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HOUSE BILL NO. 520

Offered January 10, 2018

Prefiled January 8, 2018

A BILL to amend and reenact § 54.1-3435.1 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 54.1-3435.4:01 and 54.1-3435.4:2, relating to the Board of Pharmacy; nonresident warehouseurs and nonresident third-party logistics providers; registration and regulation.

Patron—Hodges

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3435.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding sections numbered 54.1-3435.4:01 and 54.1-3435.4:2 as follows:

§ 54.1-3435.1. Denial, revocation, and suspension of license, permit, or registration of certain entities.

A. The Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor license, nonresident wholesale distributor registration, third-party logistics provider permit, *nonresident third-party logistics provider registration*, manufacturer permit, ~~or~~ nonresident manufacturer permit, *or nonresident warehouseur registration* as provided for in § 54.1-3316 or the following:

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

2. Violations of licensing requirements under previously held licenses;

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

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Drug Supply Chain Security Act of 2013, Title II of P. L. 113-54, and the requirements of Chapter 21 of the Code of Federal Regulations.

B. Wholesale drug distributors, nonresident wholesale drug distributors, third-party logistics providers, *nonresident third-party logistics providers*, manufacturers, ~~and~~ nonresident manufacturers, *and nonresident warehouseurs* 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.

§ 54.1-3435.4:01. Registration to act as a nonresident warehouseur; regulations.

A. Any warehouseur located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident warehouseur shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident warehouseurs as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident warehouseur shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located that authorizes the possession and distribution of such prescription drugs and devices and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the 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 State Police upon request within seven days of receipt of such request.

§ 54.1-3435.4:2. Registration of nonresident third-party logistics provider; renewal.

A. Any third-party logistics provider located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident third-party logistics provider shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident third-party logistics providers as it deems necessary to

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59 *implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.*
60 *C. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired*
61 *license, permit, or registration in the state in which it is located or current licensure as a third-party*
62 *logistics provider with the FDA and shall furnish proof of such upon application and at each renewal.*
63 *D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained*
64 *in such a manner that they are readily retrievable from records of distributions into other jurisdictions*
65 *and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent*
66 *of State Police upon request within seven days of receipt of such request.*