SECOND REGULAR SESSION

SENATE COMMITTEE SUBSTITUTE FOR

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 1563

96TH GENERAL ASSEMBLY

Reported from the Committee on Commerce, Consumer Protection, Energy and the Environment, May 3, 2012, with recommendation that the Senate Committee Substitute do pass.

TERRY L. SPIELER, Secretary.

5569S.03C

AN ACT

To repeal sections 195.060, 195.080, 334.747, 338.315, and 338.333, RSMo, and to enact in lieu thereof five new sections relating to prescription drugs, with a penalty provision.

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

Section A. Sections 195.060, 195.080, 334.747, 338.315, and 338.333, RSMo, are repealed and five new sections enacted in lieu thereof, to be known as sections 195.060, 195.080, 334.747, 338.315, and 338.333, to read as follows:

195.060. 1. Except as provided in subsection **[**3**]** **4** of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The

EXPLANATION–Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

2. **A pharmacist, in good faith, may sell and dispense controlled substances to any person upon a prescription of a practitioner located in another state, provided that the:**

(1) Prescription was issued according to and in compliance with the applicable laws of that state and the United States; and

(2) Quantity limitations in subsection 2 of section 195.080 apply to prescriptions dispensed to patients located in this state.

3. The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such drugs, may sell the stock to a manufacturer, wholesaler, or pharmacist, but only on an official written order.

[3.**]** **4.** A pharmacist, in good faith, may sell and dispense any Schedule II drug or drugs to any person in emergency situations as defined by rule of the department of health and senior services upon an oral prescription by an authorized practitioner.

[4.**]** **5.** Except where a bona fide physician-patient-pharmacist relationship exists, prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate user or agent by mail or other common carrier.

195.080. 1. Except as otherwise in sections 195.005 to 195.425 specifically provided, sections 195.005 to 195.425 shall not apply to the following cases: prescribing, administering, dispensing or selling at retail of liniments, ointments, and other preparations that are susceptible of external use only and that contain controlled substances in such combinations of drugs as to prevent the drugs from being readily extracted from such liniments, ointments, or preparations, except that sections 195.005 to 195.425 shall apply to all liniments, ointments, and other preparations that contain coca leaves in any quantity or combination.

2. The quantity of Schedule II controlled substances prescribed or dispensed at any one time shall be limited to a thirty-day supply. The quantity

of Schedule III, IV or V controlled substances prescribed or dispensed at any one time shall be limited to a ninety-day supply and shall be prescribed and dispensed in compliance with the general provisions of sections 195.005 to 195.425. The supply limitations provided in this subsection may be increased up to three months if the physician describes on the prescription form or indicates via telephone, fax, or electronic communication to the pharmacy to be entered on or attached to the prescription form the medical reason for requiring the larger supply. The supply limitations provided in this subsection shall not apply if**:**

(1) The prescription is issued by a practitioner located in another state according to and in compliance with the applicable laws of that state and the United States and dispensed to a patient located in another state; or

(2) The prescription is dispensed directly to a member of the United States armed forces serving outside the United States.

3. The partial filling of a prescription for a Schedule II substance is permissible as defined by regulation by the department of health and senior services.

334.747. 1. A physician assistant with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in schedule III, IV, or V of section 195.017 when delegated the authority to prescribe controlled substances in a supervision agreement. Such authority shall be listed on the supervision verification form on file with the state board of healing arts. The supervising physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the physician assistant is permitted to prescribe. Any limitations shall be listed on the supervision form. Physician assistants shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances shall be limited to a five-day supply without refill. Physician assistants who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include **[**such**] the Drug Enforcement Administration** registration **[**numbers**] number** on prescriptions for controlled substances.

2. The supervising physician shall be responsible to determine and document the completion of at least one hundred twenty hours in a four-month period by the physician assistant during which the physician assistant shall

practice with the supervising physician on-site prior to prescribing controlled substances when the supervising physician is not on-site. Such limitation shall not apply to physician assistants of population-based public health services as defined in 20 CSR 2150-5.100 as of April 30, 2009.

3. A physician assistant shall receive a certificate of controlled substance prescriptive authority from the board of healing arts upon verification of the completion of the following educational requirements:

(1) Successful completion of an advanced pharmacology course that includes clinical training in the prescription of drugs, medicines, and therapeutic devices. A course or courses with advanced pharmacological content in a physician assistant program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency shall satisfy such requirement;

(2) Completion of a minimum of three hundred clock hours of clinical training by the supervising physician in the prescription of drugs, medicines, and therapeutic devices;

(3) Completion of a minimum of one year of supervised clinical practice or supervised clinical rotations. One year of clinical rotations in a program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency, which includes pharmacotherapeutics as a component of its clinical training, shall satisfy such requirement. Proof of such training shall serve to document experience in the prescribing of drugs, medicines, and therapeutic devices;

(4) A physician assistant previously licensed in a jurisdiction where physician assistants are authorized to prescribe controlled substances may obtain a state bureau of narcotics and dangerous drugs registration if a supervising physician can attest that the physician assistant has met the requirements of subdivisions (1) to (3) of this subsection and provides documentation of existing federal Drug Enforcement Agency registration.

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 or licensed pharmacy. 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 D 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 or pharmacy distributor 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 or pharmacy distributor 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 or pharmacy distributor 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 or pharmacy

distributor, unless such drug distributor or pharmacy distributor meets the requirements of section 338.335.

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

3. The board may permit out-of-state wholesale drug distributors 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 an out-of-state wholesale drug distributor or out-of-state pharmacy distributor 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 or pharmacy distributor 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 or pharmacy distributor of this state.

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