

SENATE BILL NO. 511

102ND GENERAL ASSEMBLY

INTRODUCED BY SENATOR CRAWFORD.

1855S.011

KRISTINA MARTIN, Secretary

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Section A. Section 338.165, RSMo, is repealed and one new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

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

3 (1) "Board", the Missouri board of pharmacy;

4 (2) "Hospital", a hospital as defined in section
5 197.020;

6 (3) "Hospital clinic or facility", a clinic or
7 facility under the common control, management, or ownership
8 of the same hospital or hospital system;

9 (4) "Medical staff committee", the committee or other
10 body of a hospital or hospital system responsible for
11 formulating policies regarding pharmacy services and
12 medication management;

13 (5) "Medication order", an order for a legend drug or
14 device that is:

15 (a) Authorized or issued by an authorized prescriber
16 acting within the scope of his or her professional practice
17 or pursuant to a protocol or standing order approved by the
18 medical staff committee; and

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

19 (b) To be distributed or administered to the patient
20 by a health care practitioner or lawfully authorized
21 designee at a hospital or a hospital clinic or facility;

22 (6) "Patient", an individual receiving medical
23 diagnosis, treatment or care at a hospital or a hospital
24 clinic or facility.

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

41 3. The department of health and senior services shall
42 have **the sole** authority to promulgate rules **governing**
43 **inpatient pharmacy services in hospitals, but may promulgate**
44 **rules** in conjunction with the board governing medication
45 distribution and the provision of medication therapy
46 services, **as described in section 338.010**, by a pharmacist
47 at or within a hospital. [Rules may include, but are not
48 limited to, medication management, preparation, compounding,
49 administration, storage, distribution, packaging and
50 labeling. Until such rules are jointly promulgated,

51 hospitals shall comply with all applicable state law and
52 department of health and senior services rules governing
53 pharmacy services and medication management in hospitals.]

54 **The board shall have the sole authority to promulgate rules**
55 **governing inspection and licensure of class B pharmacies.**

56 The rulemaking authority granted herein to the department of
57 health and senior services shall not include the dispensing
58 of medication by prescription.

59 4. All pharmacists providing medication therapy
60 services shall obtain a certificate of medication
61 therapeutic plan authority as provided by rule of the
62 board. Medication therapy services may be provided by a
63 pharmacist for patients of a hospital pursuant to a
64 protocol with a physician as required by section 338.010 or
65 pursuant to a protocol approved by the medical staff
66 committee. However, the medical staff protocol shall
67 include a process whereby an exemption to the protocol for a
68 patient may be granted for clinical efficacy should the
69 patient's physician make such request. The medical staff
70 protocol shall also include an appeals process to request a
71 change in a specific protocol based on medical evidence
72 presented by a physician on staff.

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

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

78 7. Medication dispensed by a class A pharmacy located
79 in a hospital to a hospital patient for use or
80 administration outside of the hospital under a medical staff-
81 approved protocol for medication therapy shall be dispensed

82 only by a prescription order for medication therapy from an
83 individual physician for a specific patient.

84 8. Medication dispensed by a hospital to a hospital
85 patient for use or administration outside of the hospital
86 shall be labeled as provided by rules jointly promulgated by
87 the department of health and senior services and the board
88 including medication distributed for administration by or
89 under the supervision of a health care practitioner at a
90 hospital clinic or facility.

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

93 10. Any rule, as that term is defined in section
94 536.010, that is created under the authority delegated in
95 this section shall only become effective if it complies with
96 and is subject to all of the provisions of chapter 536 and,
97 if applicable, section 536.028. This section and chapter
98 536 are nonseverable and if any of the powers vested with
99 the general assembly under chapter 536 to review, to delay
100 the effective date, or to disapprove and annul a rule are
101 subsequently held unconstitutional, then the grant of
102 rulemaking authority and any rule proposed or adopted after
103 August 28, 2014, shall be invalid and void.

104 11. The board shall appoint an advisory committee to
105 review and make recommendations to the board on the merit of
106 all rules and regulations to be jointly promulgated by the
107 board and the department of health and senior services
108 pursuant to the joint rulemaking authority granted by this
109 section. The advisory committee shall consist of:

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

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

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

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

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

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

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

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