

Amend SB 410 by adding the following appropriately numbered SECTIONS to the bill and renumbering subsequent SECTIONS of the bill accordingly:

SECTION _____. The legislature finds that:

(1) prescription drugs are expensive to the point that some residents of this state have been forced to choose between purchasing prescription drugs and paying for other essentials, such as groceries or rent;

(2) prescription drugs can be purchased at much lower costs in Canada;

(3) scams offering low-cost prescription drugs are prevalent on the Internet and in spam e-mail, and these practices make it difficult for consumers in this state to determine how and where to purchase safe and effective prescription drugs at affordable prices;

(4) the Regulatory Procedures Manual of the Federal Drug Administration authorizes agency personnel to allow the importation of products regulated by that agency when the quantity and purpose are clearly for personal use and the product does not present an unreasonable risk to the user; and

(5) other states and municipalities provide Internet websites and other methods to allow residents of those states or municipalities to safely purchase prescription drugs from Canada.

SECTION _____. Subchapter A, Chapter 554, Occupations Code, is amended by adding Section 554.016 to read as follows:

Sec. 554.016. CANADIAN PHARMACY INSPECTION; DESIGNATION; FEES; INFORMATION. (a) The board shall designate at least one and not more than 10 Canadian pharmacies whose primary business is to dispense prescription drugs under prescription drug orders to Canadian residents, as having passed inspection by the board for shipping, mailing, or delivering to this state a prescription dispensed under a prescription drug order to a resident in this state.

(b) The board by rule shall set fees in amounts reasonable and necessary to cover the costs incurred by the board in inspecting Canadian pharmacies as provided by Subsection (a).

(c) The board shall establish and maintain an Internet

website to provide information necessary to enable residents of this state to conveniently order prescription drugs from Canadian pharmacies designated by the board as having passed inspection to dispense prescription drugs to residents in this state in accordance with this subtitle and board rules. The board shall include on the website a statement that the board is not liable for any act or omission of a Canadian pharmacy designated as having passed inspection to dispense prescription drugs to residents in this state.

SECTION _____. Subchapter B, Chapter 556, Occupations Code, is amended by adding Section 556.0555 to read as follows:

Sec. 556.0555. INSPECTIONS. (a) At least annually, the board shall conduct random inspections of Canadian pharmacies designated under Section 554.016 as necessary to ensure compliance with the safety standards and other requirements of this subtitle and board rules.

(b) Notwithstanding the requirements of this chapter, the board by rule may establish the standards and procedures for inspections under this section.

(c) The board may enter into a written agreement with another state for an agency or employee of the state to perform services for the board related to inspecting a Canadian pharmacy designated by the board under Section 554.016 to dispense prescription drugs to residents in this state. This subsection does not apply to the initial inspection of the pharmacy.

SECTION _____. Section 560.001, Occupations Code, is amended by adding Subsection (c) to read as follows:

(c) A pharmacy located in Canada may not ship, mail, or deliver to this state a prescription drug dispensed under a prescription drug order to a resident of this state unless the pharmacy is designated by the board under Section 554.016.

SECTION _____. Subchapter B, Chapter 560, Occupations Code, is amended by adding Section 560.0525 to read as follows:

Sec. 560.0525. ADDITIONAL QUALIFICATION REQUIREMENTS FOR CANADIAN PHARMACIES. (a) To pass an inspection by the board, a Canadian pharmacy must meet Texas licensing standards.

(b) In addition to satisfying the other requirements of this

chapter, to qualify for designation by the board under Section 554.016, a Canadian pharmacy applicant must submit to the board:

(1) evidence satisfactory to the board that the applicant holds a pharmacy license, registration, or permit in good standing issued by Canada or the Canadian province in which the pharmacy is located and is not subject to any pending disciplinary action or legal action by any regulatory authority;

(2) the name and address of the pharmacy's owner and pharmacist-in-charge for service of process;

(3) evidence of the applicant's ability to provide to the board, not later than 72 hours after the time the board requests the record, a record of a prescription drug order authorizing the pharmacy to dispense a prescription drug to a resident of this state;

(4) an affidavit by the pharmacist-in-charge that states the pharmacist has read and understands this subtitle and the rules adopted under this subtitle that relate to a Canadian pharmacy designated by the board as having passed inspection to dispense prescription drugs to residents in this state;

(5) evidence satisfactory to the board that the applicant meets the standards established by board rule to ensure customer safety for each order filled and in the dispensing, storing, packaging, shipping, and delivering of prescription drugs; and

(6) evidence satisfactory to the board that the applicant's employees hold the appropriate Canadian licenses required to dispense prescription drugs in Canada.

(c) Before a Canadian pharmacy is designated as having passed inspection to dispense prescription drugs to residents in this state, a representative of the board shall visit the pharmacy's facilities and review the pharmacy's compliance with the requirements and safety standards established under this subtitle.

SECTION ____ . Section 562.101, Occupations Code, is amended by adding Subsection (f-1) to read as follows:

(f-1) A Canadian pharmacy designated by the board as having passed inspection to dispense prescription drugs to residents in this state is required to be under the continuous on-site

supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of Canada or of the Canadian province in which the Canadian pharmacy is located to serve as the pharmacist-in-charge of the Canadian pharmacy.

SECTION _____. Subchapter C, Chapter 562, Occupations Code, is amended by adding Section 562.111 to read as follows:

Sec. 562.111. PRESCRIPTION DRUG ORDER FOR CONSUMER. (a) A pharmacy in this state may order for a consumer a prescription drug from a Canadian pharmacy designated by the board under Section 554.016 to dispense prescription drugs to residents in this state.

(b) A pharmacy may order a prescription drug under this section only with the knowledge and clear consent of the consumer.

SECTION _____. Chapter 562, Occupations Code, is amended by adding Subchapter E to read as follows:

SUBCHAPTER E. PRACTICE BY CANADIAN PHARMACY

Sec. 562.201. ADDITIONAL PRACTICE REQUIREMENTS. In addition to complying with the other requirements of this chapter, a Canadian pharmacy designated by the board under Section 554.016 shall:

(1) dispense a prescription drug to a resident of this state only under the lawful order of a practitioner licensed in the United States;

(2) dispense to a resident of this state only a prescription drug that is approved by Canada's Therapeutic Products Directorate for sale to residents of Canada;

(3) dispense to a resident of this state a prescription drug in the original, unopened manufacturer's packaging whenever possible; and

(4) dispense to a resident of this state only drugs prescribed for long-term use.

Sec. 562.202. LIMITATIONS ON PRACTICE. A Canadian pharmacy designated by the board under Section 554.016 to dispense prescription drugs to residents in this state may not:

(1) dispense to a resident of this state a prescription drug for which there is not an equivalent drug approved by the United States Food and Drug Administration for sale

in the United States;

(2) dispense to a resident of this state a prescription drug that cannot be safely shipped by mail, common carrier, or delivery service;

(3) dispense in one order to a resident of this state a quantity of a prescription drug that exceeds:

(A) a three-month supply; or

(B) the amount ordered by the practitioner;

(4) fill a prescription drug order for a consumer who is a resident of this state that the consumer indicates is the consumer's first prescription for that drug; or

(5) dispense to a resident of this state any of the following:

(A) a substance designated as a controlled substance under Chapter 481, Health and Safety Code (Texas Controlled Substances Act);

(B) a biological product, as described by Section 351, Public Health Service Act (42 U.S.C. Section 262);

(C) an infused drug, including a peritoneal dialysis solution;

(D) an intravenously injected drug; or

(E) a drug that is inhaled during surgery.

Sec. 562.203. COMPLAINT REPORT. A Canadian pharmacy designated by the board under Section 554.016 to dispense prescription drugs to residents in this state shall provide to the board periodic reports in accordance with board rules on each complaint received by the pharmacy from a consumer in this state who purchases a prescription drug from the pharmacy.

Sec. 562.204. PRICE LIST. A Canadian pharmacy designated by the board under Section 554.016 shall:

(1) compile and maintain a current price list for prescription drugs provided to residents in this state; and

(2) guarantee those prices for not less than 30 days from the date the list is effective.

SECTION _____. (a) Not later than the 30th day after the effective date of this Act, the Texas State Board of Pharmacy shall adopt the initial rules necessary to implement the changes in law

made by this Act to Subtitle J, Title 3, Occupations Code, in the manner provided by law for adoption of emergency rules. This subsection expires January 1, 2006.

(b) Not later than January 1, 2006, the Texas State Board of Pharmacy shall adopt the rules necessary to implement the changes in law made by this Act to Subtitle J, Title 3, Occupations Code.

(c) The requirements for a Canadian pharmacy to be designated under Section 554.016, Occupations Code, as added by this Act, to dispense prescription drugs in this state under Subtitle J, Title 3, Occupations Code, as amended by this Act, take effect March 1, 2006.