

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

CHAPTER 66. WHOLESAL E 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;

1 (c) is expected to generate cost savings; and

2 (d) is not a controlled substance;

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

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

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

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

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

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

26 (3) ensure that only eligible prescription drugs
27 meeting the United States food and drug administration's safety,

1 effectiveness and other standards are imported by or on behalf of
2 the state;

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

5 (5) ensure that, with respect to eligible prescription
6 drugs to be imported pursuant to the program, the program and the
7 state drug wholesaler comply with the tracking, tracing,
8 verification and identification requirements of 21 U.S.C. Sections
9 360eee and 360eee-1;

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

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

17 (8) include an audit function.

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

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

27 Sec. 66.006. IMPLEMENTATION. (a) Upon certification of

1 approval by the secretary of the United States department of health
2 and human services, the commission shall begin implementing the
3 program and begin operating the program within six months of that
4 approval. As part of the implementation process, the commission
5 shall:

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

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

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

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

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

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

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

26 (8) carry out other duties in accordance with the
27 Wholesale Prescription Drug Importation Act that the commission

1 determines to be necessary for successful implementation of the
2 program.

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

7 (1) which eligible prescription drugs and Canadian
8 suppliers are included in the program;

9 (2) the number of participating pharmacies, health
10 care providers and health insurance plans;

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

13 (4) the estimated savings to consumers, health plans,
14 employers and the state during the previous year and to date;

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

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

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

24 SECTION 3. As soon as practicable after the effective date
25 of this Act, the executive commissioner of the Health and Human
26 Services Commission and any other state agency designated by the
27 executive commissioner shall adopt rules necessary to implement

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1 Chapter 66, Health and Safety Code, as added by this Act.

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