

FIRST REGULAR SESSION  
SENATE COMMITTEE SUBSTITUTE FOR  
HOUSE COMMITTEE SUBSTITUTE FOR  
**HOUSE BILL NO. 412**  
96TH GENERAL ASSEMBLY

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Reported from the Committee on Financial and Governmental Organizations and Elections, May 5, 2011, with recommendation that the Senate Committee Substitute do pass.

1225S.03C

TERRY L. SPIELER, Secretary.

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**AN ACT**

To repeal sections 338.055 and 338.330, RSMo, and to enact in lieu thereof two new sections relating to the authority of the board of pharmacy, with an emergency clause for a certain section.

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

Section A. Sections 338.055 and 338.330, RSMo, are repealed and two new sections enacted in lieu thereof, to be known as sections 338.055 and 338.330, to read as follows:

338.055. 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section **or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.** The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

**EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.**

16 (1) Use of any controlled substance, as defined in chapter 195, or alcoholic  
17 beverage to an extent that such use impairs a person's ability to perform the work  
18 of any profession licensed or regulated by this chapter;

19 (2) The person has been finally adjudicated and found guilty, or entered  
20 a plea of guilty or nolo contendere, in a criminal prosecution under the laws of  
21 any state or of the United States, for any offense reasonably related to the  
22 qualifications, functions or duties of any profession licensed or regulated under  
23 this chapter, for any offense an essential element of which is fraud, dishonesty  
24 or an act of violence, or for any offense involving moral turpitude, whether or not  
25 sentence is imposed;

26 (3) Use of fraud, deception, misrepresentation or bribery in securing any  
27 certificate of registration or authority, permit or license issued pursuant to this  
28 chapter or in obtaining permission to take any examination given or required  
29 pursuant to this chapter;

30 (4) Obtaining or attempting to obtain any fee, charge, tuition or other  
31 compensation by fraud, deception or misrepresentation;

32 (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation  
33 or dishonesty in the performance of the functions or duties of any profession  
34 licensed or regulated by this chapter;

35 (6) Violation of, or assisting or enabling any person to violate, any  
36 provision of this chapter, or of any lawful rule or regulation adopted pursuant to  
37 this chapter;

38 (7) Impersonation of any person holding a certificate of registration or  
39 authority, permit or license or allowing any person to use his or her certificate of  
40 registration or authority, permit, license, or diploma from any school;

41 (8) Denial of licensure to an applicant or disciplinary action against an  
42 applicant or the holder of a license or other right to practice any profession  
43 regulated by this chapter granted by another state, territory, federal agency, or  
44 country whether or not voluntarily agreed to by the licensee or applicant,  
45 including, but not limited to, surrender of the license upon grounds for which  
46 denial or discipline is authorized in this state;

47 (9) A person is finally adjudged incapacitated by a court of competent  
48 jurisdiction;

49 (10) Assisting or enabling any person to practice or offer to practice any  
50 profession licensed or regulated by this chapter who is not registered and  
51 currently eligible to practice under this chapter;

52 (11) Issuance of a certificate of registration or authority, permit or license  
53 based upon a material mistake of fact;

54 (12) Failure to display a valid certificate or license if so required by this  
55 chapter or any rule promulgated hereunder;

56 (13) Violation of any professional trust or confidence;

57 (14) Use of any advertisement or solicitation which is false, misleading or  
58 deceptive to the general public or persons to whom the advertisement or  
59 solicitation is primarily directed;

60 (15) Violation of the drug laws or rules and regulations of this state, any  
61 other state or the federal government;

62 (16) The intentional act of substituting or otherwise changing the content,  
63 formula or brand of any drug prescribed by written or oral prescription without  
64 prior written or oral approval from the prescriber for the respective change in  
65 each prescription; provided, however, that nothing contained herein shall prohibit  
66 a pharmacist from substituting or changing the brand of any drug as provided  
67 under section 338.056, and any such substituting or changing of the brand of any  
68 drug as provided for in section 338.056 shall not be deemed unprofessional or  
69 dishonorable conduct unless a violation of section 338.056 occurs;

70 (17) Personal use or consumption of any controlled substance unless it is  
71 prescribed, dispensed, or administered by a health care provider who is  
72 authorized by law to do so.

73 3. After the filing of such complaint, the proceedings shall be conducted  
74 in accordance with the provisions of chapter 621. Upon a finding by the  
75 administrative hearing commission that the grounds, provided in subsection 2 of  
76 **this section**, for disciplinary action are met, the board may, singly or in  
77 combination, censure or place the person named in the complaint on probation on  
78 such terms and conditions as the board deems appropriate for a period not to  
79 exceed five years, or may suspend, for a period not to exceed three years, or  
80 revoke the license, certificate, or permit. The board may impose additional  
81 discipline on a licensee, registrant, or permittee found to have violated any  
82 disciplinary terms previously imposed under this section or by agreement. The  
83 additional discipline may include, singly or in combination, censure, placing the  
84 licensee, registrant, or permittee named in the complaint on additional probation  
85 on such terms and conditions as the board deems appropriate, which additional  
86 probation shall not exceed five years, or suspension for a period not to exceed  
87 three years, or revocation of the license, certificate, or permit.

88           4. If the board concludes that a licensee or registrant has committed an  
89 act or is engaging in a course of conduct which would be grounds for disciplinary  
90 action which constitutes a clear and present danger to the public health and  
91 safety, the board may file a complaint before the administrative hearing  
92 commission requesting an expedited hearing and specifying the activities which  
93 give rise to the danger and the nature of the proposed restriction or suspension  
94 of the licensee's or registrant's license. Within fifteen days after service of the  
95 complaint on the licensee or registrant, the administrative hearing commission  
96 shall conduct a preliminary hearing to determine whether the alleged activities  
97 of the licensee or registrant appear to constitute a clear and present danger to the  
98 public health and safety which justify that the licensee's or registrant's license  
99 or registration be immediately restricted or suspended. The burden of proving  
100 that the actions of a licensee or registrant constitute a clear and present danger  
101 to the public health and safety shall be upon the state board of pharmacy. The  
102 administrative hearing commission shall issue its decision immediately after the  
103 hearing and shall either grant to the board the authority to suspend or restrict  
104 the license or dismiss the action.

105           5. If the administrative hearing commission grants temporary authority  
106 to the board to restrict or suspend the licensee's or registrant's license, such  
107 temporary authority of the board shall become final authority if there is no  
108 request by the licensee or registrant for a full hearing within thirty days of the  
109 preliminary hearing. The administrative hearing commission shall, if requested  
110 by the licensee or registrant named in the complaint, set a date to hold a full  
111 hearing under the provisions of chapter 621 regarding the activities alleged in the  
112 initial complaint filed by the board.

113           6. If the administrative hearing commission dismisses the action filed by  
114 the board pursuant to subsection 4 of this section, such dismissal shall not bar  
115 the board from initiating a subsequent action on the same grounds.

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

3           (1) **"Legend drug", any drug or biological product;**

4           **(a) Subject to section 503(b) of the Federal Food, Drug and**  
5 **Cosmetic Act, including finished dosage forms and active ingredients**  
6 **subject to section 503(b); or**

7           **(b) Required under federal law to be labeled with one of the**  
8 **following statements prior to being dispensed or delivered:**

9           a. **"Caution: Federal law prohibits dispensing without**  
10 **prescription";**

11           b. **"Caution: Federal law restricts this drug to use by or on the**  
12 **order of a licensed veterinarian";**

13           c. **"Rx Only"; or**

14           **(c) Required by an applicable federal or state law or regulation**  
15 **to be dispensed by prescription only or that is restricted to use by**  
16 **practitioners only; and**

17           **(d) The term "drug", "prescription drug", or "legend drug" shall**  
18 **not include:**

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

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

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

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

31           **[(2)] (3) "Pharmacy distributor", any licensed pharmacy, as defined in**  
32 **section 338.210, engaged in the delivery or distribution of legend drugs to any**  
33 **other licensed pharmacy where such delivery or distribution constitutes at least**  
34 **five percent of the total gross sales of such pharmacy;**

35           **[(3)] (4) "Wholesale drug distributor", anyone engaged in the delivery or**  
36 **distribution of legend drugs from any location and who is involved in the actual,**  
37 **constructive or attempted transfer of a drug or drug-related device in this state,**  
38 **other than to the ultimate consumer. This shall include, but not be limited to,**  
39 **drug wholesalers, repackagers and manufacturers which are engaged in the**  
40 **delivery or distribution of drugs in this state, with facilities located in this state**  
41 **or in any other state or jurisdiction. A wholesale drug distributor shall not**  
42 **include any common carrier or individual hired solely to transport legend**  
43 **drugs. Any locations where drugs are delivered on a consignment basis, as**  
44 **defined by the board, shall be exempt from licensure as a drug distributor, and**

45 those standards of practice required of a drug distributor but shall be open for  
46 inspection by board of pharmacy representatives as provided for in section  
47 338.360.

Section B. Because immediate action is necessary to ensure the  
2 continuance of clinical trials in this state, the repeal and reenactment of section  
3 338.330 of section A of this act is deemed necessary for the immediate  
4 preservation of the public health, welfare, peace, and safety, and is hereby  
5 declared to be an emergency act within the meaning of the constitution, and the  
6 repeal and reenactment of section 338.330 of section A of this act shall be in full  
7 force and effect upon its passage and approval.

Unofficial ✓

Bill

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