

FIRST REGULAR SESSION

HOUSE BILL NO. 1305

101ST GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE WRIGHT.

2660H.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Section A. Section 338.165, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 338.165, to read as follows: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:

- 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 or her
- 11 professional practice or pursuant to a protocol or standing order approved by the medical staff
- 12 committee; and
- 13 (b) To be distributed or administered to the patient by a health care practitioner or
- 14 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 hospital
- 16 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 including,
19 but not limited to all parts, services, functions, support functions and activities which contribute
20 directly or indirectly to patient care of any kind whatsoever. However, the board may inspect
21 a class B pharmacy or any portion thereof that is not under the inspection authority vested in the
22 department of health and senior services by chapter 197 to determine compliance with this
23 chapter or the rules of the board. This section shall not be construed to bar the board from
24 conducting an investigation pursuant to a public or governmental complaint to determine
25 compliance by an individual licensee or registrant of the board with any applicable provisions
26 of this chapter or the rules of the board.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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