

SECOND REGULAR SESSION

HOUSE BILL NO. 2349

102ND GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE SMITH (155).

5047H.011

DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal section 338.165, RSMo, and to enact in lieu thereof one new section relating to pharmacy services in hospitals.

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

Section A. Section 338.165, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 338.165, to read as follows:

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

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

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 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, the
21 board may inspect a class B pharmacy or any portion thereof that is not under the inspection
22 authority vested in the department of health and senior services by chapter 197 to determine
23 compliance with this chapter or the rules of the board. This section shall not be construed to
24 bar the board from conducting an investigation pursuant to a public or governmental
25 complaint to determine compliance by an individual licensee or registrant of the board with
26 any applicable provisions of this chapter or the rules of the board.

27 3. The department of health and senior services shall have **sole** authority to
28 promulgate rules **governing inpatient pharmacy services in hospitals but may promulgate**
29 **rules** in conjunction with the board governing medication distribution and the provision of
30 medication therapy services, **as described in section 338.010**, by a pharmacist at or within a
31 hospital. [~~Rules may include, but are not limited to, medication management, preparation,~~
32 ~~compounding, administration, storage, distribution, packaging and labeling. Until such rules~~
33 ~~are jointly promulgated, hospitals shall comply with all applicable state law and department~~
34 ~~of health and senior services rules governing pharmacy services and medication management~~
35 ~~in hospitals]~~ **The board shall have sole authority to promulgate rules on the inspection**
36 **and licensure of class B hospital pharmacies.** The rulemaking authority granted herein to
37 the department of health and senior services shall not include the dispensing of medication by
38 prescription.

39 4. All pharmacists providing medication therapy services shall obtain a certificate of
40 medication therapeutic plan authority as provided by rule of the board. Medication therapy
41 services may be provided by a pharmacist for patients of a hospital pursuant to a protocol
42 with a physician as required by section 338.010 or pursuant to a protocol approved by the
43 medical staff committee. However, the medical staff protocol shall include a process
44 whereby an exemption to the protocol for a patient may be granted for clinical efficacy should
45 the patient's physician make such request. The medical staff protocol shall also include an
46 appeals process to request a change in a specific protocol based on medical evidence
47 presented by a physician on staff.

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

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

52 7. Medication dispensed by a class A pharmacy located in a hospital to a hospital
53 patient for use or administration outside of the hospital under a medical staff-approved

54 protocol for medication therapy shall be dispensed only by a prescription order for medication
55 therapy from an individual physician for a specific patient.

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

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

63 10. Any rule, as that term is defined in section 536.010, that is created under the
64 authority delegated in this section shall only become effective if it complies with and is
65 subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section
66 and chapter 536 are nonseverable and if any of the powers vested with the general assembly
67 under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are
68 subsequently held unconstitutional, then the grant of rulemaking authority and any rule
69 proposed or adopted after August 28, 2014, shall be invalid and void.

70 11. The board shall appoint an advisory committee to review and make
71 recommendations to the board on the merit of all rules and regulations to be jointly
72 promulgated by the board and the department of health and senior services pursuant to the
73 joint rulemaking authority granted by this section. The advisory committee shall consist of:

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

76 (2) One pharmacist designated by the Missouri Society of Health System
77 Pharmacists;

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

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

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

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

87 12. Nothing in this section shall be construed to limit the authority of a licensed
88 health care provider to prescribe, administer, or dispense medications and treatments within
89 the scope of their professional practice.

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