

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Emergency Regulation

Title of Regulation: 18VAC110-30. Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (amending 18VAC110-30-10, 18VAC110-30-20, 18VAC110-30-21, 18VAC110-30-40, 18VAC110-30-270).

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Effective Dates: January 4, 2021, through July 3, 2022.

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Preamble:

Section 2.2-4011 B of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia.

Pursuant to Chapters 609 and 610 of the 2020 Acts of Assembly, the amendments (i) define the term "practitioner" to include nurse practitioners or physician assistants for the purpose of issuance of a limited-use license; and (ii) include the allowance for issuance of a limited-use permit for nonprofit facilities for the sale of Schedule VI drugs and devices used in administration of such drugs.

18VAC110-30-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

"Board" means the Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act.

"Licensee" means a practitioner who is licensed by the Board of Pharmacy to sell controlled substances.

"Personal supervision" means the licensee must be physically present and render direct, personal control over the entire service being rendered or acts being performed. Neither prior nor future instructions shall be sufficient nor shall supervision be rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" or "practitioner of the healing arts" means a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. For the purpose of a limited-use permit for a nonprofit facility, a "practitioner" or "practitioner of the healing arts" may also mean a physician assistant with a current active license issued by the Board

of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine.

"Sale" means barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee. It does not include the gift of manufacturer's samples to a patient.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the controlled substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"U.S.P.-N.F." means the United States Pharmacopeia-National Formulary.

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 7, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

~~B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine, or podiatry issued by the Virginia Board of Medicine. Prior to engaging in the sale of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine, or podiatry; a nurse practitioner; or a physician assistant shall make application on a form provided by the board and be issued a limited-use license.~~

C. Any disciplinary action taken by the Board of Medicine, or in the case of a nurse practitioner, by the Joint Boards of Nursing and Medicine, against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

18VAC110-30-21. Application for facility permit.

A. After June 7, 2016, any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner of the healing arts shall apply for the facility permit on a form provided by the board.

B. For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of this chapter may be waived.

1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.

3. The issuance and continuation of a limited-use facility permit shall be subject to continuing compliance with the conditions set forth by the board.

4. A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances.

C. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-40. Acts to be performed by the licensee.

A. The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.

1. Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

2. A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth in § 54.1-3321 of the Code of Virginia, provided such person is not licensed to sell controlled substances and is either:

a. A pharmacy technician registered with the board; or

b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

3. Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and maintain a training manual and shall document that such licensee has successfully completed general training in the following areas:

a. The entry of prescription information and drug history into a data system or other recordkeeping system;

b. The preparation of prescription labels or patient information;

c. The removal of the drug to be dispensed from inventory;

d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;

e. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and

g. Applicable laws and regulations related to dispensing.

4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of

other equipment used in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.

5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

B. Prior to the dispensing, the licensee shall:

1. Conduct a prospective drug review and offer to counsel a patient in accordance with provisions of § 54.1-3319 of the Code of Virginia; and
2. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

C. If the record of sale is maintained in an automated data processing system as provided in 18VAC110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

18VAC110-30-270. Grounds for disciplinary action.

In addition to those grounds listed in § 54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant has had his license to practice medicine, osteopathic medicine, or podiatry or license as a physician assistant or nurse practitioner suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice in the Commonwealth of Virginia.