SECOND REGULAR SESSION

HOUSE BILL NO. 2455

102ND GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE DOLL.

DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof two new sections relating to chronic maintenance drugs.

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

Section A. Section 338.010, RSMo, is repealed and two new sections enacted in lieu 2 thereof, to be known as sections 338.010 and 338.740, to read as follows:

338.010. 1. The "practice of pharmacy" includes:

(1) The interpretation, implementation, and evaluation of medical prescription orders,
including any legend drugs under 21 U.S.C. Section 353, and the receipt, transmission, or
handling of such orders or facilitating the dispensing of such orders;

5 (2) The designing, initiating, implementing, and monitoring of a medication 6 therapeutic plan in accordance with the provisions of this section;

7 (3) The compounding, dispensing, labeling, and administration of drugs and devices 8 pursuant to medical prescription orders;

9 (4) The ordering and administration of vaccines approved or authorized by the U.S. 10 Food and Drug Administration, excluding vaccines for cholera, monkeypox, Japanese 11 encephalitis, typhoid, rabies, yellow fever, tick-borne encephalitis, anthrax, tuberculosis, 12 dengue, Hib, polio, rotavirus, smallpox, and any vaccine approved after January 1, 2023, to 13 persons at least seven years of age or the age recommended by the Centers for Disease 14 Control and Prevention, whichever is older, pursuant to joint promulgation of rules 15 established by the board of pharmacy and the state board of registration for the healing arts 16 unless rules are established under a state of emergency as described in section 44.100;

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.

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17 (5) The participation in drug selection according to state law and participation in drug18 utilization reviews;

(6) The proper and safe storage of drugs and devices and the maintenance of properrecords thereof;

(7) Consultation with patients and other health care practitioners, and veterinarians
 and their clients about legend drugs, about the safe and effective use of drugs and devices;

(8) The prescribing and dispensing of any nicotine replacement therapy product under
 section 338.665;

25 (9) The dispensing of HIV postexposure prophylaxis pursuant to section 338.730;
26 [and]

(10) The dispensing of an emergency supply of a chronic maintenance drug
under section 338.740; and

(11) The offering or performing of those acts, services, operations, or transactionsnecessary in the conduct, operation, management and control of a pharmacy.

2. No person shall engage in the practice of pharmacy unless he or she is licensedunder the provisions of this chapter.

3. This chapter shall not be construed to prohibit the use of auxiliary personnel under 34 the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. 35 This assistance in no way is intended to relieve the pharmacist from his or her responsibilities 36 for compliance with this chapter and he or she will be responsible for the actions of the 37 auxiliary personnel acting in his or her assistance.

4. This chapter shall not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

43 5. A pharmacist with a certificate of medication therapeutic plan authority may 44 provide medication therapy services pursuant to a written protocol from a physician licensed 45 under chapter 334 to patients who have established a physician-patient relationship, as 46 described in subdivision (1) of subsection 1 of section 191.1146, with the protocol physician. The written protocol authorized by this section shall come only from the physician and shall 47 not come from a nurse engaged in a collaborative practice arrangement under section 48 49 334.104, or from a physician assistant engaged in a collaborative practice arrangement under section 334.735. 50

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

54 7. Nothing in this section shall be construed to apply to or interfere with the sale of 55 nonprescription drugs and the ordinary household remedies and such drugs or medicines as 56 are normally sold by those engaged in the sale of general merchandise.

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

9. This section shall not be construed to allow a pharmacist to diagnose or
independently prescribe pharmaceuticals except to the extent described under section
338.740.

63 10. The state board of registration for the healing arts, under section 334.125, and the 64 state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the 65 use of protocols for medication therapy services. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the protocol 66 physician or similar body authorized by this section, and any other patient protection 67 68 provisions deemed appropriate by both boards. In order to take effect, such rules shall be 69 approved by a majority vote of a quorum of each board. Neither board shall separately 70 promulgate rules regulating the use of protocols for medication therapy services. Any rule or 71 portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of 72 73 the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 74 536 are nonseverable and if any of the powers vested with the general assembly pursuant to 75 chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are 76 subsequently held unconstitutional, then the grant of rulemaking authority and any rule 77 proposed or adopted after August 28, 2007, shall be invalid and void.

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

12. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a written protocol from a physician that may be specific to each patient for care by a pharmacist.

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

91 14. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary 92 medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or 93 an equivalent title means a person who has received a doctor's degree in veterinary medicine 94 from an accredited school of veterinary medicine or holds an Educational Commission for 95 Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary 96 Medical Association (AVMA).

97 15. In addition to other requirements established by the joint promulgation of rules by98 the board of pharmacy and the state board of registration for the healing arts:

99 (1) A pharmacist shall administer vaccines by protocol in accordance with treatment100 guidelines established by the Centers for Disease Control and Prevention (CDC);

101 (2) A pharmacist who is administering a vaccine shall request a patient to remain in 102 the pharmacy a safe amount of time after administering the vaccine to observe any adverse 103 reactions. Such pharmacist shall have adopted emergency treatment protocols.

104 16. In addition to other requirements by the board, a pharmacist shall receive 105 additional training as required by the board and evidenced by receiving a certificate from the 106 board upon completion, and shall display the certification in his or her pharmacy where 107 vaccines are delivered.

108 17. A pharmacist shall inform the patient that the administration of a vaccine will be 109 entered into the ShowMeVax system, as administered by the department of health and senior 110 services. The patient shall attest to the inclusion of such information in the system by signing 111 a form provided by the pharmacist. If the patient indicates that he or she does not want such 112 information entered into the ShowMeVax system, the pharmacist shall provide a written 113 report within fourteen days of administration of a vaccine to the patient's health care provider, 114 if provided by the patient, containing:

115 (1) The identity of the patient;

116 (2) The identity of the vaccine or vaccines administered;

117 (3) The route of administration;

118 (4) The anatomic site of the administration;

119 (5) The dose administered; and

120 (6) The date of administration.

121 18. A pharmacist licensed under this chapter may order and administer vaccines 122 approved or authorized by the U.S. Food and Drug Administration to address a public health 123 need, as lawfully authorized by the state or federal government, or a department or agency 124 thereof, during a state or federally declared public health emergency.

338.740. 1. For purposes of this section, the term "chronic maintenance drug" 2 means a drug that:

3 (1) Is not an opioid or a controlled substance that is prohibited from being
4 dispensed without a prescription under the Federal Food, Drug, and Cosmetic Act, 21
5 U.S.C. Section 301 et seq., as amended; and

6 (2) Is prescribed to a patient to take on a recurring basis or is used as a lifesaving 7 rescue drug for a chronic condition.

8 2. Notwithstanding any other provision of law, a pharmacist may dispense an 9 emergency supply of a chronic maintenance drug to a patient without a current, valid 10 prescription if:

11 (1) The pharmacist makes every reasonable attempt but is unable to obtain 12 authorization to refill the prescription from the prescribing health care provider or 13 another health care provider responsible for the patient's care;

14 **(2)** Either:

15 (a) The pharmacist has a record of a prescription at the pharmacy or has been 16 presented proof of a recent prescription for the chronic maintenance drug in the name 17 of the patient who is requesting the emergency supply; or

18 (b) In the pharmacist's professional judgment, the refusal to dispense an 19 emergency supply of the chronic maintenance drug will endanger the patient's health or 20 disrupt essential drug therapy for a chronic condition of the patient;

(3) The amount of the chronic maintenance drug dispensed does not exceed the
 amount of the most recent prescription or the standard quantity or unit-of-use package
 of the drug; and

24 (4) The prescriber of the drug has not indicated that no emergency refills are 25 authorized.

3. A pharmacist, the pharmacist's employer, and the original prescriber of the drug are not civilly liable for an act or omission in connection with the dispensing of a chronic maintenance drug under this section unless the act or omission constitutes negligence, recklessness, or willful or wanton misconduct.

30 4. The board of pharmacy shall adopt rules, in consultation with the state board 31 of registration for the healing arts and the state board of nursing, to establish standard procedures for pharmacists to follow in dispensing chronic maintenance drugs under 32 33 this section. The rules adopted shall include documentation requirements for a 34 pharmacist to complete when dispensing a chronic maintenance drug without a current 35 prescription. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if 36 37 it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers 38 vested with the general assembly pursuant to chapter 536 to review, to delay the 39

- 40 effective date, or to disapprove and annul a rule are subsequently held unconstitutional,
- 41 then the grant of rulemaking authority and any rule proposed or adopted after August
- 42 28, 2024, shall be invalid and void.