

# SENATE BILL NO. 1126

## 101ST GENERAL ASSEMBLY

INTRODUCED BY SENATOR THOMPSON REHDER.

4884S.01I

ADRIANE D. CROUSE, Secretary

### AN ACT

To repeal sections 338.010 and 338.165, RSMo, and to enact in lieu thereof three new sections relating to the administration of medications by pharmacists.

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

Section A. Sections 338.010 and 338.165, RSMo, are  
2 repealed and three new sections enacted in lieu thereof, to be  
3 known as sections 338.010, 338.011, and 338.165, to read as  
4 follows:

338.010. 1. The "practice of pharmacy" means the  
2 interpretation, implementation, and evaluation of medical  
3 prescription orders, including any legend drugs under 21  
4 U.S.C. Section 353; receipt, transmission, or handling of  
5 such orders or facilitating the dispensing of such orders;  
6 the designing, initiating, implementing, and monitoring of a  
7 medication therapeutic plan [as defined by the prescription  
8 order so long as the prescription order is specific to each  
9 patient for care by a pharmacist]; the compounding,  
10 dispensing, labeling, and administration of drugs and  
11 devices pursuant to medical prescription orders [and  
12 administration of viral influenza, pneumonia, shingles,  
13 hepatitis A, hepatitis B, diphtheria, tetanus, pertussis,  
14 and meningitis vaccines by written protocol authorized by a  
15 physician for persons at least seven years of age or the age  
16 recommended by the Centers for Disease Control and  
17 Prevention, whichever is higher, or the administration of

**EXPLANATION-Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.**

18 pneumonia, shingles, hepatitis A, hepatitis B, diphtheria,  
19 tetanus, pertussis, meningitis, and viral influenza vaccines  
20 by written protocol authorized by a physician for a specific  
21 patient as authorized by rule]; **the ordering and**  
22 **administration of vaccines approved or authorized by the**  
23 **United States Food and Drug Administration to persons at**  
24 **least seven years of age or the age recommended by the**  
25 **Centers for Disease Control and Prevention, whichever is**  
26 **older, pursuant to joint promulgation of rules established**  
27 **by the board of pharmacy and the state board of registration**  
28 **for the healing arts, unless rules are established under a**  
29 **state of emergency as described in section 44.100; the**  
30 participation in drug selection according to state law and  
31 participation in drug utilization reviews; the proper and  
32 safe storage of drugs and devices and the maintenance of  
33 proper records thereof; consultation with patients and other  
34 health care practitioners, and veterinarians and their  
35 clients about legend drugs, about the safe and effective use  
36 of drugs and devices; the prescribing and dispensing of any  
37 nicotine replacement therapy product under section 338.665;  
38 the dispensing of HIV postexposure prophylaxis pursuant to  
39 section 338.730; and the offering or performing of those  
40 acts, services, operations, or transactions necessary in the  
41 conduct, operation, management and control of a pharmacy.  
42 No person shall engage in the practice of pharmacy unless he  
43 or she is licensed under the provisions of this chapter.  
44 This chapter shall not be construed to prohibit the use of  
45 auxiliary personnel under the direct supervision of a  
46 pharmacist from assisting the pharmacist in any of his or  
47 her duties. This assistance in no way is intended to  
48 relieve the pharmacist from his or her responsibilities for  
49 compliance with this chapter and he or she will be

50 responsible for the actions of the auxiliary personnel  
51 acting in his or her assistance. This chapter shall also  
52 not be construed to prohibit or interfere with any legally  
53 registered practitioner of medicine, dentistry, or podiatry,  
54 or veterinary medicine only for use in animals, or the  
55 practice of optometry in accordance with and as provided in  
56 sections 195.070 and 336.220 in the compounding,  
57 administering, prescribing, or dispensing of his or her own  
58 prescriptions.

59 2. [Any pharmacist who accepts a prescription order  
60 for a medication therapeutic plan shall have a written  
61 protocol from the physician who refers the patient for  
62 medication therapy services.] **A pharmacist with a  
63 certificate of medication therapeutic plan authority may  
64 provide medication therapy services pursuant to a statewide  
65 standing order issued by the department of health and senior  
66 services or pursuant to a written protocol with a physician  
67 licensed under chapter 334. The written protocol [and the  
68 prescription order for a medication therapeutic plan]  
69 authorized by this section shall only come from the  
70 physician [only] or similar body authorized by this section,  
71 and shall not come from a nurse engaged in a collaborative  
72 practice arrangement under section 334.104, or from a  
73 physician assistant engaged in a collaborative practice  
74 arrangement under section 334.735.**

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

79 4. Nothing in this section shall be construed to apply  
80 to or interfere with the sale of nonprescription drugs and  
81 the ordinary household remedies and such drugs or medicines

82 as are normally sold by those engaged in the sale of general  
83 merchandise.

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

88 6. This section shall not be construed to allow a  
89 pharmacist to diagnose or independently prescribe  
90 pharmaceuticals.

91 7. The state board of registration for the healing  
92 arts, under section 334.125, and the state board of  
93 pharmacy, under section 338.140, shall jointly promulgate  
94 rules regulating the use of protocols [for prescription  
95 orders] for medication therapy services [and administration  
96 of viral influenza vaccines]. Such rules shall require  
97 protocols to include provisions allowing for timely  
98 communication between the pharmacist and the [referring]  
99 **protocol physician or similar body authorized by this**  
100 **section**, and any other patient protection provisions deemed  
101 appropriate by both boards. In order to take effect, such  
102 rules shall be approved by a majority vote of a quorum of  
103 each board. Neither board shall separately promulgate rules  
104 regulating the use of protocols for [prescription orders  
105 for] medication therapy services [and administration of  
106 viral influenza vaccines]. Any rule or portion of a rule,  
107 as that term is defined in section 536.010, that is created  
108 under the authority delegated in this section shall become  
109 effective only if it complies with and is subject to all of  
110 the provisions of chapter 536 and, if applicable, section  
111 536.028. This section and chapter 536 are nonseverable and  
112 if any of the powers vested with the general assembly  
113 pursuant to chapter 536 to review, to delay the effective

114 date, or to disapprove and annul a rule are subsequently  
115 held unconstitutional, then the grant of rulemaking  
116 authority and any rule proposed or adopted after August 28,  
117 2007, shall be invalid and void.

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

127 9. [Any pharmacist who has received a certificate of  
128 medication therapeutic plan authority may engage in the  
129 designing, initiating, implementing, and monitoring of a  
130 medication therapeutic plan as defined by a prescription  
131 order from a physician that is specific to each patient for  
132 care by a pharmacist.

133 [10.] Nothing in this section shall be construed to  
134 allow a pharmacist to make a therapeutic substitution of a  
135 pharmaceutical prescribed by a physician unless authorized  
136 by the written protocol or the physician's prescription  
137 order.

138 [11.] 10. "Veterinarian", "doctor of veterinary  
139 medicine", "practitioner of veterinary medicine", "DVM",  
140 "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS",  
141 or an equivalent title means a person who has received a  
142 doctor's degree in veterinary medicine from an accredited  
143 school of veterinary medicine or holds an Educational  
144 Commission for Foreign Veterinary Graduates (EDFVG)

145 certificate issued by the American Veterinary Medical  
146 Association (AVMA).

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

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

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

158 (3)] 11. In addition to other requirements by the  
159 board, a pharmacist shall receive additional training as  
160 required by the board and evidenced by receiving a  
161 certificate from the board upon completion, and shall  
162 display the certification in his or her pharmacy where  
163 vaccines are delivered.

164 [13.] 12. A pharmacist shall inform the patient that  
165 the administration of [the] a vaccine will be entered into  
166 the ShowMeVax system, as administered by the department of  
167 health and senior services. The patient shall attest to the  
168 inclusion of such information in the system by signing a  
169 form provided by the pharmacist. If the patient indicates  
170 that he or she does not want such information entered into  
171 the ShowMeVax system, the pharmacist shall provide a written  
172 report within fourteen days of administration of a vaccine  
173 to the patient's health care provider, if provided by the  
174 patient, containing:

175 (1) The identity of the patient;

- 176           (2) The identity of the vaccine or vaccines  
177 administered;
- 178           (3) The route of administration;
- 179           (4) The anatomic site of the administration;
- 180           (5) The dose administered; and
- 181           (6) The date of administration.

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

3           (1) Order and administer medication approved or  
4 authorized by the U.S. Food and Drug Administration to  
5 address a public health need, as lawfully authorized by the  
6 state or federal government, or a department or agency  
7 thereof, during a state or federally declared public health  
8 emergency; and

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

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

26 **rulemaking authority and any rule proposed or adopted after**  
27 **August 28, 2022, shall be invalid and void.**

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

3 (1) "Board", the Missouri board of pharmacy;

4 (2) "Hospital", a hospital as defined in section  
5 197.020;

6 (3) "Hospital clinic or facility", a clinic or  
7 facility under the common control, management, or ownership  
8 of the same hospital or hospital system;

9 (4) "Medical staff committee", the committee or other  
10 body of a hospital or hospital system responsible for  
11 formulating policies regarding pharmacy services and  
12 medication management;

13 (5) "Medication order", an order for a legend drug or  
14 device that is:

15 (a) Authorized or issued by an authorized prescriber  
16 acting within the scope of his or her professional practice  
17 or pursuant to a protocol or standing order approved by the  
18 medical staff committee; and

19 (b) To be distributed or administered to the patient  
20 by a health care practitioner or lawfully authorized  
21 designee at a hospital or a hospital clinic or facility;

22 (6) "Patient", an individual receiving medical  
23 diagnosis, treatment or care at a hospital or a hospital  
24 clinic or facility.

25 2. The department of health and senior services shall  
26 have sole authority and responsibility for the inspection  
27 and licensure of hospitals as provided by chapter 197  
28 including, but not limited to all parts, services,  
29 functions, support functions and activities which contribute  
30 directly or indirectly to patient care of any kind



31 whatsoever. However, the board may inspect a class B  
32 pharmacy or any portion thereof that is not under the  
33 inspection authority vested in the department of health and  
34 senior services by chapter 197 to determine compliance with  
35 this chapter or the rules of the board. This section shall  
36 not be construed to bar the board from conducting an  
37 investigation pursuant to a public or governmental complaint  
38 to determine compliance by an individual licensee or  
39 registrant of the board with any applicable provisions of  
40 this chapter or the rules of the board.

41 3. The department of health and senior services shall  
42 have authority to promulgate rules in conjunction with the  
43 board governing medication distribution and the provision of  
44 medication therapy services by a pharmacist at or within a  
45 hospital. Rules may include, but are not limited to,  
46 medication management, preparation, compounding,  
47 administration, storage, distribution, packaging and  
48 labeling. Until such rules are jointly promulgated,  
49 hospitals shall comply with all applicable state law and  
50 department of health and senior services rules governing  
51 pharmacy services and medication management in hospitals.  
52 The rulemaking authority granted herein to the department of  
53 health and senior services shall not include the dispensing  
54 of medication by prescription.

55 4. All pharmacists providing medication therapy  
56 services shall obtain a certificate of medication  
57 therapeutic plan authority as provided by rule of the  
58 board. Medication therapy services may be provided by a  
59 pharmacist for patients of a hospital pursuant to **a**  
60 **statewide standing order issued by the department of health**  
61 **and senior services, or pursuant to** a protocol with a  
62 physician as required by section 338.010 or pursuant to a

63 protocol approved by the medical staff committee. However,  
64 the medical staff protocol shall include a process whereby  
65 an exemption to the protocol for a patient may be granted  
66 for clinical efficacy should the patient's physician make  
67 such request. The medical staff protocol shall also include  
68 an appeals process to request a change in a specific  
69 protocol based on medical evidence presented by a physician  
70 on staff.

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

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

76 7. Medication dispensed by a class A pharmacy located  
77 in a hospital to a hospital patient for use or  
78 administration outside of the hospital under a medical staff-  
79 approved protocol for medication therapy shall be dispensed  
80 only by a prescription order for medication therapy from an  
81 individual physician for a specific patient.

82 8. Medication dispensed by a hospital to a hospital  
83 patient for use or administration outside of the hospital  
84 shall be labeled as provided by rules jointly promulgated by  
85 the department of health and senior services and the board  
86 including medication distributed for administration by or  
87 under the supervision of a health care practitioner at a  
88 hospital clinic or facility.

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

91 10. Any rule, as that term is defined in section  
92 536.010, that is created under the authority delegated in  
93 this section shall only become effective if it complies with  
94 and is subject to all of the provisions of chapter 536 and,

95 if applicable, section 536.028. This section and chapter  
96 536 are nonseverable and if any of the powers vested with  
97 the general assembly under chapter 536 to review, to delay  
98 the effective date, or to disapprove and annul a rule are  
99 subsequently held unconstitutional, then the grant of  
100 rulemaking authority and any rule proposed or adopted after  
101 August 28, 2014, shall be invalid and void.

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

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

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

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

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

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

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

124 12. Nothing in this section shall be construed to  
125 limit the authority of a licensed health care provider to

126 prescribe, administer, or dispense medications and  
127 treatments within the scope of their professional practice.

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