

FIRST REGULAR SESSION

HOUSE BILL NO. 513

95TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVES WELLS (Sponsor), WASSON, DENISON, POLLOCK, FRANZ, SANDER, WETER, WILSON (119), VIEBROCK, ERVIN, WILSON (130), JONES (117), WALLACE, WOOD, SCHAD, SCHLOTTACH, DIXON, DOUGHERTY, RUESTMAN, KINGERY, WRIGHT, FUNDERBURK, STORCH, HODGES, CHAPPELLE-NADAL, NIEVES, DAY, FAITH, BROWN (149), SATER, BURLISON, SMITH (150), NORR, SWINGER, BROWN (50), TILLEY, SPRENG, EL-AMIN AND JONES (63) (Co-sponsors).

1379L.01I

D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 338.010, 338.013, 338.057, 338.220, and 338.337, RSMo, and to enact in lieu thereof four new sections relating to pharmacists and pharmacies.

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

Section A. Sections 338.010, 338.013, 338.057, 338.220, and 338.337, RSMo, are
2 repealed and four new sections enacted in lieu thereof, to be known as sections 338.010,
3 338.013, 338.220, and 338.337, to read as follows:

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and
2 evaluation of medical prescription orders, including receipt, transmission, or handling of such
3 orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and
4 monitoring of a medication therapeutic plan as defined by the prescription order so long as the
5 prescription order is specific to each patient for care by a specific pharmacist; the compounding,
6 dispensing, labeling, and administration of drugs and devices pursuant to medical prescription
7 orders and administration of viral influenza, **pneumonia, and shingles** vaccines by written
8 protocol authorized by a physician for persons twelve years of age or older as authorized by rule;
9 the participation in drug selection according to state law and participation in drug utilization
10 reviews; the proper and safe storage of drugs and devices and the maintenance of proper records
11 thereof; consultation with patients and other health care practitioners about the safe and effective
12 use of drugs and devices; and the offering or performing of those acts, services, operations, or

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.

13 transactions necessary in the conduct, operation, management and control of a pharmacy. No
14 person shall engage in the practice of pharmacy unless he is licensed under the provisions of this
15 chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the
16 direct supervision of a pharmacist from assisting the pharmacist in any of his duties. This
17 assistance in no way is intended to relieve the pharmacist from his responsibilities for
18 compliance with this chapter and he will be responsible for the actions of the auxiliary personnel
19 acting in his assistance. This chapter shall also not be construed to prohibit or interfere with any
20 legally registered practitioner of medicine, dentistry, podiatry, or veterinary medicine, or the
21 practice of optometry in accordance with and as provided in sections 195.070 and 336.220,
22 RSMo, in the compounding or dispensing of his own prescriptions.

23 2. Any pharmacist who accepts a prescription order for a medication therapeutic plan
24 shall have a written protocol from the physician who refers the patient for medication therapy
25 services. The written protocol and the prescription order for a medication therapeutic plan shall
26 come from the physician only, and shall not come from a nurse engaged in a collaborative
27 practice arrangement under section 334.104, RSMo, or from a physician assistant engaged in a
28 supervision agreement under section 334.735, RSMo.

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

32 4. Nothing in this section shall be construed to apply to or interfere with the sale of
33 nonprescription drugs and the ordinary household remedies and such drugs or medicines as are
34 normally sold by those engaged in the sale of general merchandise.

35 5. No health carrier as defined in chapter 376, RSMo, shall require any physician with
36 which they contract to enter into a written protocol with a pharmacist for medication therapeutic
37 services.

38 6. This section shall not be construed to allow a pharmacist to diagnose or independently
39 prescribe pharmaceuticals.

40 7. The state board of registration for the healing arts, under section 334.125, RSMo, and
41 the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the
42 use of protocols for prescription orders for medication therapy services and administration of
43 viral influenza vaccines. Such rules shall require protocols to include provisions allowing for
44 timely communication between the pharmacist and the referring physician, and any other patient
45 protection provisions deemed appropriate by both boards. In order to take effect, such rules shall
46 be approved by a majority vote of a quorum of each board. Neither board shall separately
47 promulgate rules regulating the use of protocols for prescription orders for medication therapy
48 services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term

49 is defined in section 536.010, RSMo, that is created under the authority delegated in this section
50 shall become effective only if it complies with and is subject to all of the provisions of chapter
51 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo,
52 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter
53 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are
54 subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed
55 or adopted after August 28, 2007, shall be invalid and void.

56 8. The state board of pharmacy may grant a certificate of medication therapeutic plan
57 authority to a licensed pharmacist who submits proof of successful completion of a
58 board-approved course of academic clinical study beyond a bachelor of science in pharmacy,
59 including but not limited to clinical assessment skills, from a nationally accredited college or
60 university, or a certification of equivalence issued by a nationally recognized professional
61 organization and approved by the board of pharmacy.

62 9. Any pharmacist who has received a certificate of medication therapeutic plan authority
63 may engage in the designing, initiating, implementing, and monitoring of a medication
64 therapeutic plan as defined by a prescription order from a physician that is specific to each
65 patient for care by a specific pharmacist.

66 10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic
67 substitution of a pharmaceutical prescribed by a physician unless authorized by the written
68 protocol or the physician's prescription order.

338.013. 1. Any person desiring to assist a pharmacist in the practice of pharmacy as
2 defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy
3 technician. Such applicant shall be, at a minimum, legal working age and shall forward to the
4 board the appropriate fee and written application on a form provided by the board. Such
5 registration shall be the sole authorization permitted to allow persons to assist licensed
6 pharmacists in the practice of pharmacy as defined in this chapter.

7 2. The board may refuse to issue a certificate of registration as a pharmacy technician
8 to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo
9 contendere, of a violation of any state, territory or federal drug law, or to any felony or has
10 violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such
11 person a registration, but may authorize the person to work as a pharmacy technician provided
12 that person adheres to certain terms and conditions imposed by the board. The board shall place
13 on the employment disqualification list the name of an applicant who the board has refused to
14 issue a certificate of registration as a pharmacy technician, or the name of a person who the board
15 has issued a certificate of registration as a pharmacy technician but has authorized to work under

16 certain terms and conditions. The board shall notify the applicant of the applicant's right to file
17 a complaint with the administrative hearing commission as provided by chapter 621, RSMo.

18 3. If an applicant has submitted the required fee and an application for registration to the
19 board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed
20 pharmacist in the practice of pharmacy as defined in this chapter [for a period of up to ninety
21 days prior to the issuance of a certificate of registration]. The applicant shall keep a copy of the
22 submitted application on the premises where the applicant is employed. [When] **If** the board
23 refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant
24 shall immediately cease assisting a licensed pharmacist in the practice of pharmacy.

25 4. A certificate of registration issued by the board shall be conspicuously displayed in
26 the pharmacy or place of business where the registrant is employed.

27 5. Every pharmacy technician who desires to continue to be registered as provided in this
28 section shall, within thirty days before the registration expiration date, file an application for the
29 renewal, accompanied by the fee prescribed by the board. [No registration as provided in this
30 section shall be valid if the registration has expired and has not been renewed as provided in this
31 subsection] **The registration shall lapse and become null and void thirty days after the**
32 **expiration date.**

33 6. The board shall maintain an employment disqualification list. No person whose name
34 appears on the employment disqualification list shall work as a pharmacy technician, except as
35 otherwise authorized by the board. The board may authorize a person whose name appears on
36 the employment disqualification list to work or continue to work as a pharmacy technician
37 provided the person adheres to certain terms and conditions imposed by the board.

38 7. The board may place on the employment disqualification list the name of a pharmacy
39 technician who has been adjudicated and found guilty, or has entered a plea of guilty or nolo
40 contendere, of a violation of any state, territory [of] **or** federal drug law, or to any felony or has
41 violated any provision of subsection 2 of section 338.055.

42 8. After an investigation and a determination has been made to place a person's name on
43 the employment disqualification list, the board shall notify such person in writing mailed to the
44 person's last known address [that]:

45 (1) **That** an allegation has been made against the person, the substance of the allegation
46 and that an investigation has been conducted which tends to substantiate the allegation;

47 (2) **That** such person's name has been added in the employment disqualification list of
48 the board;

49 (3) The consequences to the person of being listed and the length of time the person's
50 name will be on the list; and

51 (4) The person's right to file a complaint with the administrative hearing commission as
52 provided in chapter 621, RSMo.

53 9. The length of time a person's name shall remain on the disqualification list shall be
54 determined by the board.

55 10. No hospital or licensed pharmacy shall knowingly employ any person whose name
56 appears on the employee disqualification list, except that a hospital or licensed pharmacy may
57 employ a person whose name appears on the employment disqualification list but the board has
58 authorized to work under certain terms and conditions. Any hospital or licensed pharmacy shall
59 report to the board any final disciplinary action taken against a pharmacy technician or the
60 voluntary resignation of a pharmacy technician against whom any complaints or reports have
61 been made which might have led to final disciplinary action that can be a cause of action for
62 discipline by the board as provided for in subsection 2 of section 338.055. Compliance with the
63 foregoing sentence may be interposed as an affirmative defense by the employer. Any hospital
64 or licensed pharmacy which reports to the board in good faith shall not be liable for civil
65 damages.

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**
5 **nondispensing activities outside of a pharmacy, subject to rules established by the board.**
6 **A permit shall not be required for an individual licensed pharmacist to administer drugs,**
7 **vaccines, and biologicals by protocol, as permitted by law, outside of a pharmacy.** The
8 following classes of pharmacy permits or licenses are hereby established:

- 9 (1) Class A: Community/ambulatory;
10 (2) Class B: Hospital outpatient 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 2. Application for such permit or license shall be made upon a form furnished to the
22 applicant; shall contain a statement that it is made under oath or affirmation and that its
23 representations are true and correct to the best knowledge and belief of the person signing same,
24 subject to the penalties of making a false affidavit or declaration; and shall be accompanied by
25 a permit or license fee. The permit or license issued shall be renewable upon payment of a
26 renewal fee. Separate applications shall be made and separate permits or licenses required for
27 each pharmacy opened, established, operated, or maintained by the same owner.

28 3. All permits, licenses or renewal fees collected pursuant to the provisions of sections
29 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of
30 pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the
31 provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general
32 assembly.

33 4. Class L: veterinary permit shall not be construed to prohibit or interfere with any
34 legally registered practitioner of veterinary medicine in the compounding or dispensing of their
35 own prescriptions.

36 5. Notwithstanding any other law to the contrary, the provisions of this section shall not
37 apply to the sale, dispensing, or filling of a pharmaceutical product or drug used for treating
38 animals.

 338.337. It shall be unlawful for any out-of-state wholesale drug distributor or
2 out-of-state pharmacy acting as a distributor to do business in this state without first obtaining
3 a license to do so from the board of pharmacy and paying the required fee. Application for an
4 out-of-state wholesale drug distributor's license under this section shall be made on a form
5 furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not
6 change or affect tax liability imposed by the Missouri department of revenue on any out-of-state
7 wholesale drug distributor or out-of-state pharmacy. Any out-of-state wholesale drug distributor
8 that is a drug manufacturer and which produces and distributes from a facility which has been
9 inspected and approved by the Food and Drug Administration within the last two years and
10 which is licensed by the state in which the distribution facility is located need not be licensed as
11 provided in this section but such out-of-state distributor shall register its business name and
12 address with the board of pharmacy and pay a filing fee [of ten dollars] **in an amount**
13 **established by the board.**

 [338.057. The board of pharmacy shall publish a list of drug products for
2 which substitution as provided in section 338.056 shall not be permitted. The list
3 of drug products to be included on this list shall be based upon a joint
4 determination made by the department of health and senior services, the state
5 board of registration for the healing arts, and the state board of pharmacy. The

6 board of pharmacy shall publish the list not less often than semiannually, and
7 shall publish amendments to the list as required.]

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