

REQUEST FOR PROPOSALS REGARDING INSULIN REIMPORTATION PROGRAMS

The Trump Administration has taken action, and is continuing to take action, to reduce the price of insulin and expand access to this critical, life-sustaining medication. As part of this effort, the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA), pursuant to President Trump’s July 24, 2020 Executive Order, requests proposals to develop new Insulin Reimportation Programs. These programs should meet the immediate needs of insulin-dependent Americans with safe, effective, FDA-approved insulin obtained from abroad.

Specifically, HHS and FDA seek proposals whereby insulin manufactured in the United States and exported to foreign countries can be reimported into the United States in a safe manner by a person other than the manufacturer of the insulin. The reimported insulin will ultimately be dispensed to patients. A proposed Insulin Reimportation Program should offer a pathway to provide safe, effective, potentially lower-cost insulin products to patients who need access to these essential medications.

HHS and FDA are aware of an emerging body of evidence that American patients are rationing insulin due to cost concerns.¹ This rationing results in patients’ loss of glycemic control and leads to poor health outcomes for vulnerable Americans, including in some cases death. Consistent with Congress’ previous authorizations, the Secretary has concluded that the widespread rationing of insulin constitutes an emergency, that insulin is required for emergency medical care, and that insulin should be available to the American people through authorized reimportation programs.

I. Background

The Secretary may authorize the reimportation of certain insulin products under section 801(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In general, the FD&C Act and the Public Health Service Act do not allow the reimportation of drugs composed wholly or partly of insulin that are manufactured in the United States and exported outside the country, unless the product is imported back into the U.S. by the manufacturer of the drug. There is an exception, however, which provides that the Secretary may authorize third parties to reimport such drugs if “required for emergency medical care.” FD&C Act, § 801(d)(2), 21 U.S.C. § 381(d)(2).

Accordingly, the Secretary invites persons to submit Insulin Reimportation Program proposals (each a “Reimportation Application”), pursuant to which insulin could be reimported in a manner that meets applicable legal requirements.

The Secretary intends to periodically reexamine authorized Insulin Reimportation Programs and may revoke reimportation authorization if conditions change. Reimportation Applications may

¹ See, e.g., Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, JAMA INTERN MED. (Jan. 2019), at 112–114 (finding that one in four patients at a diabetes center reported underusing insulin because of insulin’s cost, and that this was associated with poor glycemic control).

only be submitted for insulin products that are manufactured in the United States under FDA-approved New Drug Applications, Abbreviated New Drug Applications, or Biologics License Applications; the statutory exception in section 801(d)(2) of the FD&C Act does not apply to insulin products manufactured outside of the United States.

HHS has finalized a rule to facilitate the importation of certain prescription drugs from Canada, in order to achieve significant cost savings for American consumers, with no additional risk to the public's health and safety. That rule implements a statutory provision that applies to prescription drugs, but insulin is a biologic, not a prescription drug. The Insulin Reimportation Programs described herein are separate from the proposed rule and are authorized by a different statutory authority.

II. Insulin is Required for Emergency Medical Care

The rising price of insulin, and corresponding rationing of insulin, constitutes an emergency. There have been dramatic price increases for insulin in recent years, with the price tripling between 2002 and 2013.² Since then, prices continued to climb, nearly doubling between 2012 and 2016.³ Americans with diabetes with employer-sponsored insurance saw the average price for a 40-day supply of insulin rise from \$344 to \$666 over the course of those same years.⁴ In the past two decades, prices for the most commonly prescribed insulins have increased from about \$20 per vial to over \$250 per vial—a more than 700 percent increase after adjusting for inflation.⁵ This steep price increase has made insulin unaffordable even for some high-income individuals.⁶ For these reasons, in 2018 and again in 2019, Congress held hearings on the price of insulin and related health issues.

When individuals with diabetes go without insulin, or ration their doses, there can be tragic consequences, including death.⁷ In 2018, 34.2 million Americans, or 10.5% of the population, had diabetes, and 1.5 million Americans are diagnosed with diabetes each year.⁸ People with Type 1 diabetes need to take insulin every day to survive.⁹ 7.4 million people who rely on insulin to treat their diabetes use at least one vial of insulin each month, though some patients require multiple vials or multiple types of insulins each month.¹⁰ Adherence to an individualized

² William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 DIABETES CARE 1299, available at <https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf>.

³ John Hargraves & Amanda Frost, *Price of Insulin Prescription Doubled Between 2012 and 2016*, Health Care Cost Inst. (Nov. 29, 2017), <https://healthcostinstitute.org/diabetes-and-insulin/price-of-insulin-prescription-doubled-between-2012-and-2016>.

⁴ *Id.* Average prices were calculated from the actual amounts paid at either in-person or mail order pharmacies, and may not reflect any discounts, rebates or coupons.

⁵ Drew Pendergrass, *How Insulin Became Unaffordable*, HARV. POL. REV. (Jan. 22, 2018), <http://harvardpolitics.com/united-states/how-insulin-became-unaffordable/>.

⁶ *Id.*

⁷ *Insulin's Steep Price Leads To Deadly Rationing*, Kaiser Health News (Sept. 7, 2018).

⁸ Am. Diabetes Ass'n, *Statistics About Diabetes*, <https://www.diabetes.org/resources/statistics/statistics-about-diabetes> (last visited Sept. 23, 2020).

⁹ Ctrs. for Disease Control & Prevention, *About Diabetes*, www.cdc.gov/diabetes/basics/diabetes.html (last visited Sept. 23, 2020).

¹⁰ Endocrine Soc'y, *Increasing Insulin Affordability: An Endocrine Society Position Statement* (Nov. 1, 2018), <https://www.endocrine.org/advocacy/position-statements/increasing-insulin-affordability>.

medication regimen is critical for someone living with diabetes to avoid complications such as diabetic ketoacidosis, which can develop within 24 hours and cause severe dehydration, kidney damage, brain swelling and damage, stroke, and respiratory failure.¹¹ But a 2018 Yale University survey of patients with Type 1 or Type 2 diabetes who use insulin found that one in four patients were rationing their insulin due to cost.¹² Moreover, among patients surveyed by the American Diabetes Association in 2018, 27 percent reported that insulin costs affected their past year's purchase or use of insulin and these patients were more likely to experience adverse health effects.¹³ This is consistent with data analyzed by HHS, which suggests that as out-of-pocket costs for insulin rise, increasing numbers of people abandon insulin products. Abandonment refers to when a prescription is processed by a pharmacy but not picked up by the patient.

Americans pay significantly more for insulin than patients in other countries do. 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.¹⁴ This cost differential presents an opportunity to pass savings onto Americans who are struggling to afford this life-saving medication. The high price of insulin and the corresponding potentially dire health consequences from rationing has become an emergency, particularly since the number of Americans diagnosed with diabetes continues to rise.

III. Reimportation Applications

Reimportation Applications should address the following issues:

- **Registration and Listing**: Applications should set forth applicants' commitment to register their establishments with FDA and to procure new National Drug Code (NDC) numbers for any reimported drugs.
- **Labeling**: Applicants should describe the method they propose to ensure that any insulin products reimported under the Insulin Reimportation Program include FDA-approved labeling and a designation that the product was reimported from outside the United States.
- **Supply Chain Security and Integrity**: Applications should describe the controls applicants will use to ensure the integrity and quality of the drug supply chain. Specifically, applicants should describe the protocols, processes, and procedures they will use to do the following:

¹¹ Sari Harrar, *Insulin Rationing: What It Is and Why It's So Dangerous*, OnTrack Diabetes (Jan. 17, 2019), www.ontrackdiabetes.com/live-well/diabetes-management/insulin-rationing-what-it-whyits-so-dangerous.

¹² Herkert et al., *supra* note 1, at 113.

¹³ Am. Diabetes Ass'n, *Insulin Affordability Survey, 2018*, at 8 (May 22, 2018), www.diabetes.org/assets/pdfs/advocacy/insulin-affordability-survey.pdf.

¹⁴ HHS, ASPE, *Research Report: Comparing Insulin Prices in the U.S. to Other Countries* (Sept. 2020).

- Trace the prior distribution of the reimported insulin products from the manufacturer;
- Detect counterfeits, separate them from products qualified for reimportation, and dispose of the same;
- Ensure reimported insulin products do not enter standard U.S. wholesaler-pharmacy distribution channels in the United States. The reimported insulin products shall not be commingled with U.S. insulin that is not reimported, and patients should be aware that the insulin products they receive through the program are reimported from abroad;
- Handle and hold insulin products such that they remain safe, effective, and potent; and
- Any other measures applicants will take to ensure the integrity of the supply chain.

The plan sponsor may request a variance from the scope of this proposal, provided such variance is consistent with applicable law.

IV. Consideration of Reimportation Applications

Parties wishing to submit Reimportation Applications for Insulin Reimportation Programs should have all parties to the proposals sign such Reimportation Applications and submit them to import@hhs.gov and the [director of the FDA Import Division](#) in the region of the intended port of entry. HHS and FDA will be accepting proposals beginning on September 24, 2020 and continuing indefinitely. FDA intends to consult with HHS in the review of Reimportation Applications. FDA intends to evaluate whether the Reimportation Application adequately addresses the public health concerns and insulin product considerations described above, for one or more eligible drugs.

V. Enforcement and Revocation

In addition to FDA's typical compliance tools (e.g., import alerts, warning letters, inspections, etc.), HHS/FDA will retain broad discretion to revoke authorization of an Insulin Reimportation Program while giving due consideration for the reliance interests of patients and their health care providers.

This request for proposals does not constitute final agency action or a final order.

Dated: September 24, 2020 (updated January 12, 2021)