

SECOND REGULAR SESSION

HOUSE BILL NO. 2285

97TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE BURLISON.

6540L.011

D. ADAM CRUMBLISS, Chief Clerk

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Section A. Sections 338.059 and 338.220, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 338.059, 338.165, and 338.220, to read as follows:

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

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

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.

17 2. The label of any drug which is sold at wholesale in this state and which requires a
18 prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date,
19 if applicable, batch or lot number and national 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 common control,**
5 **management or ownership of the same hospital or hospital system;**
- 6 **(4) "Medical staff committee", the committee or other body of a hospital or hospital**
7 **system responsible for formulating policies regarding pharmacy services and medication**
8 **management;**
- 9 **(5) "Medication order", an order for a legend drug or device that is:**
 - 10 **(a) Authorized or issued by an authorized prescriber acting within the scope of his**
11 **or her professional practice or pursuant to a protocol or standing order approved by the**
12 **medical staff committee; and**
 - 13 **(b) To be distributed or administered to the patient by a health care practitioner**
14 **or lawfully authorized designee at a hospital or a hospital clinic or facility;**
- 15 **(6) "Patient", an individual receiving medical diagnosis, treatment or care at a**
16 **hospital or a hospital clinic or facility.**

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

27 **3. The department of health and senior services shall have authority to promulgate**
28 **rules in conjunction with the board governing medication distribution and the provision**
29 **of medication therapy services by a pharmacist at or within a hospital. Rules may include,**
30 **but are not limited to, medication management, preparation, compounding,**
31 **administration, storage, distribution, packaging and labeling. Until such rules are jointly**
32 **promulgated, hospitals shall comply with all applicable state law and department of health**
33 **and senior services rules governing pharmacy services and medication management in**

34 hospitals. The rulemaking authority granted herein to the department of health and senior
35 services shall not include the dispensing of medication by prescription.

36 4. All pharmacists providing medication therapy services shall obtain a certificate
37 of medication therapeutic plan authority as provided by rule of the board. Medication
38 therapy services may be provided by a pharmacist for patients of a hospital pursuant to
39 a protocol with a physician as required by section 338.010 or pursuant to a protocol
40 approved by the medical staff committee.

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

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

45 7. Medication dispensed by a hospital to a hospital patient for use or administration
46 outside of the hospital shall be labeled as provided by rules jointly promulgated by the
47 department of health and senior services and the board including, medication distributed
48 for administration by or under the supervision of a health care practitioner at a hospital
49 clinic or facility.

50 8. This section shall not be construed to preempt any law or rule governing
51 controlled substances.

52 9. Any rule, as that term is defined in section 536.010, that is created under the
53 authority delegated in this section shall only become effective if it complies with and is
54 subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This
55 section and chapter 536 are nonseverable and if any of the powers vested with the general
56 assembly under chapter 536 to review, to delay the effective date, or to disapprove and
57 annul a rule are subsequently held unconstitutional, then the grant of rulemaking
58 authority and any rule proposed or adopted after August 28, 2014, shall be invalid and
59 void.

60 10. The board shall appoint an advisory committee to review and make
61 recommendations to the board on the merit of all rules and regulations to be jointly
62 promulgated by the board and the department of health and senior services pursuant to
63 the joint rulemaking authority granted by this section. The advisory committee shall
64 consist of:

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

67 (2) One pharmacist designated by the Missouri Society of Health System
68 Pharmacists;

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

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

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

76 **(6) One pharmacist designated by the board with experience in the provision of**
77 **hospital pharmacy services.**

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

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 nondispensing
5 activities outside of a pharmacy, as provided by the rules of the board. A permit shall not be
6 required for an individual licensed pharmacist to administer drugs, vaccines, and biologicals by
7 protocol, as permitted by law, outside of a pharmacy. The following classes of pharmacy permits
8 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 (13) Class M: Specialty (bleeding disorder);
- 22 (14) Class N: Automated dispensing system (health care facility);
- 23 (15) Class O: Automated dispensing system (ambulatory care);
- 24 (16) Class P: Practitioner office/clinic.

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

32 3. All permits, licenses or renewal fees collected pursuant to the provisions of sections
33 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of
34 pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the
35 provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general
36 assembly.

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

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

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

50 7. Upon application to the board, any hospital that holds a pharmacy permit or
51 license on the effective date of this section shall be entitled to obtain a class B pharmacy
52 permit or license without fee, provided such application shall be submitted to the board on
53 or before January 1, 2015.

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