Drug Importation: Cross-Border Cure or Crisis?

U.S. employers are quietly cutting their pharmacy spend in hopes of not running afoul of laws that are rarely enforced

Written By Bruce Shutan

A promising approach for helping lower a self-insured employer's pharmacy spend in the U.S. involves drug importation, though it also can be a breeding ground for confusion and legal trouble.

There are several myths about importing drugs from other countries, according to Andrew Miller, chief delivery officer of RxFree4me. For example, he said there's no Federal Drug Administration (FDA) prohibition against personal importation of drugs, nor does it violate the terms of a pharmacy benefit management (PBM) contract. The FDA, however, must grant what's known as an individual waiver before drugs are imported.

Ashley Gillihan, a partner with Alston & Bird, says there are two routes through which drugs can be imported. One is a waiver granted to individuals under circumstances that would make it difficult for them to receive the treatment they need in the U.S. The FDA also has a waiver program for states to import drugs from Canada for their residents. There are no such formal options in the commercial insurance market.

Florida became the first state to receive approval in January 2024, limiting the use of those drugs to its Medicaid program. In addition, legislation to establish drug importation programs has passed in Colorado, Maine, New

Hampshire, New Mexico, Texas, and Vermont – five of which have submitted proposals to the FDA. While Vermont sent a concept letter to the U.S. Department of Health and Human Services and the Office of Management and Budget, Texas has not yet submitted a proposal. Some states are also exploring drug imports from other countries. North Dakota and Virginia have established workgroups to examine drug importation.

Ashley Gillihan

The way individual waiver programs have been set up is that individuals sign agreements with a third party – not their employer, Gillihan notes. "The employer is not actually importing, but we've advised clients to be careful about that because they're still paying the fee," he says. "So, they're not totally outside of this arrangement that they've got a foot in."

Any violation of the law is rarely enforced, he explains, adding that time will tell how it's handled under the Trump administration, which can be unpredictable. Still, he says it's a common practice among employer groups to import drugs.

The FDA's Regulatory Procedures Manual allows Americans to source meds from tier-one countries for personal use. "You can drive across the border and bring them over, or you can have them shipped," says Gary Becker, CEO of ScriptSourcing, "and what they've done is they're not going to say it's legal or illegal. There are no consequences for doing this. There's no fine or jail time."

However, he notes that the FDA has said U.S. Customs and Border Protection allows people to send meds over from Canada to the United States, "so we're taking advantage of that and empowering plan members on a voluntary basis to be good consumers of healthcare."

Miller says there are tradeoffs for employers to consider when it comes to drug importation. He says that while the rewards are substantially lower prices on medications, the risks are largely unknown since there isn't much enforcement.

Noting that employers need guidance on this issue, he says brokers are an integral piece of the puzzle for helping educate and guide them through deciding whether to import drugs. "Just like anything else, if a group wants to put in a new vision or dental plan, they start with a broker, who's the quarterback of their plan," he observes.

Another unfounded concern about drug importation that Miller cites involves the efficacy of drugs flowing into the U.S. from four so-called tier-one, English-speaking nations because the same ingredients are being used. The FDA classifies scripts that are imported from Canada, England, Australia, and New Zealand as mirroring the same quality control standards enforced in the U.S.

Importation is confined to drugs that the FDA approves that are manufactured in foreign FDA-inspected facilities to ensure safety and efficacy, intended only for use by U.S. consumers, and imported into the country by the drug manufacturer. "By and large, there's very little that you can import without those exceptions," Gillihan says.

HUGE COST SAVINGS

The U.S. spends more on prescription drugs per capita than most other countries, with Becker noting that prices are two to 10 times more expensive than in other countries.

His company has saved employer clients "hundreds of millions of dollars" over the past decade by focusing on a small segment of health plan members who consume more than 80% of their company's

pharmacy spend. Employers that save 50 cents to 75 cents on the dollar, depending on the medication, are able to zero out copays for their health plan members, he explains.

Gary Becker

Becker recalls years ago how one of the municipalities he did business with saved employees hundreds of dollars in drug copays per month and his contact there said, "this is the difference for my family between a good Christmas and a great Christmas!"

Not only does it help these members spend less money, but it also allows them to adhere to their medications better because there's no cost barrier. He notes that nearly one-third of hospitalizations are due to medication non-adherence.

Typically, Miller has seen employers save roughly 50% by importing drugs. "Most of the international programs that are out there are going to substantially reduce or even eliminate copays and cost-shares at the member level," he says.

There would be no need to import cheaper drugs from other countries, of course, if the U.S. government is able to get a handle on the PBM industry. "Employer plans are getting drugs solely from the PBMs," Gillihan says. "There's no other avenue from which to purchase drugs. And when you have middlemen in place, things are just going to be more expensive."

He acknowledges that employers are squeezed between running the risk of violating laws governing drug importation and facing class-action lawsuits alleging a breach in fiduciary responsibility for not being proactive about combatting inflated prices in their prescription drug plan. Multistate employers also have to be concerned with regulating drug costs through networks and providing adequate coverage, he adds.

In attempting to regulate PBMs, Gillihan says states are also seeking to regulate plan design, which is preempted by ERISA. Tennessee recently lost a case with regard to its PBM law on the basis that parts of it are preempted by ERISA. Oklahoma's PBM law is headed to the U.S. Supreme Court after the state lost a case before the Tenth Circuit U.S. Court of Appeals – a case that will be closely watched across the self-insurance community.

There are so many different elements of prescription drug plans these days that make drug importation palatable to employers, Gillihan says, noting how specialty drugs are "ridiculously expensive," which is where manufacturer assistance programs help cover their cost. "Congress is going to have to decide what the best approach is and whether we need to change the rule at the FDA to get drugs from other countries under lesser terms," he suggests.

Many transparent PBMs have embraced personal importation of drugs, and some are even wading into this business, Becker reports. "We're in the data business, and we are getting data feeds from many PBMs," he says. "We know which medications we can source for what price and from which pharmacies, and we've got a pretty large team of member advocates that are identifying plan members who are eligible for our services."■

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