



## Wide-ranging executive orders regarding pharmaceutical pricing and availability

July 27, 2020

President Trump signed four executive orders on July 24, 2020, that appear to push forward the administration's efforts to lower prescription drug costs and pass the savings on to consumers. However, it is likely that several of the orders could be challenged in court by the pharmaceutical industry, while others only reaffirm already-proceeding efforts to issue new regulations through the notice and comment rulemaking process. A summary of each of the four orders is below.

### 340B discounts

The Trump administration's executive order would require all federally-qualified health centers (FQHCs) to pass on any discounts they receive through their enrollment in the 340B program on Epi-Pens or insulin to patients with high unmet deductibles, high cost-sharing on drug claims or who are uninsured. The administration proposes to reduce future grants to FQHCs that refuse to comply with the executive order. However, HHS' rule-making authority over the 340B program is very limited under the statute that created it and does not appear to contain the ability to compel a certain use of a 340B discount or condition grants on such behavior. [Full executive order >>](#)

### Importation of foreign drugs

The re-importation of insulin products made in the U.S. would be allowed under a finding by the secretary of HHS that it is required for emergency medical care. Individuals would also be allowed to import drugs from other countries, so long as such importation results in lower costs and no additional dangers to public safety. HHS is also directed to accelerate its efforts to complete the rulemaking process begun in December 2019 to allow importation of certain drugs from Canada. [Full executive](#)

[order >>](#)

#### International reference pricing

The administration proposes to bar pharmaceutical companies from charging more than “the lowest price available in economically comparable countries for Medicare Part B drugs.” Implementation of this directive might require an accompanying redesign of how physicians are compensated for prescribing reimbursable drugs.

#### Elimination of safe-harbor protections for pharmacy discounts

The secretary of HHS is directed to continue the already-commenced rulemaking process to eliminate anti-kickback statute safe-harbor protections for certain point-of-sale discounts provided by drug manufacturers to pharmacy benefit managers, pharmacies and health plan sponsors and to instead shift the provision of those discounts directly to patients. This direction appears to be another reversal of course after the administration withdrew its support for this proposal in mid-2019. [Full executive order >>](#)

# Authors

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