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LEGISLATURE OF NEBRASKA

ONE HUNDRED EIGHTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 200

Introduced by Briese, 41.

Read first time January 09, 2023

Committee:

A BILL FOR AN ACT relating to public health; to adopt the Canadian Prescription Drug Importation Act.

Be it enacted by the people of the State of Nebraska,

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Section 1. Sections 1 to 8 of this act shall be known and may be cited as the Canadian Prescription Drug Importation Act.

Sec. 2. The Legislature finds that:

(1) Consumers in the United States pay some of the highest prescription drug prices in the world and it is estimated that United States consumers pay twice as much as Canadian consumers for patented prescription drugs and twenty percent more for generic drugs;

(2) Federal law, as codified in 21 U.S.C. 384, authorizes the federal Secretary of Health and Human Services to allow wholesale importation of prescription drugs from Canada if such importation is shown to be both safe and less costly for United States consumers;

(3) Importing prescription drugs from Canada would be both safe and less costly, as Canada has a rigorous regulatory system to license prescription drugs, equivalent to the licensing system in the United States;

(4) In the United States, Title II of the federal Drug Quality and Security Act, Public Law 113-54, referred to as the Drug Supply Chain Security Act, has significantly improved drug security and safety through a system of pharmaceutical product track-and-trace procedures; and

(5) A wholesale drug importation program for the exclusive benefit of Nebraska residents should be designed and implemented to provide Nebraska residents access to safe and less expensive prescription drugs.

Sec. 3. For purposes of the Canadian Prescription Drug Importation Act:

(1) Canadian supplier means a manufacturer, wholesale distributor, or pharmacy that is appropriately licensed or permitted under Canadian federal and provincial laws and regulations to manufacture, distribute, or dispense prescription drugs;

(2) Department means the Department of Health and Human Services;

(3) Eligible importer means:

(a) A pharmacist or wholesaler approved by the department;

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(b) A pharmacist or wholesaler employed by, or under contract with, the Department of Correctional Services, for dispensing to inmates; and

(c) Commercial plans, as defined by rules and regulations of the department and as approved by the department and the federal government;

(4) Federal act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.;

(5) Pharmacist means a pharmacist licensed under the Pharmacy Practice Act;

(6) Pharmacy has the same meaning as in section 71-425;

(7) Prescription drug has the same meaning as in section 71-7441;

(8) Program means the Canadian Prescription Drug Importation Program created in section 4 of this act;

(9) Vendor means a vendor with which the department contracts for the provision of services under the program pursuant to section 4 of this act; and

(10) Wholesaler means a wholesale drug distributor licensed under the Wholesale Drug Distributor Licensing Act.

Sec. 4. (1) The Canadian Prescription Drug Importation Program is created. The program shall be administered by the department. Upon receiving approval of the program as described in section 6 of this act, the department shall contract with one or more vendors to provide services under the program. For three years following the effective date of this act, the selection of any vendor pursuant to this subsection is exempt from the requirements of sections 73-501 to 73-510.

(2)(a) Each vendor, in consultation with the department and any other vendors, shall establish a wholesale prescription drug importation list that identifies the prescription drugs that have the highest potential for cost savings for the people of Nebraska. In developing the list, each vendor shall consider, at a minimum, which prescription drugs will provide the greatest cost savings for the people of Nebraska, including prescription drugs for which there are shortages, specialty

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prescription drugs, and high-volume prescription drugs. Each vendor shall revise the list at least annually and at the direction of the department pursuant to subdivision (2)(b) of this section.

(b) The department shall review the wholesale prescription drug importation list at least once every three months to ensure that it continues to meet the requirements of the program. The department may direct a vendor to revise the list, as necessary.

(3) Each vendor, in consultation with the department, shall identify Canadian suppliers who are in full compliance with relevant Canadian federal and provincial laws and regulations and who have agreed to export prescription drugs identified on the wholesale prescription drug importation list. Each vendor shall verify that such Canadian suppliers meet all of the requirements of the program and will export prescription drugs at prices that will provide cost savings for the people of Nebraska. Each vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import prescription drugs under the program.

(4) Each vendor shall assist the department in developing and administering a distribution program within the program.

(5) Each vendor shall assist the department with the annual report described in section 7 of this act and provide any information requested by the department for the report.

(6) Each vendor shall ensure the safety and quality of drugs imported under the program, by:

(a)(i) For an initial imported shipment, ensuring that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act; and

(ii) For any subsequent imported shipment, ensuring that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act;

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(b) Certifying that each drug:

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

(ii) Meets all of the labeling requirements under 21 U.S.C. 352.

(c) Maintaining qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section; and

(d) Maintaining documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(7) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(8) Each vendor shall maintain a list of all eligible importers that participate in the program.

(9) Each vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act, Public Law 113-54, by all Canadian suppliers, eligible importers, and other participants in the program.

(10) Each vendor shall provide the results of an annual financial audit of its operations to the department. Each vendor shall also provide the department quarterly financial reports specific to the program and shall include information concerning the performance of its subcontractors. The department shall determine the format and content of the reports.

(11) Each vendor shall submit evidence of a surety bond with any bid or initial contract negotiation documents and shall maintain documentation of evidence of such a bond with the department throughout the contract term. The surety bond may be from any state in the United States and must be in an amount of at least two hundred fifty thousand

dollars. The surety bond or comparable security arrangement must designate the State of Nebraska as a beneficiary. In lieu of the surety bond, a vendor may provide a comparable security arrangement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution that designates the State of Nebraska as a beneficiary, payable to the State of Nebraska. The purposes of the bond or other security arrangement are to:

(a) Ensure participation of the vendor in any civil or criminal legal action by the department, any other state agency, or private persons against the vendor as a result of the vendor's failure to perform under the contract, including, but not limited to, causes of actions for personal injury, negligence, and wrongful death;

(b) Ensure payment by the vendor of any judgments or penalties entered against the vendor in any civil or criminal action arising from the vendor's participation in the program. The bond or comparable security arrangement may be accessed if the vendor fails to pay any judgment or penalty within sixty days after final judgment or assessment of such penalty; and

(c) Allow for civil and criminal claims to be made against the bond or other comparable security arrangements for up to one year after the vendor's contract under the program has ended with the department, the vendor's license is no longer valid, or the program has ended, whichever occurs later.

(12) Each vendor shall maintain information and documentation submitted under this section for a period of at least seven years.

(13) The department may require each vendor to collect any other information necessary to ensure the protection of the public health.

Sec. 5. (1) An eligible importer may import a prescription drug from a Canadian supplier if:

(a) The drug meets the federal Food and Drug Administration's standards related to safety, effectiveness, misbranding, and

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adulteration;

(b) Importing the drug does not violate federal patent laws;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

(i) A controlled substance as defined in 21 U.S.C. 802;

(ii) A biological product as defined in 42 U.S.C. 262;

(iii) An infused drug;

(iv) An intravenously injected drug;

(v) A drug that is inhaled during surgery; or

(vi) A parenteral drug, the importation of which is determined by the federal Secretary of Health and Human Services to pose a threat to public health.

(2) A Canadian supplier may export prescription drugs into the state under the program if the supplier:

(a) Is in full compliance with relevant Canadian federal and provincial laws and regulations;

(b) Is identified by the vendor as eligible to participate in the program pursuant to subsection (3) of section 4 of this act; and

(c) Submits an attestation that the supplier has a registered agent in the United States, which attestation includes the name and United States address of the registered agent.

(3) The department shall:

(a) Set a maximum profit margin so that a pharmacist, pharmacy, wholesaler, commercial plan, or other participant in the program maintains a profit margin that is no greater than the profit margin that such person would have earned on the equivalent nonimported drug;

(b) Exclude generic products if the importation of the products would violate United States patent laws applicable to United States-branded products;

(c) Comply with the requirements of 21 U.S.C. 360eee to 360eee-4; and

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(d) Determine a method for covering the administrative costs of the program, which method may include a fee imposed on each prescription pharmaceutical product sold through the program or any other appropriate method as determined by the department. The department shall not require a fee or other method in an amount the department determines would significantly reduce consumer savings.

(4) Canadian suppliers and eligible importers participating under the program:

(a) Shall comply with the tracking and tracing requirements of 21 U.S.C. 360eee et seq.; and

(b) Shall not distribute, dispense, or sell prescription drugs imported under the program outside of the state.

(5) A participating eligible importer shall submit to the vendor all of following information about each drug to be acquired by the importer under the program:

(a) The name and quantity of the active ingredient of the drug;

(b) A description of the dosage form of the drug;

(c) The date on which the drug is received;

(d) The quantity of the drug that is received;

(e) The point of origin and destination of the drug; and

(f) The price paid by the importer for the drug.

(6) A participating Canadian supplier shall submit to the vendor the following information about each drug to be supplied by the Canadian supplier under the program:

(a) The original source of the drug, including:

(i) The name of the manufacturer of the drug;

(ii) The date on which the drug was manufactured; and

(iii) The country, state or province, and city where the drug was manufactured;

(b) The date on which the drug is shipped;

(c) The quantity of the drug that is shipped;

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(d) The quantity of each lot of the drug originally received and the source of the lot; and

(e) The lot or control number and the batch number assigned to the drug by the manufacturer.

(7) The department shall immediately suspend the importation of a specific drug or the importation of drugs by a specific eligible importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The department may lift the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into this state.

Sec. 6. (1) On or before September 1, 2024, the department shall submit a request to the federal Secretary of Health and Human Services for approval of the program under 21 U.S.C. 384. The department shall begin operating the program not later than six months after receiving such approval. The request shall, at a minimum:

(a) Describe the department's plan for operating the program;

(b) Demonstrate how the prescription drugs imported into the state under the program will meet the applicable federal and state standards for safety, effectiveness, misbranding, and adulteration;

(c) Include a list of prescription drugs that have the highest potential for cost savings for the people of Nebraska through importation at the time that the request is submitted;

(d) Estimate the total cost savings attributable to the program; and

(e) Include a list of potential Canadian suppliers from which the state would import prescription drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.

(2) The department may expend funds for the purpose of requesting approval of the program as described in subsection (1) of this section; but the department shall not spend any other funds to implement the

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program until the department receives such federal approval.

(3) Upon receipt of federal approval of the program, the department shall notify the Governor, the Health and Human Services Committee of the Legislature, and the Appropriations Committee of the Legislature. After such approval is received and before the start of the next regular session of the Legislature, the department shall electronically submit a proposal for program implementation and funding to the Governor and such committees.

Sec. 7. On or before December 1, 2024, and on or before each December 1 thereafter, the department shall electronically submit a report to the Governor, the Health and Human Services Committee of the Legislature, and the Appropriations Committee of the Legislature. At a minimum, the report shall include:

(1) A list of the prescription drugs that were imported under the program;

(2) The number of participating Canadian suppliers and eligible importers;

(3) The number of prescriptions dispensed through the program;

(4) The estimated cost savings during the previous fiscal year and to date;

(5) A description of the methodology used to determine which prescription drugs should be included on the wholesale prescription drug importation list established pursuant to section 4 of this act; and

(6) Documentation demonstrating how the program ensures that:

(a) The vendor verifies that Canadian suppliers participating in the program are in full compliance with relevant Canadian federal and provincial laws and regulations;

(b) Prescription drugs imported under the program are not shipped, sold, or dispensed outside of the state once in the possession of the eligible importer;

(c) Prescription drugs imported under the program are pure,

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unadulterated, potent, and safe;

(d) The program does not put consumers at a higher health and safety risk than if the program did not exist; and

(e) The program provides cost savings for the people of Nebraska on imported prescription drugs.

Sec. 8. The department shall adopt and promulgate rules and regulations as necessary to carry out the Canadian Prescription Drug Importation Act.