

Client Alert

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Update on Florida's Canadian Prescription Drug Importation Program

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This year, Florida Governor Ron DeSantis signed into law a bill that creates Florida Statute Section 381.02035, which establishes the Canadian Prescription Drug Importation Program within the Agency for Health Care Administration ("AHCA"). The program will facilitate the commercial importation of prescription drugs into Florida from approved Canadian suppliers. The drugs must meet U.S. FDA standards for effectiveness, safety, misbranding, and adulteration.

Congress had passed a similar law more than 15 years ago with the 2003 Medicare Prescription Drug Improvement and Modernization Act. Yet it still has not been implemented. However, Florida appears to be the first state to be fast tracking its efforts for federal approval of its Canadian drug importation program. Three other states, Vermont, Colorado, and Maine, have approved programs of drug importation from Canada.

On August 20, 2019, Florida officials submitted a concept plan to federal officials on how the Florida program will work. If approved by the federal government, then it will have to seek Florida legislative approval again for funding for the program. Under the Florida program, AHCA will contract with a vendor to handle the day-to-day operations of the program and to make sure that importers follow state and federal laws regarding prescription drug importation. The vendor will identify and maintain a list of eligible Canadian suppliers and will serve as an intermediary between the Canadian supplier and the eligible importers.

The eligible prescription drugs will be the same with respect to active ingredients and will have been initially purchased from an FDA-approved manufacturer or authorized distributor. The following drugs will be excluded from importation:

1. Controlled substances
2. Biological products
3. Infused and parenteral drugs
4. Intravenously injected drugs and
5. Drugs inhaled during surgery

Floridians generally will not be permitted to access these imported drugs. They will only be permitted to be sold to certain facilities funded by the state. These facilities are:

1. A wholesaler or pharmacist employed by or under contract with the Department of Health's central pharmacy, for distribution to a county health department, or free clinic for dispensing to clients treated in such a department or clinic
2. A wholesaler or pharmacist employed by or under contract with a Medicaid pharmacy enrolled/registered with the AHCA for dispensing to Medicaid recipient
3. A wholesaler or pharmacist employed by or under contract with the Department of Corrections, for dispensing to inmates in custody of the Department of Corrections
4. A wholesaler or pharmacist employed by or under contract with a developmental disabilities agency for dispensing to clients treated in such a center
5. A wholesaler or pharmacist employed by or under contract with a treatment facility for dispensing to patients treated in such a facility

Florida believes that this will yield a cost savings of over \$150 million annually. In the concept paper, Florida argues that the program could meet the track and trace and other safety requirements for the prescription drugs.

Florida believes that based on the framework established in its concept plan, it will gain approval from the federal government that implementation of its Canadian Prescription Drug Importation Program poses no additional risk to public health and safety and will yield cost savings. The specifically referenced drug wholesalers and pharmacists in Florida will want to monitor the federal approval process to determine whether this is a cost savings option for their facility.

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