

Blog Post

FDA's Safe Importation Action Plan May Give Florida's Drug Import Program a Pathway to Approval

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At both the federal level and within Florida, there are the beginnings of the seeds of change regarding drug importation policies. President Trump and Governor DeSantis have both been HUGE supporters of drug importation as a mechanism to reduce prescription drug prices.

First, at the federal level, as a result of the President's interest, in June 2018, DHHS Secretary Azar was directed by the FDA to establish a Working Group on Drug Importation to Address Price Spikes. Following on the working group's efforts, earlier this month, the FDA announced its "Safe Importation Action Plan" (the Plan) to allow the importation of prescription drugs. The Plan has two options or Pathways, as they are referenced in the Plan.

Pathway 1 allows for a Notice of Proposed Rulemaking (NPRM) which would rely on the authority in Section 804 of the Federal Food, Drug, and Cosmetic Act to authorize demonstration projects to allow importation of drugs from Canada. The NPRM would include conditions to ensure the importation poses no additional risk to the public's health and safety and that it would achieve significant cost savings to the American consumer. Pathway 1 appears to have been drafted with Florida's drug import plans in mind, though limiting

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the countries which may export drugs to just Canada, may constrain Florida's plans.

Under Pathway 2, manufacturers would be permitted to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the U.S. versions. Under this Pathway, manufacturers would use a new National Drug Code (NDC) for those products, potentially allowing them to offer a lower price than what their current distribution contracts require. Presumably, assigning a different NDC would also allow for assigning a different Average Wholesale Price or "AWP" (a price often used in pharmacy reimbursement by health plans). It may also allow the drug companies to assert a defense to claims of price discrimination since the two identical products would be assigned different NDCs.

The Florida legislature, with support from Governor DeSantis, enacted two drug importation programs: the Canadian Prescription Drug Importation Program and the International Prescription Drug Importation Program.

The Canadian Prescription Drug Importation Program, which will operate under the Agency for Health Care Administration, permits the importation of drugs from Canada to treat patients who receive their medicines from:

- Medicaid
- County Health Departments
- Department of Corrections
- Developmental Disabilities Centers
- State Mental Hospitals

The International Prescription Drug Importation Program will operate under the auspices of the Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics (DDC), but relies on the Board of

Pharmacy for the International Pharmacy Permit required for participation. This program is for all other Florida patients who are not covered by the Canadian Prescription Drug Program and will allow for certain entities in foreign countries to export and certain Florida licensed entities to import prescription drugs into Florida.

Pathway 1, once the NPRM becomes final, will allow for states such as Florida to request approval of demonstration projects. Both of the Florida drug import programs require federal approval. When approved pursuant to Pathway 1 of the federal Plan, these state programs will provide Florida an avenue to pursue approval of foreign importation of medications (at least as to importation from Canada), once the regulatory infrastructure is in place.

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