OFFICE OF LEGISLATIVE RESEARCH
Objective Research for Connecticut's Legislature

ResearchReport

Drug Importation Programs

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Issue

Provide information on drug importation programs, including (1) a brief description of the federal drug importation law, (2) summaries of other state importation laws, (3) a list of states that recently proposed drug importation legislation, and (4) a summary of sHB 7267 (2019), which would have established such a program in Connecticut.

Summary

Federal law allows the importation of drugs from Canada only if it poses no additional public health and safety risk and results in significantly reduced costs to the American consumer (21 U.S.C. § 384). Generally, drug importation (or re-importation) programs allow state agencies, pharmacists, and wholesalers to import drugs from Canada for sale or distribution to state residents. Federal law, among other things, allows importation programs if they are approved by the federal Department of Health and Human Services (HHS). To date, HHS has not approved any state prescription drug importation program, although the president has directed the HHS secretary to work with Florida towards program approval.

We were able to identify at least four states (Colorado (2019), Florida (2019), Maine (2019) and Vermont (2018)) that have recently passed enabling legislation allowing the applicable state agency to begin establishing a program and seek HHS approval. In general, each state law requires at least the federally required minimum supply chain documentation. Supply chain documentation, also known as "track-and-trace," requires importers to know the physical location of the drug at all times, as well as information about how long it spent at each location, ownership records, packaging configurations, environmental storage conditions, and other information pertinent to

maintaining the drug's safety and detecting and controlling counterfeiting, drug diversions, and mishandling.

Who may import the drugs varies by state program. For example, Florida, Maine, and Vermont require a state agency to act as, or in certain cases contract with, an importer while Colorado allows any approved pharmacist to import prescription drugs, but also specifically authorizes pharmacies and wholesalers that supply the state's Medicaid and inmate populations.

With help from the Legislative Library, we identified at least six states other than Connecticut that recently considered, but did not enact, similar legislation: Illinois, Massachusetts, Minnesota, New York, Oklahoma, and Oregon.

In Connecticut, sHB 7267 as amended would have established a Canadian prescription drug importation program that allowed Connecticut wholesalers to import prescription drugs to a pharmacy or institutional pharmacy. The legislation included track-and-trace and reporting requirements, as well provisions granting the state certain enforcement powers.

Federal Law

The federal Medicare Prescription Drug, Improvement, and Modernization Act Of 2003 authorizes a wholesaler or pharmacist to import prescription drugs from Canada under certain conditions with HHS approval (P.L. 108-173 § 1121). Specifically, federal law allows the importation of drugs from Canada only if importation poses no additional public health and safety risks and results in significantly reduced costs to U.S. consumers (21 U.S.C. § 384).

In July 2018, the HHS secretary directed the federal Food and Drug Administration (FDA) to establish a drug importation working group to address prescription drug price spikes. On July 31, 2019, HHS and FDA jointly released a "Safe Importation Action Plan" that outlines two "pathways" for importing prescription drugs.

Pathway 1 would require HHS and FDA to propose new federal rules allowing states to submit plans for demonstration projects. The projects would be time-limited and require regular reporting. The rules would address, among other things, safe importation, eligible drugs, and cost-savings requirements.

Pathway 2 would allow drug manufacturers to establish with FDA that the imported version of the drug is identical to the U.S. version. Generally, this would be done by documenting the manufacturing supply chain and testing imported drugs. Pathway 2 relies on existing authority to

approve importation programs, and would allow the drug to be sold under a new National Drug Code (NDC). Even though the imported drug must be identical to the existing U.S. version, allowing it to be sold under a new NDC gives the manufacturer the ability to price it differently.

State Laws

Colorado

This year, Colorado passed CO S 5 which requires the state Department of Health Care Policy and Financing to administer a Canadian drug importation program. It requires imported drugs be tested for authenticity and the supply chain documented. The program is open to pharmacies and wholesalers providing prescription drugs to state Medicaid recipients and inmates, as well as private commercial plans and pharmacists approved by the department.

Florida

This year, Florida passed HB 19, "Prescription Drug Importation Programs" (the enrolled version is available here).

The act establishes two drug importation programs: the Canadian Prescription Drug Importation Program and the International Prescription Drug Importation Program. For both programs, the act establishes eligibility criteria for the prescriptions drugs which may be imported and the entities that may export or import them. It also outlines the importation process, the safety standards, drug distribution requirements, and measures that may be taken against those who violate any program requirements.

Under the Canadian Prescription Drug Importation Program, state agencies, county health departments, and certain treatment facilities may import drugs from Canada. The program is run through the Florida Agency for Health Care Administration, which must (1) contract with a vendor to administer the program and (2) report annually to the governor and legislature.

Under the International Prescription Drug Importation Program, distributors, pharmacies, and pharmacists may import prescription drugs from any qualified jurisdiction (i.e., a foreign state that the federal government recognizes as adhering to good pharmaceutical manufacturing processes). Eligible exporters must apply for and receive a permit from the Florida Business and Professional Regulation Agency, and importers must maintain extensive supply chain documentation, among other requirements. The program appears to be a pilot program. However, as federal law appears to only allow importation from Canada, it is not clear this second program would be approved by HHS without statutory changes.

Maine

This year, Maine enacted S 392, which establishes the "Canadian Prescription Drug Importation Program" and requires the state Department of Health and Human Services to design the program and apply for federal approval. It generally requires manufacturers to institute track-and-trace protocols and requires the legislature to fund the program. However, Maine requires the state HHS to designate another state agency to act as the importer, and allows it to contract with distributors, pharmacies, and health insurers. The program requires the implementing agency to annually report to the legislature and to consider whether to expand the program.

Vermont

In May 2018, Vermont passed the nation's first drug importation law, which establishes a state drug importation program to act as an importing wholesaler under the federal law. The program cannot be implemented until (1) the state adopts new legislation funding it and (2) HHS approves it. The law is based on the National Academy for State Health Policy's model drug importation legislation. A summary of the act is available here. The Vermont law cannot be implemented until and unless corresponding legislation is enacted to fund the program, either through a charge on imported prescriptions or a direct appropriation. According to this local news article, Vermont plans to seek federal approval by July 2020.

Connecticut Legislation

sHB 7267 (§§ 11-19), as amended by House "A," would have required the Department of Consumer Protection (DCP) commissioner, in consultation with the Department of Public Health (DPH) commissioner, to establish the "Canadian prescription drug importation program," to import from Canada safe and effective prescription drugs with the highest potential cost savings to the state. The bill would have required the DCP commissioner to apply to HHS by January 1, 2021, and if approved, implement the program within 180 days. Generally, the bill included:

1. track-and-trace and supply chain documentation requirements;
2. initial and subsequent testing of prescription drugs, along with certification they are safe and accurately labeled and represented;
3. wholesaler and supplier record retention requirements;
4. provisions granting the DCP commissioner enforcement powers; and
5. legislative reporting requirements.

The program would be available to Connecticut wholesalers, who may import prescription drugs to a pharmacy, institutional pharmacy, or to a DPH-registered laboratory to perform analytical testing. (For a more detailed summary, see OLR's bill analysis here.)

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