

House _____ Amendment NO. _____

Offered By _____

1 AMEND House Committee Substitute for Senate Substitute for Senate Committee Substitute for
2 Senate Bill No. 843, Page 50, Section 335.021, Line 36, by inserting after all of said line the
3 following:

4 "338.315. 1. Except as otherwise provided by the board by rule, it shall be unlawful for any
5 pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive
6 any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug
7 distributor, drug outsourcer, third-party logistics provider, or licensed pharmacy. Any person who
8 violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A
9 misdemeanor. Any subsequent conviction shall constitute a class E felony.

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

14 3. Pharmacies shall establish and maintain inventories and records of all transactions
15 regarding the receipt and distribution or other disposition of legend drugs. Such records shall be
16 maintained for two years and be readily available upon request by the board or its representatives.

17 4. The board shall promulgate rules to implement the provisions of this section. Any rule or
18 portion of a rule, as that term is defined in section 536.010, that is created under the authority
19 delegated in this section shall become effective only if it complies with and is subject to all of the
20 provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
21 nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to
22 review, to delay the effective date, or to disapprove and annul a rule are subsequently held
23 unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after
24 August 28, 2012, shall be invalid and void.

25 338.330. As used in sections 338.300 to 338.370, the following terms mean:

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

28 (2) "Legend drug":

29 (a) Any drug or biological product:

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

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

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

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

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1 (iii) "Rx Only"; or

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

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

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

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

10 or
11 c. Any drug product being utilized for the purposes of conducting a clinical trial or
12 investigation that is governed or approved by an institutional review board subject to 21 CFR Part
13 56 or 45 CFR Part 46;

14 ~~[(2)]~~ (3) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no
15 physical facilities located in the state;

16 ~~[(3)]~~ (4) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210,
17 engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such
18 delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;

19 ~~[(4)]~~ (5) "Third-party logistics provider", an entity that provides or coordinates warehousing
20 or other logistics services of a product on behalf of a drug manufacturer, wholesale distributor, or
21 dispenser of a legend drug, but does not take ownership of the product, nor have responsibility to
22 direct the sale or disposition of the product;

23 (6) "Wholesale drug distributor", anyone engaged in the delivery or distribution of legend
24 drugs from any location and who is involved in the actual, constructive or attempted transfer of a
25 drug or drug-related device in this state, other than to the ultimate consumer. This shall include, but
26 not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the
27 delivery or distribution of drugs in this state, with facilities located in this state or in any other state
28 or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual
29 hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment
30 basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those
31 standards of practice required of a drug distributor but shall be open for inspection by board of
32 pharmacy representatives as provided for in section 338.360.

33 338.333. 1. Except as otherwise provided by the board of pharmacy by rule in the event of
34 an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a
35 wholesale drug distributor, drug outsourcer, third-party logistics provider, or pharmacy distributor
36 without first obtaining license to do so from the Missouri board of pharmacy and paying the
37 required fee. The board may grant temporary licenses when the wholesale drug distributor, drug
38 outsourcer, third-party logistics provider, or pharmacy distributor first applies for a license to
39 operate within the state. Temporary licenses shall remain valid until such time as the board shall
40 find that the applicant meets or fails to meet the requirements for regular licensure. No license shall
41 be issued or renewed for a wholesale drug distributor, drug outsourcer, third-party logistics
42 provider, or pharmacy distributor to operate unless the same shall be operated in a manner
43 prescribed by law and according to the rules and regulations promulgated by the board of pharmacy
44 with respect thereto. Separate licenses shall be required for each distribution, drug outsourcer or
45 third-party logistics site owned or operated by a wholesale drug distributor, drug outsourcer, third-
46 party logistics provider, or pharmacy distributor, unless such drug distributor, drug outsourcer, third-
47 party logistics provider, or pharmacy distributor meets the requirements of section 338.335.

48 2. An agent or employee of any licensed or registered wholesale drug distributor, drug

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

4 3. The board may permit out-of-state wholesale drug distributors, drug outsourcers, third-
5 party logistics providers, or out-of-state pharmacy distributors to be licensed as required by sections
6 338.210 to 338.370 on the basis of reciprocity to the extent that ~~[an out-of-state wholesale drug~~
7 ~~distributor or out-of-state pharmacy distributor]~~ the entity both:

8 (1) Possesses a valid license granted by another state pursuant to legal standards comparable
9 to those which must be met by a wholesale drug distributor, drug outsourcer, third-party logistics
10 provider, or pharmacy distributor of this state as prerequisites for obtaining a license under the laws
11 of this state; and

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

15 338.337. It shall be unlawful for any out-of-state wholesale drug distributor ~~[or]~~ , out-of-
16 state pharmacy acting as a distributor, drug outsourcer, or out-of-state third-party logistics provider
17 to do business in this state without first obtaining a license to do so from the board of pharmacy and
18 paying the required fee, except as otherwise provided by section 338.335 and this section.

19 Application for an out-of-state wholesale drug distributor's, drug outsourcer's, or out-of-state third-
20 party logistics provider's license under this section shall be made on a form furnished by the board.

21 The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability
22 imposed by the Missouri department of revenue on any ~~[out-of-state wholesale drug distributor or~~
23 ~~out-of-state pharmacy]~~ entity. Any out-of-state wholesale drug distributor that is a drug
24 manufacturer and which produces and distributes from a facility which has been inspected and
25 approved by the Food and Drug Administration, maintains current approval by the federal Food and
26 Drug Administration, and has provided a copy of the most recent Food and Drug Administration
27 Establishment Inspection Report to the board, and which is licensed by the state in which the
28 distribution facility is located, or, if located within a foreign jurisdiction, is authorized and in good
29 standing to operate as a drug manufacturer within such jurisdiction, need not be licensed as provided
30 in this section but such out-of-state distributor shall register its business name and address with the
31 board of pharmacy and pay a filing fee in an amount established by the board.

32 338.340. No person acting as principal or agent for any out-of-state wholesale drug
33 distributor ~~[or]~~ , out-of-state pharmacy distributor, drug outsourcer, or out-of-state third-party
34 logistics provider shall sell or distribute drugs in this state unless the ~~[wholesale drug distributor or~~
35 ~~pharmacy distributor]~~ entity has obtained a license pursuant to the provisions of sections 338.330 to
36 338.370."; and

37
38 Further amend said bill by amending the title, enacting clause, and intersectional references
39 accordingly.