

BILL ANALYSIS

Senate Research Center
88R20321 MPF-F

H.B. 25
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Health & Human Services
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Engrossed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Every year, per-capita prescription drug spending is astronomically higher in the United States than in all of its peer nations. Canadian consumers pay just half of what U.S. consumers pay for patented prescription drugs, despite the fact that the two countries share an equivalent regulatory system for prescribed medications.

In 2020, the Trump Administration established a pathway for states to import prescription drugs from Canada after finding that it would result in significant cost savings for patients and could be done safely. The Biden Administration later ordered the United States Food and Drug Administration (FDA) to help states implement programs. The FDA is currently reviewing proposals from Florida, Colorado, New Mexico, Maine, Vermont, and New Hampshire, and is training state representatives across the country on how to develop importation program applications.

H.B. 25 would create a Wholesale Prescription Drug Importation Program in Texas, requiring the Texas State Board of Pharmacy to work with state drug wholesalers to import safe, eligible prescription drugs from Canada. If passed, Texas would have to obtain federal approval from the FDA by submitting a proposal that proves the program would generate significant cost savings for consumers and not pose additional risks to health and safety.

H.B. 25 amends current law relating to wholesale importation of prescription drugs in this state and authorizes a fee.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 (Section 444.006, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Authorizes this Act to be cited as the Wholesale Prescription Drug Importation Act.

SECTION 2. Amends Subtitle A, Title 6, Health and Safety Code, by adding Chapter 444, as follows:

CHAPTER 444. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

Sec. 444.001. DEFINITIONS. Defines "Canadian supplier," "commission," "prescription drug wholesaler," and "program."

Sec. 444.002. ESTABLISHMENT OF WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM. (a) Requires the Health and Human Services Commission (HHSC) to establish the wholesale prescription drug importation program (program) to provide lower cost prescription drugs available outside of the United States to consumers in this state at the lower cost.

(b) Requires HHSC to 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 444.003 and publishing the list on HHSC's Internet 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 Subdivision (1) comply with the tracking, tracing, verification, and identification requirements of 21 U.S.C. Section 360eee-1;

(7) prohibiting the distribution, dispensing, or sale of prescription drugs imported under this chapter outside the boundaries of this state; and

(8) performing any other duties the executive commissioner of HHSC (executive commissioner) determines necessary to implement the program.

(c) Requires HHSC to ensure that the program meets the requirements of 21 U.S.C. Section 384.

(d) Authorizes HHSC, in developing the program, to consult with interested parties.

Sec. 444.003. ELIGIBLE PRESCRIPTION DRUGS. Authorizes a prescription drug to be imported into this state under the program only if the drug:

(1) meets the United States Food and Drug Administration's standards related to prescription drug safety, effectiveness, misbranding, and adulteration;

(2) does not violate any federal patent laws through its importation;

(3) is expected to generate cost savings for consumers; and

(4) is not:

(A) listed as a controlled substance under state or federal law;

(B) a biological product;

(C) an infused drug;

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a parenteral drug.

Sec. 444.004. ANTICOMPETITIVE BEHAVIOR MONITORING. Requires HHSC, in consultation with the attorney general, to identify and monitor any potential anticompetitive activities in industries affected by the program.

Sec. 444.005. PROGRAM FUNDING. Authorizes HHSC, in addition to money appropriated by the legislature, to impose a fee on each prescription drug sold under the program or establish another funding method to administer the program.

Sec. 444.006. AUDIT PROCEDURES. Requires the executive commissioner by rule to develop procedures to effectively audit a prescription drug wholesaler participating in the program.

Sec. 444.007. ANNUAL REPORTING. Requires HHSC, not later than December 1 of each year, to submit a report to the governor and the legislature regarding the operation of the program during the preceding state fiscal year, including:

- (1) which prescription drugs and Canadian suppliers are included in the program;
- (2) the number of health benefit plan issuers, health care providers, and pharmacies participating in the program;
- (3) the number of prescriptions dispensed through the program;
- (4) the estimated cost savings to consumers, health plans, employers, and this state since the establishment of the program and during the preceding state fiscal year;
- (5) information regarding the implementation of the audit procedures under Section 444.006; and
- (6) any other information:
 - (A) the governor or the legislature requests; or
 - (B) HHSC considers necessary.

SECTION 3. Requires the executive commissioner, as soon as practicable after the effective date of this Act, to adopt any rules necessary to implement Chapter 444, Health and Safety Code, as added by this Act.

SECTION 4. Requires a state agency, if necessary for implementation of a provision of this Act, to request a waiver or authorization from a federal agency, and authorizes a delay of implementation until such a waiver or authorization is granted.

SECTION 5. Effective date: September 1, 2023.