ENGROSSED HOUSE AMENDMENT
TO
ENGROSSED SENATE BILL NO. 977

By: Adelson, Lawler, Leftwich and Rabon of the Senate

and

Hamilton of the House

(professions and occupations - Prescription Drug Reimportation Act – codification - effective date – emergency)

AUTHORS: Add the following House Coauthors: Lindley, Brown and Shelton

AMENDMENT NO. 1. Strike the stricken title, enacting clause and entire bill and insert

"(professions and occupations - Prescription Drug Reimportation Act – codification)

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 and 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. “Permitted country” means Switzerland or a member country of the European Union as constituted as of January 1, 2003;

8. “Certified permitted country supplier” means a supplier of prescription drugs located in Switzerland or in a member country of the European Union as constituted as of January 1, 2003, and certified by the Board of Pharmacy as meeting the standards necessary for the importation of prescription drugs into this state;

9. “Pharmacist” means an individual licensed by the Board of Pharmacy to engage in the practice of pharmacy;

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

11. “Prescription drug order” means a written or oral order of a prescriber for a drug for a specific patient; and

12. “Wholesale drug distributor” means an entity 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 or a certified permitted country 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 hereby authorized to procure prescription drugs from a certified Canadian or permitted country supplier and to import those drugs into this state for dispensing to licensed pharmacists.

C. The Board of Pharmacy shall certify Canadian and permitted country suppliers of prescription drugs to distribute prescription drugs within this state who meet the following criteria:

1. Allow inspection of their facilities and review of their safety protocols by the Board;

2. Maintain licensure from Canada or a permitted country to operate as a pharmacy and comply with applicable provincial laws and regulations;

3. Maintain membership with the Canadian International Pharmacy Association if the supplier is Canadian;

4. Require that the pharmacy's employees have necessary licenses from Canada or a permitted country;

5. Provide only prescription medications that are approved by the Government of Canada's Therapeutic Products Directorate for sale in Canada if the supplier is Canadian;

6. 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;

7. Use the unopened manufacturer's packaging whenever possible; and

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

D. No person may import prescription drugs from Canada or a permitted country 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., Section 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., Section 381 et seq., are authorized to import or facilitate the importation of prescription drugs from Canada or a permitted country into the United States; provided, however, nothing herein shall be deemed to prevent a citizen of this state from procuring prescription drugs from a pharmacy in Canada or a permitted country 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, a Canadian province or a permitted country pursuant to standards comparable to those in this state, and the other state, Canadian province or permitted country extends reciprocal treatment under its laws to wholesale drug distributors of this state.

G. Any pharmacist in this state dispensing drugs procured from a certified Canadian or permitted country supplier 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 or permitted country pharmacies for personal use.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.13D of Title 59, unless there is created a duplication in numbering, reads as follows:

Sections 1 and 2 of this act shall become effective only upon certification by the Oklahoma Attorney General that the federal Food and Drug Administration has approved the importation of drugs from foreign countries.”

Passed the House of Representatives the 28th day of April, 2005.

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Presiding Officer of the House of Representatives

Passed the Senate the ____ day of _____, 2005.

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Presiding Officer of the Senate