

ENGROSSED HOUSE
BILL NO. 2844

By: Steele, Hamilton, Shelton
and Lindley of the House

and

Adelson of the Senate

An Act relating to professions and occupations; enacting the Drug Reimportation Act; authorizing the Board of Pharmacy to designate Canadian pharmacies to fill prescriptions of residents of this state; providing for inspections; specifying requirements for pharmacies to qualify for designation; providing procedures and standards for filling prescriptions; prohibiting certain actions; requiring reports; requiring certain approval prior to implementation of act; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.51 of Title 59, unless there is created a duplication in numbering, reads as follows:

This act shall be known and cited as the "Drug Reimportation Act".

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.52 of Title 59, unless there is created a duplication in numbering, reads as follows:

A. The Board of Pharmacy shall designate at least one and not more than ten 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 of this section.

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 the Drug Reimportation Act 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 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.53 of Title 59, unless there is created a duplication in numbering, reads as follows:

A. At least annually, the Board of Pharmacy shall conduct random inspections of Canadian pharmacies designated under Section 2 of the Drug Reimportation Act as necessary to ensure compliance with the safety standards and other requirements of the Drug Reimportation Act and Board rules.

B. Notwithstanding the requirements of the Drug Reimportation Act, 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 2 of this act to dispense prescription drugs to residents in this state. This subsection does not apply to the initial inspection of the pharmacy.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.54 of Title 59, unless there is created a duplication in numbering, reads as follows:

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 of Pharmacy under Section 2 of this act.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.55 of Title 59, unless there is created a duplication in numbering, reads as follows:

A. To pass an inspection by the Board of Pharmacy, a Canadian pharmacy must meet Oklahoma licensing standards.

B. In addition to satisfying the other requirements of the Drug Reimportation Act, to qualify for designation by the Board under Section 2 of this act, 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 owner of the pharmacy and pharmacist-in-charge for service of process;

3. Evidence of the ability of the applicant to provide to the Board, not later than seventy-two (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 the Drug Reimportation Act and the rules promulgated under the Drug Reimportation Act that relate to the 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 employees of the applicant 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 facilities of the pharmacy and review the compliance of the pharmacy with requirements and safety standards established under the Drug Reimportation Act.

SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.56 of Title 59, unless there is created a duplication in numbering, reads as follows:

A Canadian pharmacy designated by the Board of Pharmacy 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 7. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.57 of Title 59, unless there is created a duplication in numbering, reads as follows:

A. A pharmacy in this state may order for a consumer a prescription drug from a Canadian pharmacy designated by the Board

of Pharmacy under Section 2 of this act 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 8. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.58 of Title 59, unless there is created a duplication in numbering, reads as follows:

In addition to complying with the other requirements of the Drug Reimportation Act, a Canadian pharmacy designated by the Board of Pharmacy under Section 2 of this act 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 the Therapeutic Products Directorate in Canada for sale to residents of Canada;

3. Dispense to a resident of this state a prescription drug in the original, unopened packaging of the manufacturer whenever possible; and

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

SECTION 9. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.59 of Title 59, unless there is created a duplication in numbering, reads as follows:

A Canadian pharmacy designated by the Board of Pharmacy under Section 2 of this act 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 first prescription of the consumer 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 the Uniform Controlled Dangerous Substance Act,
- b. a biological product, as described by Section 351, Public Health Services 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.

SECTION 10. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.60 of Title 59, unless there is created a duplication in numbering, reads as follows:

A Canadian pharmacy designated by the Board of Pharmacy under Section 2 of this act 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.

SECTION 11. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.61 of Title 59, unless there is created a duplication in numbering, reads as follows:

A Canadian pharmacy designated by the Board of Pharmacy under Section 2 of this act 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 thirty (30) days from the date the list is effective.

SECTION 12. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.62 of Title 59, unless there is created a duplication in numbering, reads as follows:

The effect of the provisions of the Drug Reimportation Act shall be contingent upon approval by the United States Food and Drug Administration.

SECTION 13. This act shall become effective November 1, 2006.

Passed the House of Representatives the 16th day of March, 2006.

Presiding Officer of the House of
Representatives

Passed the Senate the ____ day of _____, 2006.

Presiding Officer of the Senate