

103RD GENERAL ASSEMBLY State of Illinois 2023 and 2024 HB4525

Introduced 1/31/2024, by Rep. Maurice A. West, II

SYNOPSIS AS INTRODUCED:

New Act

Creates the Wholesale Prescription Drug Importation Program Act. Requires the Department of Public Health to establish the Wholesale Prescription Drug Importation Program. Provides that the Department shall implement the program by: contracting with one or more prescription drug wholesalers and Canadian suppliers to import prescription drugs and provide prescription drug cost savings to consumers in this State; developing a registration process for health benefit plan issuers, health care providers, and pharmacies to obtain and dispense prescription drugs imported under the program; developing a list of prescription drugs, including the prices of those drugs, that meet certain requirements set forth under the Act and publishing the list on the Department's website; establishing an outreach and marketing plan to generate program awareness; ensuring the program and the prescription drug wholesalers that contract with this State comply with certain federal tracking, tracing, verification, and identification requirements; and other actions. Sets forth eligibility criteria for prescription drugs that may be imported into the State under the program. Contains provisions concerning anticompetitive behavior monitoring; program funding; program expansion; audit procedures; annual reporting requirements; the adoption of rules to implement the Act; and federal waiver or authorization requirements. Effective July 1, 2024.

LRB103 36423 RPS 66525 b

1 AN ACT concerning health.

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

- 4 Section 1. Short title. This Act may be cited as the
- 5 Wholesale Prescription Drug Importation Program Act.
- 6 Section 5. Definitions. As used in this Act:
- 7 "Canadian supplier" means a manufacturer, wholesale
- 8 distributor, or pharmacy that is appropriately licensed or
- 9 permitted under Canadian federal or provincial laws and rules
- 10 to manufacture, distribute, or dispense prescription drugs.
- "Department" means the Department of Public Health.
- "Director" means the Director of Public Health.
- "Prescription drug wholesaler" means a person or entity
- 14 licensed as a wholesale drug distributor under the Wholesale
- Drug Distribution Licensing Act, that contracts with this
- 16 State to import prescription drugs under the program.
- 17 "Program" means the Wholesale Prescription Drug
- 18 Importation Program.
- 19 Section 10. Wholesale Prescription Drug Importation
- 20 Program.
- 21 (a) The Department shall establish the Wholesale
- 22 Prescription Drug Importation Program to provide lower cost

- prescription drugs available outside of the United States to consumers in this State at the lower cost.
 - (b) The Department shall implement the program by:
 - (1) contracting with one or more prescription drug wholesalers and Canadian suppliers to import prescription drugs and provide prescription drug cost savings to consumers in this State;
 - (2) developing a registration process for health benefit plan issuers, health care providers, and pharmacies to obtain and dispense prescription drugs imported under the program;
 - (3) developing a list of prescription drugs, including the prices of those drugs, that meet the requirements of Section 15 and publishing the list on the Department's website;
 - (4) establishing an outreach and marketing plan to generate program awareness;
 - (5) establishing and administering a telephone call center or electronic portal to provide information about the program;
 - (6) ensuring the program and the prescription drug wholesalers that contract with this State under paragraph (1) comply with the tracking, tracing, verification, and identification requirements of 21 U.S.C. 360eee-1;
 - (7) prohibiting the distribution, dispensing, or sale of prescription drugs imported under this Act outside the

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boundaries of this State; and 1 2 (8) performing any other duties the Director 3 determines necessary to implement the program. (c) The Department shall ensure that the program meets the 5 requirements of 21 U.S.C. 384. (d) In developing the program, the Department may consult 6 7 with interested parties. 8 Section 15. Eligible prescription drugs. A prescription 9 drug may be imported into this State under the program only if 10 the drug: 11 (1)meets the United States Food and Drug 12 Administration's standards related to prescription drug 1.3 safety, effectiveness, misbranding, and adulteration; 14 (2) does not violate any federal patent laws through 15 its importation; 16 is expected to generate cost (3) savings for 17 consumers; and 18 (4) is not: 19 (A) listed as a controlled substance under State or federal law; 20 21 (B) a biological product; 22 (C) an infused drug; (D) an intravenously injected drug; 23 24 (E) a drug that is inhaled during surgery; or

(F) a parenteral drug.

- Section 20. Program expansion. In its discretion, the
 Department may by rule expand the Program to import
 prescription drugs from any other country that is allowed
 under federal law to import prescription drugs into the United
 States.
- Section 25. Anticompetitive behavior monitoring. The
 Department, in consultation with the Attorney General, shall
 identify and monitor any potential anticompetitive activities
 in industries affected by the program.
- Section 30. Program funding. In addition to money appropriated by the General Assembly, the Department may impose a fee on each prescription drug sold under the program or establish another funding method to administer the program.
- Section 35. Audit procedures. The Director, by rule, shall develop procedures to effectively audit a prescription drug wholesaler participating in the program.
- Section 40. Annual reporting. Not later than December 1, 2025, and each December 1 thereafter, the Department shall submit a report to the Governor and the General Assembly regarding the operation of the program during the preceding State fiscal year, including:

Τ.	(1) which prescription drugs and canadian suppliers
2	are included in the program;
3	(2) the number of health benefit plan issuers, health
4	care providers, and pharmacies participating in the
5	program;
6	(3) the number of prescriptions dispensed through the
7	program;
8	(4) the estimated cost savings to consumers, health
9	plans, employers, and this State since the establishment
10	of the program and during the preceding State fiscal year;
11	(5) information regarding the implementation of the
12	audit procedures under Section 35; and
13	(6) any other information:
14	(A) the Governor or the General Assembly requests;
15	or
16	(B) the Department considers necessary.
17	Section 45. Rules. As soon as practicable after the
18	effective date of this Act, the Director shall adopt any rules
1 0	necessary to implement this Act

Section 50. Federal waiver or authorization. If, before implementing any provision of this Act, a State agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision shall request the waiver or

- 1 authorization and may delay implementing that provision until
- 2 the waiver or authorization is granted.
- 3 Section 99. Effective date. This Act takes effect July 1,
- 4 2024.