HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE A. FOOD AND DRUG HEALTH REGULATIONS

Chapter 444, consisting of Secs. 444.001 to 444.007, was added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2.

For another Chapter 444, consisting of Secs. 444.001 to 444.007, added by Acts 2023, 88th Leg., R.S., Ch. 2 (S.B. 497), Sec. 2, see Sec. 444.001 et seq., post.

CHAPTER 444. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the following section.

Sec. 444.001. 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 the Health and Human Services Commission.

(3) "Prescription drug wholesaler" means a person licensed as a wholesale distributor under Subchapter N, Chapter 431, that contracts with this state to import prescription drugs under the program.

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

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the following section.

Sec. 444.002. ESTABLISHMENT OF WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM. (a) The commission shall establish the wholesale prescription drug importation program to provide lower

cost prescription drugs available outside of the United States to consumers in this state at the lower cost.

(b) The commission shall 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 the commission'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 determines necessary to implement the program.

(c) The commission shall ensure that the program meets the requirements of 21 U.S.C. Section 384.

(d) In developing the program, the commission may consult with interested parties.

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the

following section.

Sec. 444.003. ELIGIBLE PRESCRIPTION DRUGS. A prescription drug may 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.

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the following section.

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

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the following section.

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

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the following section.

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

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.

The following section was amended by the 89th Legislature. Pending publication of the current statutes, see H.B. 1620, 89th Legislature, Regular Session, for amendments affecting the following section.

Sec. 444.007. ANNUAL REPORTING. Not later than December 1 of each year, the commission shall 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) the commission considers necessary.

Added by Acts 2023, 88th Leg., R.S., Ch. 655 (H.B. 25), Sec. 2, eff. September 1, 2023.