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

Request for Industry Proposals on Reimportation of Insulin

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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 insulin at lower prices through reimportation from other countries. The insulin subject to these programs will be FDA-approved or FDA-licensed products.

Q: What does the RFP on reimportation of insulin do?

A: Americans continue to pay substantially more for insulin than patients in other countries, even for insulin that is manufactured right here in America. This RFP asks interested parties, including health care distributors such as group purchasing organizations, to propose processes for reimporting insulin back into the United States, and to distribute it to patients at a substantially lower cost than is currently being paid by Americans.

Only proposals that have a clear path for the reimportation of FDA-approved/licensed, safe, and efficacious therapies in a cost-effective manner will be accepted. Proposals would 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 affordable insulin. While the Trump Administration would prefer that Congress act to lower the price of insulin, 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: The RFP says that the FDA would work with HHS on reviewing proposals. Who would be responsible for approving any reimportation programs?

A: The proposals would be reviewed by the FDA, and ultimately approved by the Secretary of HHS pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA review helps ensure the safety and efficacy of the reimported insulin and ensure that the proposals would guarantee such safety and efficacy.

Q: How would patients receive insulin?

A: The distributors would, as part of their proposals, provide a plan for reimportation of FDA-approved/licensed insulin. Patients would obtain insulin through U.S.-licensed pharmacies operating in connection with an approved plan. The plans themselves must demonstrate how safe, effective insulin products will reach Americans in a safe manner that complies with applicable laws.

Q: How would individuals be able to trust that the reimported insulin is safe?

A: For insulin to be available for reimportation, it must have first been made here America in a FDA-registered facility pursuant to an FDA approval or license. The RFP acknowledges that insulin presents certain supply chain issues and thus requires persons interested in pursuing a plan to demonstrate how the insulin products they reimport will remain safe, effective, and potent throughout the supply chain. The FDA's review of the proposals for safety and efficacy will ensure these pathways will not operate unless sponsors demonstrate they have a plan to ensure the safety and efficacy of the reimported insulin.

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

A: As a biologic, insulin is not subject to the state importation rule. Further, 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 reimport insulin to those truly in need at vastly 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, particularly with insulin. American patients continue to pay higher amounts for insulin products 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 insulin now.

Q: How significant of price reductions can patients expect?

A: A recent HHS-commissioned study found that the average gross manufacturer price for a standard unit of insulin in 2018 in the United States was more than ten times the price in a sample of 32 foreign countries. The amount of the price reductions will depend on the details of programs under which patients will access safe, effective reimported insulin. HHS believes the savings to American patients are likely to be substantial.

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

A: HHS and FDA will begin accepting proposals on September 24, 2020 and continue indefinitely. The Secretary may authorize a reimportation program provided the criteria described in the RFP are met. Patients would be able to access insulin 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: Is insulin reimportation limited only to Canada?

A: No. Insulin may be imported from any source abroad, provided applicants demonstrate through a reimportation plan a program to implement reimportation of FDA-approved/licensed insulin in a manner that ensures the product is safe and effective and can be delivered to patients in a cost-effective manner while meeting applicable legal requirements