

House _____ Amendment NO. _____

Offered By

1 AMEND House Committee Substitute No. 2 for Senate Bill No. 710, Page 69, Section 335.257,
2 Line 4, by inserting after said section and line the following:

3
4 "338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and
5 evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353;
6 receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the
7 designing, initiating, implementing, and monitoring of a medication therapeutic plan ~~[as defined by~~
8 ~~the prescription order so long as the prescription order is specific to each patient for care by a~~
9 ~~pharmacist]~~; the compounding, dispensing, labeling, and administration of drugs and devices
10 pursuant to medical prescription orders ~~[and administration of viral influenza, pneumonia, shingles,~~
11 ~~hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol~~
12 ~~authorized by a physician for persons at least seven years of age or the age recommended by the~~
13 ~~Centers for Disease Control and Prevention, whichever is higher, or the administration of~~
14 ~~pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral~~
15 ~~influenza vaccines by written protocol authorized by a physician for a specific patient as authorized~~
16 ~~by rule]~~; the ordering and administration of vaccines approved or authorized by the United States
17 Food and Drug Administration, excluding vaccines for cholera, monkeypox, Japanese encephalitis,
18 typhoid, rabies, yellow fever, tick-borne encephalitis, and anthrax, to persons at least seven years of
19 age or the age recommended by the Centers for Disease Control and Prevention, whichever is older,
20 pursuant to joint promulgation of rules established by the board of pharmacy and the state board of
21 registration for the healing arts unless rules are established under a state of emergency as described
22 in section 44.100; the participation in drug selection according to state law and participation in drug
23 utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper
24 records thereof; consultation with patients and other health care practitioners, and veterinarians and
25 their clients about legend drugs, about the safe and effective use of drugs and devices; the
26 prescribing and dispensing of any nicotine replacement therapy product under section 338.665; the
27 dispensing of HIV postexposure prophylaxis pursuant to section 338.730; and the offering or
28 performing of those acts, services, operations, or transactions necessary in the conduct, operation,
29 management and control of a pharmacy. No person shall engage in the practice of pharmacy unless
30 he or she is licensed under the provisions of this chapter. This chapter shall not be construed to

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1 prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting
2 the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the
3 pharmacist from his or her responsibilities for compliance with this chapter and he or she will be
4 responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter
5 shall also not be construed to prohibit or interfere with any legally registered practitioner of
6 medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of
7 optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding,
8 administering, prescribing, or dispensing of his or her own prescriptions.

9 2. ~~[Any pharmacist who accepts a prescription order for a medication therapeutic plan shall~~
10 ~~have a written protocol from the physician who refers the patient for medication therapy services.]~~
11 A pharmacist with a certificate of medication therapeutic plan authority may provide medication
12 therapy services pursuant to a statewide standing order issued by the department of health and senior
13 services or pursuant to a written protocol with a physician licensed under chapter 334. The written
14 protocol [and the prescription order for a medication therapeutic plan] authorized by this section
15 shall come only from the physician [only] or similar body authorized by this section, and shall not
16 come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a
17 physician assistant engaged in a collaborative practice arrangement under section 334.735.

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

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

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

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

28 7. The state board of registration for the healing arts, under section 334.125, and the state
29 board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of
30 protocols ~~[for prescription orders]~~ for medication therapy services ~~[and administration of viral~~
31 ~~influenza vaccines]~~. Such rules shall require protocols to include provisions allowing for timely
32 communication between the pharmacist and the ~~[referring]~~ protocol physician or similar body
33 authorized by this section, and any other patient protection provisions deemed appropriate by both
34 boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each
35 board. Neither board shall separately promulgate rules regulating the use of protocols for
36 [prescription orders for] medication therapy services[and administration of viral influenza
37 vaccines]. Any rule or portion of a rule, as that term is defined in section 536.010, that is created
38 under the authority delegated in this section shall become effective only if it complies with and is
39 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 vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. 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.

~~9. [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 prescription order from a physician that is specific to each patient for care by a pharmacist.~~

~~10.]~~ 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.

~~[41.]~~ 10. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

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

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

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

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

~~[43.]~~ 12. A pharmacist shall inform the patient that the administration of ~~[the]~~ a vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's health care provider, if provided

1 by the patient, containing:

- 2 (1) The identity of the patient;
- 3 (2) The identity of the vaccine or vaccines administered;
- 4 (3) The route of administration;
- 5 (4) The anatomic site of the administration;
- 6 (5) The dose administered; and
- 7 (6) The date of administration.

8 338.011. 1. A pharmacist licensed under this chapter may:

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

13 (2) Administer medication pursuant to a statewide standing order issued by the director of
 14 the department of health and senior services if a licensed physician, or a licensed physician
 15 approved and designated by the department of health and senior services, to address a public health
 16 need.

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

25 338.165. 1. As used in this section, the following terms mean:

- 26 (1) "Board", the Missouri board of pharmacy;
- 27 (2) "Hospital", a hospital as defined in section 197.020;
- 28 (3) "Hospital clinic or facility", a clinic or facility under the common control, management,
 29 or ownership of the same hospital or hospital system;
- 30 (4) "Medical staff committee", the committee or other body of a hospital or hospital system
 31 responsible for formulating policies regarding pharmacy services and medication management;
- 32 (5) "Medication order", an order for a legend drug or device that is:
 33 (a) Authorized or issued by an authorized prescriber acting within the scope of his or her
 34 professional practice or pursuant to a protocol or standing order approved by the medical staff
 35 committee; and
 36 (b) To be distributed or administered to the patient by a health care practitioner or lawfully
 37 authorized designee at a hospital or a hospital clinic or facility;
- 38 (6) "Patient", an individual receiving medical diagnosis, treatment or care at a hospital or a
 39 hospital clinic or facility.

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

10 3. The department of health and senior services shall have authority to promulgate rules in
11 conjunction with the board governing medication distribution and the provision of medication
12 therapy services by a pharmacist at or within a hospital. Rules may include, but are not limited to,
13 medication management, preparation, compounding, administration, storage, distribution, packaging
14 and labeling. Until such rules are jointly promulgated, hospitals shall comply with all applicable
15 state law and department of health and senior services rules governing pharmacy services and
16 medication management in hospitals. The rulemaking authority granted herein to the department of
17 health and senior services shall not include the dispensing of medication by prescription.

18 4. All pharmacists providing medication therapy services shall obtain a certificate of
19 medication therapeutic plan authority as provided by rule of the board. Medication therapy services
20 may be provided by a pharmacist for patients of a hospital pursuant to a statewide standing order
21 issued by the department of health and senior services, pursuant to a protocol with a physician as
22 required by section 338.010₂, or pursuant to a protocol approved by the medical staff committee.
23 However, the medical staff protocol shall include a process whereby an exemption to the protocol
24 for a patient may be granted for clinical efficacy should the patient's physician make such request.
25 The medical staff protocol shall also include an appeals process to request a change in a specific
26 protocol based on medical evidence presented by a physician on staff.

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

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

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

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

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

1 substances.

2 10. Any rule, as that term is defined in section 536.010, that is created under the authority
3 delegated in this section shall only become effective if it complies with and is subject to all of the
4 provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
5 nonseverable and if any of the powers vested with the general assembly under chapter 536 to
6 review, to delay the effective date, or to disapprove and annul a rule are subsequently held
7 unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after
8 August 28, 2014, shall be invalid and void.

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

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

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

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

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

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

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

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

27
28 Further amend said bill by amending the title, enacting clause, and intersectional references
29 accordingly.