

White House Issues Four Executive Orders to Lower Prescription Drug Pricing

On July 24, 2020, President Trump released four executive orders on prescription drug pricing as part of the White House's ongoing drug pricing reform efforts. This announcement came with less than four months remaining before a November 4 presidential election.

The executive orders follow the Department of Health and Human Services (HHS) *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* released in May 2018 and targets the pharmacy benefits industry to lower prescription drug prices through various methodologies. The executive order finalizes the objectives provided by HHS after a period of public comment and multiple hearings in both the Senate and House of Representatives.

Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen

In a surprise inclusion, President Trump signed an executive order reforming the rebate payment model after HHS withdrew its plan on July 11, 2019. In the original model, HHS proposed the outright elimination of rebates paid for by pharmaceutical manufacturer to pharmacy benefit managers (PBMs), but the updated executive order would only eliminate "safe harbors" protections from anti-kickback laws and criminal penalties only *IF* pharmacy benefit administrators do not comply with framework to lower the "prices patient's see at the point-of-sale." The executive order directs HHS to complete rulemaking process to provide certain drug manufacturer payments at the point-of-sale for Medicare prescription coverage

Rx Solutions Commercial Impact: Point-of-sale rebate models have been available for several years with limited commercial interest. This legislation targets Medicare Part D members only at this time. Rx Solutions feels that PBMs have gotten ahead of this legislation by setting up contracting entities for the purpose of handling rebate negotiations which will limit compliance requirements to the overall law.

Executive Order on Increasing Drug Importation to Lower Prices for American Patients

The president's executive order on drug importation advances HHS framework for safe importation of certain prescription drugs presented on July 31, 2019. The original Drug Importation Act was passed by Congress in 1848 and the United States has since repeatedly expanded restrictions on cross boarder importation of medications based on drug safety. The executive order provides guidance to minimize international disparities in drug pricing by expanding safe access to lower-cost imported prescriptions through the HHS framework including creating a pathway for safe personal importation by use of individual waivers at pre-authorized US pharmacies. Providers of international medications will need to prove importation poses no additional risk to public safety and results in lower costs to American patients.

Rx Solutions Commercial Impact: Based on previous proposals and public hearings, HHS guidance has been given that only certain medications will be allowed under drug importation guidelines and strict safety protocols will be put in place. In the near future, we anticipate greater access to safe affordable medications, such as insulin, will be available to commercial clients without the risk of illegally importing prescription medication under federal law.

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Executive Order on Access to Affordable Life-saving Medications

In a move that followed CMS announcement on March 11, 2020 to lower out of pocket expenses for insulin, President Trump signed an executive order to reduce the cost of insulin and EpiPen by requiring Federally Qualified Health Centers (FQHC) to pass through sharp 340B discounts they receive through a "penny pricing" policy. Further grants permitted under the Public Health Service Act to FQHCs will be conditional on the compliance of making insulin and injectable epinephrine available at the same price paid by the FQHC (pass through pricing). The executive order pertains to members both on commercial insurance or federal programs who do not have affordable access to these medications.

Rx Solutions Commercial Impact: Rx Solutions is confident that this executive order will lower insulin and Epipen pricing over time. FQHCs will either play a larger role in distributing these medications or retail pharmacy chains will be forced to negotiate lower comparable discounts to dispense these medications at comparable prices. There are 1,368 official FQHC located in the United States and they could potentially expand, or build mail order facilities. In addition to access, we feel that commercial plans may also change benefit designs to limit coverage to these medications so that participating members meet eligibility requirements to qualify to purchase medications through this newly created executive order.

Executive Order on Creating an International Pricing Index

The final executive order may be the most interesting because it is yet to be published officially, but also because it could have greatest impact on lowering drug pricing. The executive order would cap Medicare payments for Part B prescriptions administered in a physician's office to prices paid across the 15 other developed nations. Today, Medicare Part B pricing framework today is the average selling price plus 6% commission (called "ASP plus 6") on any drug administered to a patient in their offices. This framework incentivizes doctors to prescribe more expensive prescriptions even if a more effective lower cost option is available. Manufacturers also know that if they develop infusion medications they can charge higher prices and doctors will not face PBM step therapy programs. The order will be effective on August 24 unless Congress acts to come up with a betterplan.

Rx Solutions Commercial Impact: Because commercial insurance is not tied to ASP plus 6, this would likely have limited impact on commercial market in the near future if a different plan is not developed by August 24. The industry is expecting further developed under this plan prior to August 24.

How NFP Commercial Clients Benefit

Rx Solutions continues to work closely with vendors that actively participate in these conversations creating innovative products and pricing models that provide greater flexibility for our clients. As FQHC, International Drug Wholesalers, and PBMs enact the president's executive orders, the Rx Solutions team will actively participate in building products and services with our partners to provide the most advanced product offering in the market place.