

Brief: Trump administration issues two proposals to permit drug importation

Thursday, December 19, 2019 – Yesterday, the Trump administration [released](#) two proposals to lower pharmaceutical prices in the U.S. Collectively, the proposals would effectuate the drug importation action plan released in July. U.S. Department of Health and Human Services (HHS) Secretary Alex Azar [said](#) the importation proposals “are a historic step forward in an effort to bring down drug prices at out of pocket costs.”

The first proposal, a notice of proposed rulemaking issued by the Food and Drug Administration (FDA), would create a pathway for states to import drugs from Canada through programs authorized by the agency. The second, contained in a draft guidance, is designed to help drugmakers reroute medicines intended for foreign markets to the U.S., potentially at a lower price.

Notice of Proposed Rulemaking (MPRM): Importation of Prescription Drugs

The [NPRM](#) would allow states, in collaboration with wholesalers and pharmacists, to develop pilot programs to import certain drugs from Canada. The drugs must already be FDA-approved, authorized for sale in Canada, relabeled, and undergo testing to ensure they are not degraded. Furthermore, only certain types of drugs are eligible – controlled substances, biologics, intravenously injected drugs, and any products under an FDA Risk Evaluation and Mitigation Strategy are excluded.

Draft Guidance

The [draft guidance](#) would allow manufacturers to voluntarily import their own product from Canada, where prices are cheaper due to the country’s single-payer program. In order to do so, drug companies would have to obtain a new National Drug Code (NDC) for product that had been manufactured for and intended for sale in foreign countries. Secretary Azar [noted](#) that this specific proposal would mainly be for branded drugs with extremely high rebates in the U.S.

Industry Reaction

States

Several states have already passed laws creating drug importation programs:

1. **Colorado** Governor Jared signed a bill that directs the state’s Department of Health Care Policy and Financing to create a program to import prescription pharmaceutical products from Canada to be sold to Colorado consumers. The governor issued the following [statement](#) in response to the HHS announcement: “We look forward to reviewing this rule to allow us to move forward. I’m proud our state is leading on saving people money on prescription drugs and we look forward to the work ahead. We hope the federal rulemaking process moves quickly so that we can offer much-needed relief to consumers who are struggling to afford their medications.”
2. **Florida** Governor Ron DeSantis [joined](#) HHS Secretary Azar for the announcement. DeSantis, a loyal Trump supporter, has sought [federal approval](#) to allow the state to import Canadian drugs for the state Medicaid program.
3. **Maine** Governor Janet Mills [signed](#) a bill directing the state Department of Health and Human Services to design a program for wholesale importation of prescription drugs into Maine from Canada that complies with federal requirements.

4. **Vermont** passed legislation to [create](#) a Canadian importation program that would require commercial plans to pass any cost savings to consumers by lowering premiums, deductibles, and co-pays for prescription drugs.

New York Governor Andrew Cuomo [plans](#) on creating a new commission to study the process of legally and safely importing drugs from the Canadian market as part of his 2020 State of the State proposal. "The exorbitant cost of prescription drugs is a massive burden on families across the country, and we're determined to use every tool in the tool box and pursue every available avenue to bring real relief to New Yorkers," Cuomo said Wednesday.

Canada

Canadian officials are pushing back against the proposal, noting that the country's pharmaceutical supply can't support the broader demands of the U.S. market.

Kirsten Hillman, Canada's acting ambassador to the U.S., estimated Canada represents 2 percent of the global market for pharmaceutical use vs. the U.S.'s 44 percent. In a statement issued in November she [said](#), "Not only are we too small of a market, Canada cannot increase its domestic pharmaceutical drug supply to meet U.S. demand."

"We share the goal of ensuring people can get and afford the medication they need," [said](#) Canadian health ministry spokesman Thierry Belair. "But these [Trump administration] measures will not have any significant impact on prices or access for Americans. We remain firmly focused on ensuring Canadians can access the medication they need," he added.

Trade groups

Industry trade groups also oppose the plan.

Jim Greenwood, president and CEO of the BIO, condemned the Trump administration proposal. Today's announcement is the latest empty gesture from our elected lawmakers who want us to believe they're serious about lowering patients' prescription drug costs," he said in a [statement](#).

Steve Ubl, PhRMA CEO, [characterized](#) the plan as a "scheme" that could "endanger American lives, could worsen the opioid crisis and has been called unworkable by Canadian officials." "At a time when there are pragmatic policy solutions being considered to lower costs for seniors at the pharmacy counter and increase competition in the market, it is disappointing the Administration once again put politics over patients," he said.

"While we acknowledge that the administration and proponents of state importation plans are mindful of the safety protections offered by traceability requirements ... significant concerns remain about the feasibility of an importation program from an operations perspective," the Healthcare Distribution Alliance, a trade group representing distributors, said in a [statement](#).

Economic Impact

A *POLITICO* article [predicted](#) that "Consumer savings from of the Trump proposal likely will be modest compared to the financial impact of tough drug price controls passed by House Democrats and contained in a bipartisan bill stranded in the Senate."

Wall Street analysts are predicting the rule will have little to no financial impact on the drug industry. In 2004 the CBO [concluded](#) that prospects of importation “would lead to few drugs entering the U.S., and small savings. And only drops from that pot of savings will flow to consumers.”

HHS has thus far not provided estimated potential savings or costs, noting that until it sees importation proposals from states it won't have a clear sense of those programs' scope.