

SENATE SUBSTITUTE
FOR
SENATE BILL NO. 754

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:

1 Section A. Sections 208.798, 338.059, and 338.220, RSMo,
2 are repealed and five new sections enacted in lieu thereof, to be
3 known as sections 196.990, 208.798, 338.059, 338.165, and
4 338.220, to read as follows:

5 196.990. 1. As used in this section, the following terms
6 shall mean:

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

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

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

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

1 (5) "Provide", the supply of one or more epinephrine auto-
2 injectors to an individual;

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

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

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

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

27 (1) Provide an epinephrine auto-injector to any individual
28 who the employee, agent, or other person believes in good faith

1 is experiencing anaphylaxis for immediate self-administration,
2 regardless of whether the individual has a prescription for an
3 epinephrine auto-injector or has previously been diagnosed with
4 an allergy;

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

10 5. An employee, agent, or other person described in
11 subsection 4 of this section shall successfully complete an
12 anaphylaxis training program prior to providing or administering
13 an epinephrine auto-injector made available by an authorized
14 entity and at least every two years following successful
15 completion of the initial anaphylaxis training program. Such
16 training shall be conducted by a nationally recognized
17 organization experienced in training laypersons in emergency
18 health treatment or other entity or person approved by the
19 department of health and senior services. Training may be
20 conducted online or in person and, at a minimum, shall cover:

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

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

25 (3) Emergency follow-up procedures.

26
27 The entity that conducts the training shall issue a certificate,
28 on a form developed or approved by the department of health and

1 senior services, to each person who successfully completes the
2 anaphylaxis training program.

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

8 (1) An authorized entity that possesses and makes available
9 epinephrine auto-injectors and its employees, agents, and other
10 trained persons;

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

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

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

17
18 Such immunity does not apply to acts or omissions constituting
19 gross negligence or willful or wanton conduct. The
20 administration of an epinephrine auto-injector in accordance with
21 this section shall not be considered the practice of medicine.
22 The immunity from liability provided under this subsection is in
23 addition to and not in lieu of that provided under section
24 537.037. An authorized entity located in this state shall not be
25 liable for any injuries or related damages that result from the
26 provision or administration of an epinephrine auto-injector by
27 its employees or agents outside of this state if the entity or
28 its employee or agent are not liable for such injuries or related

1 damages under the laws of the state in which such provision or
2 administration occurred.

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

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

26 208.798. The provisions of sections 208.780 to 208.798
27 shall terminate on August 28, [2014] 2017.

28 338.059. 1. It shall be the duty of a licensed pharmacist

1 or a physician to affix or have affixed by someone under the
2 pharmacist's or physician's supervision a label to each and every
3 container provided to a consumer in which is placed any
4 prescription drug upon which is typed or written the following
5 information:

6 (1) The date the prescription is filled;

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

8 (3) The patient's name;

9 (4) The prescriber's directions for usage;

10 (5) The prescriber's name;

11 (6) The name and address of the pharmacy;

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

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

16 (9) When a generic substitution is dispensed, the name of
17 the manufacturer or an abbreviation thereof shall appear on the
18 label or in the pharmacist's records as required in section
19 338.100.

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

24 338.165. 1. As used in this section, the following terms
25 mean:

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

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

28 (3) "Hospital clinic or facility", a clinic or facility

1 under the common control, management or ownership of the same
2 hospital or hospital system;

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

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

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

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

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

17 2. The department of health and senior services shall have
18 sole authority and responsibility for the inspection and
19 licensure of hospitals as provided by chapter 197 including, but
20 not limited to all parts, services, functions, support functions
21 and activities which contribute directly or indirectly to patient
22 care of any kind whatsoever. However, the board may inspect a
23 class B pharmacy or any portion thereof that is not under the
24 inspection authority vested in the department of health and
25 senior services by chapter 197 to determine compliance with this
26 chapter or the rules of the board. This section shall not be
27 construed to bar the board from conducting an investigation
28 pursuant to a public or governmental complaint to determine

1 compliance by an individual licensee or registrant of the board
2 with any applicable provisions of this chapter or the rules of
3 the board.

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

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

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

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

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

6 8. Medication dispensed by a hospital to a hospital patient
7 for use or administration outside of the hospital shall be
8 labeled as provided by rules jointly promulgated by the
9 department of health and senior services and the board including,
10 medication distributed for administration by or under the
11 supervision of a health care practitioner at a hospital clinic or
12 facility.

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

15 10. Any rule, as that term is defined in section 536.010,
16 that is created under the authority delegated in this section
17 shall only become effective if it complies with and is subject to
18 all of the provisions of chapter 536 and, if applicable, section
19 536.028. This section and chapter 536 are nonseverable and if
20 any of the powers vested with the general assembly under chapter
21 536 to review, to delay the effective date, or to disapprove and
22 annul a rule are subsequently held unconstitutional, then the
23 grant of rulemaking authority and any rule proposed or adopted
24 after August 28, 2014, shall be invalid and void.

25 11. The board shall appoint an advisory committee to review
26 and make recommendations to the board on the merit of all rules
27 and regulations to be jointly promulgated by the board and the
28 department of health and senior services pursuant to the joint

1 rulemaking authority granted by this section. The advisory
2 committee shall consist of:

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

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

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

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

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

17 (6) One pharmacist designated by the Board with experience
18 in the provision of hospital pharmacy services.

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

23 338.220. 1. It shall be unlawful for any person,
24 copartnership, association, corporation or any other business
25 entity to open, establish, operate, or maintain any pharmacy as
26 defined by statute without first obtaining a permit or license to
27 do so from the Missouri board of pharmacy. A permit shall not be
28 required for an individual licensed pharmacist to perform

1 nondispensing activities outside of a pharmacy, as provided by
2 the rules of the board. A permit shall not be required for an
3 individual licensed pharmacist to administer drugs, vaccines, and
4 biologicals by protocol, as permitted by law, outside of a
5 pharmacy. The following classes of pharmacy permits or licenses
6 are hereby established:

- 7 (1) Class A: Community/ambulatory;
- 8 (2) Class B: Hospital [outpatient] pharmacy;
- 9 (3) Class C: Long-term care;
- 10 (4) Class D: Nonsterile compounding;
- 11 (5) Class E: Radio pharmaceutical;
- 12 (6) Class F: Renal dialysis;
- 13 (7) Class G: Medical gas;
- 14 (8) Class H: Sterile product compounding;
- 15 (9) Class I: Consultant services;
- 16 (10) Class J: Shared service;
- 17 (11) Class K: Internet;
- 18 (12) Class L: Veterinary;
- 19 (13) Class M: Specialty (bleeding disorder);
- 20 (14) Class N: Automated dispensing system (health care
21 facility);
- 22 (15) Class O: Automated dispensing system (ambulatory
23 care);
- 24 (16) Class P: Practitioner office/clinic.

25 2. Application for such permit or license shall be made
26 upon a form furnished to the applicant; shall contain a statement
27 that it is made under oath or affirmation and that its
28 representations are true and correct to the best knowledge and

1 belief of the person signing same, subject to the penalties of
2 making a false affidavit or declaration; and shall be accompanied
3 by a permit or license fee. The permit or license issued shall
4 be renewable upon payment of a renewal fee. Separate
5 applications shall be made and separate permits or licenses
6 required for each pharmacy opened, established, operated, or
7 maintained by the same owner.

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

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

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

24 6. A "Class B Hospital Pharmacy" shall be defined as a
25 pharmacy owned, managed or operated by a hospital as defined by
26 section 197.020 or a clinic or facility under common control,
27 management or ownership of the same hospital or hospital system.
28 This section shall not be construed to require a class B hospital

1 pharmacy permit or license for hospitals solely providing
2 services within the practice of pharmacy under the jurisdiction
3 of, and the licensure granted by, the department of health and
4 senior services pursuant to chapter 197.

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