Risks for Employers Using Drug Import Companies to Manage Costs

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Rapidly rising prescription drug prices have created a tremendous burden on individuals and on health care plan sponsors seeking to control costs. Because of the significant price differential between drugs available inside and outside the United States, over the past decade, many individuals and some state and local governments have sought to achieve savings by buying their prescription medications from outside the United States. Some so-called "prescription referral services," facilitate these purchases. While current Food and Drug Administration (FDA) regulations prohibit this practice even for personal use, the FDA has taken a non-enforcement position with regard to individual buyers.

Now, with the cost of prescription drugs skyrocketing and the popularity of facilitated self-importation programs growing, the prescription referral services industry has begun aggressively marketing foreign drug sourcing programs to self-insured employers with promises of significant savings for the employers' benefit plans. In addition, some state and federal lawmakers have begun to pressure federal agencies to implement regulations or to pass legislation authorizing and regulating the importation of foreign drugs. However, despite the clear price differential and popular support for drug importation programs, the FDA continues to prohibit prescription drug importation. Some self-insured employers are now considering directing their employees towards these channels. This raises two questions: is it legal for self-insured employers to facilitate the outsourcing by employees of prescription drug benefits through foreign imports, and do the potential benefits outweigh the risks?

How Do Prescription Referral Services Work?

Individuals have sought to take advantage of importation services offered by international businesses, sometimes referred to as "prescription referral services," which purport to offer patients access to the same drugs available in the United States but at dramatically lower prices. The specifics may vary by program, but in general, prescription referral services do not directly purchase or sell drugs and do not act as pharmacies. Rather, they arrange for those services on behalf of American consumers.

An employer choosing to participate in a prescription referral service would inform plan beneficiaries that, in addition to other prescription benefits offered under the plan, beneficiaries would have the option to obtain drugs by contacting the prescription referral service. Beneficiaries are instructed that prescriptions obtained through the prescription referral service will likely have a lower, if not zero, copay. A beneficiary choosing to participate obtains a valid prescription order from a licensed American physician for a particular drug product. The beneficiary submits that prescription order via the internet to the prescription referral service along with a medical history form and a credit card number for payment. The prescription referral service forwards the prescription order to an international pharmacy or dispensing facility. That international pharmacy may request a local doctor to arrange for a corresponding prescription and ultimately reviews and fills the prescription order. The prescription drug product is mailed to the beneficiary's home, and both the beneficiary and the employer are charged a fraction of the cost they would have incurred had the drug product originated in the United States.

The FDA strictly regulates the interstate commerce of prescription drug products and, in most circumstances, prohibits the importation of prescription drugs by individuals. Prescription referral
services have taken the position that their process for supplying international drug products to Americans is legal because the business is merely acting as an agent of the American consumer who is exercising a right to import drugs under the FDA's "Personal Importation Policy."

**What Is the FDA's Personal Importation Policy?**

The Federal Food Drug and Cosmetic Act (FDCA) sets forth conditions that must be satisfied before a human drug product can be introduced into interstate commerce and grants the FDA the authority to regulate drugs in the United States.[1] The FDCA's purpose is to assure consumers that a drug purchased in the United States was produced under sanitary conditions, is safe and effective for the intended use, and is accurately labeled.

The FDA's Personal Importation Policy (PIP) sets forth circumstances where, as a matter of enforcement discretion, the FDA will not object to the importation of a drug by a consumer for the consumer's personal use even though such importation violates the FDCA. The PIP acknowledges that American citizens may sometimes seek foreign drug products under circumstances that do not present a high risk to public health or the individual. For example, the FDA would not interfere in a situation where a drug product is shipped to an individual in the United States, or carried in personal baggage, for the purpose of continuing a therapy that was initiated abroad. The PIP lists several factors that guide the FDA's enforcement discretion, all of which suggest reduced risk of harm to an individual and the public: (1) the drug is unapproved and intended for a serious medical condition where no effective treatment is available domestically; (2) the drug is not commercialized or promoted in the United States; (3) the drug does not represent an unreasonable health risk to the patient; (4) the request is accompanied by an affirmation that the drug is for the patient's use only; and (5) the supply is less than a three-month supply.[2]

Notwithstanding the FDA's stated position that it intends to tolerate the importation of drug products in limited circumstances, to be sure, the PIP does not legalize the importation of unapproved drugs and cannot authorize individuals to import unapproved drugs for personal use. As a matter of law, the FDCA is violated virtually every time a drug is imported into the United States by an individual for personal use.

**Drug Importation Under the FDCA**

The FDCA prohibits the manufacture, sale, distribution, or importation of unapproved drugs, adulterated drugs, and misbranded drugs.[3] Importantly for self-insured employers, FDCA also prohibits the causing of any one of those acts. Therefore, liability for a violation of the FDCA extends beyond the individual who receives the imported drug product and the entity that ships the drug product and can also include any individual or business that played a role in causing the drug product to be imported.

Prescription referral services often refer to the foreign versions of FDA-approved drugs that they arrange for import as FDA-approved product. This is a mischaracterization. FDA approvals are product-specific and manufacturer-specific and are tied to factors including manufacturing location, formulation, source and specification of active ingredients, processing methods, manufacturing controls, container, and appearance.[4] In addition, the product labels must meet U.S. labeling requirements.[5] Even where a manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval and consequently is considered unapproved.[6] Moreover, even if the drug product was manufactured in the United States, exported, and then re-imported by an individual, the re-importation would still violate the FDCA. This is because the FDCA only permits the U.S. manufacturer of a drug product to import the drug.[7] Accordingly, the FDCA is violated virtually every time a drug product is shipped or transported from another country into the United States for personal use.

**Popular Support for Foreign Drug Importation**

While the FDA does not support drug importation, self-insured employers are not alone in recognizing the valuable opportunity to contain drug prices through importation. Lawmakers have continuously pressed the federal government to expand the limits of the FDCA to permit importation. State officials have submitted citizen petitions to the FDA, have sought guidance as to whether proposed state laws allowing drug importation are acceptable, and have otherwise expressed a
desire for their citizens to be given the opportunity to obtain lower cost prescription medication outside the United States.[8]

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which would permit pharmacists, wholesalers, and individuals to import prescription drugs from Canada to the United States either through the promulgation of regulations or on a case-by-case basis.[9] However, these provisions only become effective if the Secretary of the Department of Health and Human Services (HHS) certifies to Congress that importation will be safe and cost-effective.[10] Despite pressure from states, this certification has not been made. Both the state of Vermont and Montgomery County, Maryland have filed suits against the federal government seeking to force the FDA to permit the importation of drugs from Canada. In both instances, the courts deferred to the discretion of HHS and FDA.[11] In the past several years, multiple federal bills that would make it legal for American consumers to buy prescription drugs from other countries have been introduced in the Senate.[12]

While many states have shown support for prescription drug importation, the state of Maine set precedent in 2013 by enacting legislation permitting the importation of prescription drugs into the state.[13] The legislation, entitled An Act to Facilitate the Personal Importation of Prescription Drugs from International Mail Order Pharmacies, amended the Pharmacy Practice Act by expanding the definition of a mail order pharmacy to permit entities from select countries including Canada, the United Kingdom, Australia, and New Zealand to ship prescription drug products into Maine. The battle regarding the importation of foreign drug products in Maine started in 2012 when the state directed state health plan participants to receive prescription drugs through MaineMeds, a program funded through public money and administered by an international prescription referral service, as a way to cut health care costs. In response, the Maine Merchants Association, whose members include both large chain and community pharmacies, sent a letter to the Maine Board of Pharmacy (Board) urging the Board to investigate the program. Ultimately, the Board referred the matter to the State Attorney General who issued a cease and desist letter to the prescription referral service involved, stating that the program violated state law. Shortly thereafter, supporters of MaineMeds and similar city-led programs began lobbying for legislation that would permit these programs to resume. Despite strong support, shortly after the passage of the amendment to the Maine Pharmacy Act in 2013, several parties including three trade organizations brought suit claiming that the Act was preempted by the FDCA. The court agreed and invalidated the law.[14] Therefore, despite strong efforts, prescription drug importation remains impermissible in all 50 states.

What Are the Implications For a Plan Sponsor Covering Foreign Drug Products?

Potential Liability Under the FDCA

Although the FDA has communicated its disapproval of drug importation for personal use generally through guidance and very directly through Warning Letters to companies facilitating drug importation[15], as a practical matter, the FDA faces challenges enforcing United States laws against entities located outside the border. As a policy matter, the FDA has indicated that if it were to take action, the highest enforcement priority would not be actions against consumers. At the same time, the FDA has repeatedly articulated its serious concerns regarding the inherent risks of buying prescription drugs from foreign, unregulated sources that claim to sell drugs that are as safe as FDA-approved drugs. Consequently, it is conceivable that the FDA could turn its attention to larger enforcement targets like American-based plan sponsors that incentivize beneficiaries to seek foreign-made drug products—particularly, as is often the case with self-insured employers, where the plan sponsors advertise reduced or zero copayments to beneficiaries, facilitate the transaction by connecting beneficiaries with foreign sellers, pay for the services provided by the foreign sellers and gain a significant financial benefit from the transaction. Again, the FDCA prohibits not only the acts that amount to the importation of unapproved drugs, but also the causing of any one of those acts.

Potential Tort Liability

A self-insured employer who chooses to offer coverage of foreign drug products, including by reimbursing the out-of-pocket costs of employees, faces risks beyond the threat of FDA/government enforcement of the FDCA. The FDA has stated that drugs obtained from foreign sources that purport
to be the same as FDA-approved drugs are of unknown quality, often exhibit deviations from the FDA-approved formulas, and are frequently substandard. The FDA has advised the public not to purchase drug products that do not come with the assurance of FDA approval. Without FDA assurances, an employer is left with representations from foreign manufacturers and suppliers when determining that products being imported for its plan beneficiaries will be safe, effective, and properly labeled.

In the event a plan beneficiary is injured by an illegally imported drug product, whether because of a product defect or otherwise, that beneficiary could potentially seek damages not only from the drug manufacturer or supplier but also from the plan sponsor. For example, if a plan beneficiary is injured by a drug imported through a prescription referral service facilitated by the plan sponsor, the beneficiary may first seek damages from the drug supplier or drug manufacturer. However, where the drug was not manufactured in the United States, or intended for sale in the United States by the manufacturer, the ability of the beneficiary to recover may be limited by courts in the United States. As a result, plan beneficiaries may look to other parties, including the plan sponsor who suggested, and arguably encouraged, the beneficiary to consider importation and paid for the imported drug.

Additionally, a foreign-made drug that has been imported by a plan beneficiary could be subject to a drug recall by the foreign manufacturing plant. The foreign manufacturer's process for notifying consumers will likely not include mechanisms aimed at ensuring consumers in United States are alerted to the recall. Again, if the plan beneficiary suffers injury from a recalled drug, the plan beneficiary may seek to recover from the plan sponsor, who encouraged and benefited from the beneficiary's importation of the foreign non-FDA approved drug. In addition, the health plan documents may include standard stipulations that assure beneficiaries that the plan sponsor will comply with applicable laws. This type of language could create additional liability to the extent a court finds the employer violated the law by causing the non-FDA approved drug product to be imported.

**Implications for Employees’ Taxable Income**

Another consideration is the significant potentially adverse tax implications for self-insured employers who choose to provide prescription benefits through importation of foreign products. Pursuant to Section 105 of the Internal Revenue Code (Code), coverage provided under an employer's health plan is generally excludable from the participant's taxable income but only if the coverage meets the definition of "medical care" as defined in the Code.[16] By definition, in order for a prescription drug to be considered "medical care," it must be legally procured.[17] A prescription drug obtained in a manner that violates federal law, such as the FDCA, will not be considered an expense that meets the definition of "medical care," and all reimbursement for such drug, including from a health flexible spending arrangement or a health reimbursement arrangement, must be included in the participant's taxable income.

As detailed above, in general, the importation of foreign drug products, including foreign-made versions of FDA-approved drugs and domestically made FDA-approved drugs that are exported and re-imported, is considered a violation of the FDCA. Therefore, prescription drugs that are imported for personal use would not be considered "legally procured" and consequently would not be considered "medical care." Thus, payment for these drugs would not be excludable from taxable income.

IRS guidance has explicitly addressed this issue of drug importation stating, "in general, you cannot include in your medical expenses the cost of a prescribed drug bought in (or ordered shipped from) another country. You can only include the cost of a drug that was imported legally."[18] The only exceptions to this rule are instances where the FDA has announced the drug can be legally imported or instances where the prescribed drug was purchased and consumed in another country, if the drugs are legal in both the U.S. and the other country. These exclusions are inapplicable where drug products are sourced through a foreign prescription referral service for use by American consumers. Therefore, payments or reimbursement for imported prescription drug products would generally have to be included in an employee’s taxable income resulting in limited net savings and increased administrative burden for the plan. As a result, employers must consider the extent to which the amount saved by sourcing a foreign drug product will be offset by the additional taxes and expenses.
Conclusion

In sum, popular support of drug importation for personal use is rising with domestic drug prices. To date, the FDA has chosen not to exercise its enforcement authority to interfere with the practice by individuals. Nonetheless, the importation of prescription drugs, even for personal use, clearly violates federal law. Self-insured employers should note that the FDA’s present inaction provides no guarantee that the FDA won’t seek, in the future, to hold accountable plan sponsors that facilitate the importation of foreign drug products, particularly in situations where a plan sponsor benefits financially from encouraging plan beneficiaries to purchase drugs from foreign, non-FDA-approved sources. Further, in accordance with current IRS guidance, payments by an employer, for the benefit of an employee or dependents, to cover the costs of medications sourced through foreign, non-FDA-approved suppliers must be reported by the employer as a component of the employee’s taxable income, resulting in additional expense for the plan beneficiaries and increased administrative burden for the plan sponsor, offsetting at least some of the expected savings. Moreover, by sourcing foreign drug products, a self-funded employer may be exposed to liability from the federal government and injured plan beneficiaries. In short, absent legislative changes by the United States Congress, sourcing prescription drug benefits through foreign importation is a less than perfect solution to the problem created by rising prescription drug costs. Self-insured employers presented with the opportunity to provide beneficiaries with access to foreign drug products should carefully consider whether this option is a prudent strategy for containing drug costs.

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[8] Letter from FDA to Hawaii Governor Linda Lingle (Feb. 23, 2012); Letter from FDA to Washington Department of Health Director Steven Saxe (Mar. 17, 2006); Letter from FDA to Minnesota Mayor Donn Ness (Sept. 10, 2009); Letter from FDA to Maryland County Executive Douglas Duncan (Sept. 10, 2009); Letter from FDA to Texas Attorney General Greg Abbot (Dec. 21, 2005); Citizen Petition to FDA from Springfield Massachusetts Mayor Michael J. Albano (Oct. 7, 2003).


[15] Warning Letter from FDA to Expedite-Rx and Employer Health Options, Inc. (Jan. 22, 2004); Warning Letter from FDA to CanaRx Services, Inc. (Sept. 16, 2003); Warning Letter from FDA to Canadian Discount Drugs (June 30, 2003).


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