

SECOND REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 1563

96TH GENERAL ASSEMBLY

5569H.02P

D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 338.315 and 338.333, RSMo, and to enact in lieu thereof two new sections relating to legend drugs, with a penalty provision.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 338.315 and 338.333, RSMo, are repealed and two new sections
2 enacted in lieu thereof, to be known as sections 338.315 and 338.333, to read as follows:

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

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

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

16 **4. The board shall promulgate rules to implement the provisions of this section.**
17 **Any rule or portion of a rule, as that term is defined in section 536.010, that is created**

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

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

338.333. 1. **Except as otherwise provided by the board of pharmacy by rule in the**
2 **event of an emergency or to alleviate a supply shortage,** no person or distribution outlet shall
3 act as a wholesale drug distributor or pharmacy distributor without first obtaining license to do
4 so from the Missouri board of pharmacy and paying the required fee. The board may grant
5 temporary licenses when the wholesale drug distributor or pharmacy distributor first applies for
6 a license to operate within the state. Temporary licenses shall remain valid until such time as
7 the board shall find that the applicant meets or fails to meet the requirements for regular
8 licensure. No license shall be issued or renewed for a wholesale drug distributor or pharmacy
9 distributor to operate unless the same shall be operated in a manner prescribed by law and
10 according to the rules and regulations promulgated by the board of pharmacy with respect
11 thereto. Separate licenses shall be required for each distribution site owned or operated by a
12 wholesale drug distributor or pharmacy distributor, unless such drug distributor or pharmacy
13 distributor meets the requirements of section 338.335.

14 2. An agent or employee of any licensed or registered wholesale drug distributor or
15 pharmacy distributor need not seek licensure under this section and may lawfully possess
16 pharmaceutical drugs, if he is acting in the usual course of his business or employment.

17 3. The board may permit out-of-state wholesale drug distributors or out-of-state
18 pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of
19 reciprocity to the extent that an out-of-state wholesale drug distributor or out-of-state pharmacy
20 distributor both:

21 (1) Possesses a valid license granted by another state pursuant to legal standards
22 comparable to those which must be met by a wholesale drug distributor or pharmacy distributor
23 of this state as prerequisites for obtaining a license under the laws of this state; and

24 (2) Distributes into Missouri from a state which would extend reciprocal treatment under
25 its own laws to a wholesale drug distributor or pharmacy distributor of this state.

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