SENATE AMENDMENT NO. ___

Offered by _____ **of** _____

Amend SS/SCS/House **Bill No.** 1719, **Page** 191, **Section** 337.718, **Line** 27,

by inserting after all of said line the following:

"338.315. 1. Except as otherwise provided by the board by rule, 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, drug outsourcer, third-party logistics provider, 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 E felony.

2. Notwithstanding any other provision of law to the contrary, the sale, purchase, or trade of a prescription drug by a pharmacy to other pharmacies is permissible if the total dollar volume of such sales, purchases, or trades are in compliance with the rules of the board and do not exceed five percent of the pharmacy's total annual prescription drug sales.

3. Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Such records shall be maintained for two years and be readily available upon

request by the board or its representatives.

4. The board shall promulgate rules to implement the provisions of this section. 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, 2012, shall be invalid and void.

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

(1) "Drug outsourcer", an outsourcing facility as defined by 21 U.S.C. Section 353b of the federal Drug Quality and Security Act;

(2) "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 503(b); or

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"; or

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; and

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

a. An investigational new drug, as defined by 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 and pursuant to, 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 and pursuant to, 21 CFR 312, et. seq.; or

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;

[(2)**]** (3) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

[(3)**]** (4) "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;

[(4)**]** (5) "Third-party logistics provider", an entity that provides or coordinates warehousing or other logistics services

of a product on behalf of a drug manufacturer, wholesale drug distributor, or dispenser of a legend drug, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product;

(6) "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.

338.333. 1. Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a wholesale drug distributor **[**or**]**, pharmacy distributor, drug outsourcer, or third-party logistics provider without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. The board may grant temporary licenses when the wholesale drug distributor **[**or**]**, pharmacy distributor, drug outsourcer, or third-party logistics provider first applies for a license to operate within the state.

Temporary licenses shall remain valid until such time as the board shall find that the applicant meets or fails to meet the requirements for regular licensure. No license shall be issued or renewed for a wholesale drug distributor [or], pharmacy distributor, drug outsourcer, or third-party logistics provider to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor [or], pharmacy distributor, drug outsourcer, or third-party logistics provider, unless such drug distributor [or], pharmacy distributor, drug outsourcer, or third-party logistics provider meets the requirements of section 338.335.

2. An agent or employee of any licensed or registered wholesale drug distributor [or], pharmacy distributor, drug outsourcer, or third-party logistics provider need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if [he] the agent or employee is acting in the usual course of his or her business or employment.

3. The board may permit out-of-state wholesale drug distributors, drug outsourcers, third-party logistics provider, or out-of-state pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of reciprocity to the extent that [an out-of-state wholesale drug distributor or out-of-state pharmacy distributor] the entity both:

(1) Possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor [or], pharmacy distributor, drug

outsourcers, or third-party logistics provider of this state as prerequisites for obtaining a license under the laws of this state; and

(2) Distributes into Missouri from a state which would extend reciprocal treatment under its own laws to a wholesale drug distributor **[**or**]**, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state.

338.337. It shall be unlawful for any out-of-state wholesale drug distributor **[**or**]**, out-of-state pharmacy acting as a distributor, drug outsourcers, or third-party logistics provider to do business in this state without first obtaining a license to do so from the board of pharmacy and paying the required fee, except as otherwise provided by section 338.335 and this section. Application for an out-of-state wholesale drug distributor's, drug outsourcer's, or out-of-state third-party logistics provider's license under this section shall be made on a form furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the Missouri department of revenue on any **[**out-of-state wholesale drug distributor or out-of-state pharmacy**]** entity. Any out-of-state wholesale drug distributor that is a drug manufacturer and which produces and distributes from a facility which has been inspected and approved by the Food and Drug Administration, maintains current approval by the federal Food and Drug Administration, and has provided a copy of the most recent Food and Drug Administration Establishment Inspection Report to the board, and which is licensed by the state in which the distribution facility is located, or, if located within a foreign jurisdiction, is authorized and in good

standing to operate as a drug manufacturer within such jurisdiction, need not be licensed as provided in this section but such out-of-state distributor shall register its business name and address with the board of pharmacy and pay a filing fee in an amount established by the board.

338.340. No person acting as principal or agent for any out-of-state wholesale drug distributor **[**or**]**, out-of-state pharmacy distributor, drug outsourcer, or out-of-state third-party logistics provider shall sell or distribute drugs in this state unless the **[**wholesale drug distributor or pharmacy distributor**]** entity has obtained a license pursuant to the provisions of sections 338.330 to 338.370."; and

Further amend the title and enacting clause accordingly.