

New Vermont Law Seeks to Allow Wholesale Importation of Drugs from Canada

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On May 16, 2018, Vermont Governor Phil Scott signed Senate Bill 175, which allows for the wholesale importation of prescription drugs from Canada into Vermont. The new law directs the Vermont Agency of Human Services (VAHS) to design a wholesale prescription drug importation program that complies with federal drug importation laws (21 U.S.C. § 384), including requirements for safety and cost savings. The program must:

- designate a State agency to either become a licensed drug wholesaler or contract with a licensed drug wholesaler to implement the program;
- use Canadian prescription drug suppliers regulated under the laws of Canada or of one or more Canadian provinces, or both;
- ensure that only prescription drugs meeting the FDA's safety, effectiveness, and other standards are imported by or on behalf of the State;
- import only those prescription drugs expected to generate substantial savings for Vermont consumers;
- ensure that the program complies with the federal tracking and tracing requirements;
- prohibit the distribution, dispensing, or sale of imported products outside of Vermont's borders;
- recommend a charge per prescription or another method of support to ensure that the program is funded adequately in a manner that does not jeopardize consumer savings; and
- include a robust audit function.

The chances that a Vermont drug importation program will actually be implemented are modest. Section 804 of the Federal Food, Drug, and Cosmetic Act provides that a program of importation of drugs from foreign countries may become effective only if the Secretary of Health and Human Services (HHS) certifies to Congress that the program will pose no additional risk to public health and safety and will result in a significant reduction in the cost of covered products to the American consumer. Vermont SB 175 directs the VAHS to submit a formal request for certification of Vermont's program to HHS by July 1, 2019. However, HHS has never certified an importation program since the current version of FDC Act § 804 became effective in 2003, and Secretary Alex Azar recently called importation a "gimmick". Although Donald Trump advocated importation of drugs from Canada as a way to reduce drug prices during his campaign, he has not mentioned this approach more recently, and his Administration's recently issued Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs did not include it. Nevertheless, the federal hurdles have not deterred states from pursuing this approach. Apart from Vermont, at least seven other states are considering

foreign importation legislation this year. Their hope may be to collectively exert pressure on HHS to change its historical views on drug importation.

If other states enact drug importation laws, it will not have been the first time that Vermont has set a trend. In June 2016, Vermont enacted a law requiring drug manufacturers to submit reports to the state justifying their price increases for certain drugs (see our blog post [here](#)). So far, five other states have followed suit with price increase transparency requirements or price limitations (as we reported [here](#) and [here](#)). We will continue to monitor and report on the rapidly evolving state landscape on drug pricing, as well as any concrete developments that follow from the Administration's Blueprint.