

FIRST REGULAR SESSION
[TRULY AGREED TO AND FINALLY PASSED]
SENATE COMMITTEE SUBSTITUTE FOR
HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 412

96TH GENERAL ASSEMBLY

1225S.03T

2011

AN ACT

To repeal sections 208.798, 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, 338.240, and 338.330, RSMo, and to enact in lieu thereof nine new sections relating to pharmacy, with an emergency clause for a certain section.

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

Section A. Sections 208.798, 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, 2 338.240, and 338.330, RSMo, are repealed and nine new sections enacted in lieu thereof, to be 3 known as sections 208.798, 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, 338.240, 4 and 338.330, to read as follows:

208.798. [1. The provisions of sections 208.550 to 208.568 shall terminate following 2 notice to the revisor of statutes by the Missouri RX plan advisory commission that the Medicare 3 Prescription Drug, Improvement and Modernization Act of 2003 has been fully implemented.

4 2. Pursuant to section 23.253 of the Missouri sunset act, the provisions of the new 5 program authorized under sections 208.780 to 208.798 shall automatically sunset August 28, 6 2011, unless reauthorized by an act of the general assembly] **The provisions of sections 208.780 7 to 208.798 shall terminate on August 28, 2014.**

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

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.

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**
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.

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.

338.055. 1. The board may refuse to issue any certificate of registration or authority,
2 permit or license required pursuant to this chapter for one or any combination of causes stated
3 in subsection 2 of this section **or if the designated pharmacist-in-charge, manager-in-charge,**
4 **or any officer, owner, manager, or controlling shareholder of the applicant has committed**
5 **any act or practice in subsection 2 of this section.** The board shall notify the applicant in

6 writing of the reasons for the refusal and shall advise the applicant of his or her right to file a
7 complaint with the administrative hearing commission as provided by chapter 621.

8 2. The board may cause a complaint to be filed with the administrative hearing
9 commission as provided by chapter 621 against any holder of any certificate of registration or
10 authority, permit or license required by this chapter or any person who has failed to renew or has
11 surrendered his or her certificate of registration or authority, permit or license for any one or any
12 combination of the following causes:

13 (1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to
14 an extent that such use impairs a person's ability to perform the work of any profession licensed
15 or regulated by this chapter;

16 (2) The person has been finally adjudicated and found guilty, or entered a plea of guilty
17 or nolo contendere, in a criminal prosecution under the laws of any state or of the United States,
18 for any offense reasonably related to the qualifications, functions or duties of any profession
19 licensed or regulated under this chapter, for any offense an essential element of which is fraud,
20 dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not
21 sentence is imposed;

22 (3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of
23 registration or authority, permit or license issued pursuant to this chapter or in obtaining
24 permission to take any examination given or required pursuant to this chapter;

25 (4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by
26 fraud, deception or misrepresentation;

27 (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty
28 in the performance of the functions or duties of any profession licensed or regulated by this
29 chapter;

30 (6) Violation of, or assisting or enabling any person to violate, any provision of this
31 chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

32 (7) Impersonation of any person holding a certificate of registration or authority, permit
33 or license or allowing any person to use his or her certificate of registration or authority, permit,
34 license, or diploma from any school;

35 (8) Denial of licensure to an applicant or disciplinary action against an applicant or the
36 holder of a license or other right to practice any profession regulated by this chapter granted by
37 another state, territory, federal agency, or country whether or not voluntarily agreed to by the
38 licensee or applicant, including, but not limited to, surrender of the license upon grounds for
39 which denial or discipline is authorized in this state;

40 (9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

41 (10) Assisting or enabling any person to practice or offer to practice any profession
42 licensed or regulated by this chapter who is not registered and currently eligible to practice under
43 this chapter;

44 (11) Issuance of a certificate of registration or authority, permit or license based upon
45 a material mistake of fact;

46 (12) Failure to display a valid certificate or license if so required by this chapter or any
47 rule promulgated hereunder;

48 (13) Violation of any professional trust or confidence;

49 (14) Use of any advertisement or solicitation which is false, misleading or deceptive to
50 the general public or persons to whom the advertisement or solicitation is primarily directed;

51 (15) Violation of the drug laws or rules and regulations of this state, any other state or
52 the federal government;

53 (16) The intentional act of substituting or otherwise changing the content, formula or
54 brand of any drug prescribed by written or oral prescription without prior written or oral approval
55 from the prescriber for the respective change in each prescription; provided, however, that
56 nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of
57 any drug as provided under section 338.056, and any such substituting or changing of the brand
58 of any drug as provided for in section 338.056 shall not be deemed unprofessional or
59 dishonorable conduct unless a violation of section 338.056 occurs;

60 (17) Personal use or consumption of any controlled substance unless it is prescribed,
61 dispensed, or administered by a health care provider who is authorized by law to do so.

62 3. After the filing of such complaint, the proceedings shall be conducted in accordance
63 with the provisions of chapter 621. Upon a finding by the administrative hearing commission
64 that the grounds, provided in subsection 2 **of this section**, for disciplinary action are met, the
65 board may, singly or in combination, censure or place the person named in the complaint on
66 probation on such terms and conditions as the board deems appropriate for a period not to exceed
67 five years, or may suspend, for a period not to exceed three years, or revoke the license,
68 certificate, or permit. The board may impose additional discipline on a licensee, registrant, or
69 permittee found to have violated any disciplinary terms previously imposed under this section
70 or by agreement. The additional discipline may include, singly or in combination, censure,
71 placing the licensee, registrant, or permittee named in the complaint on additional probation on
72 such terms and conditions as the board deems appropriate, which additional probation shall not
73 exceed five years, or suspension for a period not to exceed three years, or revocation of the
74 license, certificate, or permit.

75 4. If the board concludes that a licensee or registrant has committed an act or is engaging
76 in a course of conduct which would be grounds for disciplinary action which constitutes a clear

77 and present danger to the public health and safety, the board may file a complaint before the
78 administrative hearing commission requesting an expedited hearing and specifying the activities
79 which give rise to the danger and the nature of the proposed restriction or suspension of the
80 licensee's or registrant's license. Within fifteen days after service of the complaint on the
81 licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing
82 to determine whether the alleged activities of the licensee or registrant appear to constitute a
83 clear and present danger to the public health and safety which justify that the licensee's or
84 registrant's license or registration be immediately restricted or suspended. The burden of proving
85 that the actions of a licensee or registrant constitute a clear and present danger to the public
86 health and safety shall be upon the state board of pharmacy. The administrative hearing
87 commission shall issue its decision immediately after the hearing and shall either grant to the
88 board the authority to suspend or restrict the license or dismiss the action.

89 5. If the administrative hearing commission grants temporary authority to the board to
90 restrict or suspend the licensee's or registrant's license, such temporary authority of the board
91 shall become final authority if there is no request by the licensee or registrant for a full hearing
92 within thirty days of the preliminary hearing. The administrative hearing commission shall, if
93 requested by the licensee or registrant named in the complaint, set a date to hold a full hearing
94 under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed
95 by the board.

96 6. If the administrative hearing commission dismisses the action filed by the board
97 pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a
98 subsequent action on the same grounds.

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, **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. **1.** 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.

17 **2. In lieu of a registered pharmacist as required by subdivision (4) of subsection 1**
18 **of this section, a pharmacy permit holder that only holds a class L veterinary permit and**
19 **no other pharmacy permit, may designate a supervising registered pharmacist who shall**
20 **be responsible for reviewing the activities and records of the class L pharmacy permit**
21 **holder as established by the board by rule. The supervising registered pharmacist shall**
22 **not be required to be physically present on site during the business operations of a class**
23 **L pharmacy permit holder identified in subdivision (5) of subsection 1 of this section when**
24 **noncontrolled legend drugs under 21 U.S.C. Section 353 are being dispensed for use in**

25 **animals, but shall be specifically present on site when any noncontrolled drugs for use in**
26 **animals are being compounded.**

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

- 2 (1) **"Legend drug", any drug or biological product;**
3 (a) **Subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including**
4 **finished dosage forms and active ingredients subject to section 503(b); or**
5 (b) **Required under federal law to be labeled with one of the following statements**
6 **prior to being dispensed or delivered:**
7 a. **"Caution: Federal law prohibits dispensing without prescription";**
8 b. **"Caution: Federal law restricts this drug to use by or on the order of a licensed**
9 **veterinarian";**
10 c. **"Rx Only"; or**
11 (c) **Required by an applicable federal or state law or regulation to be dispensed by**
12 **prescription only or that is restricted to use by practitioners only; and**
13 (d) **The term "drug", "prescription drug", or "legend drug" shall not include:**
14 a. **An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized**
15 **for the purposes of conducting a clinical investigation of that drug or product that is**
16 **governed by, and being conducted pursuant to, 21 CFR 312, et. seq.;**
17 b. **Any drug product being utilized for the purposes of conducting a clinical**
18 **investigation that is governed by, and being conducted pursuant to, 21 CFR 312, et. seq.;**
19 **or**
20 c. **Any drug product being utilized for the purposes of conducting a clinical**
21 **investigation that is governed or approved by an institutional review board subject to 21**
22 **CFR Part 56 or 45 CFR Part 46;**
23 (2) **"Out-of-state wholesale drug distributor", a wholesale drug distributor with no**
24 **physical facilities located in the state;**
25 [(2)] (3) **"Pharmacy distributor", any licensed pharmacy, as defined in section 338.210,**
26 **engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where**
27 **such delivery or distribution constitutes at least five percent of the total gross sales of such**
28 **pharmacy;**
29 [(3)] (4) **"Wholesale drug distributor", anyone engaged in the delivery or distribution**
30 **of legend drugs from any location and who is involved in the actual, constructive or attempted**
31 **transfer of a drug or drug-related device in this state, other than to the ultimate consumer. This**
32 **shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are**
33 **engaged in the delivery or distribution of drugs in this state, with facilities located in this state**
34 **or in any other state or jurisdiction. A wholesale drug distributor shall not include any common**

35 carrier or individual hired solely to transport legend drugs. Any locations where drugs are
36 delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a
37 drug distributor, and those standards of practice required of a drug distributor but shall be open
38 for inspection by board of pharmacy representatives as provided for in section 338.360.

Section B. Because immediate action is necessary to ensure the continuance of clinical
2 trials in this state, the repeal and reenactment of section 338.330 of section A of this act is
3 deemed necessary for the immediate preservation of the public health, welfare, peace, and safety,
4 and is hereby declared to be an emergency act within the meaning of the constitution, and the
5 repeal and reenactment of section 338.330 of section A of this act shall be in full force and effect
6 upon its passage and approval.

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