

FIRST REGULAR SESSION

HOUSE BILL NO. 496

96TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVES JONES (117) (Sponsor), FALLERT, LONG, GUERNSEY,
TORPEY, HOUGH AND HINSON (Co-sponsors).

1252L.011

D. ADAM CRUMBLISS, Chief Clerk

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Section A. Sections 338.010, 338.140, 338.150, 338.210, 338.220, 338.240, 338.315, 2 and 338.330, RSMo, are repealed and eight new sections enacted in lieu thereof, to be known 3 as sections 338.010, 338.140, 338.150, 338.210, 338.220, 338.240, 338.315, and 338.330, to 4 read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and 2 evaluation of medical prescription orders, including **any legend drugs under 21 U.S.C. Section** 3 **353**; receipt, transmission, or handling of such orders or facilitating the dispensing of such 4 orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan 5 as defined by the prescription order so long as the prescription order is specific to each patient 6 for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and 7 devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, 8 shingles and meningitis vaccines by written protocol authorized by a physician for persons 9 twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, 10 and meningitis vaccines by written protocol authorized by a physician for a specific patient as 11 authorized by rule; the participation in drug selection according to state law and participation in 12 drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance 13 of proper records thereof; consultation with patients and other health care practitioners, **and**

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.

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

27 2. Any pharmacist who accepts a prescription order for a medication therapeutic plan
28 shall have a written protocol from the physician who refers the patient for medication therapy
29 services. The written protocol and the prescription order for a medication therapeutic plan shall
30 come from the physician only, and shall not come from a nurse engaged in a collaborative
31 practice arrangement under section 334.104, or from a physician assistant engaged in a
32 supervision agreement under section 334.735.

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

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

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

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

43 7. The state board of registration for the healing arts, under section 334.125, and the state
44 board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of
45 protocols for prescription orders for medication therapy services and administration of viral
46 influenza vaccines. Such rules shall require protocols to include provisions allowing for timely
47 communication between the pharmacist and the referring physician, and any other patient
48 protection provisions deemed appropriate by both boards. In order to take effect, such rules shall
49 be approved by a majority vote of a quorum of each board. Neither board shall separately

50 promulgate rules regulating the use of protocols for prescription orders for medication therapy
51 services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term
52 is defined in section 536.010, that is created under the authority delegated in this section shall
53 become effective only if it complies with and is subject to all of the provisions of chapter 536
54 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of
55 the powers vested with the general assembly pursuant to chapter 536 to review, to delay the
56 effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the
57 grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be
58 invalid and void.

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

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

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

72 **11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary**
73 **medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB",**
74 **"MRCVS", or an equivalent title means a person who has received a doctor's degree in**
75 **veterinary medicine from an accredited school of veterinary medicine or holds an**
76 **Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by**
77 **the American Veterinary Medical Association (AVMA).**

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

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

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

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

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

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

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

338.210. 1. Pharmacy refers to any location where the practice of pharmacy occurs or
2 such activities are offered or provided by a pharmacist or another acting under the supervision
3 and authority of a pharmacist, including every premises or other place:

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

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

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

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

15 2. All activity or conduct involving the practice of pharmacy as it relates to an
16 identifiable prescription or drug order shall occur at the pharmacy location where such

17 identifiable prescription or drug order is first presented by the patient or the patient's authorized
18 agent for preparation or dispensing, unless otherwise expressly authorized by the board.

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

22 4. The board is hereby authorized to enact rules waiving the requirements of subsection
23 2 of this section and establishing such terms and conditions as it deems necessary, whereby any
24 activities related to the preparation, dispensing or recording of an identifiable prescription or
25 drug order may be shared between separately licensed facilities.

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

30 6. Nothing in this section shall be construed to supersede the provisions of section
31 197.100.

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

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

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

28 3. All permits, licenses or renewal fees collected pursuant to the provisions of sections
29 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of
30 pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the
31 provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general
32 assembly.

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

37 5. [Notwithstanding any other law to the contrary] **Except for any legend drugs under**
38 **21 U.S.C. Section 353,** the provisions of this section shall not apply to the sale, dispensing, or
39 filling of a pharmaceutical product or drug used for treating animals.

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

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

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

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

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

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

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

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

- 2 (1) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no
3 physical facilities located in the state;
- 4 (2) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210,
5 engaged in the delivery or distribution of legend drugs **under 21 U.S.C. Section 353** to any other
6 licensed pharmacy where such delivery or distribution constitutes at least five percent of the total
7 gross sales of such pharmacy;
- 8 (3) "Wholesale drug distributor", anyone engaged in the delivery or distribution of
9 legend drugs **under 21 U.S.C. Section 353** from any location and who is involved in the actual,
10 constructive or attempted transfer of a drug or drug-related device in this state, other than to the
11 ultimate consumer. This shall include, but not be limited to, drug wholesalers, repackagers and
12 manufacturers which are engaged in the delivery or distribution of drugs in this state, with
13 facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor
14 shall not include any common carrier or individual hired solely to transport legend drugs **under**
15 **21 U.S.C. Section 353**. Any locations where drugs are delivered on a consignment basis, as
16 defined by the board, shall be exempt from licensure as a drug distributor, and those standards
17 of practice required of a drug distributor but shall be open for inspection by board of pharmacy
18 representatives as provided for in section 338.360.