FIRST REGULAR SESSION

HOUSE BILL NO. 667

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HELMS.

1572H.01I DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal sections 338.240, 338.250, 338.270, 338.315, 338.333, 338.337, and 338.340, RSMo, and to enact in lieu thereof nine new sections relating to pharmacies.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 338.240, 338.250, 338.270, 338.315, 338.333, 338.337, and 338.340, RSMo, are repealed and nine new sections enacted in lieu thereof, to be known as sections 195.422, 338.222, 338.240, 338.250, 338.270, 338.315, 338.333, 338.337, and 338.340, to read as follows:

195.422. No state official or law enforcement officer shall impede or inhibit the importation of a prescription drug for personal use so long as the patient has a valid prescription from a prescriber.

338.222. The board shall allow a pharmacy located in a country outside of the United States to be licensed in this state if such pharmacy is licensed in its local jurisdiction under legal standards comparable to those that are to be met by a pharmacy in this state.

338.240. 1. Upon evidence satisfactory to the said Missouri board of pharmacy:

(1) That the pharmacy for which a permit, or renewal thereof, is sought, will be conducted in full compliance with sections 338.210 to 338.300, with existing laws, and with the rules and regulations as established hereunder by said board;

(2) That the equipment and facilities of such pharmacy are such that it can be operated in a manner not to endanger the public health or safety;

(3) That such pharmacy is equipped with proper pharmaceutical and sanitary appliances and kept in a clean, sanitary and orderly manner;

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

(4) That the management of said pharmacy is under the supervision of either a registered pharmacist, or an owner or employee of the owner, who has at his or her place of business a registered pharmacist employed for the purpose of compounding physician's or veterinarian's prescriptions in the event any such prescriptions are compounded or sold;

(5) That said pharmacy is operated in compliance with the rules and regulations legally prescribed with respect thereto by the Missouri board of pharmacy, a permit or renewal thereof shall be issued to such persons as the said board of pharmacy shall deem qualified to conduct such pharmacy.

2. In lieu of a registered pharmacist as required by subdivision (4) of subsection 1 of this section, a pharmacy permit holder that only holds a class L veterinary permit and no other pharmacy permit may designate a supervising registered pharmacist who shall be responsible for reviewing the activities and records of the class L pharmacy permit holder as established by the board by rule. The supervising registered pharmacist shall not be required to be physically present on site during the business operations of a class L pharmacy permit holder identified in subdivision (5) of subsection 1 of this section when noncontrolled legend drugs under 21 U.S.C. Section 353 are being dispensed for use in animals, but shall be specifically present on site when any noncontrolled drugs for use in animals are being compounded.

3. If practicable and if it would maintain the board's ability to uphold the public health or safety of a patient, for any pharmacy located outside of the United States, the board shall allow any evidence required under subsection 1 of this section to be provided electronically.

338.250. No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals, so that the practice of pharmacy may be accurately and properly performed. The board shall prescribe the minimum of technical equipment which the pharmacy shall at all times possess. Such requirements may vary, depending upon the population served, but shall be consistently and uniformly enforced. No permit shall be issued or renewed for the operation of a pharmacy unless the pharmacy shall be operated in a manner and according to the rules and regulations prescribed by law and by the Missouri board of pharmacy with respect to obtaining and maintaining such a permit. Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as **drug laws of this** state and **[**~~federal drug laws~~**] the United States** on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

338.270. 1. Application blanks for renewal permits shall be mailed to each permittee on or before the first day of the month in which the permit expires and, if application for renewal of permit is not made before the first day of the following month, the existing permit, or renewal

thereof, shall lapse and become null and void upon the last day of that month. **If a pharmacy is located outside of the United States, the application for a renewal permit may be sent electronically under the time frame provided for in this subsection.**

2. The board of pharmacy shall not renew a nonresident pharmacy license if the renewal applicant does not hold a current pharmacy license or its equivalent in the state in which the nonresident pharmacy is located. **As used in this subsection, "nonresident pharmacy" also includes any pharmacy located outside of the United States.**

338.315. 1. Except as otherwise provided by the board by rule, it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug distributor, drug outsourcer, third-party logistics provider, or licensed pharmacy. **A drug distributor, drug outsourcer, third-party logistics provider, or pharmacy possessing a valid license or registration granted by another country located outside of the United States under legal standards comparable to those that are to be met by a drug distributor, drug outsourcer, third-party logistics provider, or pharmacy provider of this state is sufficient to satisfy the requirements of this section.** Any person who violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A misdemeanor. Any subsequent conviction shall constitute a class E felony.

2. Notwithstanding any other provision of law to the contrary, the sale, purchase, or trade of a prescription drug by a pharmacy to other pharmacies is permissible if the total dollar volume of such sales, purchases, or trades are in compliance with the rules of the board and do not exceed five percent of the pharmacy's total annual prescription drug sales.

3. Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Such records shall be maintained for two years and be readily available upon request by the board or its representatives.

4. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2012, shall be invalid and void.

338.333. 1. Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a

wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. The board may grant temporary licenses when the wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider first applies for a license to operate within the state. Temporary licenses shall remain valid until such time as the board shall find that the applicant meets or fails to meet the requirements for regular licensure. No license shall be issued or renewed for a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider, unless such drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider meets the requirements of section 338.335.

2. An agent or employee of any licensed or registered wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if the agent or employee is acting in the usual course of his or her business or employment.

3. The board may permit out-of-state wholesale drug distributors, drug outsourcers, third-party logistics provider, or out-of-state pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of reciprocity to the extent that the entity both:

(1) Possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state as prerequisites for obtaining a license under the laws of this state; and

(2) Distributes into Missouri from a state which would extend reciprocal treatment under its own laws to a wholesale drug distributor, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state.

4. The provisions of subsection 3 of this section shall not apply if a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider is located outside of the United States and licensed in its local jurisdiction under legal standards comparable to those that are to be met by a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider of this state.

338.337. **Except if a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider is located outside of the United States and licensed in its local jurisdiction under legal standards comparable to those that are to be met by a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider of this state,** it shall be

unlawful for any out-of-state wholesale drug distributor, out-of-state pharmacy acting as a distributor, drug outsourcers, or third-party logistics provider to do business in this state without first obtaining a license to do so from the board of pharmacy and paying the required fee, except as otherwise provided by section 338.335 and this section. Application for an out-of-state wholesale drug distributor's, drug outsourcer's, or out-of-state third-party logistics provider's license under this section shall be made on a form furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the Missouri department of revenue on any entity. Any out-of-state wholesale drug distributor that is a drug manufacturer and which produces and distributes from a facility which has been inspected and approved by the Food and Drug Administration, maintains current approval by the federal Food and Drug Administration, and has provided a copy of the most recent Food and Drug Administration Establishment Inspection Report to the board, and which is licensed by the state in which the distribution facility is located, or, if located within a foreign jurisdiction, is authorized and in good standing to operate as a drug manufacturer within such jurisdiction, need not be licensed as provided in this section but such out-of-state distributor shall register its business name and address with the board of pharmacy and pay a filing fee in an amount established by the board.

338.340. **Except if a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider is located outside of the United States and licensed in its local jurisdiction under legal standards comparable to those that are to be met by a drug distributor, pharmacy, drug outsourcer, or third-party logistics provider of this state,** no person acting as principal or agent for any out-of-state wholesale drug distributor, out-of-state pharmacy distributor, drug outsourcer, or out-of-state third-party logistics provider shall sell or distribute drugs in this state unless the entity has obtained a license pursuant to the provisions of sections 338.330 to 338.370.

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