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HOUSE BILL NO. 1736

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions
on February 3, 2015)

(Patron Prior to Substitute—Delegate Hodges)

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 orders.*

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 Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

C. A wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection B unless the notice was given in bad faith or with malicious intent.

D. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a wholesale distributor pursuant to subsection B.

E. 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 Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

E. A nonresident wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection D unless the notice was given in bad faith or with malicious intent.

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60 *F. The Board shall not impose any disciplinary or enforcement action against any licensee or permit*
61 *holder solely on the basis of a notice received from a nonresident wholesale distributor pursuant to*
62 *subsection D.*

63 *G. This section shall not apply to persons who distribute prescription drugs directly to a licensed*
64 *wholesale distributor located within this the Commonwealth.*