

STATE OF OKLAHOMA

1st Session of the 50th Legislature (2005)

SENATE BILL 977

By: Adelson

AS INTRODUCED

An Act relating to professions and occupations; creating the Prescription Drug Reimportation Act; providing short title; defining terms; providing for certification of Canadian suppliers of prescription drugs according to specified criteria; prohibiting importation of drugs without certain certification; specifying list of entities authorized to import certain drugs; providing exception; providing for violation of provisions and punishment; prohibiting certain action without a license and paying fees; providing for license application and reciprocity; providing for certain notification to specified consumer or patient; providing for promulgation and content of rules; authorizing certain procurement; 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 353.13B of Title 59, unless there is created a duplication in numbering, reads as follows:

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

B. As used in the Prescription Drug Reimportation Act:

1. "Board" means the Board of Pharmacy;

2. "Certified Canadian Supplier" means a supplier of prescription drugs located in Canada, certified by the Board of Pharmacy as meeting the standards necessary for the importation of prescription drugs into this state;

3. "Delivery" means the actual, constructive or attempted transfer of a drug or drug device from one person to another, whether or not for a consideration;

4. "Dispense" or "Dispensing" means the preparation and delivery of a drug to a patient or a patient's agent pursuant to a prescription drug order in a suitable container with appropriate labeling for subsequent administration to or use by a patient;

5. "Distributing" means the delivery of a drug other than by administration or dispensing;

6. "Drug" or "prescription drug", means any drug for human consumption required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to the provisions of Section 503(b) of the Federal Food, Drug and Cosmetic Act as amended through January 1, 1991, other than:

- a. a controlled dangerous substance as defined in Section 2-101 of Title 63 of the Oklahoma Statutes,
- b. a biological product; as defined in Section 351 of the Public Health Service Act (42 U.S.C. 262),
- c. an infused drug, including peritoneal dialysis solutions,
- d. an intravenously injected drug, or
- e. a drug that is inhaled during surgery;

7. "Pharmacist" means an individual licensed by the Board of Pharmacy to engage in the practice of pharmacy;

8. "Pharmacy" means any place licensed by the Board of Pharmacy where drugs are dispensed and pharmaceutical care is provided to residents of this state;

9. "Prescription drug order" means a written or oral order of a prescriber for a drug for a specific patient; and

10. "Wholesale drug distributor" means a wholesale drug distributor engaged in the wholesale distribution of prescription drugs.

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.13C of Title 59, unless there is created a duplication in numbering, reads as follows:

A. Any licensed pharmacist in this state is authorized, with a valid prescription, to procure prescription drugs from a certified Canadian supplier and to import those drugs into this state for dispensing to patients residing in this state.

B. Any licensed wholesale drug distributor in this state is authorized to procure prescription drugs from a certified Canadian supplier and to import those drugs into this state for dispensing to licensed pharmacists.

C. The Board of Pharmacy shall certify Canadian suppliers of prescription drugs for distribution within this state who meet the following criteria:

1. Are located in Canada;
  2. Allow inspection of their facilities and review of their safety protocols by the Board;
  3. Maintain Canadian licensure to operate as a pharmacy and comply with applicable provincial and Canadian laws and regulations;
  4. Maintain membership with the Canadian International Pharmacy Association;
  5. Require that the pharmacy's employees have necessary Canadian licenses;
  6. Provide only prescription medications that are approved by the Government of Canada's Therapeutic Products Directorate for sale in Canada;
  7. Exclude drugs for which there is no equivalent approved by the Food and Drug Administration for sale in the United States and drugs that cannot be safely shipped via mail order;
  8. Use the unopened manufacturer's packaging whenever possible;
- and

9. Provide periodic reports to the Board regarding any complaints from Oklahoma customers.

D. No person may import prescription drugs from Canada for resale in this state without first being certified by the Board of Pharmacy or having authority from the Food and Drug Administration pursuant to subchapter VIII of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 381 et seq. A violation of this provision is a felony punishable by up to two (2) years imprisonment, a fine of up to Two Thousand Dollars (\$2,000.00), or both.

E. Only licensed wholesalers, pharmacies or pharmacists or persons authorized pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 381 et seq. are authorized to import or facilitate the importation of prescription drugs from Canada into the United States; provided, however, nothing herein shall be deemed to prevent a citizen of this state from procuring prescription drugs from a Canadian pharmacy for personal use. A violation of this provision shall be a felony punishable by up to two (2) years imprisonment, a fine of up to Two Thousand Dollars (\$2,000.00), or both.

F. No out-of-state wholesale drug distributor may conduct business in this state without first obtaining a license from the Board and paying the license fee set by the Board. Application for an out-of-state wholesale drug distributor license under this section shall be made on a form provided by the Board. An out-of-state wholesale drug distributor may obtain the license required by this act on the basis of reciprocity if the out-of-state wholesale drug distributor possesses a valid license granted by another state or a Canadian province pursuant to standards comparable to those in this state, and the other state or Canadian province extends reciprocal treatment under its laws to wholesale drug distributors of this state.

G. Any pharmacist in this state dispensing drugs procured from a Canadian source shall notify the consumer or patient of such fact prior to dispensing the drug.

H. The Board of Pharmacy may promulgate rules to implement the issuance of the certification required by subsection D of this section, and the enforcement provisions of this act. The rules may include the following:

1. Definition of terms;
2. Use of prescribed forms;
3. Reporting requirements;
4. Enforcement procedures; and
5. Fee requirements.

I. Citizens of this state shall be authorized to procure prescription drugs from Canadian pharmacies for personal use.

SECTION 3. This act shall become effective November 1, 2005.

50-1-1121

CJ

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