

House \_\_\_\_\_ Amendment NO. \_\_\_\_\_

Offered By

1 AMEND House Committee Substitute for Senate Substitute for Senate Bill No. 198, Page 39,  
2 Section 302.181, Line 113, by inserting after all of the said section and line the following:

3  
4 "338.165. 1. As used in this section, the following terms mean:

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

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

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

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

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

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

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

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

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

28 3. The department of health and senior services shall have sole authority to promulgate rules  
29 governing pharmacy services in hospitals but may promulgate rules in conjunction with the board  
30 governing medication distribution and the provision of medication therapy services, as described in

Action Taken \_\_\_\_\_ Date \_\_\_\_\_

1 section 338.010, by a pharmacist at or within a hospital. [Rules may include, but are not limited to,  
2 medication management, preparation, compounding, administration, storage, distribution, packaging  
3 and labeling. Until such rules are jointly promulgated, hospitals shall comply with all applicable  
4 state law and department of health and senior services rules governing pharmacy services and  
5 medication management in hospitals] The board shall have sole authority to promulgate rules on the  
6 inspection and licensure of class B hospital pharmacies. The rulemaking authority granted herein to  
7 the department of health and senior services shall not include the dispensing of medication by  
8 prescription.

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

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

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

21       7. Medication dispensed by a class A pharmacy located in a hospital to a hospital patient for  
22 use or administration outside of the hospital under a medical staff-approved protocol for medication  
23 therapy shall be dispensed only by a prescription order for medication therapy from an individual  
24 physician for a specific patient.

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

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

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

38       11. The board shall appoint an advisory committee to review and make recommendations to  
39 the board on the merit of all rules and regulations to be jointly promulgated by the board and the

1 department of health and senior services pursuant to the joint rulemaking authority granted by this  
2 section. The advisory committee shall consist of:

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

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

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

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

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

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

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

17  
18 Further amend said bill by amending the title, enacting clause, and intersectional references  
19 accordingly.