SECOND REGULAR SESSION

[P E R F E C T E D**]**

SENATE SUBSTITUTE NO. 2 FOR

SENATE BILL NO. 754

97TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Offered April 16, 2014.

Senate Substitute No. 2 adopted, April 16, 2014.

Taken up for Perfection April 16, 2014. Bill declared Perfected and Ordered Printed, as amended.

TERRY L. SPIELER, Secretary.

5477S.05P

AN ACT

To repeal sections 208.798, 338.059, and 338.220, RSMo, and to enact in lieu thereof five new sections relating to pharmacy.

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

Section A. Sections 208.798, 338.059, and 338.220, RSMo, are repealed and five new sections enacted in lieu thereof, to be known as sections 196.990, 208.798, 338.059, 338.165, and 338.220, to read as follows:

196.990. 1. As used in this section, the following terms shall mean:

(1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;

(2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present, including but not limited to restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas;

(3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(4) "Physician", a physician licensed in this state under chapter 334;

(5) "Provide", the supply of one or more epinephrine auto-

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

injectors to an individual;

(6) "Self-administration", a person's discretionary use of an epinephrine auto-injector.

2. A physician may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists, physicians, and other persons authorized to dispense prescription medications may dispense epinephrine auto-injectors under a prescription issued in the name of an authorized entity.

3. An authorized entity may acquire and stock a supply of epinephrine auto-injectors under a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements established by the department of health and senior services by rule. An authorized entity shall designate employees or agents who have completed the training required under this section to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4. An employee or agent of an authorized entity or any other person who has completed the training required under this section may use epinephrine auto-injectors prescribed under this section on the premises of or in connection with the authorized entity to:

(1) Provide an epinephrine auto-injector to any individual who the employee, agent, or other person believes in good faith is experiencing anaphylaxis for immediate self-administration, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy;

(2) Administer an epinephrine auto-injector to any individual who the employee, agent, or other person believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

5. An employee, agent, or other person described in subsection 4 of this section shall successfully complete an anaphylaxis training program prior to providing or administering an epinephrine auto-injector made available by an authorized entity and at least every two years following successful completion of the initial anaphylaxis

training program. Such training shall be conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or other entity or person approved by the department of health and senior services. Training may be conducted online or in person and, at a minimum, shall cover:

(1) Techniques on how to recognize symptoms of severe allergic reactions, including anaphylaxis;

(2) Standards and procedures for the storage and administration of an epinephrine auto-injector; and

(3) Emergency follow-up procedures.

The entity that conducts the training shall issue a certificate, on a form developed or approved by the department of health and senior services, to each person who successfully completes the anaphylaxis training program.

6. The following persons and entities shall not be liable for any injuries or related damages that result from the administration of, self-administration of, or failure to administer an epinephrine auto-injector in accordance with this section that may constitute ordinary negligence:

(1) An authorized entity that either does or does not possess and make available epinephrine auto-injectors and its employees, agents, and other trained persons;

(2) Any person who uses an epinephrine auto-injector made available under this section;

(3) A physician that prescribes epinephrine auto-injectors to an authorized entity; or

(4) Any person or entity that conducts the training described in subsection 5 of this section.

Such immunity does not apply to acts or omissions constituting gross negligence or willful or wanton conduct. The administration of an epinephrine auto-injector in accordance with this section shall not be considered the practice of medicine. The immunity from liability provided under this subsection is in addition to and not in lieu of that provided under section 537.037. An authorized entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or agents outside of this state if the entity or its

employee or agent are not liable for such injuries or related damages under the laws of the state in which such provision or administration occurred.

7. An authorized entity that possesses and makes available epinephrine auto-injectors shall submit to the department of health and senior services, on a form developed by the department, a report of each incident on the authorized entity's premises involving the administration of an epinephrine auto-injector. The department shall annually publish a report that summarizes all reports submitted to it under this subsection, but shall not include any identifying information regarding the persons to whom such epinephrine auto-injectors were administered.

8. An authorized entity that acquires a stock supply of epinephrine auto-injectors under a prescription issued in accordance with this section may make such epinephrine auto-injectors available to individuals other than the trained persons described in subsection 4 of this section if the epinephrine auto-injectors are stored in a locked secure container in accordance with manufacturer specifications and are made available only upon remote authorization by a physician via audio, televideo, or other similar means of electronic communication. Consultation with a physician for such purpose shall not be considered the practice of telemedicine or otherwise be construed as violating any law or rule regulating the physician's professional practice.

208.798. The provisions of sections 208.780 to 208.798 shall terminate on August 28, **[**2014**]** **2017**.

338.059. 1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug upon which is typed or written the following information:

(1) The date the prescription is filled;

(2) The sequential number **or other unique identifier**;

(3) The patient's name;

(4) The prescriber's directions for usage;

(5) The prescriber's name;

(6) The name and address of the pharmacy;

(7) The exact name and dosage of the drug dispensed;

(8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";

(9) When a generic substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist's records as required in section 338.100.

2. The label of any drug which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.

338.165. 1. As used in this section, the following terms mean:

(1) "Board", the Missouri board of pharmacy;

(2) "Hospital", a hospital as defined in section 197.020;

(3) "Hospital clinic or facility", a clinic or facility under the common control, management or ownership of the same hospital or hospital system;

(4) "Medical staff committee", the committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management;

(5) "Medication order", an order for a legend drug or device that is:

(a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and

(b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

(6) "Patient", an individual receiving medical diagnosis, treatment or care at a hospital or a hospital clinic or facility.

2. The department of health and senior services shall have sole authority and responsibility for the inspection and licensure of hospitals as provided by chapter 197 including, but not limited to all parts, services, functions, support functions and activities which contribute directly or indirectly to patient care of any kind whatsoever. However, the board may inspect a class B pharmacy or

any portion thereof that is not under the inspection authority vested in the department of health and senior services by chapter 197 to determine compliance with this chapter or the rules of the board. This section shall not be construed to bar the board from conducting an investigation pursuant to a public or governmental complaint to determine compliance by an individual licensee or registrant of the board with any applicable provisions of this chapter or the rules of the board.

3. The department of health and senior services shall have authority to promulgate rules in conjunction with the board governing medication distribution and the provision of medication therapy services by a pharmacist at or within a hospital. Rules may include, but are not limited to, medication management, preparation, compounding, administration, storage, distribution, packaging and labeling. Until such rules are jointly promulgated, hospitals shall comply with all applicable state law and department of health and senior services rules governing pharmacy services and medication management in hospitals. The rulemaking authority granted herein to the department of health and senior services shall not include the dispensing of medication by prescription.

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board. Medication therapy services may be provided by a pharmacist for patients of a hospital pursuant to a protocol with a physician as required by section 338.010 or pursuant to a protocol approved by the medical staff committee.

5. Medication may be dispensed by a class B hospital pharmacy pursuant to a prescription or a medication order.

6. A drug distributor license shall not be required to transfer medication from a class B hospital pharmacy to a hospital clinic or facility for patient care or treatment.

7. Medication dispensed by a hospital to a hospital patient for use or administration outside of the hospital under a medical staff-approved protocol for medication therapy shall be dispensed only by a prescription order for medication therapy from an individual physician for a specific patient.

8. Medication dispensed by a hospital to a hospital patient for

use or administration outside of the hospital shall be labeled as provided by rules jointly promulgated by the department of health and senior services and the board including, medication distributed for administration by or under the supervision of a health care practitioner at a hospital clinic or facility.

9. This section shall not be construed to preempt any law or rule governing controlled substances.

10. Any rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall only become effective 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 under 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, 2014, shall be invalid and void.

11. The board shall appoint an advisory committee to review and make recommendations to the board on the merit of all rules and regulations to be jointly promulgated by the board and the department of health and senior services pursuant to the joint rulemaking authority granted by this section. The advisory committee shall consist of:

(1) Two representatives designated by the Missouri Hospital Association, one of whom shall be a pharmacist;

(2) One pharmacist designated by the Missouri Society of Health System Pharmacists;

(3) One pharmacist designated by the Missouri Pharmacy Association;

(4) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that does not exceed fifty beds or from a critical access hospital as defined by the department of social services for purposes of MO HealthNet reimbursement;

(5) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that exceeds two hundred beds; and

(6) One pharmacist designated by the Board with experience in

the provision of hospital pharmacy services.

12. Nothing in this section shall be construed to limit the authority of a licensed health care provider to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

338.220. 1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. A permit shall not be required for an individual licensed pharmacist to perform nondispensing activities outside of a pharmacy, as provided by the rules of the board. A permit shall not be required for an individual licensed pharmacist to administer drugs, vaccines, and biologicals by protocol, as permitted by law, outside of a pharmacy. The following classes of pharmacy permits or licenses are hereby established:

(1) Class A: Community/ambulatory;

(2) Class B: Hospital **[**outpatient**]** pharmacy;

(3) Class C: Long-term care;

(4) Class D: Nonsterile compounding;

(5) Class E: Radio pharmaceutical;

(6) Class F: Renal dialysis;

(7) Class G: Medical gas;

(8) Class H: Sterile product compounding;

(9) Class I: Consultant services;

(10) Class J: Shared service;

(11) Class K: Internet;

(12) Class L: Veterinary;

(13) Class M: Specialty (bleeding disorder);

(14) Class N: Automated dispensing system (health care facility);

(15) Class O: Automated dispensing system (ambulatory care);

(16) Class P: Practitioner office/clinic.

2. Application for such permit or license shall be made upon a form furnished to the applicant; shall contain a statement that it is made under oath or affirmation and that its representations are true and correct to the best knowledge and belief of the person signing same, subject to the penalties of making a false affidavit or declaration; and shall be accompanied by a permit or license fee. The permit or license issued shall be renewable upon payment of a

renewal fee. Separate applications shall be made and separate permits or licenses required for each pharmacy opened, established, operated, or maintained by the same owner.

3. All permits, licenses or renewal fees collected pursuant to the provisions of sections 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general assembly.

4. Class L: veterinary permit shall not be construed to prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, or medicine, drug, or pharmaceutical product to be used for animals.

5. Except for any legend drugs under 21 U.S.C. Section 353, the provisions of this section shall not apply to the sale, dispensing, or filling of a pharmaceutical product or drug used for treating animals.

6. A "Class B Hospital Pharmacy" shall be defined as a pharmacy owned, managed or operated by a hospital as defined by section 197.020 or a clinic or facility under common control, management or ownership of the same hospital or hospital system. This section shall not be construed to require a class B hospital pharmacy permit or license for hospitals solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by, the department of health and senior services pursuant to chapter 197.

7. Upon application to the board, any hospital that holds a pharmacy permit or license on the effective date of this section shall be entitled to obtain a class B pharmacy permit or license without fee, provided such application shall be submitted to the board on or before January 1, 2015.

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