SENATE SUBSTITUTE

FOR

SENATE COMMITTEE SUBSTITUTE

FOR

SENATE BILL NO. 41

AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof two 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	Section A. Section 338.010, RSMo, is repealed and two new
2	sections enacted in lieu thereof, to be known as sections
3	338.010 and 338.012, to read as follows:
	338.010. 1. The "practice of pharmacy" [means]
2	includes:
3	(1) The interpretation, implementation, and evaluation
4	of medical prescription orders, including any legend drugs
5	under 21 U.S.C. Section 353[;], and the receipt,
6	transmission, or handling of such orders or facilitating the
7	dispensing of such orders;
8	(2) The designing, initiating, implementing, and
9	monitoring of a medication therapeutic plan [as defined by
10	the prescription order so long as the prescription order is
11	specific to each patient for care by a pharmacist] <u>in</u>
12	accordance with the provisions of this section;
13	(3) The compounding, dispensing, labeling, and
14	administration of drugs and devices pursuant to medical
15	prescription orders [and administration of viral influenza,
16	pneumonia, shingles, hepatitis A, hepatitis B, diphtheria,
17	tetanus, pertussis, and meningitis vaccines by written
18	protocol authorized by a physician for persons at least
19	seven years of age or the age recommended by the Centers for

20 Disease Control and Prevention, whichever is higher, or the 21 administration of pneumonia, shingles, hepatitis A, 22 hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza vaccines by written protocol authorized by a 23 physician for a specific patient as authorized by rule]; 24 25 (4) The ordering and administration of vaccines approved or authorized by the U.S. Food and Drug 26 27 Administration, excluding vaccines for cholera, monkeypox, Japanese encephalitis, typhoid, rabies, yellow fever, tick-28 29 borne encephalitis, anthrax, tuberculosis, dengue, Hib, polio, rotavirus, smallpox, and any vaccine approved after 30 31 January 1, 2023, to persons at least seven years of age or 32 the age recommended by the Centers for Disease Control and Prevention, whichever is older, pursuant to joint 33 promulgation of rules established by the board of pharmacy 34 and the state board of registration for the healing arts 35 unless rules are established under a state of emergency as 36 37 described in section 44.100;

38 (5) The participation in drug selection according to
39 state law and participation in drug utilization reviews;

40 (6) The proper and safe storage of drugs and devices
41 and the maintenance of proper records thereof;

42 (7) Consultation with patients and other health care
43 practitioners, and veterinarians and their clients about
44 legend drugs, about the safe and effective use of drugs and
45 devices;

46 (8) The prescribing and dispensing of any nicotine
47 replacement therapy product under section 338.665;

48 (9) The dispensing of HIV postexposure prophylaxis
49 pursuant to section 338.730; and

50 (10) The offering or performing of those acts,
51 services, operations, or transactions necessary in the
52 conduct, operation, management and control of a pharmacy.

53 <u>2.</u> No person shall engage in the practice of pharmacy
54 unless he or she is licensed under the provisions of this
55 chapter.

3. This chapter shall not be construed to prohibit the 56 use of auxiliary personnel under the direct supervision of a 57 pharmacist from assisting the pharmacist in any of his or 58 59 her duties. This assistance in no way is intended to 60 relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be 61 62 responsible for the actions of the auxiliary personnel acting in his or her assistance. 63

64 <u>4.</u> This chapter shall [also] not be construed to
65 prohibit or interfere with any legally registered
66 practitioner of medicine, dentistry, or podiatry, or
67 veterinary medicine only for use in animals, or the practice
68 of optometry in accordance with and as provided in sections
69 195.070 and 336.220 in the compounding, administering,
70 prescribing, or dispensing of his or her own prescriptions.

71 [2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written 72 protocol from the physician who refers the patient for 73 74 medication therapy services.] 5. A pharmacist with a certificate of medication therapeutic plan authority may 75 76 provide medication therapy services pursuant to a written 77 protocol from a physician licensed under chapter 334 to 78 patients who have established a physician-patient 79 relationship, as described in subdivision (1) of subsection 1 of section 191.1146, with the protocol physician. 80 The written protocol [and the prescription order for a 81 82 medication therapeutic plan] authorized by this section 83 shall come only from the physician [only,] and shall not come from a nurse engaged in a collaborative practice 84 85 arrangement under section 334.104, or from a physician

86 assistant engaged in a collaborative practice arrangement 87 under section 334.735.

88 [3.] <u>6.</u> Nothing in this section shall be construed as
89 to prevent any person, firm or corporation from owning a
90 pharmacy regulated by sections 338.210 to 338.315, provided
91 that a licensed pharmacist is in charge of such pharmacy.

92 [4.] 7. Nothing in this section shall be construed to 93 apply to or interfere with the sale of nonprescription drugs 94 and the ordinary household remedies and such drugs or 95 medicines as are normally sold by those engaged in the sale 96 of general merchandise.

97 [5.] <u>8.</u> No health carrier as defined in chapter 376
98 shall require any physician with which they contract to
99 enter into a written protocol with a pharmacist for
100 medication therapeutic services.

101 [6.] <u>9.</u> This section shall not be construed to allow a
102 pharmacist to diagnose or independently prescribe
103 pharmaceuticals.

[7.] 10. The state board of registration for the 104 healing arts, under section 334.125, and the state board of 105 pharmacy, under section 338.140, shall jointly promulgate 106 107 rules regulating the use of protocols [for prescription] 108 orders] for medication therapy services [and administration 109 of viral influenza vaccines]. Such rules shall require 110 protocols to include provisions allowing for timely communication between the pharmacist and the [referring] 111 112 protocol physician or similar body authorized by this section, and any other patient protection provisions deemed 113 appropriate by both boards. In order to take effect, such 114 rules shall be approved by a majority vote of a quorum of 115 each board. Neither board shall separately promulgate rules 116 117 regulating the use of protocols for [prescription orders 118 for] medication therapy services [and administration of

119 viral influenza vaccines]. Any rule or portion of a rule, 120 as that term is defined in section 536.010, that is created 121 under the authority delegated in this section shall become 122 effective only if it complies with and is subject to all of 123 the provisions of chapter 536 and, if applicable, section 124 536.028. This section and chapter 536 are nonseverable and 125 if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective 126 127 date, or to disapprove and annul a rule are subsequently 128 held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 129 130 2007, shall be invalid and void.

[8.] 11. The state board of pharmacy may grant a 131 certificate of medication therapeutic plan authority to a 132 licensed pharmacist who submits proof of successful 133 completion of a board-approved course of academic clinical 134 135 study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a 136 137 nationally accredited college or university, or a certification of equivalence issued by a nationally 138 recognized professional organization and approved by the 139 board of pharmacy. 140

141 [9.] <u>12.</u> Any pharmacist who has received a certificate 142 of medication therapeutic plan authority may engage in the 143 designing, initiating, implementing, and monitoring of a 144 medication therapeutic plan as defined by a [prescription 145 order] written protocol from a physician that [is] may be 146 specific to each patient for care by a pharmacist.

147 [10.] <u>13.</u> Nothing in this section shall be construed 148 to allow a pharmacist to make a therapeutic substitution of 149 a pharmaceutical prescribed by a physician unless authorized 150 by the written protocol or the physician's prescription 151 order.

[11.] 14. "Veterinarian", "doctor of veterinary 152 153 medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", 154 or an equivalent title means a person who has received a 155 156 doctor's degree in veterinary medicine from an accredited 157 school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) 158 159 certificate issued by the American Veterinary Medical 160 Association (AVMA).

161 [12.] <u>15.</u> In addition to other requirements 162 established by the joint promulgation of rules by the board 163 of pharmacy and the state board of registration for the 164 healing arts:

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

168 (2) A pharmacist who is administering a vaccine shall 169 request a patient to remain in the pharmacy a safe amount of 170 time after administering the vaccine to observe any adverse 171 reactions. Such pharmacist shall have adopted emergency 172 treatment protocols;

173 [(3)] <u>16.</u> In addition to other requirements by the 174 board, a pharmacist shall receive additional training as 175 required by the board and evidenced by receiving a 176 certificate from the board upon completion, and shall 177 display the certification in his or her pharmacy where 178 vaccines are delivered.

179 [13.] <u>17.</u> A pharmacist shall inform the patient that 180 the administration of [the] <u>a</u> vaccine will be entered into 181 the ShowMeVax system, as administered by the department of 182 health and senior services. The patient shall attest to the 183 inclusion of such information in the system by signing a 184 form provided by the pharmacist. If the patient indicates

that he or she does not want such information entered into 185 186 the ShowMeVax system, the pharmacist shall provide a written 187 report within fourteen days of administration of a vaccine to the patient's health care provider, if provided by the 188 189 patient, containing: 190 The identity of the patient; (1)The identity of the vaccine or vaccines 191 (2)192 administered; 193 The route of administration; (3) 194 (4) The anatomic site of the administration; 195 (5) The dose administered; and The date of administration. (6) 196 197 18. A pharmacist licensed under this chapter may order 198 and administer vaccines approved or authorized by the U.S. 199 Food and Drug Administration to address a public health 200 need, as lawfully authorized by the state or federal 201 government, or a department or agency thereof, during a 202 state or federally declared public health emergency. 338.012. 1. A pharmacist with a certificate of medication therapeutic plan authority may provide influenza, 2 group A streptococcus, and COVID-19 medication therapy 3 services pursuant to a statewide standing order issued by 4 5 the director or chief medical officer of the department of 6 health and senior services if that person is a licensed 7 physician, or a licensed physician designated by the 8 department of health and senior services. 9 2. The state board of registration for the healing arts, pursuant to section 334.125, and the state board of 10 pharmacy, pursuant to section 338.140, shall jointly 11 12 promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is 13 defined in section 536.010, that is created under the 14 15 authority delegated in this section shall become effective

- 16 only if it complies with and is subject to all of the
- 17 provisions of chapter 536 and, if applicable, section
- 18 536.028. This section and chapter 536 are nonseverable and
- 19 if any of the powers vested with the general assembly
- 20 pursuant to chapter 536 to review, to delay the effective
- 21 date, or to disapprove and annul a rule are subsequently
- 22 held unconstitutional, then the grant of rulemaking
- 23 authority and any rule proposed or adopted after August 28,
- 24 2023, shall be invalid and void.