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Imported Drugs: (Possibly) Coming Soon to a State Near You

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In recent years, states have been exploring innovative avenues to address rising healthcare costs and ensure access to affordable medication for their residents. One idea gaining traction involves pursuing authorization from the US Food and Drug Administration (FDA) for importation programs under Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA) to import prescription drugs from Canada. These "Section 804 Importation Programs" (SIPs), if approved, would enable states to import prescription drugs from Canada, often at significantly lower prices than those available in the United States.

After years of legal and other challenges to the rule, on January 5, 2024, the FDA authorized Florida's SIP proposal. While eight other states have laws that permit drug importation, and six of them are seeking FDA approval, this is the first time that the FDA has approved a state entity to import drugs from another country. Following Florida's example, Colorado and other states are moving forward with their own SIP plans.

IN DEPTH

BACKGROUND

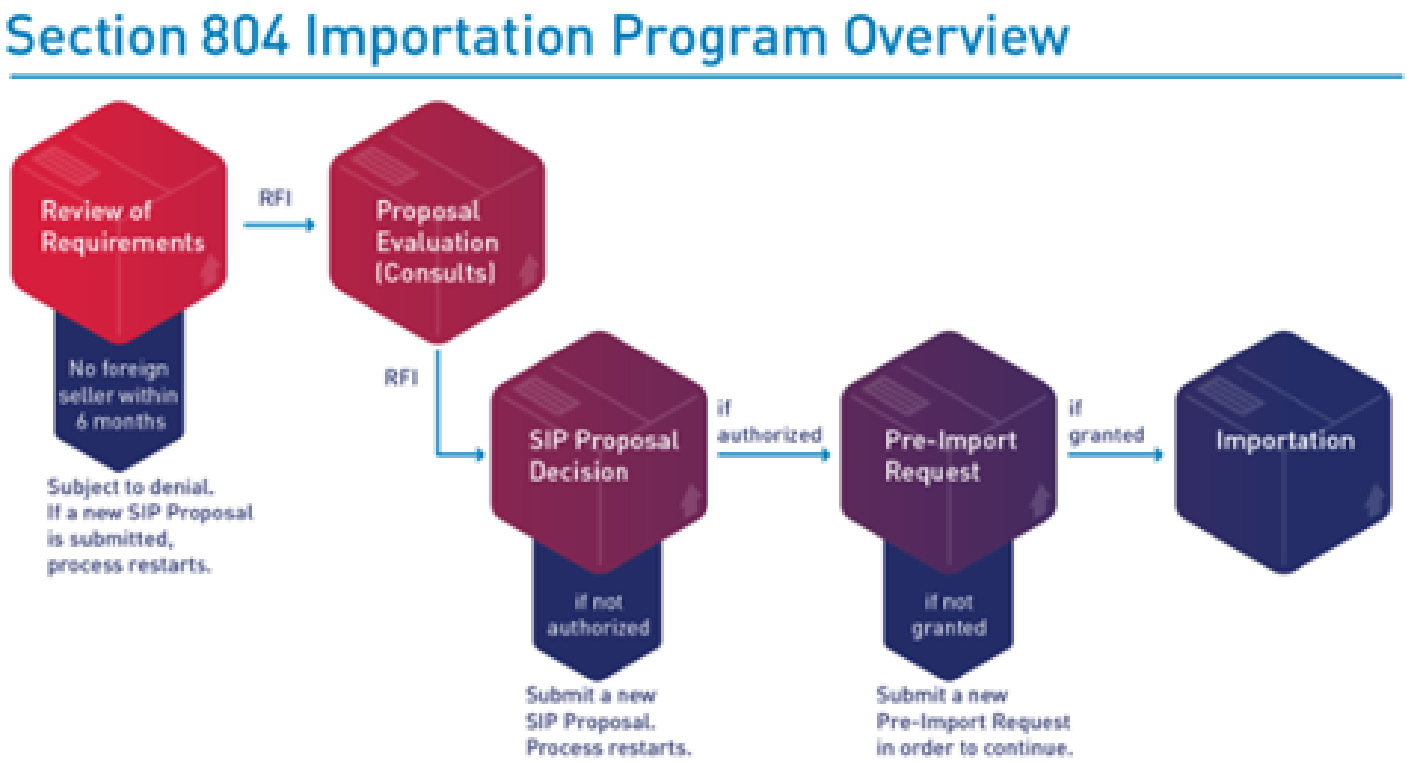
As we previously discussed, the US Department of Health and Human Services (HHS) issued a final

rule in October 2020 that allows states and Indian tribes to authorize commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs known as SIPs.

Under Section 804 of the FDCA, state and Indian tribes may commercially import certain prescription drugs from Canada, with multiple requirements and caveats. For example, the sponsor must prove in their SIP proposals that importation will significantly reduce the cost of these drugs to the American consumer without imposing additional risk to public health and safety. Currently, SIP proposals require a state or Indian tribe to serve as the sponsor or co-sponsor. After a two-year period beginning on the date of the first import entry of drugs under a SIP, HHS may permit pharmacists or wholesalers to submit SIP proposals without a state or Indian tribe as the sponsor or co-sponsor.

In the SIP proposal, the sponsor must identify an importer in the United States that will purchase the drugs from the Canadian seller. This importer must be a licensed state-licensed pharmacist or a state- or FDA-licensed wholesale distributor. The sponsor also must specify the drugs that will be imported, and those drugs must be approved by Health Canada's Health Products and Food Branch, which is the Canadian equivalent of the FDA. These and other requirements must be evidenced in the sponsor's SIP proposal, which must be approved by FDA. If a new SIP proposal answering open questions from the FDA is submitted, the process restarts.

Once the SIP proposal is authorized, but before importing drugs from Canada, the importer must submit a Pre-Import Request to the FDA 30 calendar days before the drugs' arrival at the authorized port of entry. The Pre-Import Request must include basic information about the Foreign Seller, the imported drugs, an attestation from the manufacturer that the information about the drugs is correct and an executed batch record. In other words, the sponsor must ensure that each imported drug is relabeled in a manner that is consistent with FDA-required labeling for the US market and that any drug it intends to import meets FDA specifications and standards through testing. Once the Pre-Import Request is granted, the drugs may be imported.



Source: *FDA importation program under Section 804 of the FDCA*

FLORIDA'S FATE

Florida's authorization comes over three years after its original proposal was submitted by the Florida Agency for Health Care Administration (AHCA). Florida's plan is based on an approach developed under the Trump administration and executed under the Biden administration, following an executive order issued by US President Joe Biden in July 2021 directing the FDA to work with states to import prescription drugs from Canada.

Under the SIP, the AHCA is authorized to import a specific set of drugs from Canada for a period of two years. Florida's SIP appears to be starting small – it only seeks to import 14 prescription medications limited to diseases (*e.g.*, HIV/AIDS, mental illness) and only for consumers receiving services through certain government programs, including patients served through county health departments, recipients of Medicaid and inmates in the custody of the Florida Department of Corrections. Florida says in its proposal that, after the program has proven successful, the state intends to amend its SIP to expand the list of medications that will be imported.

However, in addition to overcoming the regulatory burdens for SIPs, Florida may also face foreign and domestic opposition. A few days after the FDA authorized Florida's SIP proposal, Health Canada issued a statement restating its long-held position that "bulk importation will not provide an effective solution to the problem of high drug prices in the U.S." and indicated that Canada will take "all necessary action to safeguard the drug supply and ensure Canadians have access to the prescription drugs they need." This statement aligns with the Canadian rule issued in 2020 that prevents Canadian-based manufacturers and wholesalers from exporting drugs in short supply.

Additionally, Florida may face pushback from the US pharmaceutical industry and other stakeholders. When Florida issued its first SIP proposal in November 2020, three organizations filed a complaint challenging the FDA's 2020 final importation rule. While that case was dismissed in February 2023 for lack of standing, there may be a renewed interest in litigation with the first SIP proposal authorization. After the FDA announced its approval of Florida's SIP, more than 70 pharmacy groups signed onto a joint statement expressing concern about the important plan. The letter suggests that the importation plans may raise patient safety concerns and points to the lack of a Canadian equivalent to the federal Drug Quality and Security Act passed in 2013.

OTHER STATES PURSUING SIPs

On the heels of Florida's authorization, Colorado is renewing its interest in participating in a SIP.

In February 2024, Colorado submitted to the FDA a revised version of its SIP proposal, which amends its initial proposal submitted in December 2022. Most notably, Colorado reduced its initial proposal's importation drug list from 112 drugs to 24 drugs. The revised proposal's listed drugs treat blood clots, cystic fibrosis, respiratory illnesses, cancer, type 2 diabetes, HIV/AIDS, and psoriatic and rheumatoid arthritis.

Four of the drugs listed in Colorado's SIP overlap with Florida's authorized importation drug list. In its revised proposal, Colorado flags its difficulty negotiating with drug manufacturers in Canada to allow exportation of their drugs to the United States and seeks guidance from the FDA on how to address this issue.

In addition to Colorado, several other states are actively pursuing the importation of prescription drugs from Canada.

- Vermont was the first state to pass drug importation legislation in 2018. However, its original proposal in 2019 was deemed incomplete because the SIP regulations had not been finalized. Vermont has not submitted a new proposal.
- Similarly, Maine submitted a proposal to the FDA in May 2020 prior to the SIP pathway being finalized. Main has not submitted a new proposal complying with the SIP regulations.
- New Mexico submitted its proposal to the FDA in December 2020 and is still awaiting a response from the FDA.
- New Hampshire submitted a proposal in August 2021, which the FDA rejected in November 2022 because the proposal was lacking essential information, such as a Foreign Seller. New Hampshire has not submitted a revised application.

Other states have shown interest in potentially importing drugs but have not taken any steps to submit SIP proposals to the FDA for approval. In April 2021, North Dakota passed a bill that requires a study on the potential impacts of prescription drug importation. In June 2023, Texas enacted legislation to establish an importation program and, in December 2023, published a wholesale prescription drug importation report with recommendations to support implementation of the program.

NEXT STEPS

While the FDA's authorization of Florida's SIP is progress towards making state importation of drugs a reality, Florida still has to navigate many hurdles to make the program a reality. We will continue to monitor the progress of Florida's SIP as well as other state activity and industry interest in state SIPs. Time will tell whether there will be further movement from the FDA on the pending SIP proposals, but it seems likely that other states will use Florida's authorized SIP proposal as a model when exploring their own approval pathways.

Nathan Gray also contributed to this article.

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