Trump's New Drug Pricing Executive Orders: Much More Bark Than Bite

July 29, 2020

On July 24, 2020, President Trump issued three Executive Orders ("EOs") relating to drug pricing and announced that a fourth may be released next month. These EOs require various actions by the Department of Health and Human Services ("HHS")—including rulemaking—to become effective. It is therefore unclear whether any of these EOs will ultimately be implemented. Even if rulemaking is initiated immediately, it is unlikely that any rules would be finalized before the upcoming presidential election. Any rulemaking proceeding that has not been completed by Inauguration Day (January 21, 2021) could be cancelled if there is a change in administration.

Insulin/Epinephrine EO. This EO, if implemented, would make insulin (used to treat diabetes) and epinephrine (used to stop severe allergic reasons) available at discounted prices at Federal Qualified Health Centers ("FQHCs") (community healthcare facilities in underserved areas). Under the 340B prescription drug program, FQHCs receive certain drugs at significantly discounted prices. The EO directs HHS to condition grants to FQHCs on their making insulin and injectable epinephrine available at the prices paid under the 340B program, plus a small administrative fee, to low income individuals who either have a high cost-sharing requirement for these drugs, a high unmet deductible or no health insurance. Even if implemented, this proposal would likely have a minimal impact on insulin and epinephrine manufacturers, as they already provide these drugs under the 340B program and the volume increase from low income individuals who do not qualify for Medicare or Medicaid and obtain medicines from FQHCs is likely to be relatively small.

Drug Importation EO. For years, the Trump administration and some elected officials have argued that one way to reduce drug prices is to allow the importation of drugs from countries with price controls, such as Canada. This EO contains three provisions that are aimed at promoting importation of certain drugs:

- HHS is directed to facilitate grants to individuals of waivers that would allow them to import prescription drugs ***if*** "importation poses no additional risk to public safety and results in lower costs to American patients." This provision notably

contemplates waivers for individuals—not pharmacies, distributors or wholesalers—and issuance of such waivers likely would require rulemaking.

- HHS is directed to authorize the reimportation of insulin to the United States without the manufacturer's consent ***if*** HHS makes a finding that it is required for emergency medical care.

- HHS is directed to complete rulemaking to implement statutory provisions relating to importation of prescription drugs by pharmacists and wholesalers from Canada to the United States.

It is uncertain when, if ever, the EO's objectives will be implemented because HHS has long taken the position that it cannot ensure the safety of drugs that are imported through an unregulated process due in part to concerns associated with the potential influx of dangerous counterfeit drugs. If HHS maintains this view—which seems likely—then HHS may not take the actions contemplated by this EO. Moreover, if attempts to import drugs from Canada to the United States reach a meaningful volume, manufacturers may take a number of steps to prevent or limit importation, such as by conditioning the sale of certain drugs to Canadian purchasers on them being distributed and used only in Canada.

Anti-Kickback Statute Safe Harbor for Rebates EO. The Trump administration has argued that pharmacy benefit managers ("PBMs") have contributed to rising drug prices for beneficiaries of the Medicare Part D program (which covers senior citizens). The administration has focused on the PBM practice of conditioning the placement of a drug on a Part D formulary on the manufacturers' willingness to provide a significant rebate. Such rebates are typically used to reduce the overall costs of the Part D plan or taken in part by the PBM as profit. These rebates are permitted under a regulatory safe harbor to the federal Anti-Kickback Statute.

This EO directs HHS to engage in rulemaking that would exclude from the safe harbor rebates that were provided to Part D plan sponsors, pharmacies, and PBMs and would establish new safe harbors for rebates applied at the point of sale. The EO, however, is contingent upon HHS confirming that taking such actions would not increase federal spending, Medicare premiums, or total out-of-pocket costs.

We believe this EO is unlikely to be implemented because the proposal, if adopted, is likely to result in increases in federal spending and Part D premiums. If rebates no longer can be applied to offset the cost of Part D plans, the price of administering Part D plans would be expected to rise. As the costs of Part D premiums are then split between the federal government and senior citizen beneficiaries (in most cases), the contemplated proposals would result in the federal government spending more and Part

D premiums becoming more expensive. Indeed, the administration abandoned a similar proposal last year, likely for these reasons.

Medicare Part B Drug Pricing—Potential Future EO. Finally, the Trump administration expressed concern about the prices paid for Part B drugs, which are administered in outpatient clinical settings, such as doctors' offices and hospital outpatient departments. Currently, Part B drugs are reimbursed at an effective rate of the Average Sales Price plus a 4.3% "add-on," which is intended to cover the cost of processing the drug order, storage and handling. In November 2018, HHS released an Advance Notice of Proposed Rulemaking ("ANPRM"), addressed here, describing a proposal to implement price controls on Part B drugs and changed the process by which Part B drugs are distributed. A proposed rule, however, has not been issued in response to the ANPRM. President Trump has threatened that if unspecified negotiations with drug companies are not successful, an EO regarding Part B drug pricing will be released on August 24, 2020. Although the details of the threatened EO have not been released, they likely would direct implementation of a plan with price controls similar to what were contemplated in the ANPRM. Given the complexity of any attempt to revise reimbursement for the Part B program, the issuance and implementation of any final rule relating to this issue will likely be evaluated after inauguration day by the next administration.

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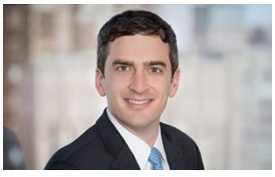

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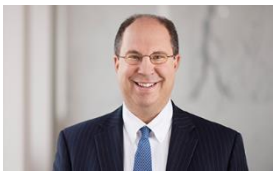
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