Virginia Administrative Code

CHAPTER 30

REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

Part I

Definitions and Fees

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" means a doctor of medicine, ~~osteopathy~~ osteopathic medicine or podiatry who possesses a current active license issued by the Board of 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.

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Fee for initial license for a practitioner of the healing arts to sell controlled substances.

1. The application fee for initial licensure shall be ~~$200~~ 240.

2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.

C. Renewal of license for a practitioner of the healing arts to sell controlled substances.

1. The annual fee for renewal of an active license shall be $90.

2. The annual fee for renewal of an inactive license shall be $45.

3. The late fee for renewal of a license within ~~60 days~~ one year after the expiration date is $30 in addition to the annual renewal fee.

4. The ~~delinquent~~ fee for reinstatement of a ~~lapsed~~ license expired for more than one year ~~is $70 in addition to all unpaid renewal fees~~ shall be $210.

D. The fee for reinspection of any facility shall be $150.

Part II

Licensure Requirements

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.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice medicine shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

C. For good cause shown, the board may issue a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. The license 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 regulations may be waived. The following conditions shall apply:

1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice;

2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board~~; and~~

~~3. Application for a limited-use license is contingent on the practitioner selling only controlled substances which have been received prepackaged in ready-to-dispense quantities and containers needing only the addition of required labeling~~.

18VAC110-30-30. Renewal of license.

A. A license so issued shall be valid until December 31 of the year of issue. Renewal of the license shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license by payment of these fees for ~~60 days~~ <u>one year</u> from the date of expiration.

C. Failure to renew the license to sell within ~~60 days~~ one year following expiration shall cause the license to lapse. The selling of controlled substances with a lapsed license shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf ~~upon submission of a reinstatement application, payment of all unpaid renewal fees, and the delinquent fee~~ provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a license that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted unless another practitioner at the same location has held an active license to sell controlled substances during that period. A practitioner seeking reinstatement shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-35. ~~Inactive status.~~ Repealed

~~A. A licensee who intends to cease selling controlled substances may take inactive status. An inactive license may be reactivated by applying to the board for reactivation and paying any unpaid portion of the current renewal fee for an active license.~~

~~B. A licensee with inactive status shall not engage in the sale of controlled substances. Engaging in the sale of controlled substances with an inactive license shall constitute grounds for disciplinary action by the board.~~

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. ~~Only one person who is not a licensee may be present in the storage and selling area at any given time for the purpose of assisting the licensee in the preparation, packaging and labeling of a controlled substance.~~ 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 § 54.1-3321 of the Code of Virginia, provided such person 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.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on ~~an inactive~~ expired status ~~or may be surrendered~~.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license pursuant to this section may request that it be made current again at anytime within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

Part III

Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for licenses which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a license and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

~~E~~ F. No license shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the ~~board or its authorized agent~~ the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-110. Minimum equipment.

The licensee shall be responsible for maintaining the following equipment in the designated area:

1. A current dispensing information reference source, either hard copy or electronic;

2. A refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained;

~~3. A current copy of the Virginia Drug Control Act and board regulations;~~

~~4. A current copy of the Virginia Voluntary Formulary;~~

~~5~~ 3. ~~A laminar flow hood~~ Equipment consistent with requirements of §54.1-3410.2 of the Code of Virginia and USP-NF standards, if sterile products are to be prepared; ~~and~~

~~6~~ 4. Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in ~~extemporaneous compounding~~ dispensing activities that require the weighing of components~~.~~ ; and

5. Other equipment, supplies, and references consistent with the practitioner's scope of practice and with the public safety.

18VAC110-30-130. Selling area enclosures.

A. The controlled substance selling and storage area of the licensee shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be construed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty;

2. The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the controlled substances;

3. Entrances to the enclosed area must have a door which extends from the floor and which is at least as high as the adjacent counters or adjoining partitions; and

4. Doors to the area must have locking devices which will prevent entry in the absence of the licensee.

B. The door keys or other means of entry and alarm access code to the selling and storage area shall be subject to the following requirements:

1. Only the licensee shall be in possession of the alarm access code and any keys or other means of entry to the locking device on the door to such enclosure;

2. The selling and storage area must be locked when the licensee is not present and engaged in preparation or selling of drugs; and

3. The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee. In lieu of the licensee's signature across a seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.

C. The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision.

18VAC110-30-150. Expired controlled substances; security.

Any controlled substance which has exceeded the expiration date shall not be dispensed or sold and shall be separated from the stock used for selling ~~and may~~ but shall be maintained in ~~a designated~~ the selling and storage area ~~with the unexpired stock~~ prior to the disposal of the expired controlled substances.

Part IV

Written Prescription and Record Keeping Standards

18VAC110-30-170. Sign and written prescription requirements.

~~A. The licensee shall provide the patient with a written prescription whether or not he intends to sell the controlled substance to the patient.~~

~~B~~ A. The licensee shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled.

~~C~~ B. The licensee ~~after delivery of the written prescription to the patient~~ shall~~, in each case,~~ advise the patient of their right to obtain the controlled substance from him or from a pharmacy.

C. If the patient chooses to obtain the controlled substance from a pharmacy, the licensee shall either provide the patient with a written prescription or transmit the prescription orally, electronically or by fax to a pharmacy of his choice.

D. If the patient chooses to purchase the controlled substance from the licensee, the licensee shall either:

1. Have the patient sign the written prescription ~~shall be returned~~ and return it to the licensee ~~and signed by the patient.~~ If the licensee chooses to use the hard copy prescription as his record of sale,

he shall record all information and file as required by 18VAC110-30-190. If the licensee chooses to record the sale in book form or maintain it in an automated data system, he shall mark the prescription void, file chronologically, and maintain for a period of two years; or

2. In lieu of a written prescription, have the patient sign a separate waiver form to be maintained for at least two years with the dispensing records according to date of dispensing. The waiver form may not be kept in the patient's chart.

18VAC110-30-180. Manner of maintaining inventory records for licensees selling controlled substances.

Each licensee shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in Schedule II shall be maintained separately from all other records of the licensee;

2. Inventories and records of controlled substances listed in Schedules III, IV and V may be maintained separately or with records of Schedule VI controlled substances but shall not be maintained with other records of the licensee;

3. All records of Schedule II through V controlled substances shall be maintained at the same location as the stock of controlled substances to which the records pertain except that records maintained in an off-site database shall be retrieved and made available for inspection within 48 hours of a request by the board or an authorized agent;

4. In the event that an inventory is taken as the result of a theft of controlled substances pursuant to §54.1-3404 of the Drug Control Act of the Code of Virginia, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date; and

5. All inventories required by §54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business.

~~5~~ 6. All records required by this section shall be filed chronologically.

18VAC110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold.

A. A hard copy prescription shall be placed on file for every new prescription dispensed and be maintained for two years from date of last refill. All prescriptions shall be filed chronologically form date of initial dispensing. In lieu of a hard copy prescription, a licensee may have an alternative record of all drugs sold maintained for two years from date of dispensing or of refilling an order. Such record shall be in chronological order by date of initial dispensing with refills listed with initial dispensing information or by date of dispensing.

B. The hard copy prescription or records of sale for Schedule II controlled substances shall be maintained as follows:

1. They shall be maintained separately from other records; and

2. They shall be maintained in chronological order and shall show the selling date, a number which identifies the sale, the name and address of the patient, the name and strength of the controlled substance, the initials of the licensee, and the quantity sold.

~~B~~ C. The hard copy prescription or records of sale for Schedule III through V controlled substances shall be maintained as follows:

1. They shall be maintained in the manner set forth in subsection A of this section; and

2. The hard copy prescription or records of sale for Schedule III through V controlled substances may be maintained separately from other selling records or may be maintained with selling records for Schedule VI controlled substances provided the Schedule III through V controlled substance records are readily retrievable from the selling records for Schedule VI controlled substances. The records shall be deemed readily retrievable if a red "C" is placed uniformly on the record entry line for each Schedule III through V controlled substance sold. However, if the licensee employs an automated data processing system or other electronic recordkeeping system for prescriptions that

permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy record with a red "C" is waived.

18VAC110-30-200. Automated data processing records of sale.

A. An automated data processing system may be used for the storage and retrieval of the sale of controlled substances instead of manual recordkeeping requirements, subject to the following conditions:

1. Any computerized system shall also provide retrieval via computer monitor display or printout of the sale of all controlled substances during the past two years, the listing to be in chronological order and shall include all information required by the manual method;

2. If the system provides a printout of each day's selling activity, the printout shall be verified, dated and signed by the licensee. The licensee shall verify that the data indicated is correct and then sign the document in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). In place of such printout, the licensee shall maintain a bound log book, or separate file, in which the licensee shall sign a statement each day, in the manner previously described, attesting to the fact that the selling information entered into the computer that day under his initials has been reviewed by him and is correct as shown; and

~~3. A hard copy prescription shall be placed on file chronologically and maintained for a period of two years.~~

B. Any computerized system shall have the capability of producing a printout of any selling data which the practitioner is responsible for maintaining under the Drug Control Act and such printout shall be provided within 48 hours of a request of an authorized agent.

Part V

Packaging, Repackaging and Label Standards

18VAC110-30-210. Repackaging of controlled substances; records required; labeling requirements.

A. A licensee repackaging controlled substances shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the controlled substances repackaged, strength, if any, quantity prepared, initials of the licensee supervising the process, the assigned control number, or the manufacturer's or distributor's name and control number, and an expiration date.

B. The controlled substance name, strength, if any, the assigned control number, or the manufacturer's or distributor's name and control number, and an appropriate expiration date determined by the licensee in accordance with USP-NF guidelines shall appear on any subsequently repackaged or reconstituted units ~~as follows:~~ .

~~1. If U.S.P.-N.F. Class B or better packaging material is used for oral unit dose packages, an expiration date not to exceed six months or the expiration date shown on the original manufacturing bulk containers, whichever is less, shall appear on the repackaged units;~~

~~2. If it can be documented that the repackaged unit has a stability greater than six months, an appropriate expiration date may be assigned; and~~

~~3. If U.S.P.-N.F. Class C or less packaging material is used for oral, solid medication, an expiration date not to exceed 30 days shall appear on the repackaged units.~~

18VAC110-30-220. Labeling of prescription as to content and quantity.

Any controlled substances sold by a licensee shall bear on the label of the container, in addition to other requirements, the following information:

1. The name and address of the practitioner and the name of the patient;

2. The date of the dispensing;

3. The drug name and strength, when strength is applicable:

a. For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label.

b. If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and ~~in accordance with §32.1-87-A of the Code of Virginia,~~ the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed; and

4. The number of dosage units or, if liquid, the number of millimeters dispensed.

18VAC110-30-240. Special packaging.

A. Each controlled substance sold to a person in a household shall be sold in special packaging, except when otherwise requested by the purchaser, or when such controlled substance is exempted from such requirements promulgated pursuant to the Poison Prevention Packaging Act of 1970, 15 USC §§1471-1476.

B. Each licensee may have a sign posted near the compounding and selling area advising the patients that nonspecial packaging may be requested.

C. If nonspecial packaging is requested, a ~~signed~~ release of such request shall be obtained ~~pursuant to §54.1-3427 of the Code of Virginia~~ from the patient or the patient's authorized agent and maintained for two years from the date of dispensing.

Part VI

Patient's Choice of Supplier, Purchase of Drugs, and Return of Controlled Substances

18VAC110-30-260. Returning of controlled substances.

Controlled substances shall not be accepted for return or exchange by any licensee for resale after such controlled substances have been taken from the premises where sold, unless such controlled substances are in the manufacturer's original sealed container or in a unit-dose container which meets the U.S.P.-N.F. Class A or Class B container requirement, have ~~not~~ been stored under conditions in which official compendium storage requirements can be assured ~~whereby they may~~

~~have become contaminated~~, and provided such return or exchange is consistent with federal law and regulation.

Part VII

Grounds for Disciplinary Action

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, ~~osteopathy~~ osteopathic medicine or podiatry suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice ~~medicine~~ in the Commonwealth of Virginia.

Certification

I certify that this regulation is full, true, and correctly dated.

_____

Elizabeth Scott Russell

Executive Director
Virginia Board of Pharmacy

Date: _____