

FIRST REGULAR SESSION

SENATE BILL NO. 29

96TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR BROWN.

Pre-filed December 1, 2010, and ordered printed.

TERRY L. SPIELER, Secretary.

0331L.01I

AN ACT

To repeal sections 338.010, 338.140, 338.150, 338.210, 338.220, 338.240, 338.315, and 338.330, RSMo, and to enact in lieu thereof eight new sections relating to veterinary legend drugs, with penalty provisions.

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

Section A. Sections 338.010, 338.140, 338.150, 338.210, 338.220, 338.240, 338.315, and 338.330, RSMo, are repealed and eight new sections enacted in lieu thereof, to be known as sections 338.010, 338.140, 338.150, 338.210, 338.220, 338.240, 338.315, and 338.330, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including **any legend drugs under 21 U.S.C. Section 353**; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, **and**

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

17 **veterinarians and their clients about legend drugs**, about the safe and
18 effective use of drugs and devices; and the offering or performing of those acts,
19 services, operations, or transactions necessary in the conduct, operation,
20 management and control of a pharmacy. No person shall engage in the practice
21 of pharmacy unless he is licensed under the provisions of this chapter. This
22 chapter shall not be construed to prohibit the use of auxiliary personnel under
23 the direct supervision of a pharmacist from assisting the pharmacist in any of his
24 **or her** duties. This assistance in no way is intended to relieve the pharmacist
25 from his **or her** responsibilities for compliance with this chapter and he **or she**
26 will be responsible for the actions of the auxiliary personnel acting in his **or her**
27 assistance. This chapter shall also not be construed to prohibit or interfere with
28 any legally registered practitioner of medicine, dentistry, **or** podiatry, or
29 veterinary medicine **only for use in animals**, or the practice of optometry in
30 accordance with and as provided in sections 195.070 and 336.220 in the
31 compounding, **administering, prescribing**, or dispensing of his **or her** own
32 prescriptions **or any medicine, drug, or pharmaceutical product**.

33 2. Any pharmacist who accepts a prescription order for a medication
34 therapeutic plan shall have a written protocol from the physician who refers the
35 patient for medication therapy services. The written protocol and the prescription
36 order for a medication therapeutic plan shall come from the physician only, and
37 shall not come from a nurse engaged in a collaborative practice arrangement
38 under section 334.104, or from a physician assistant engaged in a supervision
39 agreement under section 334.735.

40 3. Nothing in this section shall be construed as to prevent any person,
41 firm or corporation from owning a pharmacy regulated by sections 338.210 to
42 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

43 4. Nothing in this section shall be construed to apply to or interfere with
44 the sale of nonprescription drugs and the ordinary household remedies and such
45 drugs or medicines as are normally sold by those engaged in the sale of general
46 merchandise.

47 5. No health carrier as defined in chapter 376 shall require any physician
48 with which they contract to enter into a written protocol with a pharmacist for
49 medication therapeutic services.

50 6. This section shall not be construed to allow a pharmacist to diagnose
51 or independently prescribe pharmaceuticals.

52 7. The state board of registration for the healing arts, under section

53 334.125, and the state board of pharmacy, under section 338.140, shall jointly
54 promulgate rules regulating the use of protocols for prescription orders for
55 medication therapy services and administration of viral influenza vaccines. Such
56 rules shall require protocols to include provisions allowing for timely
57 communication between the pharmacist and the referring physician, and any
58 other patient protection provisions deemed appropriate by both boards. In order
59 to take effect, such rules shall be approved by a majority vote of a quorum of each
60 board. Neither board shall separately promulgate rules regulating the use of
61 protocols for prescription orders for medication therapy services and
62 administration of viral influenza vaccines. Any rule or portion of a rule, as that
63 term is defined in section 536.010, that is created under the authority delegated
64 in this section shall become effective only if it complies with and is subject to all
65 of the provisions of chapter 536 and, if applicable, section 536.028. This section
66 and chapter 536 are nonseverable and if any of the powers vested with the
67 general assembly pursuant to chapter 536 to review, to delay the effective date,
68 or to disapprove and annul a rule are subsequently held unconstitutional, then
69 the grant of rulemaking authority and any rule proposed or adopted after August
70 28, 2007, shall be invalid and void.

71 8. The state board of pharmacy may grant a certificate of medication
72 therapeutic plan authority to a licensed pharmacist who submits proof of
73 successful completion of a board-approved course of academic clinical study
74 beyond a bachelor of science in pharmacy, including but not limited to clinical
75 assessment skills, from a nationally accredited college or university, or a
76 certification of equivalence issued by a nationally recognized professional
77 organization and approved by the board of pharmacy.

78 9. Any pharmacist who has received a certificate of medication therapeutic
79 plan authority may engage in the designing, initiating, implementing, and
80 monitoring of a medication therapeutic plan as defined by a prescription order
81 from a physician that is specific to each patient for care by a pharmacist.

82 10. Nothing in this section shall be construed to allow a pharmacist to
83 make a therapeutic substitution of a pharmaceutical prescribed by a physician
84 unless authorized by the written protocol or the physician's prescription order.

85 11. **"Veterinarian", "doctor of veterinary medicine", "practitioner**
86 **of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet**
87 **Science)", "VMB", "MRCVS", or an equivalent title means a person who**
88 **has received a doctor's degree in veterinary medicine from an**

89 **accredited school of veterinary medicine or holds an Educational**
90 **Commission for Foreign Veterinary Graduates (EDFVG) certificate**
91 **issued by the American Veterinary Medical Association (AVMA).**

338.140. 1. The board of pharmacy shall have a common seal, and shall
2 have power to adopt such rules and bylaws not inconsistent with law as may be
3 necessary for the regulation of its proceedings and for the discharge of the duties
4 imposed pursuant to sections 338.010 to 338.198, and shall have power to employ
5 an attorney to conduct prosecutions or to assist in the conduct of prosecutions
6 pursuant to sections 338.010 to 338.198.

7 2. The board shall keep a record of its proceedings.

8 3. The board of pharmacy shall make annually to the governor and, upon
9 written request, to persons licensed pursuant to the provisions of this chapter a
10 written report of its proceedings.

11 4. The board of pharmacy shall appoint an advisory committee composed
12 of ~~[five]~~ **six** members, one of whom shall be a representative of pharmacy but who
13 shall not be a member of the pharmacy board, three of whom shall be
14 representatives of wholesale drug distributors as defined in section 338.330, ~~[and]~~
15 one of whom shall be a representative of drug manufacturers, **and one of whom**
16 **shall be a licensed veterinarian recommended to the board of pharmacy**
17 **by the board of veterinary medicine.** The committee shall review and make
18 recommendations to the board on the merit of all rules and regulations dealing
19 with pharmacy distributors, wholesale drug distributors ~~[and]~~, drug
20 manufacturers, **and veterinary legend drugs** which are proposed by the board.

21 5. A majority of the board shall constitute a quorum for the transaction
22 of business.

23 6. Notwithstanding any other provisions of law to the contrary, the board
24 may issue letters of reprimand, censure or warning to any holder of a license or
25 registration required pursuant to this chapter for any violations that could result
26 in disciplinary action as defined in section 338.055.

338.150. Any person authorized by the board of pharmacy is hereby given
2 the right of entry and inspection upon all open premises purporting or appearing
3 to be drug or chemical stores, apothecary shops, pharmacies or places of business
4 for exposing for sale, or the dispensing or selling of drugs, pharmaceuticals,
5 medicines, chemicals or poisons or for the compounding of physicians' **or**
6 **veterinarians'** prescriptions.

338.210. 1. Pharmacy refers to any location where the practice of

2 pharmacy occurs or such activities are offered or provided by a pharmacist or
3 another acting under the supervision and authority of a pharmacist, including
4 every premises or other place:

5 (1) Where the practice of pharmacy is offered or conducted;

6 (2) Where drugs, chemicals, medicines, **any legend drugs under 21**
7 **U.S.C. Section 353**, prescriptions, or poisons are compounded, prepared,
8 dispensed or sold or offered for sale at retail;

9 (3) Where the words "pharmacist", "apothecary", "drugstore", "drugs", and
10 any other symbols, words or phrases of similar meaning or understanding are
11 used in any form to advertise retail products or services;

12 (4) Where patient records or other information is maintained for the
13 purpose of engaging or offering to engage in the practice of pharmacy or to comply
14 with any relevant laws regulating the acquisition, possession, handling, transfer,
15 sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.

16 2. All activity or conduct involving the practice of pharmacy as it relates
17 to an identifiable prescription or drug order shall occur at the pharmacy location
18 where such identifiable prescription or drug order is first presented by the
19 patient or the patient's authorized agent for preparation or dispensing, unless
20 otherwise expressly authorized by the board.

21 3. The requirements set forth in subsection 2 of this section shall not be
22 construed to bar the complete transfer of an identifiable prescription or drug
23 order pursuant to a verbal request by or the written consent of the patient or the
24 patient's authorized agent.

25 4. The board is hereby authorized to enact rules waiving the requirements
26 of subsection 2 of this section and establishing such terms and conditions as it
27 deems necessary, whereby any activities related to the preparation, dispensing
28 or recording of an identifiable prescription or drug order may be shared between
29 separately licensed facilities.

30 5. If a violation of this chapter or other relevant law occurs in connection
31 with or adjunct to the preparation or dispensing of a prescription or drug order,
32 any permit holder or pharmacist-in-charge at any facility participating in the
33 preparation, dispensing, or distribution of a prescription or drug order may be
34 deemed liable for such violation.

35 6. Nothing in this section shall be construed to supersede the provisions
36 of section 197.100.

338.220. 1. It shall be unlawful for any person, copartnership,

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

- 10 (1) Class A: Community/ambulatory;
- 11 (2) Class B: Hospital outpatient pharmacy;
- 12 (3) Class C: Long-term care;
- 13 (4) Class D: Nonsterile compounding;
- 14 (5) Class E: Radio pharmaceutical;
- 15 (6) Class F: Renal dialysis;
- 16 (7) Class G: Medical gas;
- 17 (8) Class H: Sterile product compounding;
- 18 (9) Class I: Consultant services;
- 19 (10) Class J: Shared service;
- 20 (11) Class K: Internet;
- 21 (12) Class L: Veterinary.

22 2. Application for such permit or license shall be made upon a form
23 furnished to the applicant; shall contain a statement that it is made under oath
24 or affirmation and that its representations are true and correct to the best
25 knowledge and belief of the person signing same, subject to the penalties of
26 making a false affidavit or declaration; and shall be accompanied by a permit or
27 license fee. The permit or license issued shall be renewable upon payment of a
28 renewal fee. Separate applications shall be made and separate permits or
29 licenses required for each pharmacy opened, established, operated, or maintained
30 by the same owner.

31 3. All permits, licenses or renewal fees collected pursuant to the
32 provisions of sections 338.210 to 338.370 shall be deposited in the state treasury
33 to the credit of the Missouri board of pharmacy fund, to be used by the Missouri
34 board of pharmacy in the enforcement of the provisions of sections 338.210 to
35 338.370, when appropriated for that purpose by the general assembly.

36 4. Class L: veterinary permit shall not be construed to prohibit or
37 interfere with any legally registered practitioner of veterinary medicine in the

38 compounding, **administering, prescribing,** or dispensing of their own
39 prescriptions, **or medicine, drug, or pharmaceutical product to be used**
40 **for animals.**

41 5. [Notwithstanding any other law to the contrary] **Except for any**
42 **legend drugs under 21 U.S.C. Section 353,** the provisions of this section shall
43 not apply to the sale, dispensing, or filling of a pharmaceutical product or drug
44 used for treating animals.

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

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

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

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

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

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

338.315. It shall be unlawful for any pharmacist, pharmacy owner or
2 person employed by a pharmacy to knowingly purchase or receive any legend
3 drugs **under 21 U.S.C. Section 353** from other than a licensed or registered
4 drug distributor or licensed pharmacy. Any person who violates the provisions
5 of this section shall, upon conviction, be adjudged guilty of a class A
6 misdemeanor. Any subsequent conviction shall constitute a class D felony.

338.330. As used in sections 338.300 to 338.370, the following terms
2 mean:

3 (1) "Out-of-state wholesale drug distributor", a wholesale drug distributor
4 with no physical facilities located in the state;

5 (2) "Pharmacy distributor", any licensed pharmacy, as defined in section
6 338.210, engaged in the delivery or distribution of legend drugs **under 21 U.S.C.**
7 **Section 353** to any other licensed pharmacy where such delivery or distribution
8 constitutes at least five percent of the total gross sales of such pharmacy;

9 (3) "Wholesale drug distributor", anyone engaged in the delivery or
10 distribution of legend drugs **under 21 U.S.C. Section 353** from any location and
11 who is involved in the actual, constructive or attempted transfer of a drug or
12 drug-related device in this state, other than to the ultimate consumer. This shall
13 include, but not be limited to, drug wholesalers, repackagers and manufacturers
14 which are engaged in the delivery or distribution of drugs in this state, with
15 facilities located in this state or in any other state or jurisdiction. A wholesale
16 drug distributor shall not include any common carrier or individual hired solely
17 to transport legend drugs **under 21 U.S.C. Section 353**. Any locations where
18 drugs are delivered on a consignment basis, as defined by the board, shall be
19 exempt from licensure as a drug distributor, and those standards of practice
20 required of a drug distributor but shall be open for inspection by board of
21 pharmacy representatives as provided for in section 338.360.