

SENATE BILL NO. 41

102ND GENERAL ASSEMBLY

INTRODUCED BY SENATOR THOMPSON REHDER.

0719S.01I

KRISTINA MARTIN, 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2 repealed and three new sections enacted in lieu thereof, to be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
18 pneumonia, shingles, hepatitis A, hepatitis B, diphtheria,
19 tetanus, pertussis, meningitis, and viral influenza vaccines

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

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, excluding**
24 **vaccines for cholera, monkeypox, Japanese encephalitis,**
25 **typhoid, rabies, yellow fever, tick-borne encephalitis, and**
26 **anthrax, to persons at least seven years of age or the age**
27 **recommended by the Centers for Disease Control and**
28 **Prevention, whichever is older, pursuant to joint**
29 **promulgation of rules established by the board of pharmacy**
30 **and the state board of registration for the healing arts**
31 **unless rules are established under a state of emergency as**
32 **described in section 44.100; the participation in drug**
33 selection according to state law and participation in drug
34 utilization reviews; the proper and safe storage of drugs
35 and devices and the maintenance of proper records thereof;
36 consultation with patients and other health care
37 practitioners, and veterinarians and their clients about
38 legend drugs, about the safe and effective use of drugs and
39 devices; the prescribing and dispensing of any nicotine
40 replacement therapy product under section 338.665; the
41 dispensing of HIV postexposure prophylaxis pursuant to
42 section 338.730; and the offering or performing of those
43 acts, services, operations, or transactions necessary in the
44 conduct, operation, management and control of a pharmacy.
45 No person shall engage in the practice of pharmacy unless he
46 or she is licensed under the provisions of this chapter.
47 This chapter shall not be construed to prohibit the use of
48 auxiliary personnel under the direct supervision of a
49 pharmacist from assisting the pharmacist in any of his or
50 her duties. This assistance in no way is intended to
51 relieve the pharmacist from his or her responsibilities for

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

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

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

82 4. Nothing in this section shall be construed to apply
83 to or interfere with the sale of nonprescription drugs and

84 the ordinary household remedies and such drugs or medicines
85 as are normally sold by those engaged in the sale of general
86 merchandise.

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

91 6. This section shall not be construed to allow a
92 pharmacist to diagnose or independently prescribe
93 pharmaceuticals.

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

116 general assembly pursuant to chapter 536 to review, to delay
117 the effective date, or to disapprove and annul a rule are
118 subsequently held unconstitutional, then the grant of
119 rulemaking authority and any rule proposed or adopted after
120 August 28, 2007, shall be invalid and void.

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

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

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

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

148 certificate issued by the American Veterinary Medical
149 Association (AVMA).

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

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

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

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

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

178 (1) The identity of the patient;

179 (2) The identity of the vaccine or vaccines
180 administered;

181 (3) The route of administration;

182 (4) The anatomic site of the administration;

183 (5) The dose administered; and

184 (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 United States Food and Drug Administration
5 to address a public health need, as lawfully authorized by
6 the 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, 2023, 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, pursuant to** a protocol with a physician
62 as required by section 338.010, or pursuant to a protocol

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

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

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

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

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

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

90 10. Any rule, as that term is defined in section
91 536.010, that is created under the authority delegated in
92 this section shall only become effective if it complies with
93 and is subject to all of the provisions of chapter 536 and,
94 if applicable, section 536.028. This section and chapter

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

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

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

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

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

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

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

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

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

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

✓