

SECOND REGULAR SESSION

# SENATE BILL NO. 942

97TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time February 26, 2014, and ordered printed.

TERRY L. SPIELER, Secretary.

5946S.011

## AN ACT

To repeal sections 338.059 and 338.220, RSMo, and to enact in lieu thereof three new sections relating to pharmacy licensure.

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

Section A. Sections 338.059 and 338.220, RSMo, are repealed and three  
2 new sections enacted in lieu thereof, to be known as sections 338.059, 338.165,  
3 and 338.220, to read as follows:

338.059. 1. It shall be the duty of a licensed pharmacist or a physician  
2 to affix or have affixed by someone under the pharmacist's or physician's  
3 supervision a label to each and every container provided to a consumer in which  
4 is placed any prescription drug upon which is typed or written the following  
5 information:

- 6 (1) The date the prescription is filled;
- 7 (2) The sequential number **or other unique identifier**;
- 8 (3) The patient's name;
- 9 (4) The prescriber's directions for usage;
- 10 (5) The prescriber's name;
- 11 (6) The name and address of the pharmacy;
- 12 (7) The exact name and dosage of the drug dispensed;
- 13 (8) There may be one line under the information provided in subdivisions  
14 (1) to (7) of this subsection stating "Refill" with a blank line or squares following  
15 or the words "No Refill";
- 16 (9) When a generic substitution is dispensed, the name of the  
17 manufacturer or an abbreviation thereof shall appear on the label or in the  
18 pharmacist's records as required in section 338.100.

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

19           2. The label of any drug which is sold at wholesale in this state and which  
20 requires a prescription to be dispensed at retail shall contain the name of the  
21 manufacturer, expiration date, if applicable, batch or lot number and national  
22 drug code.

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

- 2           **(1) "Board", the Missouri board of pharmacy;**  
3           **(2) "Hospital", a hospital as defined in section 197.020;**  
4           **(3) "Hospital clinic or facility", a clinic or facility under the**  
5 **common control, management or ownership of the same hospital or**  
6 **hospital system;**  
7           **(4) "Medical staff committee", the committee or other body of a**  
8 **hospital or hospital system responsible for formulating policies**  
9 **regarding pharmacy services and medication management;**  
10          **(5) "Medication order", an order for a legend drug or device that**  
11 **is:**  
12           **(a) Authorized or issued by an authorized prescriber acting**  
13 **within the scope of his or her professional practice or pursuant to a**  
14 **protocol or standing order approved by the medical staff committee;**  
15 **and**  
16           **(b) To be distributed or administered to the patient by a health**  
17 **care practitioner or lawfully authorized designee at a hospital or a**  
18 **hospital clinic or facility;**  
19          **(6) "Patient", an individual receiving medical diagnosis,**  
20 **treatment or care at a hospital or a hospital clinic or facility.**

21           2. The department of health and senior services shall have sole  
22 authority and responsibility for the inspection and licensure of  
23 hospitals as provided by chapter 197 including, but not limited to all  
24 parts, services, functions, support functions and activities which  
25 contribute directly or indirectly to patient care of any kind  
26 whatsoever. However, the board may inspect a class B pharmacy or  
27 any portion thereof that is not under the inspection authority vested  
28 in the department of health and senior services by chapter 197 to  
29 determine compliance with this chapter or the rules of the board. This  
30 section shall not be construed to bar the board from conducting an  
31 investigation pursuant to a public or governmental complaint to  
32 determine compliance by an individual licensee or registrant of the  
33 board with any applicable provisions of this chapter or the rules of the

34 **board.**

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

47 **4. All pharmacists providing medication therapy services shall**  
48 **obtain a certificate of medication therapeutic plan authority as**  
49 **provided by rule of the board. Medication therapy services may be**  
50 **provided by a pharmacist for patients of a hospital pursuant to a**  
51 **protocol with a physician as required by section 338.010 or pursuant to**  
52 **a protocol approved by the medical staff committee.**

53 **5. Medication may be dispensed by a class B hospital pharmacy**  
54 **pursuant to a prescription or a medication order.**

55 **6. A drug distributor license shall not be required to transfer**  
56 **medication from a class B hospital pharmacy to a hospital clinic or**  
57 **facility for patient care or treatment.**

58 **7. Medication dispensed by a hospital to a hospital patient for**  
59 **use or administration outside of the hospital shall be labeled as**  
60 **provided by rules jointly promulgated by the department of health and**  
61 **senior services and the board including, medication distributed for**  
62 **administration by or under the supervision of a health care**  
63 **practitioner at a hospital clinic or facility.**

64 **8. This section shall not be construed to preempt any law or rule**  
65 **governing controlled substances.**

66 **9. Any rule, as that term is defined in section 536.010, that is**  
67 **created under the authority delegated in this section shall only become**  
68 **effective if it complies with and is subject to all of the provisions of**  
69 **chapter 536 and, if applicable, section 536.028. This section and chapter**  
70 **536 are nonseverable and if any of the powers vested with the general**

71 assembly under chapter 536 to review, to delay the effective date, or to  
72 disapprove and annul a rule are subsequently held unconstitutional,  
73 then the grant of rulemaking authority and any rule proposed or  
74 adopted after August 28, 2014, shall be invalid and void.

75       **10. The board shall appoint an advisory committee to review and**  
76 **make recommendations to the board on the merit of all rules and**  
77 **regulations to be jointly promulgated by the board and the department**  
78 **of health and senior services pursuant to the joint rulemaking**  
79 **authority granted by this section. The advisory committee shall consist**  
80 **of:**

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

83           **(2) One pharmacist designated by the Missouri Society of Health**  
84 **System Pharmacists;**

85           **(3) One pharmacist designated by the Missouri Pharmacy**  
86 **Association;**

87           **(4) One pharmacist designated by the department of health and**  
88 **senior services from a hospital with a licensed bed count that does not**  
89 **exceed fifty beds or from a critical access hospital as defined by the**  
90 **department of social services for purposes of MO HealthNet**  
91 **reimbursement;**

92           **(5) One pharmacist designated by the department of health and**  
93 **senior services from a hospital with a licensed bed count that exceeds**  
94 **two hundred beds; and**

95           **(6) One pharmacist designated by the Board with experience in**  
96 **the provision of hospital pharmacy services.**

97       **11. Nothing in this section shall be construed to limit the**  
98 **authority of a licensed health care provider to prescribe, administer,**  
99 **or dispense medications and treatments within the scope of their**  
100 **professional practice.**

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 [outpatient] 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 2. Application for such permit or license shall be made upon a form  
27 furnished to the applicant; shall contain a statement that it is made under oath  
28 or affirmation and that its representations are true and correct to the best  
29 knowledge and belief of the person signing same, subject to the penalties of  
30 making a false affidavit or declaration; and shall be accompanied by a permit or  
31 license fee. The permit or license issued shall be renewable upon payment of a  
32 renewal fee. Separate applications shall be made and separate permits or  
33 licenses required for each pharmacy opened, established, operated, or maintained  
34 by the same owner.

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

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

44 animals.

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

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

56           **7. Upon application to the board, any hospital that holds a**  
57 **pharmacy permit or license on the effective date of this section shall be**  
58 **entitled to obtain a class B pharmacy permit or license without fee,**  
59 **provided such application shall be submitted to the board on or before**  
60 **January 1, 2015.**

Bill ✓

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