SPONSOR: Sen. Sokola & Rep. Baumbach
Sens. Hansen, Hoffner, Huxtable, Walsh; Reps. K. Johnson, Morrison, Osienski, K. Williams, Wilson-Anton

DELAWARE STATE SENATE
152nd GENERAL ASSEMBLY

SENATE BILL NO. 332

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO A WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Part II, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Chapter 30R. Wholesale Prescription Drug Importation Program.

§ 3001R. Definitions.

For purposes of this chapter:

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

(2) "Eligible prescription drug" means a prescription drug that is eligible for importation through the program by satisfying all of the following:

a. Meets the United States Food and Drug Administration's standards related to safety, effectiveness, branding, and adulteration.

b. Does not violate federal patent laws.

c. Is not a controlled substance as defined under federal law or the laws of this State.

d. Is expected to generate substantial cost savings to Delaware consumers.

(3) "State wholesaler" means the Department or a Delaware-licensed wholesale distributor that contracts with the Department to import eligible prescription drugs from a Canadian supplier.

(4) "Program" means the wholesale prescription drug importation program created under this chapter.

§ 3002R. Wholesale prescription drug importation program design.

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(a) The Department, in consultation with interested stakeholders and appropriate federal and state officials, shall design a program that complies with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings. The program must do all of the following:

(1) Designate whether the Department shall become a state wholesaler or contract with a state wholesaler to import eligible prescription drugs and provide substantial cost savings to Delaware consumers.

(2) Use Canadian suppliers regulated under the laws of Canada or of one or more Canadian provinces, or both.

(3) Ensure that only eligible prescription drugs meeting the United States Food and Drug Administration's safety, effectiveness, branding, and adulteration standards are imported by or on behalf of this State.

(4) Have a process to sample the purity, chemical composition, and potency of imported eligible prescription drugs.

(5) Import only those eligible prescription drugs that would not violate federal patent laws.

(6) Import only those eligible prescription drugs expected to generate substantial savings for Delaware consumers.

(7) Ensure compliance to the extent practicable with the tracking and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 before the state wholesaler takes possession of eligible prescription drugs and full compliance after the state wholesaler takes possession of eligible prescription drugs.

(8) Prohibit the distribution, dispensing, or sale of eligible prescription drugs outside of this State.

(9) Recommend a charge per prescription or another method of support to ensure adequate funding in a manner that does not jeopardize substantial consumer cost savings.

(10) Include a robust audit function.

(b) On or before January 1, 2025, the Department shall submit the proposed design for the program to the House Health & Human Development Committee, Senate Health & Social Services Committee, and the Joint Finance Committee, with a copy to the Controller General and the Director of the Division of Research.

§ 3003R. Monitoring for restraints on trade or commerce.

The Department shall consult with the Attorney General to identify the potential for and monitor anticompetitive behavior in industries that would be affected by the program.

§ 3004R. Federal compliance and approval of program.

(a) On or before May 1, 2025, the Department shall submit a formal request to the Secretary of the United States Department of Health and Human Services for certification of the program.

(b) The Department shall seek the appropriate federal approvals, waivers, exemptions, or agreements, or a combination thereof, as needed to enable all covered entities enrolled in or eligible for the federal 340B Drug Pricing Program to fully participate in the program without jeopardizing a covered entity's eligibility for the 340B Program.

(c) On receipt of a response to the Department's request under subsection (a) of this section, the Department shall provide notice of the response to all of the following:

(1) The President Pro Tempore of the Senate.

(2) The Speaker of the House of Representatives.

(3) The Chair and Vice Chair of the Joint Finance Committee.

(4) The Chair of the Senate Health & Social Services Committee.

(5) The Chair of the House Health & Human Development Committee.

(6) The Controller General.

(7) The Director of the Division of Research.

(d) On receipt of any denial of the Department's request under subsection (a) of this section or under this subsection, the Department shall do all of the following:

(1) Make any necessary changes to the proposed design for the program in consultation with interested stakeholders and appropriate federal and state officials.

(2) Submit another formal request to the Secretary of the United States Department of Health and Human Services for certification of the program within 6 months.

(3) Provide notice of any response to the Department's request to the officials identified in subsection (c) of this section.

§ 3005R. Implementation.

(a) On receipt of certification and approval of the program by the Secretary of the United States Department of Health and Human Services, the Department shall do all of the following:

(1) Implement the program.

(2) Begin operating the program within 6 months.

(b) In implementing the program, the Department shall, consistent with state procurement and contract laws, rules, and procedures, do all of the following:

(1) Become or enter into a contract with a state wholesaler.

(2) Contract with one or more Delaware-licensed distributors.

(3) Contract with one or more Canadian suppliers.

(4) Engage with health insurance plans, employers, pharmacies, health care providers, and consumers.

(5) Develop a registration process for health insurance plans, pharmacies, and prescription drug-administering health care providers willing to participate in the program.

(6) List the prices of eligible prescription drugs on the Department's website.

(7) Create an outreach and marketing plan to generate program awareness.

(8) Before the program becomes operational, create and staff a hotline to answer questions and address the needs of consumers, employers, health insurance plans, pharmacies, health care providers, and other affected parties.

(9) Establish the audit function and a 2-year audit work-plan cycle.

(10) Conduct any other activities that the Secretary determines to be important for successful implementation of the program.

§ 3006R. Annual reporting.

(a) The Department shall annually prepare a report detailing all of the following:

(1) The eligible prescription drugs included in the program.

(2) The number of participating pharmacies, health care providers, and health insurance plans.

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

(4) The estimated savings to consumers, health plans, employers, and this State during the previous calendar year and to date.

(5) Information regarding implementation of the audit plan and audit findings.

(6) Any other information the Secretary deems relevant.

(b) The Department shall submit the report to all of the following not later than January 15 of each year:

(1) The President Pro Tempore and Secretary of the Senate, for distribution to all Senators.

(2) The Speaker and Chief Clerk of the House of Representatives, for distribution to all Representatives.

(3) The Controller General.

(4) The Director and Librarian of the Division of Research of Legislative Council.

(5) The Director of the Delaware Public Archives.

(6) The Governor.

§ 3007R. Regulatory authority.

The Department may adopt regulations to implement, administer, or enforce this chapter.

SYNOPSIS

This Act requires the Department of Health and Social Services, in consultation with persons interested in the sale and pricing of prescription drugs as well as interested federal and state officials and agencies, to design and implement a

wholesale prescription drug importation program for the benefit of, and that generates savings for, Delaware residents. The Act establishes requirements for the program including all of the following:

(1) The Department must become or contract with a state wholesaler and seek federal certification and approval to import eligible prescription drugs.

(2) The program must comply with federal regulations and import from Canadian suppliers only those eligible prescription drugs that do not violate patent laws, that are not controlled substances, and for which importation creates substantial cost savings.

(3) The Department must ensure that eligible prescription drugs imported under the program are not distributed, dispensed, or sold outside of Delaware.

(4) Before submitting the proposed program to the federal government for certification, the Department must submit the proposal to the General Assembly.

(5) The program must have an audit procedure to ensure compliance with the Act's requirements and requires submission of an annual report to the General Assembly to track the program's progress.

Author: Senator Sokola