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HOUSE BILL NO. 2649

Offered January 10, 2007

Prefiled January 10, 2007

A BILL to amend and reenact §§ 54.1-3316, 54.1-3434.3, 54.1-3435.1, and 54.1-3435.3 of the Code of Virginia, and to repeal §§ 54.1-3315, 54.1-3322, and 54.1-3435.5 of the Code of Virginia, relating to the grounds for which the Board of Pharmacy may deny, or take disciplinary action against a license, permit, certificate, or registration.

Patron—Jones, S.C.

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3316, 54.1-3434.3, 54.1-3435.1, and 54.1-3435.3 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3316. Refusal; revocation; suspension and denial.

~~The Board of Pharmacy may revoke, suspend or refuse to issue or renew any license, permit, or registration or may deny any application if it finds that the applicant~~*The Board may refuse to admit an applicant to any examination; refuse to issue a license, permit, certificate, or registration to any applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke any license, permit, certificate, or registration if it finds that an applicant or a person holding a license, permit, certificate, or registration:*

1. *Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;*

2. *Has been guilty of engaged in unprofessional conduct specified in regulations promulgated by the Board;*

3. *Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of his a mental or physical condition;*

4. *Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;*

5. *Has engaged in or attempted any fraud or deceit upon the consumer, any third-party payor, including Medicaid, any individual or group accident and sickness insurance policy or subscription contract providing coverage under a health services plan, or any health care plan, any practitioner or the Board in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;*

6. *Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;*

7. *Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board of any regulation of the Board;*

8. *Has had revoked or suspended any his registration issued by the United States Drug Enforcement Administration or other federal agency registration to dispense controlled substances that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board revoked or suspended;*

9. *Has been convicted of violating engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state; or has had his license to practice pharmacy suspended or revoked in any other state; or*

10. *Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;*

11. *Has been convicted of any felony or of any misdemeanor involving moral turpitude;*

12. *Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;*

13. *Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or*

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59 1014. Has failed to comply with requirements of this chapter or any regulation of the Board relating
60 to continuing education.

61 § 54.1-3434.3. Denial, revocation, suspension of registration, summary proceedings.

62 The Board may deny, revoke, ~~or~~ suspend, *or take other disciplinary actions against* a nonresident
63 pharmacy registration *as provided for in § 54.1-3316*~~for conduct which causes serious bodily or serious~~
64 ~~psychological injury to a resident of the Commonwealth.~~

65 The Board shall immediately suspend, without a hearing, the registration of any nonresident
66 pharmacy upon receipt of documentation by the licensing agency in the jurisdiction where a nonresident
67 pharmacy registered with the Board is located, that the nonresident pharmacy has had its license,
68 certificate, permit, or registration as a pharmacy revoked or suspended by that agency and has not been
69 reinstated, or if the Board has received notification from the licensing agency that the pharmacy in the
70 resident state no longer holds a valid unexpired license, permit, certificate, or registration as a pharmacy.
71 The Board shall provide written notice of the suspension to the nonresident pharmacy at the address of
72 record on file with the Board and to the resident-state licensing agency. The nonresident pharmacy may
73 apply for reinstatement of the registration only after it has been reinstated by and holds a current and
74 unrestricted license, certificate, permit, or registration as a pharmacy from the licensing agency in the
75 jurisdiction where it is located. Such nonresident pharmacy shall be entitled to a hearing not later than
76 the next regular meeting of the Board after the expiration of 30 days from the receipt of such
77 application, and shall have the right to be represented by counsel and to summon witnesses to testify on
78 its behalf.

79 The Board may summarily suspend the registration of any nonresident pharmacy without a hearing,
80 simultaneously with the institution of proceedings for a hearing, if it finds that there is a substantial
81 danger to the public health or safety that warrants such action. The Board may meet by telephone
82 conference call when summarily suspending the registration if a good faith effort to assemble a quorum
83 of the Board has failed and, in the judgment of a majority of the members of the Board, the continued
84 dispensing by the nonresident pharmacy constitutes a substantial danger to the public health or safety.
85 Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension.
86 The hearing shall be scheduled within a reasonable time of the date of the summary suspension. The
87 Board may consider other information concerning possible violations of Virginia law at a hearing, if
88 reasonable notice is given to such nonresident pharmacy of the information.

89 A nonresident pharmacy with a suspended registration shall not ship, mail, or deliver any Schedule II
90 through VI drugs into the Commonwealth unless reinstated by the Board.

91 The Board may refer complaints concerning nonresident pharmacies to the regulatory or licensing
92 agency in the jurisdiction where the pharmacy is located. The Board may take other disciplinary action
93 against a nonresident pharmacy in accordance with §§ 54.1-2400 and 54.1-3316 following notice and the
94 opportunity for a hearing.

95 § 54.1-3435.1. Denial, revocation, and suspension of license as wholesale distributor or of registration
96 as a nonresident wholesale distributor.

97 A. The license as a wholesale distributor ~~or registration as a nonresident wholesale distributor of~~
98 ~~prescription drugs may be denied, suspended, or revoked by the Board for any of the following~~*The*
99 *Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor*
100 *license or nonresident wholesale distributor registration as provided for in § 54.1-3316 or the following:*

101 1. Any conviction of the applicant, ~~or licensee, or registrant~~ under federal or state laws relating to
102 controlled substances, including, but not limited to, drug samples and wholesale or retail prescription
103 drug distribution;

104 2. Any felony conviction of the applicant ~~or licensee~~;

105 3. Any misdemeanor conviction of the applicant ~~or licensee~~ for a crime involving moral turpitude;

106 4. Conduct in the manufacture or distribution of prescription drugs contrary to the protection of the
107 health, safety, and welfare of the public;

108 5. Fraud or deceit in any application for licensure or permit under this chapter;

109 6. Denial, suspension, revocation, or restriction of any federal or state license previously or currently
110 held by the applicant ~~or licensee~~ for the manufacture or distribution of any drug;

111 7. Violations of licensing requirements under previously held licenses;

112 8. Failure to maintain and make available to the Board or to federal regulatory officials those
113 records required to be maintained by wholesale distributors of prescription drugs; *or*

114 9. Violations of the minimum requirements for qualifications, personnel, storage, and handling of
115 prescription drugs and maintenance of prescription drug records as set forth in the federal Prescription
116 Drug Marketing Act of 1987 (21 U.S.C. §§ 333, 353 and 381) and Part 205 of Chapter 21 of the Code
117 of Federal Regulations; ~~or~~.

118 10. Violations of any provision of this chapter or regulations of the Board governing wholesale
119 distributors.

120 B. Wholesale drug distributors shall allow the Board or its authorized agents to enter and inspect, at

reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

§ 54.1-3435.3. Inspection and audit.

A. The permit as a medical equipment supplier may be denied, suspended, or revoked by the Board for any of the following:

1. Any conviction of the applicant or permit holder under federal or state laws relating to wholesale or retail distribution or delivery of prescription drugs or devices or controlled substances;

2. Any felony conviction of the applicant or permit holder;

3. Any misdemeanor conviction of the applicant or permit holder for a crime involving moral turpitude;

4. Violations of any provision of this chapter or regulations of the Board governing medical equipment suppliers;

5. Fraud or deceit in any application for licensure or permit under this chapter; or

6. Engaging in or attempting any fraud upon the consumer.

B. Medical equipment suppliers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures.

2. That §§ 54.1-3315, 54.1-3322, and 54.1-3435.5 of the Code of Virginia are repealed.