

LD1623813

HOUSE BILL NO. 1286

Offered January 25, 1994

A BILL to amend and reenact §§ 54.1-3434.1 and 54.1-3435.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3435.01, relating to regulation of nonresident pharmacies and nonresident wholesale distributors of prescription drugs.

Patrons—Ruff, Albo, Dudley, Forbes, Giesen, Griffith, Howell, Ingram, Katzen, Kidd, Kilgore, McDonnell, Wardrup and Way; Senators: Stolle and Woods

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3434.1 and 54.1-3435.1 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3435.01as follows:

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

A. Any pharmacy located outside this Commonwealth which ships, mails, or delivers, in any manner, Schedule II through ~~IV~~ VI drugs or devices pursuant to a prescription into this 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 Commonwealth. A report containing this information shall be made on an annual basis and within thirty 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 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 license, permit, or registration to conduct the pharmacy in compliance with the laws of the state 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 in which it is located.

3. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in this 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.*

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 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 Commonwealth.

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

§54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on or before January 1 of each year; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

D. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

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

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60 as a nonresident wholesale distributor.

61 A. The license as a wholesale distributor *or registration as a nonresident wholesale distributor* of
62 prescription drugs may be denied, suspended, or revoked by the Board for any of the following:

63 1. Any conviction of the applicant or licensee under federal or state laws relating to controlled
64 substances, including, but not limited to, drug samples and wholesale or retail prescription drug
65 distribution;

66 2. Any felony conviction of the applicant or licensee;

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

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

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

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

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

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

76 9. Violations of the minimum requirements for qualifications, personnel, storage, and handling of
77 prescription drugs and maintenance of prescription drug records as set forth in the federal Prescription
78 Drug Marketing Act of 1987 and Part 205 of Chapter 21 of the Code of Federal Regulations; or

79 10. Violations of any provision of this chapter or regulations of the Board governing wholesale
80 distributors.

81 B. Wholesale drug distributors shall allow the Board or its authorized agents to enter and inspect, at
82 reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their
83 records and written operating procedures. Such agents shall be required to show appropriate
84 identification prior to being permitted access to wholesale drug distributors' premises and delivery
85 vehicles.