



Center for State **Rx** Drug Pricing

Wholesale Importation Legislation Q&As

What is a wholesale drug importation program?

A wholesale drug importation program allows a state to create an infrastructure that uses its existing drug supply chain to assure safety and efficacy when importing wholesale drugs from Canada. Because of its rigorous testing and documentation requirements, it will not support personal importation, where little to no regulatory oversight or consumer protection exists.

Does federal law allow for state wholesale drug importation programs?

Under federal law, the US Secretary of Health and Human Services has the authority to allow wholesale importation from Canada if certain standards are met. The US [Food, Drug, and Cosmetic Act](#) allows for drug importation if safety and consumer savings can be assured. Opioids, biologics, injectable medications, and certain other drugs may not be imported.

Does the United States currently import any drugs or active pharmaceutical ingredients? If so, how does the United States ensure the safety of imported drugs?

The pharmaceutical industry is already a global one. According to the Government Accountability Office's 2016 [drug safety report](#), about 40 percent of drugs sold in the United States are manufactured in other countries, and 80 percent of raw materials in US drugs come from abroad. More than 30 Canadian drug manufacturers are registered with the US Food and Drug Administration (FDA) to produce drugs for US markets, and safety standards in Canada are comparable to those in the United States. Additionally, federal regulations already ensure the safety of foreign-produced drugs entering the US market.

Will drugs imported from Canada meet US safety standards? How?

Yes, a state wholesale drug importation program will leverage the FDA's drug manufacturing inspection program and existing pharmaceutical distribution supply chains to import commercial quantities of select high-cost drugs from Canada to US importers for use by consumers in the United States. The FDA already inspects and approves international drug manufacturing facilities before the facilities can be used to produce drugs for US consumers. These same FDA-approved facilities are supply sources for drugs in other markets, including Canada. The imported drugs, which will be made in the FDA-approved facilities, will be repackaged and relabeled by FDA-registered re-packagers and re-labelers to ensure drug labeling matches US requirements. The same carriers, freight forwarders, customs house brokers, and trucking companies that currently provide the United States with most of its pharmaceuticals will move these imported drugs.

Will importation increase the amount of counterfeit and adulterated drugs in the United States?

No, those who claim counterfeit drugs from less-developed countries would enter the United States at a higher rate under a wholesale importation program are conflating individuals using unlicensed, unregulated, and rogue internet pharmacies pretending to be located in Canada with this state-regulated, FDA-approved wholesale importation program. To obtain federal approval for launching an importation program, the state will need to ensure imported drugs are the FDA-approved versions and meet existing FDA safety standards already in effect for importation of finished drugs and active pharmaceutical ingredients.

Enacted in 2013, the Drug Supply Chain Security Act (DSCSA) created an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This law was designed to protect consumers from counterfeit drugs and to remove potentially dangerous drugs from the supply chain. By extending DSCSA requirements deeper into the international supply chain, the same regulatory mechanism currently used for ensuring proper labeling, safety, and effectiveness of drugs will be used to ensure the safety and quality of drugs imported under a state importation program. As noted in a previous question, drugs imported from Canada to the United States will be manufactured in facilities the FDA has already inspected and approved.

What would a state need to do to set up an importation program and assure drug safety?

A state would require that drugs imported under the importation program mirror the current FDA-approved supply chain and contract with qualified entities to administer the program in compliance with FDA laws and regulations. A state would need to develop licensing standards for new entities and have the power to suspend or revoke licenses.

What would the supply chain and distribution chain look like under an importation program?

Supply and distribution chains under an importation program would follow the current supply chains already managing the importation of millions of annual drug shipments into the United States, which take place every day. Under federal law, in an importation program, the first foreign recipient of a qualifying drug to be imported into the United States must be able to document it has purchased the drug from an FDA-authorized manufacturer or distributor, and that the drug was lawful in the first purchaser's foreign country. Additionally, the Canadian seller would be required to register with the FDA and to appoint a US agent for FDA purposes. When the first foreign purchaser and the foreign seller are the same entity, importation would follow the same basic supply chain as other prescription drugs imported into the United States, except there will need to be a re-packaging and/or re-labeling step prior to export from Canada. The state could license and/or contract with qualified entities. Because of the testing components in the importation program, this supply chain would actually be more robust than that of ordinary drug importation chains.

Who would assure "track and trace" and audit for program compliance? Wouldn't a state need to create a mini-FDA to pull this off?

Currently, states already inspect domestic, licensed prescription drug wholesale distributors. Under the importation program, the state would extend the existing US prescription drug wholesale track and trace requirements (as well as product examination and supplier pedigree requirements) into the imported drug supply chain. US importers and Canadian suppliers would be required to secure an audit or inspection by an acceptable third party to obtain and to maintain an active and unencumbered state license to import any drugs under the importation program into the state. These third-party inspections are already routine in the prescription drug distribution industry and are designed to ensure compliance with drug storage, distribution, labeling, purchasing, and sales requirements under both federal and state authorities. The margin between the acquisition cost and sales price for Canadian-sourced drugs will cover the cost of the third-party inspection process. The state agencies would be performing largely the same types of services they already provide, while relying on additional data generated by acceptable third-party auditors and inspections by other states, the FDA, and regulatory agencies in other countries.

How will insurers pay for the drugs? How will savings be assured for consumers?

Insurers will pay for these drugs using current billing processes. Each drug will come with an FDA-authorized National Drug Code (NDC) number that insurers now use to pay for drugs. The NDC number for the imported drugs will bear a labeler code belonging to the state to assure the drug is dispensed only in that specific state and that the correct price is paid. The state will want to make sure mechanisms are in place that guarantee discounts are passed on to the consumers.

Will an importation program generate savings? How does the bill ensure consumers receive savings?

A state can identify the drugs that represent the greatest cost to commercial payers and compare their costs to Canadian prices. Vermont recently compared the costs of just 17 drugs, based on spending by two of their three insurers, and identified [savings](#) of \$1 to \$5 million annually, despite a proposed, significant markup to account for program costs. To ensure consumers receive savings, a state can limit imported drug markups and profit margins of suppliers, wholesalers, and distributors, as well as what those entities charge for their administrative services. In addition, a state can require pharmacies and other dispensers to charge payers the Canadian price without any markup and/or eliminate co-pays and cost sharing for these drugs.

Is importation currently being implemented in any state?

In 2018, Vermont became the first state to pass a [law](#) to implement a wholesale Canadian drug importation program. As of March 2019, 15 other states are also considering importation bills this legislative session.

What additional resources does the National Academy for State Health Policy (NASHP) offer to explain how wholesale importation would work?

NASHP has created three [infographics](#) to explain the safety, savings, and implementation of a drug importation program. NASHP also obtained an [analysis](#) from the regulatory consulting firm FDAImports.com about the legality and feasibility of a wholesale importation program.

NASHP helps state leaders advance legislation to contain prescription drug prices and tracks states' efforts at its [Rx State Legislative Tracker](#). State officials who are interested in the importation model legislation can access a legislator's guide and additional background materials. Contact [Jennifer Reck](#) to receive this material for state officials only.