SECOND REGULAR SESSION

HOUSE BILL NO. 2568

99TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HAEFNER.

6596H.01I D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 338.330 and 338.343, RSMo, and to enact in lieu thereof three new sections relating to wholesale distribution of controlled substances.

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

Section A. Sections 338.330 and 338.343, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 338.330, 338.343, and 338.345, to read as follows:

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

(1) **"Controlled substance", a drug, substance, or immediate precursor in Schedules I through V listed in chapter 195;**

(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:

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.

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)** "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.

338.343. **1.** Any licensee licensed under the provisions of sections 338.330 to 338.340 must maintain required records to guarantee security, storage and accountability. These records shall be available for inspection by the board.

2. Each licensee licensed under sections 338.330 to 338.340 shall make monthly reports to the attorney general of every sale, delivery, and other disposition by the licensee of any controlled substance to or within the state.

338.345. 1. Each licensee licensed under sections 338.330 to 338.340 shall design and operate a system to disclose to the licensee suspicious orders of controlled substances. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

2. Each licensee licensed under sections 338.330 to 338.340 shall promptly notify the attorney general of each suspicious order of controlled substances to or within the state that is identified by the licensee.

3. Each licensee licensed under sections 338.330 to 338.340 shall notify the attorney general of any theft or significant loss of any controlled substances within the state within one business day of the licensee's discovery of the theft or loss. When determining whether a loss is significant for purposes of this subsection, a licensee shall consider, among other factors, the following:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;

(5) If known, whether the specific controlled substances are likely candidates for diversion; and

(6) If known, local trends and other indicators of the diversion potential of the missing controlled substances.

4. The attorney general shall have the authority to promulgate all rules necessary for the administration of 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, 2018, shall be invalid and void.

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