# JUST A SIP:

# CAN CANADA QUENCH U.S. THIRST FOR IMPORTED PRESCRIPTION DRUGS?

By Alston & Bird Health Benefits Practice

In late 2020, the Food and Drug Administration ("FDA") issued a final rule announcing a "Safe Importation Action Plan" ("SIP") for states (and tribes) to legally import prescription drugs from Canada. Florida became the first state to have its importation plan approved by federal regulators in early 2024. This FDA approval does not mean that Florida can now begin to import drugs from Canada immediately, and Florida still has additional steps to complete before importation can begin.

It is still illegal for self-insured plans to import drugs from Canada or other countries. Self-insured plans and their plan sponsors are not able to apply for a drug importation program

on their own behalf, and it remains to be seen whether the FDA would approve an SIP designed to benefit private-payer employee benefit plans. Florida's SIP application limited the beneficiaries to state programs such as Medicaid and patients served through other state government entities. To date, no states other than Florida have received federal approval. In the meantime, resistance from other industry stakeholders is likely, and Canada is under no obligation to meet U.S. demand.

## BACKGROUND

Although the FDA generally prohibits importation for commercial use of unapproved drugs manufactured in other countries, the agency issued a final rule in 2020 that provides a pathway for states to legally import drugs from Canada. The pathway requires states to submit an SIP proposal that shows, among other things, that the program will result in a significant reduction in the cost of prescription drugs for consumers without posing any additional public health and safety risk. Although several states have passed laws to allow prescription drug importation, only a handful have submitted SIP applications. Colorado's application is pending, New Hampshire's application was denied, Vermont's application was deemed incomplete, and only Florida's application has been approved. It has been reported that Texas is working on its SIP proposal and hopes to submit it this year. Florida still has some additional steps to complete before importation can begin, and other states are sure to be watching carefully.

## WHAT ARE SOME LIMITATIONS TO A STATE DRUG IMPORTATION PROGRAM?

The application process is onerous, requiring sponsors to identify drug manufacturers and importers, obtain Canadian inspection reports, detail how the sponsor will maintain compliance with FDA rules, and address how the SIP sponsor will ensure the security of the supply chain. Supply chain security could become a challenging issue, especially as more states seek to import drugs from the same sources.

States cannot choose to import any drug from Canada. The FDA excludes certain types of drugs from importation, including biological products, infused drugs (including insulin), drugs that are injected into a vein, spine, or eyes, and drugs that are subject to a risk evaluation and mitigation strategy (REMS). Florida, for example, initially intends to import medications to treat HIV/AIDS, mental health conditions, and prostate cancer.

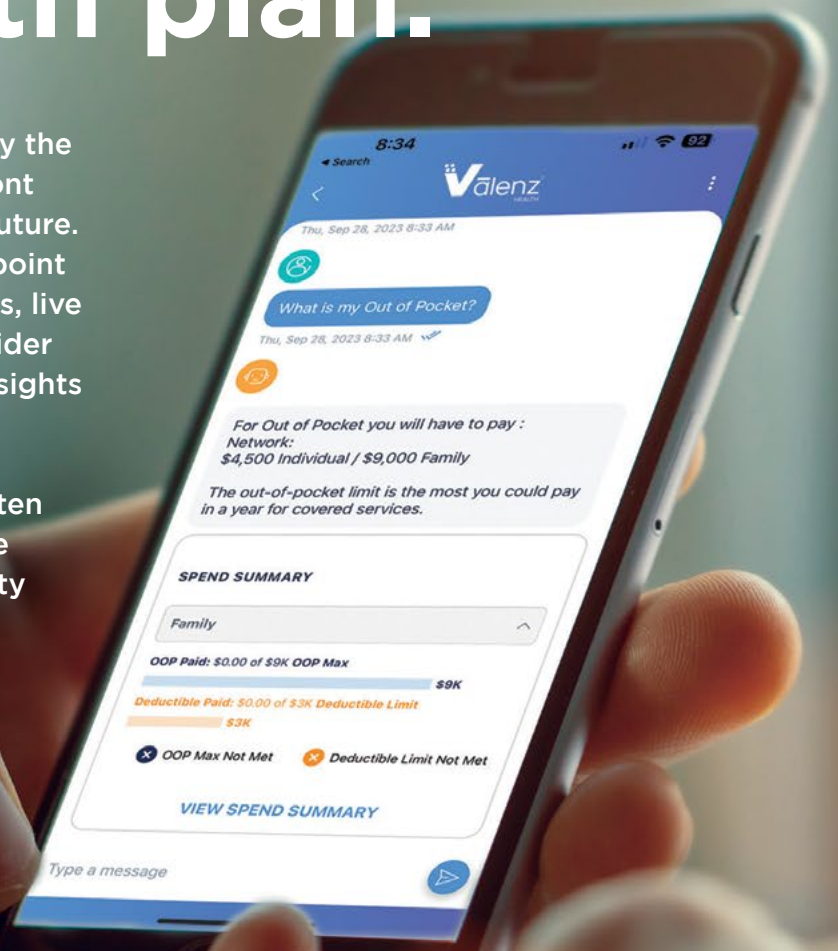
Drugs cannot be immediately imported from Canada upon approval of the SIP. Even after the FDA grants approval, there are additional steps that a state needs to take before imported drugs can reach consumers. The state needs to contract with importers, who in turn need to submit a pre-import request to the FDA. Once imported, the drugs need to be examined by a government agency and tested for authenticity and compliance with FDA rules. After testing, the drugs need to be relabeled to the FDA's specifications. A state will also have ongoing compliance requirements, including quarterly reporting to the FDA. SIPs are authorized for two years, with the opportunity to renew and propose modifications. The FDA can suspend or revoke a SIP at any time. The specific requirements for SIP proposals are set forth in the Final Rule at 85 Fed. Reg. 62094, and the FDA website includes links to additional materials.

Not everyone in the state will necessarily be able to benefit from a state's drug importation program. Although a state will need to explain in its proposal how drug importation will lower costs for consumers, there is no requirement that the SIP benefits all residents of the state. Florida's SIP will benefit patients receiving services through certain state agencies and government programs, with a particular focus on the state's 4.5 million Medicaid recipients.

# Open a digital front door to your health plan.

For deeper member engagement, deploy the industry's first fully integrated digital front door supporting the health plan of the future. **zConnect** from Vālenz® Health and zakipoint Health offers 24/7 access, AI capabilities, live chat with Valenz nurse navigators, provider search, and actionable real-time care insights across mobile and desktop platforms.

Learn how you can engage early and often with members to simplify the healthcare experience, while optimizing cost, quality and utilization of care for your plan.




**Elevate the healthcare experience with a fully integrated digital front door for smarter, better, faster healthcare: valenzhealth.com/digital-solutions or (866) 762-4455.**

Vālenz® HEALTH

SIIA Proud to be a Diamond Member

### CAN SELF-INSURED PLANS BENEFIT FROM A STATE DRUG IMPORTATION PROGRAM?

There is nothing in the FDA final rule that would prevent a state from expanding the prospective beneficiaries of the SIP to include private payers like self-insured plans. Colorado's pending proposed SIP, for example, contemplates distribution of the imported drugs to participating Colorado pharmacies. If the FDA authorizes Colorado's SIP as proposed, the SIP could benefit self-insured plans that participate in the Colorado SIP pharmacy network, although the details of any proposal are subject to change during the application process. Colorado's proposed SIP targets commonly prescribed drugs, such as blood thinners and drugs for women's health, and a variety of drugs to treat Type 2 diabetes, asthma, cancer, HIV and other conditions. In response to the application process and its discussions with the FDA, Colorado intends to update its proposed SIP early this year, and it is not yet known if the updated SIP will alter this possible gain for private payer plans.

### WHAT OTHER CHALLENGES ARE DRUG IMPORTATION PROGRAMS FACING?

Shortly after the FDA issued the final rule in 2020 to open the drug importation pathway to states, a group of industry stakeholders challenged the rule, but that challenge was dismissed because at the time the FDA had yet to approve a SIP. Now that Florida's SIP has been authorized, there is likely to be increased activity in this area that could jeopardize state importation programs, especially if state programs are expanded to include private as well as public payers, which could threaten other stakeholders.

# Let’s put the power at members’ fingertips.

Personalized support from our Member Advocacy team, the freedom to choose from over 65,000 pharmacies nationwide and the convenience of managing everything through our Drexi Mobile App.

With Drexi, we’re ushering in a new era of convenience and efficiency in PBM. Put your members’ healthcare needs first and experience the difference today.

Learn more at **drexi.com**

Drexi | amps


Another potential challenge to drug importation from Canada is Canada's interest in prioritizing its own citizens, especially in the event of a drug shortage. The SIP proposal requires states to explain the steps they will take to ensure the security of the supply chain. Canadian law prohibits exporting drugs intended for the Canadian market if exportation would cause or worsen a drug shortage. The total population of Canada is roughly 39 million, while Florida's population is about 22 million. Texas, which is also working on an SIP proposal, has a population of close to 30 million. Whether Canadian drug manufacturers could increase production to meet U.S. demand is another challenge to the stability of a state drug importation program.

## CAN INDIVIDUALS IMPORT DRUGS FROM OTHER COUNTRIES FOR PERSONAL MEDICAL USE?

Although the same statute that authorized the FDA to issue regulations for a state drug importation program also authorized the FDA to issue regulations for a personal drug importation program, the FDA has yet to release any such regulations. Consequently, the importation of prescription drugs from another country for personal use, even personal medical use, is illegal. However, a nonenforcement personal importation policy ("PIP") does exist for limited situations. After approval of the Florida SIP, the Congressional Research Service (CRS) updated its background report on drug importation, noting that the enforcement discretion "is not intended as a way for consumers to bring lower-priced prescription drugs into the United States; rather, FDA intended this enforcement discretion to allow individuals to access treatments not otherwise available in the United States." Maintenance

medications available for sale in the U.S. would not be within the limited scope of the nonenforcement policy.

Although the FDA's PIP may allow individuals to import certain drugs into the U.S. for personal use, the policy is entirely discretionary. Individuals hoping to benefit from the PIP are technically still in violation of FDA rules, which treat such violations as a misdemeanor punishable by up to a year in prison or a fine up to $1,000, or both. More serious violations may result in up to three years in prison and/or fines of up to $10,000.

May self-insured plans reimburse individuals who import drugs from other countries for personal medical use or import drugs from Canada or other countries?

It is important to emphasize that although this nonenforcement PIP makes it possible for individuals to import certain drugs from other countries for personal use, it does not make the importation legal. This distinction between being possible versus being legal is what bars a self-insured ERISA plan from reimbursing a participant for a drug illegally imported from another country, regardless of the nonenforcement policy. Consequently, the nonenforcement PIP is of no use to self-insured ERISA plans. Also, because importation would be illegal, any reimbursement would be taxable to the participant. Similarly, it would be illegal for a self-insured plan to engage in the importation of drugs from another country to be provided to participants and beneficiaries.

The CRS background report noted that the importation of prescription drugs for commercial use is prohibited except as approved by the Secretary of Health and Human Services (HHS) pursuant to a drug shortage or pursuant to an SIP. One question that is somewhat unclear is whether a self-insured plan (e.g., a flexible spending account or health reimbursement arrangement) would be permitted

to reimburse a participant's cost share or out-of-pocket expenses for a drug legally obtained under a state SIP where, like Florida's SIP, the state SIP is limited to a governmental program (e.g., Medicaid). We believe such instances will be rare, but this is an issue that should be addressed as such limited SIPs get up and running.

## WHAT'S NEXT FOR DRUG IMPORTATION FROM CANADA?

States that have passed laws to allow drug importation, which so far include Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas and Vermont, will no doubt be watching as Florida completes the final steps necessary for drug importation to actually begin.

If Florida realizes its anticipated savings from the program—projected to be as much as $180 million in its first full year of importation—other states will be eager to follow in Florida's path. The progress of Colorado's SIP application, and possibly even Texas's forthcoming application, will be of interest to self-insured plans that may be able to realize some of these savings themselves. Challenges from other stakeholders are also likely to arise, and Canada may take additional protective measures to safeguard its country's drug supply. ■

*Attorneys John R. Hickman, Ashley Gillihan, Steven Mindy, Ken Johnson, Amy Heppner, and Laurie Kirkwood provide the answers in this column. John is partner in charge of the Health Benefits Practice with Alston & Bird, LLP, an Atlanta, New York, Los Angeles, Charlotte, Dallas and Washington, D.C. law firm. Ashley and Steven are partners in the practice, and Ken, Amy, and Laurie are senior members in the Health Benefits Practice. Answers are provided as general guidance on the subjects covered in the question and are not provided as legal advice to the questioner's situation. Any legal issues should be reviewed by your legal counsel to apply the law to the particular facts of your situation. Readers are encouraged to send questions by E-MAIL to John at john.hickman@alston.com.*