

Key Message

While reducing drug prices is an important priority, importation is an ineffective solution that will endanger patient safety.

Background

[Current law](#) allows wholesale importation (meaning importation of drugs by healthcare providers and distributors on a larger scale, rather than by individuals on a small scale) only in very limited circumstances. It requires the Department of Health & Human Services (HHS) Secretary to certify to Congress that allowing the importation of drugs will not put public health and safety at risk and that it will result in significant savings. No Secretary has ever been able to make such a certification. Although states (e.g., Florida and Colorado) have passed wholesale importation laws, those laws cannot take effect until the state has crafted an importation plan, the Food and Drug Administration (FDA) has approved it, and the HHS Secretary has made the required certification to Congress.

The Safe Importation Action Plan (the “Plan”), announced on July 31, 2019, was the first step in the process of implementing state importation laws. The FDA proposed rule, [Importation of Prescription Drugs](#) (the “proposed rule”) issued December 18, 2019, is the next step in the implementation of these laws. The proposed rule codifies the first pathway of the Plan, which solicits importation program proposals from pharmacists, wholesalers, and states (in conjunction with pharmacists and wholesalers) that comply with the importation provision that currently exists in the Food, Drug, & Cosmetic Act.

The proposed rule states that importation programs that are authorized and approved will be subject to stringent oversight and compliance requirements. These include, but are not limited to, compliance with FDA labeling requirements, track and trace requirements, and testing requirements. The importation programs are also limited in which drugs they can import – many of the highest-cost products, including biologics, inhalation drugs, CII, drugs inhaled during surgery, infusion and intravenous drugs, and REMS drugs, are excluded.

It will be difficult to operationalize the proposed rule in a manner that meets all of its requirements and still delivers meaningful cost savings.

Comments on the proposed rule are due March 9, 2020.

Key Talking Points

Importation poses unacceptable safety risks.

- Importation short-circuits the safety requirements that protect the American drug supply and is unlikely to result in significant cost savings for patients.
- Importation may potentially bypass safety requirements intended to protect against contaminated or counterfeit medications.
 - A 2016 [survey](#) by the National Association of Boards of Pharmacy found that 96 percent of pharmacies claiming to sell Canadian drugs are fake, meaning that the drugs they sell do not enter the legitimate Canadian supply chain. We should not accept these risks, particularly when this approach is unlikely to yield meaningful cost savings for patients.

STATES SHOULD OPPOSE WHOLESALE DRUG IMPORTATION

- Importation creates new risks for states.
 - Once any state has begun importation, it will be difficult, if not impossible, to confine imported products to that state's borders.

Importation is unlikely to generate meaningful cost savings and is not a solution to high drug prices.

- While the concept of pharmaceutical importation may seem as simple as a U.S. manufacturer making and shipping drugs to Canada, and Americans purchasing them to be sent back to the U.S., the reality is more complicated.
- Because of safety risks associated with imported drugs, the FDA's proposed rule excludes many of the highest-cost drugs from importation (e.g., biologics, infusion and intravenous drugs, REMS drugs, etc.). As a result, the potential for importation to reduce costs is inherently limited.
- Savings are likely to be further reduced by compliance costs under the program, including:
 - relabeling drugs to match U.S. labeling requirements;
 - drug testing;
 - written recall plans for each imported drug; and
 - track and trace compliance.
- Even if states could set up the infrastructure and oversight to import drugs, the size of the Canadian pharmaceutical market is only a small fraction of the U.S. market. It is unrealistic to believe Canada will be a significant source of low-cost drugs.
 - Canada is also taking steps to prevent the export of drugs to the United States.

Importation of drugs in shortages remains necessary to respond to pressing patient needs.

- Limited importation in shortage situations is appropriate because of its restricted duration and intense FDA scrutiny.
- Imported shortage drugs are sourced from specific manufacturing facilities and can be accounted for in the supply chain.
- Determining sourcing and arranging supply during shortages is time-consuming and somewhat unpredictable, making it unappealing as a large-scale solution.

Rather than focusing on the false promise of importation, ASHP urges state and federal policymakers to focus on bipartisan proposals that:

- Increase the availability of low-cost generic medications.
- End the perverse system of rebates from drugmakers to health insurers that keep drug prices high at the expense of patients.
- Prohibit drugmakers from paying to keep generic competitors off the market.