

House _____ Amendment NO. _____

Offered By _____

1 AMEND House Committee Substitute for Senate Substitute for Senate Bill No. 580, Page 68,
2 Section 338.200, Line 41, by inserting after all of said section and line the following:

3
4 "338.035. 1. Every person who desires to be licensed as an intern pharmacist shall file with
5 the board of pharmacy an application, on a form to be provided by the board of pharmacy.

6 2. If an applicant for an intern pharmacist license has complied with the requirements of this
7 section and with the rules and regulations of the board of pharmacy and is not denied a license on
8 any of the grounds listed in section 338.055, the board of pharmacy may issue to him a license to
9 practice as an intern pharmacist.

10 3. Any intern pharmacist who wishes to renew his license shall within thirty days before the
11 license expiration date file an application for a renewal.

12 4. A licensed intern pharmacist may practice pharmacy only under the direct supervision of
13 a pharmacist licensed by the board; provided, however, that an intern pharmacist working at a
14 remote dispensing site pharmacy may be remotely supervised by a pharmacist working at a
15 supervising pharmacy as provided for in section 338.215.

16 5. The board of pharmacy shall promulgate rules and regulations which shall further
17 regulate the duties of intern pharmacists and shall set the amount of the fees which shall accompany
18 the license and renewal applications for intern pharmacists.

19 6. No rule or portion of a rule promulgated under the authority of this chapter shall become
20 effective unless it has been promulgated pursuant to the provisions of section 536.024."; and

21 338.210. 1. Pharmacy refers to any location where the practice of pharmacy occurs or such
22 activities are offered or provided by a pharmacist or another acting under the supervision and
23 authority of a pharmacist, including every premises or other place:

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

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

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

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

34 (5) Where the practice of pharmacy occurs or is offered at a remote dispensing pharmacy
35 site.

36 2. All activity or conduct involving the practice of pharmacy as it relates to an identifiable

Action Taken _____ Date _____

1 prescription or drug order shall occur at the pharmacy location where such identifiable prescription
 2 or drug order is first presented by the patient or the patient's authorized agent for preparation or
 3 dispensing, unless otherwise expressly authorized by the board.

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

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

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

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

16 338.215. 1. For purposes of this section, the following terms mean:

17 (1) "Remote dispensing site pharmacy", any location in this state where the practice of
 18 pharmacy occurs and that is licensed as a pharmacy to dispense prescription drugs and is staffed by
 19 one or more qualified pharmacy technicians or intern pharmacists, whose activities are supervised
 20 by a pharmacist at a supervising pharmacy through a continuous real-time audio and video link.
 21 "Remote dispensing site pharmacy" does not include the office of a dispensing prescriber or an
 22 automated device;

23 (2) "Supervising pharmacy", a pharmacy licensed in this state under the provisions of
 24 chapter 338 that oversees the dispensation activities of a remote dispensing site pharmacy.

25 2. A supervising pharmacy that operates a remote dispensing site pharmacy, and the remote
 26 dispensing site pharmacy, shall be licensed as a pharmacy by the board of pharmacy. The board
 27 shall issue a license to a remote dispensing site pharmacy that meets the requirements of this
 28 subsection. The remote dispensing site pharmacy shall:

29 (1) Submit an application and pay the licensing fee established by the board;

30 (2) Be jointly owned by a supervising pharmacy; and

31 (3) Maintain a policy and procedures manual that includes the following:

32 (a) A description of how the supervising pharmacy and remote dispensing site pharmacy
 33 will comply with federal and state laws, rules, and regulations;

34 (b) The procedure for the supervising pharmacy to supervise the remote dispensing site
 35 pharmacy and counsel patients in accordance with the laws of this state prior to the dispensing of a
 36 prescription drug under this section;

37 (c) The procedure for reviewing the prescription drug inventory and drug records
 38 maintained by the remote dispensing site pharmacy;

39 (d) The policy and procedure for providing appropriate security to protect the confidentiality
 40 and integrity of patient information;

41 (e) The written plan for recovery from an event that interrupts or prevents a pharmacist from
 42 supervising the operation of the remote dispensing site pharmacy;

43 (f) The specific duties, tasks, and functions that a registered pharmacy technician or intern
 44 pharmacist is authorized to perform at the remote dispensing site pharmacy under the remote
 45 supervision of a licensed pharmacist at the supervising pharmacy; and

46 (g) The procedure for maintaining an up-to-date inventory of all controlled substances.

47 3. A remote dispensing site pharmacy shall be under the supervision and control of a
 48 supervising pharmacist employed by the supervising pharmacy. The supervising pharmacist shall
 49 not be required to be immediately physically present to supervise activities at the remote dispensing

1 site pharmacy, but shall make monthly visits to the remote dispensing site pharmacy in order to
 2 ensure compliance with this section.

3 4. A supervising pharmacist and a remote dispensing site pharmacy shall share common
 4 ownership. A pharmacist shall neither be designated nor act as a supervising pharmacist for more
 5 than two remote dispensing site pharmacies at one time.

6 5. A pharmacist at the supervising pharmacy shall verify each prescription before it leaves
 7 the remote dispensing site pharmacy. Verification shall occur through the use of technology that
 8 includes bar coding and visual review via remote video. As applicable, a pharmacist, intern
 9 pharmacist, and pharmacy technician's initials or unique identifier shall appear in the prescription
 10 record to identify the name and specific activities of each pharmacist, intern pharmacist, or
 11 pharmacy technician involved in the dispensing process.

12 6. Unless a pharmacist is onsite at the remote dispensing site pharmacy, counseling shall be
 13 done by a supervising pharmacist at the supervising pharmacy via a HIPAA-compliant continuous
 14 real-time video and audio link before a drug or medical device is released to the patient. The system
 15 being used to perform the consultation shall retain the initials or unique identifier of the pharmacist
 16 who performs the consultation. The pharmacist providing counseling under this subsection shall be
 17 employed by and located at the supervising pharmacy and have access to all relevant patient
 18 information maintained by the remote dispensing site pharmacy.

19 7. A remote dispensing site pharmacy shall be located at least ten miles from an existing
 20 retail pharmacy unless:

21 (1) The remote dispensing site pharmacy is part of a community mental health center,
 22 federally qualified health center, hospital, rural health clinic, or outpatient clinic setting;

23 (2) An applicant of a proposed remote dispensing site pharmacy demonstrates to
 24 the board how the proposed remote dispensing site pharmacy will promote public health.

25 8. The remote dispensing pharmacy shall be staffed by a pharmacist at least eight hours a
 26 month and shall reconcile the up-to-date controlled substance inventory twice a month. The
 27 supervising pharmacist may provide services as allowed in 338.010 and as provided by policies and
 28 procedures.

29 9. If the average number of prescriptions dispensed per day by the remote dispensing site
 30 pharmacy exceeds one hundred fifty prescriptions, the remote dispensing site pharmacy shall, within
 31 ten days, apply to the board for licensure as a class A, B, or C pharmacy, as applicable. The average
 32 number of prescriptions dispensed per day shall be determined by averaging the number of
 33 prescriptions dispensed per day over the previous ninety-day period.

34 10. Unless otherwise approved by the board, the supervising pharmacy shall be located in
 35 this state and within fifty road miles of a remote dispensing site pharmacy to ensure that the remote
 36 dispensing site pharmacy is sufficiently supported by the supervising pharmacy and that necessary
 37 personnel or supplies may be delivered to the remote dispensing site pharmacy within a reasonable
 38 period of time of an identified need.

39 11. The board of pharmacy may promulgate all necessary rules and regulations for the
 40 implementation of this section, provided that no such rules and regulations shall restrict the practice
 41 of pharmacy at a remote dispensing site pharmacy. Any rule or portion of a rule, as that term is
 42 defined in section 536.010, that is created under the authority delegated in this section shall become
 43 effective only if it complies with and is subject to all of the provisions of chapter 536 and, if
 44 applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the
 45 powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective
 46 date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of
 47 rulemaking authority and any rule proposed or adopted after August 28, 2020, shall be invalid and
 48 void.

49 338.220. 1. It shall be unlawful for any person, copartnership, association, corporation or

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

- (1) Class A: Community/ambulatory;
- (2) Class B: Hospital pharmacy;
- (3) Class C: Long-term care;
- (4) Class D: Nonsterile compounding;
- (5) Class E: Radio pharmaceutical;
- (6) Class F: Renal dialysis;
- (7) Class G: Medical gas;
- (8) Class H: Sterile product compounding;
- (9) Class I: Consultant services;
- (10) Class J: Shared service;
- (11) Class K: Internet;
- (12) Class L: Veterinary;
- (13) Class M: Specialty (bleeding disorder);
- (14) Class N: Automated dispensing system (health care facility);
- (15) Class O: Automated dispensing system (ambulatory care);
- (16) Class P: Practitioner office/clinic; and
- (17) Class Q: Remote dispensing site pharmacy.

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

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

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

5. Except for any legend drugs under 21 U.S.C. Section 353, the provisions of this section shall not apply to the sale, dispensing, or filling of a pharmaceutical product or drug used for treating animals.

6. A "class B hospital pharmacy" shall be defined as a pharmacy owned, managed, or operated by a hospital as defined by section 197.020 or a clinic or facility under common control, management or ownership of the same hospital or hospital system. This section shall not be construed to require a class B hospital pharmacy permit or license for hospitals solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by, the department of health and senior services under and pursuant to chapter 197.

7. Upon application to the board, any hospital that holds a pharmacy permit or license on

1 August 28, 2014, shall be entitled to obtain a class B pharmacy permit or license without fee,
2 provided such application shall be submitted to the board on or before January 1, 2015.

3 338.260. 1. No person shall carry on, conduct or transact a business under a name which
4 contains as part of the name the words "pharmacist", "pharmacy", "apothecary", "apothecary shop",
5 "chemist shop", "drug store", "druggist", "drugs", "consultant pharmacist", or any word of similar or
6 like import, unless the place of business is supervised by a licensed pharmacist.

7 2. Nothing in this chapter shall be construed to prevent any person from using a historical
8 name in reference to any building, structure, or business so long as the person is not engaged in the
9 practice of pharmacy as defined in section 338.010.

10 3. Notwithstanding the provisions of subsection 2 of this section, the board of pharmacy
11 shall retain authority to enforce the provisions of subsection 1 of this section against any person
12 offering for sale any naturopathic or homeopathic service or any herbal, nutritional, vitamin, dietary,
13 mineral, or other supplement intended for human application, absorption, or consumption.

14 4. Supervision of a licensed remote dispensing site pharmacy shall not require a pharmacist
15 to be physically present at the remote dispensing site pharmacy location, provided that dispensing
16 activities are supervised by a supervising pharmacist located at a Missouri-licensed supervising
17 pharmacy through the use of a continuous real-time audio and video link." and
18

19 Further amend said bill by amending the title, enacting clause, and intersectional references
20 accordingly.