HB3490

LRB10327325CPF53696b

103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB3490

Introduced 2/17/2023, by Rep. Hoan Huynh

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 by 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.

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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 5. Legislative findings. The General Assembly finds:

(1) United States consumers pay some of the highest prescription drug prices in the world, and it is estimated that United States consumers pay twice as much as the amount Canadian consumers pay for patented prescription drugs and 20% more for generic drugs.

(2) Federal law, as codified in 21 U.S.C. 384, authorizes the Secretary of the United States Department 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) Although importing prescription drugs would be less costly, there may be risks posed to consumer health and safety if the source, quality, and purity of prescription drugs sold by online pharmacies cannot be verified.

(4) Canada has a rigorous regulatory system to license prescription drugs, equivalent to the licensing system in the

United States.

(5) In the United States, Title II of the federal Drug Quality and Security Act, 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.

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

Section 10. Definitions. As used in this Act:

"Canadian supplier means a manufacturer, wholesale distributor, or pharmacy that is appropriately licensed or permitted under Canadian federal and provincial laws and regulations to manufacturer, distribute, or dispense prescription drugs.

"Department" means the Department of Public Health.

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

"Eligible importer" means an importer that is:

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

(2) 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;

(3) a commercial plan, as defined by rules adopted by the Department and as approved by the federal government; and

(4) a licensed pharmacist under the Pharmacy Practice Act or registered wholesaler approved by the Department.

"Federal act" means the federal Food, Drug, and Cosmetic 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 and active and unencumbered license to practice pharmacy under the Pharmacy Practice Act.

"Program" means the Canadian prescription drug importation program created in this Act.

"Vendor" means a vendor with which the State who contracts for the provision of services under the program pursuant to subsection (a) of Section 15.

Section 15. Canadian prescription drug importation program; importation process; contract with vendor; vendor duties.

(a) The Canadian prescription drug importation program is

created in the Department. Upon receiving approval of the program as described in Section 25, the Department shall contract with one or more vendors to provide services under the program. For 3 years following the effective date of this Act, the selection of any vendor pursuant to this subsection is exempt from the requirements of the Illinois Procurement Code.

(b) 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 to the State. In developing the list, each vendor shall consider, at a minimum, which prescription drugs will provide the greatest cost savings to the State, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs. Each vendor shall revise the list at least annually and at the direction of the State department pursuant to this subsection. The Department shall review the wholesale prescription drug importation list at least every 3 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. 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 to the State. 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. Each vendor shall assist the Department in developing and administering a distribution program within the program. Each vendor shall assist the Department with the annual report described in this Act and provide any information requested by the Department for the report. Each vendor shall ensure the safety and quality of drugs imported under the program, as follows:

(1) for an initial imported shipment, 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, and for any subsequent imported shipment, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act;

(2) certify 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;

(3) 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; and

(4) 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.

(c) 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.

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

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

(f) Each vendor shall provide an annual financial audit of its operations to the Department. Each vendor shall also provide quarterly financial reports specific to the program and shall include information concerning the performance of its subcontractors and vendors. The Department shall determine the format and contents of the reports.

(g) 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 this State or any other State in the United States and must be in an amount of at least $25,000. The surety bond or comparable security arrangement must include the State as a beneficiary. In lieu of the surety bond, a vendor may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution that includes the State as a beneficiary, payable to the State. The purposes of the bond or other security arrangement are to:

(1) ensure participation of the vendor in any civil or criminal legal action by the State department, any other State agency, or private individuals or entities against the vendor because 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;

(2) ensure payment by the vendor through the use of a bond or other comparable security arrangement of any legal judgments and claims that are awarded to the State, other entities acting on behalf of the State, individuals, or organizations if the vendor is assessed a final judgment or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable

security arrangement may be accessed if the vendor fails to pay any judgment or claim within 60 days after final judgment; and

(3) allow for civil and criminal litigation 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 last.

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

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

Section 20. Eligible prescription drugs; eligible Canadian suppliers; eligible importers; distribution requirements.

(a) An eligible importer may import a prescription drug from a Canadian supplier 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.

(b) A Canadian supplier may export prescription drugs into the 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.

(c) The following entities are eligible importers and may obtain imported prescription drugs:

(1) a pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the

pharmacy's Medicaid recipients;

(2) 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;

(3) commercial plans, as defined by rules promulgated by the State Board and as approved by the federal government; and

(4) a licensed pharmacist or wholesaler approved by the Department under the Pharmacy Practice Act.

(d) The Department shall designate an office or division that must be a licensed pharmaceutical wholesaler or that shall contract with a licensed pharmaceutical wholesaler licensed pursuant to Part 3 of Article 42.5 of Title 12. The office or division designated by the Department shall:

(1) set a maximum profit margin so that a wholesaler, distributor, pharmacy, or other licensed provider participating in the program maintains a profit margin that is no greater than the profit margin that the wholesaler, distributor, pharmacy, or other licensed provider whole have earned on the equivalent nonimported drug;

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

(3) comply with the requirements of 21 U.S.C. 360eee

through 360eee-4 as enacted in Title II of the federal Drug Quality and Security Act; and

(4) 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, but the Department shall not require a fee in an amount the Department determines would significantly reduce consumer savings.

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

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

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

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

(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.

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

(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.

(h) 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 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 25. Federal approval.

(a) On or before September 1, 2023, the Department shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 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, effectiveness, misbranding, and adulteration;

(3) 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;

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

(5) 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.

(b) Notwithstanding any provision of this subsection to the contrary, the Department may expend money for the purpose of requesting approval of the program as described in subsection (a), but the Department shall not spend any other

money to implement the program until the Department receives approval of the program as described in subsection (a).

(c) Upon receipt of federal approval of the program, the Department shall notify the President of the Senate and the Speaker of the House of Representatives, as well as the Health and Human Services Committee of the Senate and the Health and Insurance Committee of the House of Representatives, or any successor committees. 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 specified in this subsection a proposal for program implementation and program funding.

Section 30. Reports. On or before December 1, 2024, and on or before December 1 each year thereafter, 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 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 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 in full compliance with relevant Canadian federal and provincial laws;

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

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

Section 35. Importation program authorized; rulemaking.

(a) Upon approval by the Secretary, in accordance with Section 30, the Department shall administer an importation program.

(b) The Department shall approve a method of financing and administrative costs of the importation program, which method

may include imposing a fee on each prescription pharmaceutical product sold through the importation program or any other appropriate method determined by the Department to finance administrative costs. The Department shall not require a fee in an amount that the Department determines would significantly reduce consumer savings.

(c) The Department shall adopt rules necessary to implement this Act.