HB3310

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103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB3310

Introduced 2/17/2023, by Rep. Joe C. Sosnowski

SYNOPSIS AS INTRODUCED:

New Act

Creates the Canadian Prescription Drug Importation Act. Provides that the Department of Public Health shall establish the Canadian Prescription Drug Importation Program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the State. Provides that the Department shall contract with a vendor to provide services under the program. Provides that on or before December 1, 2023, and each year thereafter, the vendor shall develop a wholesale prescription drug importation list identifying the prescription drugs that have the highest potential for cost savings to the State. Provides that the vendor shall identify Canadian suppliers that are in full compliance with the provisions of the Act and contract with the Canadian suppliers to import drugs under the program. Provides for: a bond requirement; requirements for eligible prescription drugs; requirements for eligible Canadian suppliers; requirements for eligible importers; distribution requirements; federal approval; prescription drug supply chain documentation; immediate suspension of specified imported drug; requirements of an annual report; notification of federal approval. Provides that the Department shall adopt rules necessary to implement the Act. Effective immediately.

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A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Canadian Prescription Drug Importation Act.

Section 3. Findings. The General Assembly finds:

(1) United States citizens pay some of the highest prices for prescription drugs in the world, and the Canadian government estimates that United States consumers pay twice as much as Canadians for patented prescription drugs and 20% more for generics.

(2) Under the United States Food and Drug Administration's discretion not to enforce the law, individual patients may import from Canada a 90-day supply of prescription drugs that are less expensive than drugs licensed by the Food and Drug Administration in the United States.

(3) Individual importation via the Internet increases consumer health and safety risks because many Internet pharmacies are not licensed in Canada, and it is difficult to verify the validity, reputation, actual identity, and pharmacy practices of online pharmacies outside of the United States.

(4) The United States allows patients to travel to other countries for surgeries and other high-risk medical treatments without regulating that activity, and insurers sometimes facilitate and pay for treatments outside of the United States.

(5) The United States Food and Drug Administration estimates that currently 40% of finished prescription drug products are produced outside of the United States, and 80% of raw products for United States pharmaceutical manufacturing come from outside the United States.

(6) The United States Food and Drug Administration recently signed reciprocity agreements with European Union regulators to accept the results of European Union inspections of pharmaceutical manufacturing plants. Since 1973, the United States Food and Drug Administration has had in place a Memorandum of Understanding for regulatory cooperation around pharmaceuticals with the Canadian regulatory authorities.

(7) Canada has a rigorous regulatory system to license prescription drugs that is considered to be on par with the United States licensing system.

(8) The enactment of Title II of the federal Drug Quality and Security Act (P.L. 113-54) has resulted in improvements in drug security and safety by implementing a pharmaceutical track-and-trace system that could be leveraged for the safe importation of pharmaceuticals.

(9) The Secretary of the United States Department of Health and Human Services may certify a prescription drug reimportation program that is safe and saves consumers money.

(10) The State can ensure that wholesale importation of prescription drugs from Canada into the State will be safe and cost-effective for State consumers.

Section 5. Program established. The Department of Public Health shall establish the Canadian Prescription Drug Importation Program for the importation from Canada of safe and effective prescription drugs that have the highest potential for cost savings to the State.

Section 10. Definitions. As used in this Act:

"Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

"County health department" means a health care facility established under Division 5-25 of the Counties Code.

"Department" means the Department of Public Health.

"Drug" or "prescription drug" has the same meaning as "drugs" in Section 1 of the Pharmacy Practice Act.

"Federal act" means the Federal Food, Drug, and Cosmetic Act as amended by the federal Drug Quality and Security Act.

"Free clinic" means a free medical clinic as defined in subsection (b) of Section 30 of the Good Samaritan Act.

"Medicaid pharmacy" means a pharmacy licensed under the Pharmacy Practice Act that has a Medicaid provider agreement in effect with the State and is in good standing with the State.

"Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy under the Pharmacy Practice Act.

"Program" means the Canadian Prescription Drug Importation Program created under this Act.

"Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the federal Drug Quality and Security Act.

"Vendor" means the entity contracted by the Department to manage specified functions of the program.

Section 15. Importation process.

(a) The Department shall contract with a vendor to provide services under the program.

(b) On or before December 1, 2023, and on or before December 1 of each year thereafter, the vendor shall develop a wholesale prescription drug importation list identifying the prescription drugs that have the highest potential for cost savings to the State. In developing the list, the vendor shall

consider, at a minimum, which prescription drugs will provide the greatest cost savings to State programs, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs. The Department, in consultation with the federal department, shall review the wholesale prescription drug importation list every 3 months to ensure that it continues to meet the requirements of the programs and may direct the vendor to revise the list as necessary.

(c) The vendor shall identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the federal act and who have agreed to export drugs identified on the list at prices that will provide cost savings to the State. The vendor must verify that such Canadian suppliers meet all of the requirements of the program while meeting or exceeding the federal and State track-and-trace laws and regulations.

(d) The vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

(e) The vendor shall maintain a list of all registered importers that participate in the program.

(f) The vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act by all suppliers, importers and other distributors, and participants in the program.

(g) The vendor shall assist the Department in the preparation of the annual report required by Section 60 of this Act including the timely provision of any information requested by the Department.

(h) The vendor shall provide an annual financial audit of its operations to the Department as required by the Department. The vendor shall also provide quarterly financial reports specific to the program and shall include information on the performance of its subcontractors and vendors. The Department shall determine the format and contents of the reports.

Section 20. Bond requirement. The Department shall require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance or fraudulent or dishonest acts committed by the vendor, any employees of the vendor, or its subcontractors.

Section 25. Eligible prescription drugs. Eligible importers, as described in Section 35 of this Act, may import a drug from an eligible Canadian supplier, as described in Section 30 of this Act, if:

(1) the drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(2) importing the drug would not violate federal

patent laws;

(3) importing the drug is expected to generate cost savings; and

(4) 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 drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

Section 30. Eligible Canadian suppliers. A Canadian supplier may export prescription drugs into this State under the program if the supplier:

(1) is in full compliance with relevant Canadian federal and provincial laws and regulations;

(2) is identified by the vendor as eligible to participate in the program; and

(3) submits an attestation that the supplier has a registered agent in the United States, including the name and United States address of the registered agent.

Section 35. Eligible importers. The following entities may import prescription drugs from an eligible Canadian supplier under the program:

(1) a pharmacist or wholesaler employed by or under contract with the Department's central pharmacy, for distribution to a county health department or free clinic for dispensing to clients treated in such department or clinic;

(2) a pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients;

(3) a pharmacist or wholesaler employed by or under contract with the Department of Corrections, for dispensing to inmates in the custody of the Department of Corrections;

(4) a pharmacist or wholesaler employed by or under contract with the Department of Juvenile Justice, for dispensing to inmates in the custody of the Department of Juvenile Justice;

(5) a pharmacist or wholesaler employed by or under contract with a developmental disabilities center, as defined in the Mental Health and Developmental Disabilities Administrative Act, for dispensing to clients treated in such center; and

(6) a pharmacist or wholesaler employed by or under

contract with a residential treatment facility, or "facility" as defined in the Specialized Mental Health Rehabilitation Act of 2013 for dispensing to patients treated in such facility.

Section 40. Distribution requirements. Eligible Canadian suppliers and eligible importers participating under the program:

(1) must comply with the tracking and tracing requirements of 21 U.S.C. 360; and

(2) may not distribute, dispense, or sell prescription drugs imported under the program outside of the State.

Section 45. Federal approval. On or before July 1, 2023, the Department shall submit a request to the United States Secretary of Health and Human Services for approval of the program under paragraph (1) of 21 U.S.C. 384. The Department shall begin operating the program within 6 months after receiving such approval. The request must, at a minimum:

(1) describe the Department's plan for operating the program;

(2) demonstrate how the prescription drugs imported into this State under the program will meet the applicable federal and State standards for safety and effectiveness;

(3) demonstrate how the drugs imported into this State under the program will comply with federal tracing

procedures;

(4) include a list of proposed prescription drugs that have the highest potential for cost savings to the State through importation at the time that the request is submitted;

(5) estimate the total cost savings attributable to the program;

(6) provide the costs of program implementation to the State; and

(7) include a list of potential Canadian suppliers from which the State would import drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and State laws and regulations.

Section 50. Prescription drug supply chain documentation.

(a) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

(1) for an initial imported shipment of a specific drug by an importer, ensure 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;

(2) for every subsequent imported shipment of that drug by that importer, ensure that a statistically valid

sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act;

(3) certify that the 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;

(4) maintain 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.

(5) maintain 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.

(b) 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.

(c) The vendor shall maintain information and documentation submitted under this Section for a period of at least 7 years.

(d) A participating importer must submit all of the following information to the vendor:

(1) the name and quantity of the active ingredient of the drug;

(2) a description of the dosage form of the drug;

(3) the date on which the drug is received;

(4) the quantity of the drug that is received;

(5) the point of origin and destination of the drug; and

(6) the price paid by the importer for the drug;

(e) A participating Canadian supplier must submit the following information and documentation to the vendor specifying all of the following:

(1) 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 location including the country, state or province, and city, where the drug was manufactured;

(2) the date on which the drug is shipped;

(3) the quantity of the drug that is shipped;

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

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

(f) The Department may require that the vendor collect any other information necessary to ensure the protection of the public health.

Section 55. Immediate suspension. The Department shall immediately suspend the importation of a specific drug or the importation of drugs by a specific 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 revoke 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.

Section 60. Annual report. On or before December 1 of each year, the Department shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the program during the previous fiscal year. The report must include, at a minimum:

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

(2) the number of participating entities;

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

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

(5) a description of the methodology used to determine which drugs should be included on the wholesale prescription drug importation list; and

(6) documentation as to how the program ensures the

following that:

(i) Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all federal laws and regulations and State laws and rules;

(ii) prescription drugs imported under the program are not shipped, sold, or dispensed outside of this State once in the possession of the importer;

(iii) prescription drugs imported under the program are pure, unadulterated, potent, and safe;

(iv) the program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

(v) the program provides cost savings to the State on imported prescription drugs.

Section 65. Notification of federal approval. Upon receipt of federal approval of the program, the Department shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. After approval is received and before the start of the next regular session of the General Assembly in which the proposal could be funded, the Department shall submit to all parties a proposal for program implementation and program funding.

Section 70. Rulemaking. The Department shall adopt rules necessary to implement this Act.

Section 99. Effective date. This Act takes effect upon becoming law.