



COMPLIANCE ALERT



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President Trump Issues Executive Orders Intending to Lower the Cost of Prescription Drugs

On July 24, 2020, President Trump issued several Executive Orders intending to lower prescription drug costs by (1) modifying anti-kickback laws to lower drug prices, (2) reducing trade barriers to increase importation of drugs and lower prices, and (3) improving access to insulin and epinephrine for individuals with diabetes or severe allergies. Each of the executive orders is explained in more detail below.

Modifying Anti-Kickback Laws to Improve Drug Prices

The President's **"Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen"** recognizes that insurance companies, health plan sponsors, and pharmacy benefits managers (PBMs) are able to negotiate significant discounts on drug prices and potentially collect large rebates, while Medicare patients' cost sharing for prescription drugs is often based on the list price for these drugs. This can result in out-of-pocket costs for Medicare patients above those typically experienced by participants in employer-sponsored group health plans.

Therefore, the Executive Order requires the U.S. Department of Health and Human Services (HHS) to develop rules to: (1) subject certain rebates provided to health plan sponsors, pharmacies, and PBMs operating in the Medicare Part D program to federal anti-kickback rules (from which they currently enjoy a regulatory exemption); and (2) establish new

safe harbors so health plan sponsors, pharmacies, and PBMs can lower patients' out of pocket costs by allowing for discounts at the point of sale and permitting the use of certain bona fide PBM service fees. The Executive Order requires HHS to confirm publicly that any actions taken is not projected to increase federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs. This caveat may make it difficult to implement this Executive Order, as government actuaries estimated significant premium increases if rebates were no longer paid directly to Medicare Part D plans, which in turn increases federal spending because the government subsidizes Part D premiums.

Creating a Pathway to Safely Import Prescription Drugs from Other Countries

Citing the disparities in the cost of drugs in other countries and the United States, the President issued the **"Executive Order on Increasing Drug Importation to Lower Prices for American Patients,"** which permits HHS to use authority under existing laws to: (1) grant individual waivers (for states, wholesalers, and pharmacies) to existing laws that prohibit importing prescription drugs from other countries, but only if there would be no increased risk to public safety and lower prices would result; (2) permit insulin products to be re-imported for emergency medical care; and (3) complete the rule-making process to allow certain prescription drugs to be imported from Canada.

Improve Access to Insulin and Epinephrine

The “Executive Order on Access to Affordable Life-Saving Medications” states that prices for life-saving epinephrine and insulin have dramatically increased over time, even for individuals who access prescription drugs through private insurance or federal programs, such as Medicare or Medicaid. The Executive Order further provides that Federally Qualified Health Centers (FQHCs) receive significantly discounted prices for such life-saving medications through the federal 340B prescription drug program. Therefore, the Executive Order authorizes HHS, to the extent permitted under the Public Health Service Act (PHSA), to ensure future grants awarded by the agency to 340B hospitals are conditioned upon 340B hospitals having established practices to make insulin and injectable epinephrine available at the 340B discounted price to individuals with low incomes who: (1) have high cost-sharing for insulin or injectable epinephrine; (2) have a high unmet deductible; or (3) have no health insurance.

Medicare Drug Pricing

President Trump also stated that he is considering a fourth Executive Order that would require Medicare to price-match drugs by purchasing drugs at the same price the drugs cost in other countries. The President is meeting with the heads of drug manufacturing companies to discuss this particular proposal, but will release the Executive Order on August 24th if they cannot come up with a solution to lower drug prices by that deadline.

Conclusion

While many of these proposals may impact group health plans, because they are primarily executive actions operating within the confines of existing laws, they would not be permanent requirements. Moreover, due to the cost controls (i.e., no increase to federal spending) and/or because the proposals would take time to implement, depending on the results of the upcoming election, we may never see them come to fruition.

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