HB 1250 Rep. Marvin E. Nelson District 9

January 18, 2021

House Industry, Business, & Labor Committee, Rep. Mike Lefor, Chairman

Mr. Chairman and Members of the House Industry Business and Labor Committee, I am Representative of District 9, Marvin E. Nelson.

HB 1250 looks to save the state money on its health plan by allowing reimbursement for employees to get prescription pharmaceuticals from Canada and pay a $25 co-pay.

It is subject to a section of US Code which I include a copy of that for your information.

Why would we do this? Well simply to save money. Often name brand drugs are much lower priced in Canada. It is not unusual anymore for a prescription to be $1000 a month or even more. Price differentials on name brand drugs are usually from 40 to 80% lower in Canada.

To give you some idea, the inhaler I used had a total cost in Canada about the same as my co-pay. Cash price was around $800 here and about $175 in Canada.

The idea was inspired by the state of Utah, their insurance provider flies employees to California, then they cross into Mexico and buy a three-month supply. The insurance provider pays participants $500 to take advantage of the program. I include a printout from their website explaining the program. The drugs listed are a good starting point.

Now how I would envision this is employees with a few drugs with significant differentials in pricing would be given the opportunity to get their prescriptions from Canada and receive reimbursement. I put a $25 co-pay, but a preapproval process could mean even that we, like Utah would pay the employee to save us money.

One area that receives a lot of attention is diabetic medications like insulin. Most diabetic supplies and drugs are over the counter in Canada. Recently, we see a movement to restrict out of pocket costs to the patient. For instance Eli Lilly was promoting their program where the patient would pay a $30 fee for a month of insulin. Sounds good, until one checks Canada and finds the price of their Humalog is about $25 in total for a month's prescription. So they would be a bit unusual being prescriptions here and over the counter there. Plus drugs like insulin require special handling because they are susceptible to high temperatures. So using Canadian insulin likely wouldn't save the employee much out of pocket but would save us money.

The program could either start soon but I don't believe our current insurance provider would run it, it would need to be run within the PERS program but I do not believe there would be very many employees using it, or it could start with our next contract. Some insurance companies do medical tourism for more than prescriptions, but I don't know of any right in our region.

The ultimate goal of course is to pressure drug prices to bring us more in line with the rest of the world.

Orchard - Unchanged

Menu

Pharmacy Tourism Program

Please note this program is currently suspended due to the current COVID-19 pandemic.

Savings on Prescription Medications Filled Abroad

To help you save money on your prescriptions, PEHP offers members who are not enrolled in Medicare the option to fill select medications (from list below) at a designated pharmacy tourism location in Canada or Mexico. If you're enrolled in the Traditional Plan, the medications are covered by your PEHP pharmacy benefit at no extra cost. If you're enrolled in a STAR HSA Plan, the cost is covered by your PEHP pharmacy benefit once you meet your deductible. The PEHP Pharmacy Tourism Program allows you to fill 90-day supply of medications you are currently taking.

If you want to fill a prescription (from list below) from a designated pharmacy in Canada or Mexico, PEHP will coordinate travel and cover the following costs associated with the program:

- Roundtrip airfare from Salt Lake City International Airport to either San Diego or Vancouver International Airport
- If needed, transportation to and from clinic location and overnight hotel stay

You are responsible for food expenses and a valid passport. Please visit travel.state.gov (https://travel.state.gov/content/travel/en.html) for travel requirements to Canada and Mexico.

Medications currently included in the PEHP Pharmacy Tourism Program**

» Aubagio 14mg

» Avonex

» Copaxone 40mg

» Cosentyx

» Enbrel 25mg, 50mg

» Forteo

» Humira 40mg maintenance pack

» Orencia

» Otezla

» Stelara 45mg/0.5ml

» Tecfidera

» Xeljanz 5mg

» Xtandi

**Medications are subject to change at the discretion of the PEHP Pharmacy Department.

The PEHP Pharmacy Department will contact you if you're eligible for the program. To learn more, call us at 801-366-7551 or 888-366-7551.

*Please note Jordan School District, Salt Lake City School District, and USBA members are not eligible for the pharmacy tourism benefit.

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(https://www.youtube.com/channel/UCCfNGFSc_KjNUxolwZ-pdBw)

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21 USC 384 : Importation of prescription drugs Text contains those laws in effect on January 16, 2021
From Title 21-FOOD AND DRUGSCHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACTSUBCHAPTER VIII-IMPORTS AND EXPORTS
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§384. Importation of prescription drugs

(a) Definitions

In this section:

(1) Importer

The term "importer" means a pharmacist or wholesaler.

(2) Pharmacist

The term "pharmacist" means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(3) Prescription drug

The term "prescription drug" means a drug subject to section 353(b) of this title, other than-
(A) a controlled substance (as defined in section 802 of this title);
(B) a biological product (as defined in section 262 of title 42);
(C) an infused drug (including a peritoneal dialysis solution);
(D) an intravenously injected drug;
(E) a drug that is inhaled during surgery; or
(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 381(d)(1) of this title shall continue to apply.

(4) Qualifying laboratory

The term "qualifying laboratory" means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

(5) Wholesaler

(A) In general

The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 353(e)(2)(A) of this title.

(B) Exclusion

The term "wholesaler" does not include a person authorized to import drugs under section 381(d)(1) of this title.

(b) Regulations

The Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

(c) Limitation

The regulations under subsection (b) shall-
(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 355 of this title (including with respect to being safe and effective for the intended use of the prescription drug), with sections 351 and 352 of this title, and with other applicable requirements of this chapter;

(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

(d) Information and records

(1) In general

The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

(A) The name and quantity of the active ingredient of the prescription drug.

(B) A description of the dosage form of the prescription drug.

(C) The date on which the prescription drug is shipped.

(D) The quantity of the prescription drug that is shipped.

(E) The point of origin and destination of the prescription drug.

(F) The price paid by the importer for the prescription drug.

(G) Documentation from the foreign seller specifying-

(i) the original source of the prescription drug; and

(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

(I) The name, address, telephone number, and professional license number (if any) of the importer.

(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug-

(i) is approved for marketing in the United States and is not adulterated or misbranded; and

(ii) meets all labeling requirements under this chapter.

(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

(2) Maintenance by the Secretary

The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

(e) Testing

The regulations under subsection (b) shall require-

(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

(2) if the tests are conducted by the importer-

(A) that information needed to-

(i) authenticate the prescription drug being tested; and

(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this chapter;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this chapter; and

(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

(f) Registration of foreign sellers

Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

(g) Suspension of importation

The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

(h) Approved labeling

The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

(i) Charitable contributions

Notwithstanding any other provision of this section, section 381(d)(1) of this title continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

(j) Waiver authority for importation by individuals

(1) Declarations

Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should-

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make such importations in circumstances in which-

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

(2) Waiver authority

(A) In general

The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

(B) Guidance on case-by-case waivers

The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

(3) Drugs imported from Canada

In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that-

(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(B) is accompanied by a copy of a valid prescription;

(C) is imported from Canada, from a seller registered with the Secretary;

(D) is a prescription drug approved by the Secretary under subchapter V;

(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 360 of this title; and

(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

(k) Construction

Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 381(d)(1) of this title as provided in this section.

(l) Effectiveness of section

(1) Commencement of program

This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will-

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(2) Termination of program

(A) In general

If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

(B) Procedure

The Secretary shall not submit a certification under subparagraph (A) unless, after a hearing on the record under sections 556 and 557 of title 5, the Secretary-

(i)(I) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

(II) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

(III) identifies specifically the causes of the increased risk; and

(IV)(aa) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

(bb) if the Secretary determines that any measures described in item (aa) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

(ii) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

(iii)(I) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

(II) determines that the benefits do not outweigh the detriment.

(m) Authorization of appropriations

There are authorized to be appropriated such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, §804, as added Pub. L. 108–173, title XI, §1121(a), Dec. 8, 2003, 117 Stat. 2464 ; amended Pub. L. 114–125, title VIII, §802(d)(2), Feb. 24, 2016, 130 Stat. 210 .)

PRIOR PROVISIONS

A prior section 384, act June 25, 1938, ch. 675, §804, as added Pub. L. 106–387, §1(a) [title VII, §745(c)(2)], Oct. 28, 2000, 114 Stat. 1549 , 1549A-36, related to importation of covered products, prior to repeal by Pub. L. 108–173, title XI, §1121(a), Dec. 8, 2003, 117 Stat. 2464 .

CHANGE OF NAME

"Commissioner of U.S. Customs and Border Protection" substituted for "Commissioner of Customs" in subsec. (b) on authority of section 802(d)(2) of Pub. L. 114–125, set out as a note under section 211 of Title 6, Domestic Security.

TRANSFER OF FUNCTIONS

For transfer of functions, personnel, assets, and liabilities of the United States Customs Service of the Department of the Treasury, including functions of the Secretary of the Treasury relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see sections 203(1), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6. For establishment of U.S. Customs and Border Protection in the Department of Homeland Security, treated as if included in Pub. L. 107–296 as of Nov. 25, 2002, see section 211 of Title 6, as amended generally by Pub. L. 114–125, and section 802(b) of Pub. L. 114–125, set out as a note under section 211 of Title 6.

STUDY AND REPORT ON IMPORTATION OF DRUGS

Pub. L. 108–173, title XI, §1122, Dec. 8, 2003, 117 Stat. 2469, directed the Secretary of Health and Human Services to conduct a study on the importation of drugs into the United States pursuant to this section and to submit to Congress, not later than 12 months after Dec. 8, 2003, a report providing the findings of such study.

EX. ORD. NO. 13938. INCREASING DRUG IMPORTATION TO LOWER PRICES FOR AMERICAN PATIENTS

Ex. Ord. No. 13938, July 24, 2020, 85 F.R. 45757, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* 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. For example, in the European Union, a market characterized by price controls and significant barriers to entry, the parallel trade of drugs has existed for decades and has been estimated to reduce the price of certain drugs by up to 20 percent. Accordingly, my Administration supports the goal of safe importation of prescription drugs.

Sec. 2. *Permitting the Importation of Safe Prescription Drugs from Other Countries.* The Secretary of Health and Human Services shall, as appropriate and consistent with applicable law, take action to expand safe access to lower-cost imported prescription drugs by:

(a) facilitating grants to individuals of waivers of the prohibition of importation of prescription drugs, provided such importation poses no additional risk to public safety and results in lower costs to American patients, pursuant to section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 384(j)(2);

(b) authorizing the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care pursuant to section 801(d) of the FDCA, 21 U.S.C. 381(d); and

(c) completing the rulemaking process regarding the proposed rule to implement section 804(b) through (h) of the FDCA, 21 U.S.C. 384(b) through (h), to allow importation of certain prescription drugs from Canada.

Sec. 3. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.