January 5, 2024

FDA Green Lights FL Drug Importation Program

Manufacturers Likely Sue, Canada Doesn't Want to Play Ball, Savings Likely Minimal

Relevant Companies

Our Take & Next Up

We see this as the first of many steps in what is likely to be an experiment that does not generate meaningful savings. The two-year importation program only applies to medicines (biologics or specialty pharmaceuticals are excluded) via state-run health care programs, such as Medicaid. Today, the Food and Drug Administration authorized Florida's Agency for Health Care Administration's drug importation program (here). Florida's plan is the first SIP that has been authorized by the agency. Now, several steps must take place for the program to start, which would likely take months, with legal proceedings likely.

Key Points

More of a headline, for now, versus an impactful policy. State drug importation pilots have been tried in the past to purchase medicines in bulk for state healthcare programs (including Medicaid). However, efforts have largely failed due to costs and operational challenges.

Several steps & hurdles remain before the FL program may start. (1) FL will have to list the drugs it wants to import (2) Canada will have to agree to the new scheme (3) FL will be obligated to directly negotiate with manufacturers (Canadian wholesalers are prohibited from exporting to the US per their contracts). (4) FL must submit a pre-import request to the FDA at least 30 daysbefore the scheduled date of arrival for a shipment containing an eligible prescription drug. (5) Manufacturer or importer must complete appropriate testing of the drugs to be imported (6) The importer must make "labeling corrections" specified by FDA (7) The only port authorized by FDA to allow a shipment of drugs is Detroit, MI. Florida and any future states will have to continue to navigate the pre-import process, find sellers in Canada, and create an importation and safety review system that will ensure timely deliveries.

The Canadian government is publicly opposed to bulk drug importation due to domestic supply concerns. It has set up regulatory guardrails to prevent exportation for drugs in short supply. Recall Canada has 40 M citizens, with the US having almost 10x that number.

Florida is seeking to import certain prescription drugs for two years under the FDA's importation program for state programs like Medicaid. Under the section 804 importation program (SIP) (here), the FDA allows states and Indian tribes to import certain drugs that reduce the cost of drugs for consumers, and which do not impose additional risk to public health and safety.

- Florida's Agency for Health Care Administration must submit additional drug-specific info for FDA review, ensure that the drugs for importation have been tested to comply with FDA specifications and standards, and be relabeled to be consistent with FDA-approved labeling.

- The state agency must also submit a quarterly report to the FDA that includes information about the imported drugs, cost savings, and any potential safety and quality issues.

Not all drugs are eligible for importation -- biologics and specialty pharmaceuticals are excluded. Drugs excluded from the FDA's importation include controlled substances, biologics (like insulin), infusion drug, drug subject to REMS, IV injected drugs, drugs that are inhaled during surgery, and intrathecally or intraocularly injected drugs. The state also cannot import any drugs that cannot be relabeled without affecting the container closure system, such as a blister pack, complicating implementation.

The savings generated from the Florida program -- if it ever goes into effect -- are likely to be minimal. Biologics and products like insulin are excluded. PhRMA is opposed to importation and cites the following data points:

- Safety concerns. PhRMA points to concerns of counterfeit and adulterated medicines which may bypass the typical FDA manufacturing regulatory system through importation.
- Lack of actual savings. A 2004 CBO report that found importation would produce a negligible reduction in drug spending.

Colorado looks to re-apply for importation approval next. Eight other states — Colorado, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont, and Wisconsin — have laws allowing for a state drug importation program. Colorado is expected to submit an updated SIP to the FDA in early 2024.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET
