

FIRST REGULAR SESSION

# HOUSE BILL NO. 412

## 96TH GENERAL ASSEMBLY

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INTRODUCED BY REPRESENTATIVE SMITH (150).

1225L.011

D. ADAM CRUMBLISS, Chief Clerk

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### AN ACT

To repeal section 338.330, RSMo, and to enact in lieu thereof one new section relating to wholesale drug distributors.

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

Section A. Section 338.330, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 338.330, to read as follows:

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**";

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

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

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

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

26           **c. Any drug product being utilized for the purposes of conducting a clinical trial**  
27 **or investigation that is governed or approved by an institutional review board subject to**  
28 **21 CFR Part 56 or 45 CFR Part 46;**

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