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HOUSE BILL NO. 1129

Offered January 9, 2008

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A BILL to amend and reenact §§ 54.1-3434, 54.1-3434.2, 54.1-3435, 54.1-3435.01, 54.1-3435.2, 54.1-3435.4, and 54.1-3439 of the Code of Virginia, relating to the expiration of various pharmacy licenses.

Patron—Jones, S.C.

Referred to Committee on General Laws

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3434, 54.1-3434.2, 54.1-3435, 54.1-3435.01, 54.1-3435.2, 54.1-3435.4, and 54.1-3439 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire ~~on December 31 of each year~~ *annually on a date determined by the Board in regulation.*

Every pharmacy must be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3434.2. Permit to be issued.

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~~ *a date determined by the Board in regulation.*

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

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this 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 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 ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; notify the Board within thirty 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.

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 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~~ *a date determined by the Board in regulation*; 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.

§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; and remit a fee as determined by the Board.

B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful

order by a prescriber authorized to prescribe such drugs and devices.

D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.

§ 54.1-3435.4. Permit to act as warehouser; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a warehouser, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a warehouser in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; and remit a fee as determined by the Board.

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

C. Warehousers 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 warehousers' premises and delivery vehicles.

§ 54.1-3439. Application for nonrestricted manufacturing permit; fee.

Every person desiring to manufacture any drug or proprietary medicines shall annually apply to the Board for a nonrestricted manufacturing permit. The application shall be accompanied by the required fee. Separate applications shall be made and separate permits issued for each specific place of manufacturing. Each such permit shall expire ~~on December 31~~ *annually on a date determined by the Board in regulation.*

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.