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HOUSE BILL NO. 2538

Offered January 12, 2005

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A BILL to amend and reenact §§ 54.1-3434.1 through 54.1-3434.4 of the Code of Virginia, relating to registration of nonresident pharmacies; summary proceedings.

Patron—Jones, S.C.

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3434.1 through 54.1-3434.4 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside ~~this~~*the* Commonwealth which ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into ~~this~~*the* Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs or devices to residents of ~~this~~*the* Commonwealth. A report containing this information shall be made on an annual basis and within ~~thirty~~ 30 days after any change of office, corporate officer, or principal pharmacist.

2. That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the ~~Commonwealth~~*jurisdiction* in which it is licensed as well as with all requests for information made by the Board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a ~~valid unexpired~~*current unrestricted* license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the ~~state~~*jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States*, in which it is a resident. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the ~~state~~*jurisdiction* in which it is located.

3. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in ~~this~~*the* Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

4. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone service to facilitate communication between patients in ~~this~~*the* Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in ~~this~~*the* Commonwealth.

C. The registration fee shall be the fee specified for pharmacies within Virginia.

D. A nonresident pharmacy shall only deliver controlled substances, that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

§ 54.1-3434.2. Permit to be issued.

~~No out-of-state pharmacy doing business in this Commonwealth which has not obtained a permit shall conduct the business of selling or distributing drugs in Virginia without registering as a nonresident pharmacy. The Board shall only register nonresident pharmacies that maintain a current unrestricted license, certificate, permit, or registration as a pharmacy in a jurisdiction within the United States, or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States.~~

Applications for a nonresident pharmacy registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident pharmacy registration shall be renewed annually on or before January 1 of each year.

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

The Board may deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily or serious psychological injury to a resident of the Commonwealth if the Board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to initiate an investigation within forty-five days of the referral.

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

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

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

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

§ 54.1-3434.4. Prohibited acts.

~~It is unlawful for any nonresident pharmacy person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise its services in Virginia the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. or Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy which has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy to dispense prescriptions obtain controlled substances.~~