

SECOND REGULAR SESSION

HOUSE BILL NO. 2422

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE STEPHENS (128).

5232H.02I

DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal sections 338.035, 338.210, 338.220, and 338.260, RSMo, and to enact in lieu thereof five new sections relating to remote dispensing site pharmacies.

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

Section A. Sections 338.035, 338.210, 338.220, and 338.260, RSMo, are repealed and
2 five new sections enacted in lieu thereof, to be known as sections 338.035, 338.210, 338.215,
3 338.220, and 338.260, to read as follows:

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

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

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

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

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

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.

16 6. No rule or portion of a rule promulgated under the authority of this chapter shall
17 become effective unless it has been promulgated pursuant to the provisions of section 536.024.

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 353,
6 prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at
7 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 **(5) Where the practice of pharmacy occurs or is offered at a remote dispensing**
16 **pharmacy site.**

17 2. All activity or conduct involving the practice of pharmacy as it relates to an
18 identifiable prescription or drug order shall occur at the pharmacy location where such
19 identifiable prescription or drug order is first presented by the patient or the patient's authorized
20 agent for preparation or dispensing, unless otherwise expressly authorized by the board.

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

24 4. The board is hereby authorized to enact rules waiving the requirements of subsection
25 2 of this section and establishing such terms and conditions as it deems necessary, whereby any
26 activities related to the preparation, dispensing or recording of an identifiable prescription or
27 drug order may be shared between separately licensed facilities.

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

32 6. Nothing in this section shall be construed to supersede the provisions of section
33 197.100.

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

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

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

11 2. A supervising pharmacy that operates a remote dispensing site pharmacy, and
12 the remote dispensing site pharmacy, shall be licensed as a pharmacy by the board of
13 pharmacy. The board shall issue a license to a remote dispensing site pharmacy that meets
14 the requirements of this subsection. The remote dispensing site pharmacy shall:

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

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

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

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

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

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

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

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

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

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

34 3. A remote dispensing site pharmacy shall be under the supervision and control
35 of a supervising pharmacist employed by the supervising pharmacy. The supervising
36 pharmacist shall not be required to be immediately physically present to supervise
37 activities at the remote dispensing site pharmacy, but shall make monthly visits or shall

38 designate a pharmacist to make monthly visits to the remote dispensing site pharmacy in
39 order to ensure compliance with this section.

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

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

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

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

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

62 (2) The remote dispensing site pharmacy is located in a city with a population of
63 five thousand or more inhabitants as shown in the most recent federal census; or

64 (3) An applicant of a proposed remote dispensing site pharmacy demonstrates to
65 the board how the proposed remote dispensing site pharmacy will promote public health.

66 8. The remote dispensing site pharmacy shall be staffed by a pharmacist for at least
67 eight hours a month. While onsite, the pharmacist shall reconcile the up-to-date controlled
68 substance inventory and make available to the community general health care services that
69 may include immunizations, health screenings, or medication therapy management, as
70 deemed necessary and appropriate by the supervising pharmacist and as provided by
71 policies and procedures.

72 9. If the average number of prescriptions dispensed per day by the remote
73 dispensing site pharmacy exceeds one hundred fifty prescriptions, the remote dispensing

74 site pharmacy shall, within ten days, apply to the board for licensure as a class A, B, or C
75 pharmacy, as applicable. The average number of prescriptions dispensed per day shall be
76 determined by averaging the number of prescriptions dispensed per day over the previous
77 ninety-day period.

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

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

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 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 (13) Class M: Specialty (bleeding disorder);
22 (14) Class N: Automated dispensing system (health care facility);
23 (15) Class O: Automated dispensing system (ambulatory care);
24 (16) Class P: Practitioner office/clinic; **and**
25 **(17) Class Q: Remote dispensing site pharmacy.**

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

33 3. All permits, licenses or renewal fees collected pursuant to the provisions of sections
34 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of
35 pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the
36 provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general
37 assembly.

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

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

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

51 7. Upon application to the board, any hospital that holds a pharmacy permit or license
52 on August 28, 2014, shall be entitled to obtain a class B pharmacy permit or license without fee,
53 provided such application shall be submitted to the board on or before January 1, 2015.

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

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

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

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

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