

CONSUMERS:

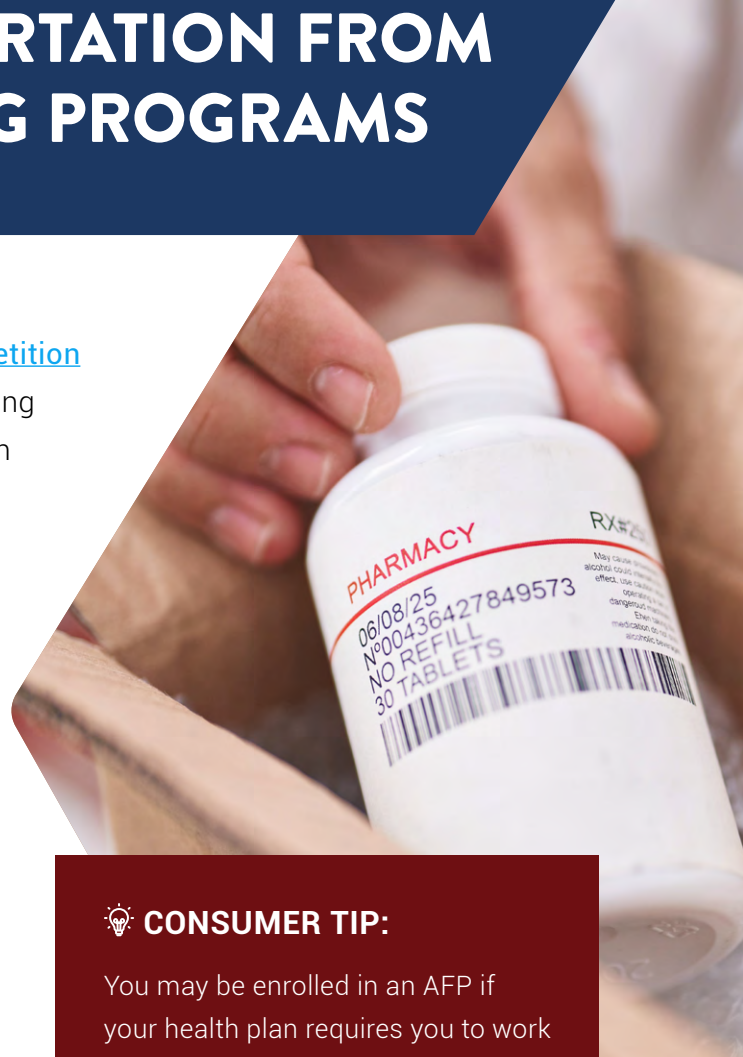
HOW TO PUSH BACK ON MANDATED INTERNATIONAL IMPORTATION FROM ALTERNATIVE FUNDING PROGRAMS

On March 1, 2024, Aired 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). Aired Alliance requested that FDA clarify how these programs were consistent with federal law – FDA recently confirmed they are not.

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 often 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
Aired Alliance, Alternative Funding Programs, <https://aimedalliance.org/alternative-funding-programs/>.



CONSUMER TIP:

You may be enrolled in an AFP if your health plan requires you to work with a third-party, not your specialty pharmacy or PBM, to access your medication. You may be asked to complete a HIPAA release form, sign power of attorney agreements, or share other personal and financial information with the AFP.

What did the FDA say about AFPs and international importation?

On August 28, 2024, FDA provided an [interim response](#) to Aimed Alliance and stated that it was unable to reach a decision on the petition due to the complexity of the issues and required additional time for review.

On March 27, 2026, 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:

- Confirmed that “Alternative funding programs as described in the Petition are not permitted to import drugs under section 804.”
- 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.
- Confirmed that under the [Regulatory Procedures Manual](#), which provides operating procedures for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail, FDA does not consider the cost of an FDA-approved prescription drug as a consideration for permissible importation.

What does this mean for consumers?

The FDA's March 2026 response critically recognizes that AFPs are not permissible under Section 804 of the Food, Drug, and Cosmetic Act. Therefore, AFPs can only allege their programs are permissible under FDA's personal importation policy established in the Regulatory Procedures Manual. However, the FDA also confirmed that there is an enumerated list of factors FDA considers when determining if a prescription drug can be permissibly imported from Canada, and the cost of the drug is not an enumerated factor.

My health plan is working with an AFP and wants me to import my prescription drug from outside the United States. How can I push back?

Request to have your covered prescription drug processed through the health plan's standard pharmacy benefit, as the FDA's petition response demonstrates this type of importation is not permissible under federal law. Specifically, FDA's recent response confirms that mandated international importation is not permissible under Section 804, and that personal importation determinations do not consider the cost of a prescription drug within the United States. Therefore, your health plan should not require you to import your medication in a manner that violates federal law.

CONSUMER TIP:

Share a copy of the FDA's March 2026 response with your health plan and AFP as evidence of the FDA's position on this issue. If your health plan and/or AFP continues to push international importation, request they reconcile their policy with the FDA's 2026 response. The following provides an example:

Dear health plan and AFP:

My health plan is currently requiring me to work with [AFP name], who has informed me that I am required to import my prescription drug from outside the United States. However, based on the FDA's response to Aimerd Alliance in March 2026, mandated international importation is not permissible under federal law. The FDA explicitly confirmed this type of importation is not permissible under the FD&C Act Section 804.

Moreover, when determining if a prescription drug may be imported from Canada, the FDA relies on the enumerated list of considerations within the Regulatory Procedures Manual, which provides operating procedures for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail. The enumerated list considers several factors, including whether effective treatment is available domestically either through commercial or clinical means. The FDA confirmed that cost is not a consideration. Therefore, because my medication is effective and available within the U.S., the personal importation policy does not apply.

Therefore, I should not be required to import my prescription drug from an international pharmacy in a manner that is inconsistent with federal law. Please process my prescription drug as a standard pharmacy benefit in a manner consistent with my health plan's terms and cost-sharing requirements.

Thank you.

If you need additional support, contact Aimerd Alliance at policy@aimedalliance.org.

The response says the FDA denied the petition. Does that mean AFP conduct is permissible?

No. While the FDA denied the request for formal guidance confirming how AFPs are inconsistent with federal law, the FDA did confirm that there are existing regulations that apply to AFPs and international importation and that AFP conduct is not consistent with those requirements.





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