

Fulfilling President Trump's Executive Order on Facilitating Drug Importation to Lower Prices for American Patients

Request for Industry Proposals for Personal Importation of Prescription Drugs

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

Frequently Asked Questions

Q: What has been announced?

A: The Department of Health and Human Services (HHS) has announced a request for proposals (RFP) asking private sector partners for information on how they might operate programs to allow Americans to obtain prescription drugs at lower prices through importation for personal use. The prescription drugs subject to these programs will be FDA-approved/licensed products.

Q: What does the RFP on personal importation do?

A: This RFP asks the private sector to propose ways that American patients could purchase their prescription drugs at the same or lower prices compared with those paid in other countries. State-licensed pharmacies would be allowed to operate as authorized Individual Waiver Importation Plans (IWIPs) and would be permitted to dispense an FDA-approved prescription drug imported from an Acceptable Foreign Source. Individuals would then be able to apply for waivers through a portal, and receive the drug through such a pharmacy.

Only proposals that have a clear path for the importation of FDA-approved, safe, and efficacious therapies in a cost-effective manner will be accepted. Proposals will be required to meet applicable legal requirements.

Q: Why is this action being taken now?

A: President Trump has been firm and unwavering in his determination to give Americans access to fair drug prices. While the Trump Administration would prefer that Congress act to lower the price of prescription drugs, to date they have failed to do so. Consistent with the laws Congress has already passed, President Trump is taking action to fulfill his commitment to the American people.

Q: What type of entities can apply to become an authorized Individual Waiver Importation Plan (IWIP)?

A: An IWIP sponsor may be any interested person, including a distributor, wholesaler, or pharmacy.

Q: How do you get a waiver?

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A: HHS will establish a process and an electronic portal by which individuals seeking to import prescription drugs through an authorized IWIP can seek, on a case-by-case basis, section 804(j)(2) waivers from the Secretary.

Q: Can you buy from an online pharmacy?

A: Prescription drugs in the program would be dispensed to patients through authorized state-licensed pharmacies. These pharmacies would be specified in an authorized Individual Waiver Importation Plan (IWIPs). This pathway would not authorize individuals in the United States to purchase prescription drugs through the Internet, directly from a foreign pharmacy, or from any other foreign seller.

Q: When does this go into effect? When can patients expect to access prescription drugs through the program?

A: HHS and FDA will begin accepting proposals on September 24, 2020, and continue indefinitely. The Secretary may authorize a personal importation program provided the criteria described in the RFP are met. Patients would be able to access prescription drugs soon after a program is authorized. The Secretary may similarly revoke an authorization if the criteria are no longer met or for other reasons, provided that the Secretary gives due consideration for the reliance interests of patients and their health care providers.

Q: How significant of price reductions can patients expect?

A: As the President’s recent executive order explained:

Americans spend more per capita on pharmaceutical drugs than residents of any other developed country. Americans often pay more for the exact same drugs, even when they are produced and shipped from the exact same facilities.

One way to minimize international disparities in price is to increase the trade of prescription drugs between nations with lower prices and those with persistently higher ones. Over time, reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs.

The amount of the price reductions will depend on the details of programs under which patients access safe, effective prescription drugs obtained from abroad. HHS believes the savings to American patients would likely to be substantial.

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Q: How quickly will there be a price reduction?

A: The timing of the price reductions will depend on industry’s response to the RFP. HHS is committed to reviewing applications in a timely manner.

Q: Can individuals trust that imported prescription drugs are safe?

A: Only drugs that have already been approved by the FDA and that are manufactured in FDA-registered facilities will qualify for the personal importation program. [A recent study](#) based on the largest ever comparative test of the quality attributes of prescription drugs legally marketed in the United States concluded that “difficult-to-make prescription pharmaceuticals marketed in the US consistently meet quality standards even when manufactured outside the US.” The FDA’s review of the proposals for safety and efficacy will ensure these pathways are not available unless sponsors demonstrate that they have a plan to ensure the safety and efficacy of the imported drugs.

Q: How is this action different from the actions taken through the state importation final rule?

A: While the state importation rule, as planned, would allow for varying drugs to be imported via agreements with individual states, this RFP would harness the power of private sector stakeholders to facilitate personal importation of prescription drugs for those truly in need at lower costs than Americans are paying today.

Q: Why not just make manufacturers lower the prices they charge American patients?

A: The Trump Administration is exploring all options available under the law to put an end to current price gouging practices. American patients continue to pay higher amounts for prescription drugs than patients abroad, in effect subsidizing each drug company’s inability—or unwillingness—to negotiate better prices with other countries. While these policies take shape, the implementation of the President’s executive order will bring needed relief to everyday Americans who need affordable access to prescription drugs now.

Q: How would patients receive prescription drugs?

A: Private-sector partners would, as part of their proposals, provide a plan for the importation of FDA-approved/licensed prescription drugs. Patients would obtain drugs through U.S.-licensed pharmacies operating in connection with an approved plan. The plans themselves must demonstrate how safe, effective products will reach Americans in a way that complies with applicable laws.

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Q: The RFP says that the FDA would work with HHS on reviewing proposals. Who would be responsible for approving any of these programs?

A: The proposals would be reviewed by the FDA for the safety and efficacy of the prescription drugs listed in the proposals. By law, the Secretary of HHS grants the waiver to import prescription drugs. But only proposals that have a clear path for the importation of FDA-approved, safe, and efficacious therapies in a cost-effective manner will be accepted.

Q: Is personal importation limited to Canada? What countries will patients be able to import prescription drugs from?

A: The personal importation program is not limited to Canada. Foreign sources from which patients will be able to import prescription drugs (defined as an “Acceptable Foreign Source” in the RFP) include the following countries: Australia, Canada, the European Union or a country in the European Economic Area, Israel, Japan, New Zealand, Switzerland, South Africa, or the United Kingdom.

Q: Once an individual receives a waiver, how will they get their drug?

A: Individuals would apply for a waiver for a specific drug, and waiver in hand, along with a valid prescription, can pick up the prescription drug from an American pharmacy operating under an approved plan.

Q: Are all prescription drugs eligible for personal importation?

A: No. While most prescription drugs in the FDA’s Orange Book will qualify for importation, this policy excludes controlled substances, biological products, infused drugs, intravenously injected drugs, intrathecally injected drugs, infused drugs, drugs inhaled during surgery, and parenteral drugs.