

15101789D

HOUSE BILL NO. 1736

Offered January 14, 2015

Prefiled January 12, 2015

A *BILL to amend and reenact §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia, relating to wholesale distributors; notice to Board of Pharmacy when ceasing distribution to a dispenser due to suspicious ordering.*

Patron—Hodges

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in ~~this the~~ Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in ~~this the~~ Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within ~~thirty~~ 30 days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. *A wholesale distributor that ceases distribution of controlled substances to a licensed or permitted dispenser located in the Commonwealth due to suspicious ordering of controlled substances by the dispenser shall notify the Board of Pharmacy of the cessation of distribution to the dispenser within five days of notifying the U.S. Drug Enforcement Administration of the suspicious order pursuant to 21 C.F.R. § 1301.74. For the purpose of this subsection, "suspicious ordering" means placing of orders of unusual size, orders that deviate substantially from a normal pattern, and orders of unusual frequency. A wholesale distributor that, in good faith and without malicious intent, reports cessation of distribution due to suspicious ordering in accordance with this subsection shall be immune from civil liability resulting therefrom.*

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

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

A. Any person located outside ~~this the~~ Commonwealth who engages in the wholesale distribution of prescription drugs into ~~this the~~ 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 a date determined by the Board in regulation; notify the Board within ~~thirty~~ 30 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 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 the Department of State Police upon request within seven days of receipt of such request.

D. *A nonresident wholesale distributor that ceases distribution of controlled substances to a licensed or permitted dispenser located in the Commonwealth due to suspicious ordering of controlled substances by the dispenser shall notify the Board of Pharmacy of the cessation of distribution to the dispenser within five days of notifying the U.S. Drug Enforcement Administration of the suspicious order pursuant to 21 C.F.R. § 1301.74. For the purpose of this subsection, "suspicious ordering" means placing of orders of unusual size, orders that deviate substantially from a normal pattern, and orders of unusual frequency. A nonresident wholesale distributor that, in good faith and without malicious intent, reports cessation of distribution due to suspicious ordering in accordance with this subsection shall be immune from civil liability resulting therefrom.*

E. This section shall not apply to persons who distribute prescription drugs directly to a licensed

INTRODUCED

HB1736

59 wholesale distributor located within this Commonwealth.