By: Talarico, Frank, Burrows, Rose, KlickH.B. No. 25Substitute the following for H.B. No. 25:C.S.H.B. No. 25

A BILL TO BE ENTITLED

1	AN ACT
2	relating to wholesale importation of prescription drugs in this
3	state; authorizing a fee.
4	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
5	SECTION 1. This Act may be cited as the Wholesale
6	Prescription Drug Importation Act.
7	SECTION 2. Subtitle A, Title 6, Health and Safety Code, is
8	amended by adding Chapter 444 to read as follows:
9	CHAPTER 444. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM
10	Sec. 444.001. DEFINITIONS. In this chapter:
11	(1) "Canadian supplier" means a manufacturer,
12	wholesale distributor, or pharmacy that is appropriately licensed
13	or permitted under Canadian federal or provincial laws and rules to
14	manufacture, distribute, or dispense prescription drugs.
15	(2) "Commission" means the Health and Human Services
16	Commission.
17	(3) "Prescription drug wholesaler" means a person
18	licensed as a wholesale distributor under Subchapter N, Chapter
19	431, that contracts with this state to import prescription drugs
20	under the program.
21	(4) "Program" means the wholesale prescription drug
22	importation program established under this chapter.
23	Sec. 444.002. ESTABLISHMENT OF WHOLESALE PRESCRIPTION DRUG
24	IMPORTATION PROGRAM. (a) The commission shall establish the

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1	wholesale prescription drug importation program to provide lower
2	cost prescription drugs available outside of the United States to
3	consumers in this state at the lower cost.
4	(b) The commission shall implement the program by:
5	(1) contracting with one or more prescription drug
6	wholesalers and Canadian suppliers to import prescription drugs and
7	provide prescription drug cost savings to consumers in this state;
8	(2) developing a registration process for health
9	benefit plan issuers, health care providers, and pharmacies to
10	obtain and dispense prescription drugs imported under the program;
11	(3) developing a list of prescription drugs, including
12	the prices of those drugs, that meet the requirements of Section
13	444.003 and publishing the list on the commission's Internet
14	website;
15	(4) establishing an outreach and marketing plan to
16	generate program awareness;
17	(5) establishing and administering a telephone call
18	center or electronic portal to provide information about the
19	program;
20	(6) ensuring the program and the prescription drug
21	wholesalers that contract with this state under Subdivision (1)
22	comply with the tracking, tracing, verification, and
23	identification requirements of 21 U.S.C. Section 360eee-1;
24	(7) prohibiting the distribution, dispensing, or sale
25	of prescription drugs imported under this chapter outside the
26	boundaries of this state; and
27	(8) performing any other duties the executive

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1	commissioner determines necessary to implement the program.
2	(c) The commission shall ensure that the program meets the
3	requirements of 21 U.S.C. Section 384.
4	(d) In developing the program, the commission may consult
5	with interested parties.
6	Sec. 444.003. ELIGIBLE PRESCRIPTION DRUGS. A prescription
7	drug may be imported into this state under the program only if the
8	<u>drug:</u>
9	(1) meets the United States Food and Drug
10	Administration's standards related to prescription drug safety,
11	effectiveness, misbranding, and adulteration;
12	(2) does not violate any federal patent laws through
13	its importation;
14	(3) is expected to generate cost savings for
15	consumers; and
16	(4) is not:
17	(A) listed as a controlled substance under state
18	or federal law;
19	(B) a biological product;
20	(C) an infused drug;
21	(D) an intravenously injected drug;
22	(E) a drug that is inhaled during surgery; or
23	(F) a parenteral drug.
24	Sec. 444.004. ANTICOMPETITIVE BEHAVIOR MONITORING. The
25	commission, in consultation with the attorney general, shall
26	identify and monitor any potential anticompetitive activities in
27	industries affected by the program.

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1	Sec. 444.005. PROGRAM FUNDING. In addition to money
2	appropriated by the legislature, the commission may impose a fee on
3	each prescription drug sold under the program or establish another
4	funding method to administer the program.
5	Sec. 444.006. AUDIT PROCEDURES. The executive commissioner
6	by rule shall develop procedures to effectively audit a
7	prescription drug wholesaler participating in the program.
8	Sec. 444.007. ANNUAL REPORTING. Not later than December 1
9	of each year, the commission shall submit a report to the governor
10	and the legislature regarding the operation of the program during
11	the preceding state fiscal year, including:
12	(1) which prescription drugs and Canadian suppliers
13	are included in the program;
14	(2) the number of health benefit plan issuers, health
15	care providers, and pharmacies participating in the program;
16	(3) the number of prescriptions dispensed through the
17	program;
18	(4) the estimated cost savings to consumers, health
19	plans, employers, and this state since the establishment of the
20	program and during the preceding state fiscal year;
21	(5) information regarding the implementation of the
22	audit procedures under Section 444.006; and
23	(6) any other information:
24	(A) the governor or the legislature requests; or
25	(B) the commission considers necessary.
26	SECTION 3. As soon as practicable after the effective date
27	of this Act, the executive commissioner of the Health and Human

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Services Commission shall adopt any rules necessary to implement
Chapter 444, Health and Safety Code, as added by this Act.

3 SECTION 4. If before implementing any provision of this Act 4 a state agency determines that a waiver or authorization from a 5 federal agency is necessary for implementation of that provision, 6 the agency affected by the provision shall request the waiver or 7 authorization and may delay implementing that provision until the 8 waiver or authorization is granted.

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SECTION 5. This Act takes effect September 1, 2023.