AIMEDALLIANCE

EMPLOYERS:

WHAT YOU NEED TO KNOW ABOUT MANDATED INTERNATIONAL IMPORTATION OF COVERED PHARMACY BENEFITS

On March 1, 2024, Aimed Alliance submitted a Citizen Petition to the U.S. Food and Drug Administration (FDA) addressing the increasing use of mandated international prescription drug importation by alternative funding programs (AFPs). Aimed Alliance requested that FDA clarify:

1. Whether employers or their third party partners may lawfully require employees to import prescription drugs from outside the United States; and
2. Whether third party AFP vendors may import prescription drugs on behalf of plan participants.

What are alternative funding programs (AFPs)?

AFPs are third-party vendors that partner with self-funded employer health plans to reduce specialty drug costs by classifying covered specialty medications as nonessential health benefits, effectively requiring enrollees to participate in the program or pay the full cost of their medication without credit toward deductibles or out-of-pocket limits. Once enrolled, the health plan denies standard coverage and steers consumers to an alternative sourcing pathway, such as the use of international pharmacies.[1] These practices have prompted the Department of Homeland Security to initiate criminal investigations against AFPs, warning that AFPs depend on unverified and potentially illicit supply chains.

1. AFPs also pursue patient assistance programs, charitable assistance programs, and copay assistance programs. Aimed Alliance, Alternative Funding Programs, https://aimedalliance.org/alternative-funding-programs/.

FDA Acknowledges Legal and Patient Safety Risks Posed by AFP Drug Importation Practices

In an interim response dated August 28, 2024, FDA stated that it was unable to reach a decision on the petition within the statutory time frame due to the complexity of the issues and required additional time for review.

In its final determination, FDA recognized that the agency has "taken steps to address the distribution of unapproved new drugs and misbranded drugs to U.S. consumers," and explicitly acknowledged and shared concerns regarding the risks posed by international drug importation outside established statutory safeguards. Specifically, FDA:

- Emphasized that "FDA has repeatedly made clear that, in most circumstances, it is illegal for individuals to import drugs into the United States for personal use."
- Cautioned that medications marketed as "Canadian" are often neither sourced from Canada nor approved by Canadian regulators, warning that these "drugs are obtained from ever-evolving illicit sources of supply."
- Explained that it has taken enforcement action, including placing firms on Import Alert 66-57, and issuing warning letters in February 2019 and March 2023 to entities facilitating drug dispensing from foreign pharmacies to U.S. employees.
- Explained that the Regulatory Procedures Manual, which provides operating procedures for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail, does not include the cost of an FDA-approved prescription drug as a consideration for importation.
- Confirmed that "Alternative funding programs as described in the Petition are not permitted to import drugs under section 804."

Patient Safety and Regulatory Uncertainty Surrounding AFPs

Federal agency actions have underscored serious legal and patient safety risks associated with AFPs' reliance on international drug importation, and national media coverage has further underscored the regulatory uncertainty surrounding these practices. Notably, a recent CNBC report recognized FDA's acknowledgment of patient safety risks associated with drugs that bypass regulatory safeguards. At the same time, FDA has declined to issue AFP specific guidance despite evidence that some programs rely on foreign drug sourcing that may violate U.S. import laws. Taken together, these developments reinforce concerns raised by Aimed Alliance and illustrate the expanding use of AFPs within a persistent regulatory gray area.

ERISA Requirements of a Prudent Fiduciary

The Employee Retirement Income and Security Act (ERISA) governs how employers establish benefits, including health insurance, for their employees. Under ERISA, employers are required to act as prudent fiduciaries when administering plan benefits. Therefore, employers must consider how requiring their employees to import their prescription drugs from outside the United States, in a manner inconsistent with federal law, is consistent with their fiduciary duties under ERISA.

1455 Pennsylvania Ave, NW, Suite 400
Washington, DC 20004

(202) 349-4089

AimedAlliance.org