Prescription drug importation gets renewed attention

By Mercer's Kaye Pestaina and Catherine Stamm
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In this article

While federal restrictions on drug importation and reimportation from other countries have not changed in recent years, there is a renewed call for action at the federal and state level. In July 2019, the Trump administration (Administration) issued its Safe Importation Plan — designed to eventually allow importation and reimportation. This GRIST provides highlights of current regulatory standards that govern drug importation, the Administration's new initiatives, and key takeaways for employers looking to address the rising costs of prescription drugs through importation.

Highlights

Below are highlights of the key compliance issues and activities concerning importation and reimportation.

Importation is generally prohibited. The federal Food and Drug Administration (FDA) generally maintains that importing prescription drugs into the US by anyone other than the manufacturer is a violation of federal law. The federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the interstate shipment of "unapproved drugs," which includes the importation of unapproved drugs from outside the US (21 USC § 331; 21 USC § 355(a)). Unapproved drugs include those not manufactured according to FDA standards.

FDA approval process. The FDA approval process is lengthy and requires a manufacturer to demonstrate the drug's safety and efficacy. Drugs not approved by the FDA are considered "misbranded" and importing or otherwise moving them within the US (except for personal use) is subject to criminal and

other penalties for all involved. Information on the FDA website setting out the importation prohibition has not changed since its issuance in 1998.

FDA assurance. The rationale behind the prohibition is that the FDA cannot adequately assure the public that drug products imported to the US from foreign countries meet FDA standards, or (if reimported) are the same products approved by the FDA. The FD&C Act prohibits importation not only by those directly involved in the importation, but by all entities "causing" the activity. Therefore, plan sponsors that facilitate access to imported medications for group health plan enrollees have some risk of violating the law.

Reimportation is also restricted. The FD&C Act also prohibits reimporting drugs into the US unless done so by the manufacturer (21 USC § 381(d)) with some exceptions. Amendments to the FD&C Act in 2003 (the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)) directed the FDA to set up a process to allow pharmacies and wholesalers to import certain FDA-approved drugs from Canada. However, implementation of the process required certification by the Secretary of Health and Human Services (HHS) that importation (1) poses no additional risk to public health and safety and (2) results in a significant reduction in the cost of drugs to the American consumer (21 USC § 384 (Section 804 of the FD&C Act)). To date, HHS has not made this certification, so no waivers allowing reimportation from Canada have been approved.

Personal use policy. While importing unapproved drugs is illegal, the FDA's longstanding policy — explained in the FDA Regulatory Procedures Manual — is to not enforce the law where drug importation is for an individual's own personal use in certain circumstances. Use of this policy is at the FDA's discretion and in practice likely could be applied more broadly or narrowly than set out in the manual. Most importation today likely occurs through this personal use policy, with individuals (including employees) directly making arrangements with online pharmacies to receive certain medications.

Federal enforcement and penalties. Criminal penalties could apply to any person violating the law. Unintended violations are treated as misdemeanors and can result in up to a year in prison and a $1,000 fine. Violations committed with an intent to mislead or defraud can be charged as a felony with up to three years in prison and fines up to $250,000 (21 USC § 333). Importing controlled substances could carry a higher penalty. Other than nonenforcement for personal use, the government continues to enforce importation restriction violations. For instance, on Feb. 26, 2019, the FDA sent a warning letter to a Canadian drug distributor. The letter claimed the distributor was operating as a prescription drug provider in violation of US federal law by causing the introduction of unapproved and misbranded drugs into interstate commerce. In a related press release, the FDA urged "employers and any enrolled employees not to use any medicines" from the distributor, stating that "the FDA will pursue additional enforcement actions as needed."

State activity. The FDA has never approved a state plan to allow importation or reimportation from Canada under the 2003 law. In the years immediately following the passage of the 2003 law, courts in at least two jurisdictions rejected attempts by state and local governments to force HHS to waive legal requirements and certify importation for their government programs. See Vermont v. Leavitt, 405 F. Supp. 2d 466 (D. Vt. 2005) and Montgomery County, Md. v. Leavitt, 445 F. Supp. 2d 505 (D. Md. 2006).

Trump administration's Safe Importation Action Plan

A Safe Importation Action Plan, released by HHS and FDA, outlined two pathways for allowing importation of certain prescription drugs: the Section 804 Importation Program or SIP (Pathway 1), for states, wholesalers, or pharmacists and the Manufacturer Reimportation Program (Pathway 2) for manufacturers of FDA-approved drug products.

Pathway 1 program to allow importation from Canada. HHS and FDA have proposed regulations under the 2003 law to authorize a demonstration project that would allow states, wholesalers or pharmacists to apply for participation by submitting a proposal to HHS for to import prescription drugs from Canada. The project excludes controlled substances, biological products, infused drugs, and intravenously injected drugs, among others. States would have to propose an arrangement with a wholesaler or pharmacist as part of the application process. The project would last for two years starting from the time the state imports its first eligible prescription drug, with the possibility of extensions for two-year periods. Specifics on the application, time limit, reporting and other details are set out in proposed regulations.

States will drive and oversee this pathway. Proposed rules require that only a state, tribal or territorial governmental entity may sponsor a Pathway 1 program. Wholesalers and pharmacists can cosponsor SIPs, and are authorized to serve as importers of eligible prescription drugs. The FDA seeks comments on whether entities such as group purchasing organizations, pharmacy benefit managers (PBMs) or union health and welfare benefit plans should also be permitted to cosponsor SIPs.

Several steps involved in implementation. The proposed process would start with the state submitting an SIP Proposal to the FDA that includes specific information, including the eligible drugs to be imported, the name of the Canadian-licensed foreign seller that will purchase the drug from its manufacturer, and the name of the importer (who must be a US-licensed wholesaler or pharmacist). The SIP Proposal must explain (1) how the program poses no additional risk to the public's health and safety, (2) will result in a significant cost reduction, and (3) how the state will ensure that various testing and supply chain requirements are met. If the FDA authorizes the proposal, the proposed regulations list various steps that the foreign seller and the approved importer must complete to meet FDA testing and labeling requirements.

Recent passage of importation laws in four states. Most recently, Colorado, Florida, Maine and Vermont have passed legislation with the goal of seeking federal authorization to import drugs from Canada. These states could use Pathway 1 to import drugs. Other states could follow the lead by passing legislation should HHS approve a state plan. The National Academy for State Health Policy (NASHP) has created model state legislation and published other resources in hopes that other states will join this effort. In August 2019, Florida released a concept paper to HHS explaining how the state could implement a reimportation plan. Vermont followed with its own concept paper in October. While Florida is focused first on developing a program to address the high cost of drugs in its state programs, the Vermont concept paper addresses reducing costs for consumers who receive drugs through commercial plans regulated by the state.

Pathway 2 program to allow drug manufacturers to import their own drugs into the US. Under Pathway 2, manufacturers of FDA-approved drug products could sell a foreign version of a drug in the US as long as they could prove to the FDA that the foreign and US versions are the same. The Safe Importation Action Plan says that manufacturers could sell the foreign drug under a different National Drug Code (NDC) than the US version, allowing them to introduce the drug at a lower price than current distribution contracts require for the US version.

Draft guidance issued in December 2019 sets out the process for a drug manufacturer to obtain an additional NDC. The draft guidance and an accompanying federal register notice state that "the FDA has become aware that some drug manufacturers may be interested in offering certain of their drugs at lower cost and that obtaining additional NDCs for these drugs may help them to address certain challenges in the private market." The documents don't provide specifics on how Pathway 2 would lower costs, but it's possible that the manufacturer of a brand drug with a new NDC could avoid paying the higher and agreed-upon rebates to an insurance plan or PBM for the same drug under the original NDC. In theory, this could allow the manufacturer to lower the price and result in lower out-of-pocket costs for consumers. Unlike Pathway 1, Pathway 2 is not limited to medications from Canada, and would not exclude biologics, insulin or intravenous or injectable drugs. Comments on this guidance were due on Feb. 21, 2020.

Employer issues

- Employers continue to get contacted by various vendors seeking to assist them in reducing prescription drug costs by obtaining imported or reimported drugs for their group health plan participants. While employers should seek the assistance of counsel to review current FDA restrictions on drug importation and reimportation, these restrictions could change due to the Trump action plan.

- It's difficult to predict the timing of initiatives to advance the Administration's announcements on this issue. The Pathway 1 Safe Importation Plan will require final agency rulemaking before any state plan

is approved, and no plan can be approved unless the requisite safety and cost reduction conditions are demonstrated. Comments are due on the proposed regulation by March 9, 2020. Pathway 2 will require drug manufacturers' voluntary participation in a program that could reduce the amount of money they would otherwise receive from selling the same prescription medications in the US. However, this might not be the case if the pathway allows them to avoid current contractual obligations that reduce profits. Final guidance is expected this year.

- When evaluating importation as an option, employers will want to consider and discuss the following with experts:
  - Will either pathway to importation result in real cost savings? If both pathways are implemented as announced, what specific medications will be available at reduced costs? Are these medications the major cost drivers for group health plans?
  - Will the cost of getting FDA approvals for importation, through either of the new pathways, diminish any cost savings achieved through importation? Will drug manufacturers react by increasing prices to US importers?
  - Is there any assurance that the medications will be sold in the US at lower prices? How specifically will private employer plans be able to access any savings that states obtain through Pathway 1? Will this process and the drugs available differ by state? Will Pathway 1 be limited to insured group health plans? Will drugs imported through Pathway 1 be treated differently on plan formularies or have different negotiated rebates than the same drugs distributed through normal FDA processes in the US?
  - Even if less costly imported medications are allowed, will the volume of drugs available at the lower price be sufficient and safe? If the importation is limited to the pathway program involving only Canada, will there be sufficient amounts of lower-priced drugs available for those outside of the state and local governmental programs where some states are focused on obtaining savings? Will Canada take action to prevent or restrict US importation under Pathway 1?

Related resources

Non-Mercer resources

- Proposed regulation on the importation of prescription drugs (Pathway 1) (Dec. 23, 2019)
- Draft guidance on importation of certain FDA-approved drugs, including biological products (Pathway 2)(December 2019)
- Administration's Safe Importation Action Plan (July 2019)
- FDA policy on importation of drugs (FDA, 1998)
- Drug importation: Model legislation (National Academy for State Health Policy)
- Regulatory Procedures Manual: Chapter 9 (Food and Drug Administration, December 2017)

Mercer Law & Policy resources

- Healthcare law and policy outlook for 2020 (Feb. 18, 2020)
- Roundup of selected state health developments, fourth-quarter 2019 (Jan. 21, 2020)
- Roundup of selected state health developments — second-quarter 2019 (July 29, 2019)
- Roundup of selected state health developments — first-quarter 2019 (May 8, 2019)