

SECOND REGULAR SESSION

# SENATE BILL NO. 976

100TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time February 5, 2020, and ordered printed.

ADRIANE D. CROUSE, Secretary.

5267S.011

## 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 supervision of pharmacy interns at a remote dispensing site pharmacy.

*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  
2 repealed and five new sections enacted in lieu thereof, to be known as sections  
3 338.035, 338.210, 338.212, 338.220, and 338.260, to read as follows:

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

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

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

11 4. A licensed intern pharmacist may practice pharmacy only under the  
12 direct supervision of a pharmacist licensed by the board, **provided, however,**  
13 **that an intern pharmacist working at a remote dispensing site**  
14 **pharmacy may be remotely supervised by a pharmacist working at a**  
15 **supervising pharmacy as provided in section 338.212.**

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

19 pharmacists.

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

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

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

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

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

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

16           **(5) Where the practice of pharmacy occurs or is offered at a**  
17 **remote dispensing pharmacy site.**

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

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

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

32           5. If a violation of this chapter or other relevant law occurs in connection

33 with or adjunct to the preparation or dispensing of a prescription or drug order,  
34 any permit holder or pharmacist-in-charge at any facility participating in the  
35 preparation, dispensing, or distribution of a prescription or drug order may be  
36 deemed liable for such violation.

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

**338.212. 1. For purposes of this section, "remote dispensing site  
2 pharmacy" shall mean any location located in the state of Missouri  
3 where the practice of pharmacy occurs, that is licensed as a pharmacy  
4 to dispense prescription drugs pursuant to sections 338.210 to 338.315,  
5 and is staffed by one or more qualified pharmacy technicians or intern  
6 pharmacists, whose activities are supervised by a pharmacist at a  
7 supervising pharmacy through a continuous, real-time audio and video  
8 link. Remote dispensing site pharmacy shall not include the office of  
9 a dispensing prescriber or an automated device.**

10 **2. A supervising pharmacy that operates a remote dispensing site  
11 pharmacy, and the remote dispensing site pharmacy, shall be licensed  
12 as a pharmacy by the board of pharmacy pursuant to sections 338.210  
13 to 338.315. The board shall issue a license to a remote dispensing site  
14 pharmacy meeting the following criteria:**

15 **(1) Is jointly owned by a supervising pharmacy;**

16 **(2) Maintains a policy and procedures manual which shall  
17 include:**

18 **(a) A description of the supervising pharmacy and remote  
19 dispensing site pharmacy's procedure for complying with federal and  
20 state laws, rules, and regulations;**

21 **(b) The procedure for supervising the remote dispensing site  
22 pharmacy and counseling patients prior to the dispensing of a  
23 prescription drug;**

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

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

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

31 **(f) The specific duties, tasks, and functions that a registered**

32 pharmacy technician or intern pharmacist is authorized to perform at  
33 the remote dispensing site pharmacy under the remote supervision of  
34 a licensed pharmacist at the supervising pharmacy; and

35 (g) The procedure for maintaining a perpetual inventory of all  
36 controlled substances.

37 3. A remote dispensing site pharmacy shall be under the  
38 supervision and control of a pharmacist in charge employed by the  
39 supervising pharmacy. The pharmacist in charge shall not be required  
40 to be immediately, physically present to supervise any activities at the  
41 remote dispensing site pharmacy, but shall designate a pharmacist to  
42 make monthly visits to the remote dispensing site pharmacy in order  
43 to ensure compliance with this section.

44 4. A pharmacist shall not be designated, nor act as the  
45 pharmacist in charge for more than two remote dispensing site  
46 pharmacies at one time.

47 5. A pharmacist at the supervising pharmacy shall verify each  
48 prescription before such prescription leaves the remote dispensing site  
49 pharmacy. Verification shall occur through the use of technology,  
50 which shall include bar coding and visual review via remote video. As  
51 applicable, pharmacist, intern pharmacist, and pharmacy technician  
52 initials or unique identifiers shall appear in the prescription record to  
53 identify the name and specific activities of each pharmacist, intern  
54 pharmacist, or pharmacy technician involved in the dispensing process.

55 6. Unless a pharmacist is available onsite, patient consultations  
56 shall be provided by a pharmacist via a federal Health Insurance  
57 Portability and Accountability Act (HIPAA)-compliant video and audio  
58 link prior to dispensing any drug or medical device. Such system shall  
59 retain the initials or unique identifier of the pharmacist performing the  
60 consultation. The pharmacist providing consultation shall be employed  
61 and located at the supervising pharmacy and shall have access to all  
62 relevant patient information maintained by the supervising pharmacy.

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

65 (1) The remote dispensing site pharmacy located less than ten  
66 miles from the existing retail pharmacy is part of a community mental  
67 health center as defined in section 205.975, federally qualified health  
68 center as defined in 42 U.S.C. Section 1395 of the Public Health Service

69 Act, as amended, hospital, rural health clinic, or outpatient clinical  
70 setting;

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

74 (3) The applicant with the proposed remote dispensing site  
75 pharmacy demonstrates to the board the manner in which the proposed  
76 remote dispensing site pharmacy will promote public health.

77 8. The remote dispensing site pharmacy shall be staffed by a  
78 pharmacist for at least eight hours per month who shall reconcile the  
79 perpetual controlled substance inventory, and provide general health  
80 care services, which may include immunizations, health screenings, or  
81 medication therapy management, as deemed necessary and appropriate  
82 by the pharmacist in charge and as provided by policies and  
83 procedures.

84 9. If the average number of prescriptions dispensed per day by  
85 the remote dispensing site pharmacy exceeds one hundred fifty  
86 prescriptions, the remote dispensing site pharmacy shall, within ten  
87 days, apply to the board for licensure as a class A, B, or C pharmacy as  
88 set forth in section 338.220, as applicable. The average number of  
89 prescriptions dispensed per day shall be determined by averaging the  
90 number of prescriptions dispensed per day over the previous ninety-  
91 day period.

92 10. Unless otherwise approved by the board, the supervising  
93 pharmacy shall be located in Missouri and within fifty miles of a  
94 remote dispensing site pharmacy to ensure the remote dispensing site  
95 pharmacy is sufficiently supported by the supervising pharmacy and  
96 that necessary personnel or supplies may be delivered to the remote  
97 dispensing site within a reasonable period of time.

98 11. The board of pharmacy shall promulgate rules and  
99 regulations to regulate, but not to restrict, the practice of pharmacy at  
100 a remote dispensing site pharmacy. Any rule or portion of a rule, as  
101 that term is defined in section 536.010, that is created under the  
102 authority delegated in this section shall become effective only if it  
103 complies with and is subject to all of the provisions of chapter 536 and,  
104 if applicable, section 536.028. This section and chapter 536 are  
105 nonseverable and if any of the powers vested with the general assembly

106 pursuant to chapter 536 to review, to delay the effective date, or to  
107 disapprove and annul a rule are subsequently held unconstitutional,  
108 then the grant of rulemaking authority and any rule proposed or  
109 adopted after August 28, 2020, shall be invalid and void.

338.220. 1. It shall be unlawful for any person, copartnership,  
2 association, corporation or any other business entity to open, establish, operate,  
3 or maintain any pharmacy as defined by statute without first obtaining a permit  
4 or license to do so from the Missouri board of pharmacy. A permit shall not be  
5 required for an individual licensed pharmacist to perform nondispensing activities  
6 outside of a pharmacy, as provided by the rules of the board. A permit shall not  
7 be required for an individual licensed pharmacist to administer drugs, vaccines,  
8 and biologicals by protocol, as permitted by law, outside of a pharmacy. The  
9 following classes of pharmacy permits or licenses are hereby established:

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

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

33 renewal fee. Separate applications shall be made and separate permits or  
34 licenses required for each pharmacy opened, established, operated, or maintained  
35 by the same owner.

36 3. All permits, licenses or renewal fees collected pursuant to the  
37 provisions of sections 338.210 to 338.370 shall be deposited in the state treasury  
38 to the credit of the Missouri board of pharmacy fund, to be used by the Missouri  
39 board of pharmacy in the enforcement of the provisions of sections 338.210 to  
40 338.370, when appropriated for that purpose by the general assembly.

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

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

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

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

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

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

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

15           **4. Supervision of a licensed remote dispensing site pharmacy**  
16 **shall not require a pharmacist to be physically present at the remote**  
17 **dispensing site location provided that dispensing activities are**  
18 **supervised by a pharmacist located at a Missouri licensed supervisory**  
19 **pharmacy through the use of a continuous, real-time audio and visual**  
20 **link, as provided in section 338.212.**

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Bill

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