has been evident since May 2018 at the time of the release of the HHS' Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, which debuted a number of the policy changes reflected in these executive orders, including changes directed at specific pharmaceutical products, such as insulin and epinephrine.^[1] These policies, if enacted, are likely to have a substantial impact on prices of FDA-approved drugs in the U.S. market.

The Access to Affordable Life-saving Medications executive order would require Federally Qualified Health Centers (FQHCs), which receive discounted prices through the 340B Prescription Drug Program on prescription drugs, to pass along to patients the discounts they receive on insulin and injectable epinephrine. Specifically, the executive order provides that the Secretary of HHS shall take action to ensure future grants under section 330(e) of the Public Health Service Act are conditioned upon FQHCs having established practices to make insulin and injectable epinephrine available at the discounted price paid by the FQHC grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes who (a) have a high cost-sharing requirement for either insulin or injectable epinephrine, (b) have a high unmet deductible, or (c) have no health insurance.

President Trump's colorfully named Lowering Prices for Patients by Eliminating Kickbacks to Middlemen executive order targets for elimination what the Administration characterizes as drug distribution chain "middlemen," including health plan sponsors and PBMs. The executive order seeks to narrow the Anti-Kickback Statute's safe-harbor protections that otherwise protect manufacturer rebates paid to these entities from characterization as kickbacks.

Specifically, the executive order authorizes HHS to complete the rulemaking process seeking to: (a) exclude from safe-harbor protections under the anti-kickback statute, section 1128B(b) of the Social Security Act, 42 U.S.C.

§ 1320a–7b, certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program; and (b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient’s point-of-sale in order to lower the patient’s out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees.

The executive orders grant a substantial amount of the authority to the Secretary of HHS to enact the policy objectives of the President’s executive orders. For more on that, please visit Winston’s [Benefit’s Blast blog post](#).

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

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For further information or questions on the Trump Administration’s executive orders and plans for implementation, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher M. Parker, or your Winston relationship attorney.

¹ See HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22692-01 (May 16, 2018).

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