

SECOND REGULAR SESSION  
HOUSE COMMITTEE SUBSTITUTE FOR  
**HOUSE BILL NO. 2452**  
**101ST GENERAL ASSEMBLY**

5157H.02C

DANA RADEMAN MILLER, Chief Clerk

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**AN ACT**

To repeal sections 338.010 and 338.165, RSMo, and to enact in lieu thereof three new sections relating to the administration of medications by pharmacists.

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

Section A. Sections 338.010 and 338.165, RSMo, are repealed and three new sections  
2 enacted in lieu thereof, to be known as sections 338.010, 338.011, and 338.165, to read as  
3 follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation,  
2 and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C.  
3 Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of  
4 such orders; the designing, initiating, implementing, and monitoring of a medication  
5 therapeutic plan [~~as defined by the prescription order so long as the prescription order is~~  
6 ~~specific to each patient for care by a pharmacist~~]; the compounding, dispensing, labeling, and  
7 administration of drugs and devices pursuant to medical prescription orders [~~and~~  
8 ~~administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria,~~  
9 ~~tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for~~  
10 ~~persons at least seven years of age or the age recommended by the Centers for Disease~~  
11 ~~Control and Prevention, whichever is higher, or the administration of pneumonia, shingles,~~  
12 ~~hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza vaccines~~  
13 ~~by written protocol authorized by a physician for a specific patient as authorized by rule~~]; **the**  
14 **ordering and administration of vaccines approved or authorized by the United States**  
15 **Food and Drug Administration, excluding vaccines for cholera, monkeypox, Japanese**  
16 **encephalitis, typhoid, rabies, yellow fever, tick-borne encephalitis, and anthrax, to**  
17 **persons at least seven years of age or the age recommended by the Centers for Disease**

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.

18 **Control and Prevention, whichever is older, pursuant to joint promulgation of rules**  
19 **established by the board of pharmacy and the state board of registration for the healing**  
20 **arts unless rules are established under a state of emergency as described in section**  
21 **44.100;** the participation in drug selection according to state law and participation in drug  
22 utilization reviews; the proper and safe storage of drugs and devices and the maintenance of  
23 proper records thereof; consultation with patients and other health care practitioners, and  
24 veterinarians and their clients about legend drugs, about the safe and effective use of drugs  
25 and devices; the prescribing and dispensing of any nicotine replacement therapy product  
26 under section 338.665; the dispensing of HIV postexposure prophylaxis pursuant to section  
27 338.730; and the offering or performing of those acts, services, operations, or transactions  
28 necessary in the conduct, operation, management and control of a pharmacy. No person shall  
29 engage in the practice of pharmacy unless he or she is licensed under the provisions of this  
30 chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under  
31 the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties.  
32 This assistance in no way is intended to relieve the pharmacist from his or her responsibilities  
33 for compliance with this chapter and he or she will be responsible for the actions of the  
34 auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to  
35 prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry,  
36 or veterinary medicine only for use in animals, or the practice of optometry in accordance  
37 with and as provided in sections 195.070 and 336.220 in the compounding, administering,  
38 prescribing, or dispensing of his or her own prescriptions.

39 2. ~~[Any pharmacist who accepts a prescription order for a medication therapeutic plan~~  
40 ~~shall have a written protocol from the physician who refers the patient for medication therapy~~  
41 ~~services.]~~ **A pharmacist with a certificate of medication therapeutic plan authority may**  
42 **provide medication therapy services pursuant to a statewide standing order issued by**  
43 **the department of health and senior services or pursuant to a written protocol with a**  
44 **physician licensed under chapter 334.** The written protocol ~~[and the prescription order for a~~  
45 ~~medication therapeutic plan]~~ **authorized by this section** shall come **only** from the physician  
46 ~~[only]~~ **or similar body authorized by this section**, and shall not come from a nurse engaged  
47 in a collaborative practice arrangement under section 334.104, or from a physician assistant  
48 engaged in a collaborative practice arrangement under section 334.735.

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

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

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

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

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

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

83           9. [~~Any pharmacist who has received a certificate of medication therapeutic plan~~  
84 ~~authority may engage in the designing, initiating, implementing, and monitoring of a~~  
85 ~~medication therapeutic plan as defined by a prescription order from a physician that is~~  
86 ~~specific to each patient for care by a pharmacist.~~

87           ~~10.]~~ Nothing in this section shall be construed to allow a pharmacist to make a  
88 therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by  
89 the written protocol or the physician's prescription order.

90           ~~11.]~~ **10.** "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary  
91 medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or

92 an equivalent title means a person who has received a doctor's degree in veterinary medicine  
93 from an accredited school of veterinary medicine or holds an Educational Commission for  
94 Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary  
95 Medical Association (AVMA).

96 ~~[12. In addition to other requirements established by the joint promulgation of rules  
97 by the board of pharmacy and the state board of registration for the healing arts:~~

98 ~~(1) A pharmacist shall administer vaccines by protocol in accordance with treatment  
99 guidelines established by the Centers for Disease Control and Prevention (CDC);~~

100 ~~(2) A pharmacist who is administering a vaccine shall request a patient to remain in  
101 the pharmacy a safe amount of time after administering the vaccine to observe any adverse  
102 reactions. Such pharmacist shall have adopted emergency treatment protocols;~~

103 ~~(3)]~~ 11. In addition to other requirements by the board, a pharmacist shall receive  
104 additional training as required by the board and evidenced by receiving a certificate from the  
105 board upon completion, and shall display the certification in his or her pharmacy where  
106 vaccines are delivered.

107 ~~[13.]~~ 12. A pharmacist shall inform the patient that the administration of ~~[the]~~ a  
108 vaccine will be entered into the ShowMeVax system, as administered by the department of  
109 health and senior services. The patient shall attest to the inclusion of such information in the  
110 system by signing a form provided by the pharmacist. If the patient indicates that he or she  
111 does not want such information entered into the ShowMeVax system, the pharmacist shall  
112 provide a written report within fourteen days of administration of a vaccine to the patient's  
113 health care provider, if provided by the patient, containing:

- 114 (1) The identity of the patient;  
115 (2) The identity of the vaccine or vaccines administered;  
116 (3) The route of administration;  
117 (4) The anatomic site of the administration;  
118 (5) The dose administered; and  
119 (6) The date of administration.

**338.011. 1. A pharmacist licensed under this chapter may:**

2 (1) **Order and administer medication approved or authorized by the United**  
3 **States Food and Drug Administration to address a public health need, as lawfully**  
4 **authorized by the state or federal government, or a department or agency thereof,**  
5 **during a state or federally declared public health emergency; and**

6 (2) **Administer medication pursuant to a statewide standing order issued by the**  
7 **director of the department of health and senior services if a licensed physician, or a**  
8 **licensed physician approved and designated by the department of health and senior**  
9 **services, to address a public health need.**

10           **2. The board of pharmacy may promulgate rules to implement the provisions of**  
11 **this section. Any rule or portion of a rule, as that term is defined in section 536.010, that**  
12 **is created under the authority delegated in this section shall become effective only if it**  
13 **complies with and is subject to all of the provisions of chapter 536 and, if applicable,**  
14 **section 536.028. This section and chapter 536 are nonseverable, and if any of the powers**  
15 **vested with the general assembly pursuant to chapter 536 to review, to delay the**  
16 **effective date, or to disapprove and annul a rule are subsequently held unconstitutional,**  
17 **then the grant of rulemaking authority and any rule proposed or adopted after August**  
18 **28, 2022, shall be invalid and void.**

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

- 2           (1) "Board", the Missouri board of pharmacy;
- 3           (2) "Hospital", a hospital as defined in section 197.020;
- 4           (3) "Hospital clinic or facility", a clinic or facility under the common control,  
5 management, or ownership of the same hospital or hospital system;
- 6           (4) "Medical staff committee", the committee or other body of a hospital or hospital  
7 system responsible for formulating policies regarding pharmacy services and medication  
8 management;
- 9           (5) "Medication order", an order for a legend drug or device that is:  
10           (a) Authorized or issued by an authorized prescriber acting within the scope of his or  
11 her professional practice or pursuant to a protocol or standing order approved by the medical  
12 staff committee; and  
13           (b) To be distributed or administered to the patient by a health care practitioner or  
14 lawfully authorized designee at a hospital or a hospital clinic or facility;
- 15           (6) "Patient", an individual receiving medical diagnosis, treatment or care at a  
16 hospital or a hospital clinic or facility.

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

27           3. The department of health and senior services shall have authority to promulgate  
28 rules in conjunction with the board governing medication distribution and the provision of

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

36 4. All pharmacists providing medication therapy services shall obtain a certificate of  
37 medication therapeutic plan authority as provided by rule of the board. Medication therapy  
38 services may be provided by a pharmacist for patients of a hospital pursuant to **a statewide**  
39 **standing order issued by the department of health and senior services, pursuant to a**  
40 protocol with a physician as required by section 338.010, or pursuant to a protocol approved  
41 by the medical staff committee. However, the medical staff protocol shall include a process  
42 whereby an exemption to the protocol for a patient may be granted for clinical efficacy should  
43 the patient's physician make such request. The medical staff protocol shall also include an  
44 appeals process to request a change in a specific protocol based on medical evidence  
45 presented by a physician on staff.

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

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

50 7. Medication dispensed by a class A pharmacy located in a hospital to a hospital  
51 patient for use or administration outside of the hospital under a medical staff-approved  
52 protocol for medication therapy shall be dispensed only by a prescription order for medication  
53 therapy from an individual physician for a specific patient.

54 8. Medication dispensed by a hospital to a hospital patient for use or administration  
55 outside of the hospital shall be labeled as provided by rules jointly promulgated by the  
56 department of health and senior services and the board including medication distributed for  
57 administration by or under the supervision of a health care practitioner at a hospital clinic or  
58 facility.

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

61 10. Any rule, as that term is defined in section 536.010, that is created under the  
62 authority delegated in this section shall only become effective if it complies with and is  
63 subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section  
64 and chapter 536 are nonseverable and if any of the powers vested with the general assembly  
65 under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are

66 subsequently held unconstitutional, then the grant of rulemaking authority and any rule  
67 proposed or adopted after August 28, 2014, shall be invalid and void.

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

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

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

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

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

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

83 (6) One pharmacist designated by the board with experience in the provision of  
84 hospital pharmacy services.

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

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