

FDA Allows First-ever Canadian Drug Imports to the United States

On Jan. 5, 2023, the U.S. Food and Drug Administration (FDA) announced that it will allow Florida to import prescription drugs from Canada directly. This first-in-the-nation move represents a major policy shift that could dramatically reduce the price of prescription drugs for Americans. Florida's Agency for Health Care Administration has previously estimated that Canadian drug imports could save the state \$150 million annually. However, drug importation is fiercely opposed by the U.S. pharmaceutical industry and, therefore, is likely to face multiple hurdles.

“Just the idea that a state could bring in drugs from Canada might help with negotiations over discounts and rebates.”

- Dan Ollendorf, chief scientific officer at the Institute for Clinical and Economic Review

The FDA's new policy will allow Florida to buy prescription drugs in bulk. These medications will be available to residents through various state-run health care programs, such as Medicaid. However, Florida must meet certain requirements, such as testing and relabeling the imported drugs to be consistent with FDA-approved labeling. The state must also submit a quarterly report to the FDA, which contains information about the imported drugs, cost savings, and any potential safety and quality issues under the new policy.

The plan is authorized for two years from the date the FDA is informed about Florida's first drug import

shipment. However, the FDA has the authority to extend the authorization for an additional two years at a time. The FDA regulator has also announced its commitment to working with other states seeking to import drugs from Canada. Other states have already applied for the program, including Vermont, Colorado and New Hampshire.

Challenges to Implementation

Previously, Canada has opposed U.S. plans to purchase prescription medicines over concerns that it would threaten Canada's drug supply and raise costs for citizens. The Canadian government has already taken steps to block the export of prescription drugs that are in short supply. Additionally, some drug manufacturers have agreements with Canadian wholesalers not to export their medicines, which could make implementing drug importation plans challenging. The approval is also expected to face legal challenges from the pharmaceutical industry's major lobbying organization, the Pharmaceutical Research and Manufacturers of America, which has sued over previous importation efforts.

Employer Takeaways

U.S. drug prices are higher than in Canada and other countries where government-run health care systems negotiate prices for individual prescription drugs. Reducing the cost of prescription drugs in the United States is critical to combat rising health care costs for both employers and employees. Prescription drug importation offers one way to potentially increase access and affordability to necessary and life-saving drugs for many Americans. However, the implementation of these programs is likely to face numerous obstacles. Therefore, employers should continue to monitor this issue closely.

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