

## FDA Clears Way for Florida's State Programs to Import Drugs

On January 5, 2024, the U.S. Food and Drug Administration ("FDA") approved Florida's drug importation program under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") Sec. 804 which provides a pathway for states and tribes to develop and apply for approval to import drugs from Canada under a Sec. 804 Importation Program ("SIP").

Below you will find a high-level summary:

- **Applicability.** The program is limited to state programs including Medicaid, the prison system, and facilities run by the Department of Children & Families ("DCF"). Private sector employer group health plans are not eligible to create a SIP. Public employers such as cities and counties are likewise not eligible to create a SIP.
- **Term.** Florida's SIP is authorized for two years from the date the FDA is notified of the first shipment of drugs to be imported.
- **Start date/process.** Importation will not begin immediately. Before drugs can be imported, Florida's Agency for Health Care Administration must do all of the following:
  - Submit additional drug-specific information for the FDA's review and approval.
  - Ensure that the drugs Florida seeks to import have been tested for, among other things, authenticity and compliance with the FDA-approved drugs' specifications and standards.
  - Relabel the drugs to be consistent with the FDA-approved labeling.
  - Set up a distribution center.
  - Submit a quarterly report to the FDA that includes information about the imported drugs, cost savings and any potential safety and quality issues.

Note that the onerous administrative requirements may offset expected savings.



- Challenges. Pharmaceutical Research and Manufacturers of America (“PhRMA”), the pharmaceutical industry’s largest lobbying group, is expected to sue Florida regarding the program. In addition, there appear to be accessibility concerns as (1) some drug manufacturers have agreements that prohibit exporting prescription drugs out of the country and (2) Canada has taken steps to limit/prohibit exporting when their supply is low, as reiterated in a statement from Health Canada issued on January 8, 2024. Note that Canada’s population is 40 million, Florida’s population is 22 million, and the U.S. market is nearly 10 times bigger than Canada’s.

According to the proposal, Florida will begin by providing prescription drugs in a small number of drug classes which will include maintenance medications to help individuals who have chronic health conditions such as HIV/AIDS, mental illness, prostate cancer, and urea cycle disorder. These drugs will be for individuals who are under the care of the Agency for Persons with Disabilities (“APD”), DCF, Department of Corrections (“FDC”), and Department of Health (“DOH”). The program will then expand to include providing imported prescription drugs for Medicaid members across the state. The submitted cost savings estimate for importing prescription drugs from Canada is up to \$183 million per year once the program is fully implemented.

Other states, including Colorado, Vermont, and New Mexico are seeking approval for similar programs.

It is important to note that the SIP program is only allowed to import drugs from Canada. Importation of drugs from other countries (e.g., Turks and Caicos, Australia, and Turkey) is not allowed. Employers should understand that, currently, the approval of this program does not change the importation rules as they exist with respect to private sector employer plans or local state employers. Drug importation is still generally illegal and employers should be wary of vendors indicating otherwise and carefully evaluate the compliance risks associated with these programs.

We will keep you apprised of developments.