HOUSE _____ AMENDMENT NO.___

Offered By

_____ _____

AMEND House Committee Substitute for Senate Bill No. 284, Page 9, Section 144.030, Line 279, by inserting immediately after said line the following:

"338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of

his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy,

including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).; and

Further amend said substitute, Page 12, Section 338.055, Line 99, by inserting immediately after said line the following:

"338.140. 1. The board of pharmacy shall have a common seal, and shall have power to adopt such rules and bylaws not inconsistent with law as may be necessary for the regulation of its proceedings and for the discharge of the duties imposed pursuant to sections 338.010 to 338.198, and shall have power to employ an attorney to conduct prosecutions or to assist in the conduct of prosecutions pursuant to sections 338.010 to 338.198.

2. The board shall keep a record of its proceedings.

3. The board of pharmacy shall make annually to the governor and, upon written request, to persons licensed pursuant to the provisions of this chapter a written report of its proceedings.

4. The board of pharmacy shall appoint an advisory committee composed of **[**five**]** six members, one of whom shall be a representative of pharmacy but who shall not be a member of the pharmacy board, three of whom shall be representatives of wholesale drug distributors as defined in section 338.330, **[**and**]** one of whom shall be a representative of drug manufacturers, and one of whom shall be a licensed veterinarian recommended to the board of pharmacy by the board of veterinary medicine. The committee shall review and make recommendations to the board on the merit of all rules and regulations dealing with pharmacy distributors, wholesale drug distributors **[**and**]**, drug manufacturers, and veterinary legend drugs which are proposed by the

board.

5. A majority of the board shall constitute a quorum for the transaction of business.

6. Notwithstanding any other provisions of law to the contrary, the board may issue letters of reprimand, censure or warning to any holder of a license or registration required pursuant to this chapter for any violations that could result in disciplinary action as defined in section 338.055.

338.150. Any person authorized by the board of pharmacy is hereby given the right of entry and inspection upon all open premises purporting or appearing to be drug or chemical stores, apothecary shops, pharmacies or places of business for exposing for sale, or the dispensing or selling of drugs, pharmaceuticals, medicines, chemicals or poisons or for the compounding of physicians' or veterinarians' prescriptions.

338.210. 1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:

(1) Where the practice of pharmacy is offered or conducted;

(2) Where drugs, chemicals, medicines, any legend drugs under 21 U.S.C. Section 353, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;

(3) Where the words "pharmacist", "apothecary", "drugstore", "drugs", and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;

(4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.

2. All activity or conduct involving the practice of pharmacy as it relates to an identifiable prescription or drug order shall occur at the pharmacy location where such identifiable prescription or drug order is first presented by the patient or the patient's authorized agent for preparation or dispensing, unless otherwise expressly authorized by the board.

3. The requirements set forth in subsection 2 of this section shall not be construed to bar the complete transfer of an identifiable prescription or drug order pursuant to a verbal request by or the written consent of the patient or the patient's authorized agent.

4. The board is hereby authorized to enact rules waiving the requirements of subsection 2 of this section and establishing such terms and conditions as it deems necessary, whereby any activities related to the preparation, dispensing or recording of an identifiable prescription or drug order may be shared between separately licensed facilities.

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct

to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

6. Nothing in this section shall be construed to supersede the provisions of section 197.100.

338.220. 1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. A permit shall not be required for an individual licensed pharmacist to perform nondispensing activities outside of a pharmacy, as provided by the rules of the board. A permit shall not be required for an individual licensed pharmacist to administer drugs, vaccines, and biologicals by protocol, as permitted by law, outside of a pharmacy. The following classes of pharmacy permits or licenses are hereby established:

(1) Class A: Community/ambulatory;

(2) Class B: Hospital outpatient pharmacy;

(3) Class C: Long-term care;

(4) Class D: Nonsterile compounding;

(5) Class E: Radio pharmaceutical;

(6) Class F: Renal dialysis;

(7) Class G: Medical gas;

(8) Class H: Sterile product compounding;

(9) Class I: Consultant services;

(10) Class J: Shared service;

(11) Class K: Internet;

(12) Class L: Veterinary.

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

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

assembly.

4. Class L: veterinary permit shall not be construed to prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, or medicine, drug, or pharmaceutical product to be used for animals. 5. **[**Notwithstanding any other law to the contrary**]** Except for any legend drugs under 21 U.S.C. Section 353, the provisions of this section shall not apply to the sale, dispensing, or filling of a pharmaceutical product or drug used for treating animals.

338.240. 1. Upon evidence satisfactory to the said Missouri board of pharmacy:

(1) That the pharmacy for which a permit, or renewal thereof, is sought, will be conducted in full compliance with sections 338.210 to 338.300, with existing laws, and with the rules and regulations as established hereunder by said board;

(2) That the equipment and facilities of such pharmacy are such that it can be operated in a manner not to endanger the public health or safety;

(3) That such pharmacy is equipped with proper pharmaceutical and sanitary appliances and kept in a clean, sanitary and orderly manner;

(4) That the management of said pharmacy is under the supervision of either a registered pharmacist, or an owner or employee of the owner, who has at his or her place of business a registered pharmacist employed for the purpose of compounding physician's or veterinarian's prescriptions in the event any such prescriptions are compounded or sold;

(5) That said pharmacy is operated in compliance with the rules and regulations legally prescribed with respect thereto by the Missouri board of pharmacy, a permit or renewal thereof shall be issued to such persons as the said board of pharmacy shall deem qualified to conduct such pharmacy.

2. In lieu of a registered pharmacist as required by subdivision (4) of subsection 1 of this section, a pharmacy permit holder that only holds a class L veterinary permit and no other pharmacy permit, may designate a supervising registered pharmacist who shall be responsible for reviewing the activities and records of the class L pharmacy permit holder as established by the board by rule. The supervising registered pharmacist shall not be required to be physically present on site during the business operations of a class L pharmacy permit holder identified in subdivision (5) of subsection 1 of this section when noncontrolled legend drugs under 21 U.S.C. Section 353 are being dispensed for use in animals, but shall be specifically present on site when any noncontrolled drugs for use in animals are being compounded.

338.315. It shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug distributor or licensed pharmacy. Any person who

violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A misdemeanor. Any subsequent conviction shall constitute a class D felony."; and

Further amend said substitute, Page 12, Section 338.330, by striking all of said section and inserting in lieu thereof the following:

"338.330. As used in sections 338.300 to 338.370, the following terms mean:

(1) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

(2) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;

(3) "Legend drug":

(a) Any drug or biological product:

a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such section;

b. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:

(i) "Caution: Federal law prohibits dispensing without prescription";

(ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(iii) "Rx only";

c. Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only;

(b) The term "drug", "prescription drug", or "legend drug" shall not include:

a. An investigational new drug, as defined in 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such drug or product that is governed by and being conducted under 21 CFR 312, et seq.;

b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by and being conducted under 21 CFR 312, et seq.;

c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46;

(4) "Wholesale drug distributor", anyone engaged in the delivery or distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug or drug-related device in this state, other than to the ultimate consumer. This shall include,

but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state, with facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360."; and

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