By:  Talarico H.B. No. 25

A BILL TO BE ENTITLED

AN ACT

relating to wholesale importation of prescription drugs for resale to Texas residents.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1.  SHORT TITLE. This Act shall be known as the "Wholesale Prescription Drug Importation Act."

SECTION 2.  WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM. Subtitle C, Title 2, Health and Safety Code is amended by adding Chapter 66 to read as follows:

CHAPTER 66. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM SUBCHAPTER A. GENERAL PROVISIONS.

Sec. 66.001.  DEFINITIONS. In 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)  "Commission" means Health and Human Services Commission.

(3)  "Eligible prescription drug" means a drug eligible for importation that:

(a)  meets the United States federal food and drug administration's standards related to safety, effectiveness, misbranding and adulteration;

(b)  does not violate federal patent laws;

(c)  is expected to generate cost savings; and

(d)  is not a controlled substance;

(4)  "Program" means the wholesale prescription drug importation program; and

(5)  "State drug wholesaler" means a licensed wholesale drug distributor that contracts with the state to import eligible prescription drugs from a Canadian supplier.

Sec. 66.002.  CONSTRUCTION OF CHAPTER; PURPOSE.  (a) The purpose of this chapter is to establish a program to make prescription drugs that are available at lower costs outside the United States available to consumers in Texas at those lower costs.

Sec. 66.003.  ESTABLISHMENT OF WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM.  (a) The commission shall design a "wholesale prescription drug importation program" that complies with the applicable requirements of 21 U.S.C. Section 384, including the requirements regarding safety and cost savings. The commission shall explore all potential mechanisms, to the extent allowable under law, for the importation of eligible prescription drugs. The program design shall:

(1)  contract with one or more state drug wholesalers to seek federal certification and approval to import safe, eligible prescription drugs from Canadian suppliers and provide significant prescription drug cost savings to Texas consumers;

(2)  allow the importation of eligible prescription drugs sold by Canadian suppliers;

(3)  ensure that only eligible prescription drugs meeting the United States food and drug administration's safety, effectiveness and other standards are imported by or on behalf of the state;

(4)  import only those eligible prescription drugs expected to generate substantial savings for Texas consumers;

(5)  ensure that, with respect to eligible prescription drugs to be imported pursuant to the program, the program and the state drug wholesaler comply with the tracking, tracing, verification and identification requirements of 21 U.S.C. Sections 360eee and 360eee-1;

(6)  prohibit the distribution, dispensing or sale of eligible prescription drugs imported pursuant to the Wholesale Prescription Drug Importation Act outside the exterior boundaries of the state;

(7)  recommend a charge per prescription or another method of support to ensure that the program is funded adequately in a manner that does not jeopardize significant consumer savings; and

(8)  include an audit function.

Sec. 66.004.  MONITORING FOR ANTI-COMPETITIVE BEHAVIOR.  (a) The commission shall consult with the attorney general to identify the potential, and to monitor, for anti-competitive behavior in industries that would be affected by the program.

Sec. 66.005.  FEDERAL COMPLIANCE.  (a) The commission shall submit a formal request to the secretary of the United States department of health and human services for certification of the state's program.

Sec. 66.006.  IMPLEMENTATION.  (a) Upon certification of approval by the secretary of the United States department of health and human services, the commission shall begin implementing the program and begin operating the program within six months of that approval. As part of the implementation process, the commission shall:

(1)  enter into contracts in accordance with the Procurement Code with one or more state drug wholesalers and Texas licensed drug distributors and contract with one or more approved Canadian suppliers;

(2)  consult with interested stakeholders, including the committee, the legislature, health insurance plans, employers, pharmacies, health care providers and consumers;

(3)  develop a registration process for health insurance plans, pharmacies and prescription drug administering health care providers who choose to participate in the program;

(4)  make a list of imported eligible prescription drugs and their prices and make that list available to all participating entities and the general public;

(5)  create an outreach and marketing plan to generate program awareness;

(6)  create and staff a helpline to answer questions and address the needs of consumers, employers, health insurance plans, pharmacies, health care providers and other affected sectors;

(7)  require annual specific audits of the program; and

(8)  carry out other duties in accordance with the Wholesale Prescription Drug Importation Act that the commission determines to be necessary for successful implementation of the program.

Sec. 66.007.  ANNUAL REPORTING.  (a) Annually, after implementation, the commission shall report to the governor and the legislature regarding the operation of the program during the previous year, including:

(1)  which eligible prescription drugs and Canadian suppliers are 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 the state during the previous year and to date;

(5)  information regarding implementation of the audit plan and the correction plans for audit findings; and

(6)  any other information requested by the governor or the legislature or state health authority deems relevant.

Sec. 66.008.  COUNTRIES OTHER THAN CANADA ALLOWED BY FEDERAL LAW.  (a) The provisions of the Wholesale Prescription Drug Importation Act may be extended to any other country allowed by federal law to import prescription drugs into the United States, at the discretion of the commission.

SECTION 3.  As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission and any other state agency designated by the executive commissioner shall adopt rules necessary to implement Chapter 66, Health and Safety Code, as added by this Act.

SECTION 4.  This Act takes effect September 1, 2023.