|  |  |  |
| --- | --- | --- |
|  | ***Commonwealth of Virginia*** |  |
|  | Virginia Board of Pharmacy **Regulations**  **for**  **Practitioners of the Healing Arts**  **to sell controlled substances**  **Title of Regulations: 18 VAC 110-30-10 et seq.**  **Statutory Authority: § 54.1-2400 and Chapters 33 and 34**  **of Title 54.1 of the *Code of Virginia***  **Effective Date: June 28, 2017** | |
|  | **9960 Mayland Drive, Suite 300** **Phone: 804-367-4456**  **Henrico, VA 23233-1464 Fax: 804-527-4472**  **email: pharmbd@dhp.virginia.gov** | |

**TABLE OF CONTENTS**

[Part I. Definitions and Fees. 3](#_Toc486232143)

[18VAC110-30-10. Definitions. 3](#_Toc486232144)

[18VAC110-30-15. Fees. 3](#_Toc486232145)

[Part II. Licensure and Permit Requirements. 4](#_Toc486232146)

[18VAC110-30-20. Application for licensure. 4](#_Toc486232147)

[18VAC110-30-21. Application for facility permit. 4](#_Toc486232148)

[18VAC110-30-30. Renewal of license or permit. 5](#_Toc486232149)

[18VAC110-30-35. (Repealed.) 5](#_Toc486232150)

[18VAC110-30-40. Acts to be performed by the licensee. 5](#_Toc486232151)

[18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal. 7](#_Toc486232152)

[18VAC110-30-60. (Repealed.) 7](#_Toc486232153)

[Part III. Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances. 7](#_Toc486232154)

[18VAC110-30-70. Practitioner in charge in a permitted facility. 7](#_Toc486232155)

[18VAC110-30-80. Inspection and notice required. 8](#_Toc486232156)

[18VAC110-30-90. Physical standards. 8](#_Toc486232157)

[18VAC110-30-100. Access to selling area. 9](#_Toc486232158)

[18VAC110-30-110. Minimum equipment. 9](#_Toc486232159)

[18VAC110-30-120. Safeguards against diversion of controlled substances. 9](#_Toc486232160)

[18VAC110-30-130. Selling area enclosures. 10](#_Toc486232161)

[18VAC110-30-140. Prescriptions awaiting delivery. 10](#_Toc486232162)

[18VAC110-30-150. Expired controlled substances; security. 11](#_Toc486232163)

[18VAC110-30-160. Disposal of Schedule II through VI controlled substances. 11](#_Toc486232164)

[Part IV. Written Prescription and Record Keeping Standards. 11](#_Toc486232165)

[18VAC110-30-170. Sign and written prescription requirements. 11](#_Toc486232166)

[18VAC110-30-180. Manner of maintaining inventory records for licensees selling controlled substances. 12](#_Toc486232167)

[18VAC110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold. 12](#_Toc486232168)

[18VAC110-30-200. Automated data processing records of sale. 13](#_Toc486232169)

[Part V. Packaging, Repackaging and Label Standards. 13](#_Toc486232170)

[18VAC110-30-210. Repackaging of controlled substances; records required; labeling requirements. 13](#_Toc486232171)

[18VAC110-30-220. Labeling of prescription as to content and quantity. 14](#_Toc486232172)

[18VAC110-30-230. Packaging standards for controlled substance sold. 14](#_Toc486232173)

[18VAC110-30-240. Special packaging. 14](#_Toc486232174)

[Part VI. Patient's Choice Of Supplier, Purchase Of Drugs, And Return Of Controlled Substances. 15](#_Toc486232175)

[18VAC110-30-250. Choice of controlled substance supplier. 15](#_Toc486232176)

[18VAC110-30-255. Purchase of drugs. 15](#_Toc486232177)

[18VAC110-30-260. Returning of controlled substances. 15](#_Toc486232178)

[Part VII. Grounds for Disciplinary Action. 15](#_Toc486232179)

[18VAC110-30-270. Grounds for disciplinary action. 15](#_Toc486232180)

# 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, 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. Initial application fees.

1. License for practitioner of the healing arts to sell controlled substances: $180.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

C. Annual renewal fees.

1. License for practitioner of the healing arts to sell controlled substances: $90.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substances: $30.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $40.

E. Reinstatement fees. Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. License for practitioner of the healing arts to sell controlled substances: $150.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely: $500.

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit. Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change.

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

H. The fee for a returned check shall be $35.

# Part II. Licensure and Permit 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. 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. Any disciplinary action taken by the Board of 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.

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.

## 18VAC110-30-30. Renewal of license or permit.

A. A license or facility permit 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 or facility permit to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license or facility permit by payment of these fees for one year from the date of expiration.

C. Failure to renew the license or facility permit to sell within one year following expiration shall cause the license or permit to lapse. The selling of controlled substances with a lapsed license or permit shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license or permit, 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 provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a facility permit that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted. A practitioner seeking reinstatement of a facility permit shall not stock drugs until approved by the board or its authorized agent.

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

## 18VAC110-30-35. (Repealed.)

## 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 § 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 expired status. If no other practitioner of the healing arts licensed to sell controlled substances intends to sell controlled substances from the same location, the practitioner shall also surrender the facility permit, and the permit will be placed on expired status.

B. Any Schedules 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 or facility permit pursuant to this section may request that it be made current again at any time 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.

## 18VAC110-30-60. (Repealed.)

# Part III. Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances.

## 18VAC110-30-70. Practitioner in charge in a permitted facility.

A facility with a permit for practitioners of the healing arts to sell controlled substances shall:

1. Designate a practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;

2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedules II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

## 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 facility permits that indicate a requested inspection date, or requests that 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 that 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 facility permit 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.

F. No facility permit 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 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.

## 18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within 20 feet of the selling and storage area and not located within an examination room or restroom; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

## 18VAC110-30-100. Access to selling area.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area. The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the office is at least 40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

## 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. 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;

4. Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in 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.

## 18VAC110-30-120. Safeguards against diversion of controlled substances.

A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device;

2. The device shall be maintained in operating order;

3. The device shall fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed;

4. The alarm system must have an auxiliary source of power;

5. The alarm system shall be capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located;

6. The alarm system is controlled only by the licensee; and

7. An emergency key or access code to the system may be maintained as set forth in 18VAC110-30-130 B of this chapter.

## 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 constructed 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 locked and alarmed at all times when the licensee is not on duty.

3. The enclosure shall be capable of being locked in a secure manner at any time the licensee on duty is not present in the storage and selling area.

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

restricted to the licensee with the following exceptions:

1. Other persons authorized to assist the licensee in the selling and storage area may possess a key or other means of entry into a locked area only when the licensee is on duty. Such key or other means of entry shall not allow entry when the licensee is not on duty; and

2. 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 for emergency access. 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.

## 18VAC110-30-140. Prescriptions awaiting delivery.

Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the controlled substance selling area and access to the prescriptions restricted by the licensee to designated assistants. The prepared prescriptions may be transferred to the patient whether or not the licensee is on duty with prior approval of the licensee.

## 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 but shall be maintained in the selling and storage area prior to the disposal of the expired controlled substances.

## 18VAC110-30-160. Disposal of Schedule II through VI controlled substances.

A. If a licensee wishes to dispose of unwanted Schedule II through VI controlled substances, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess Schedule II through VI drugs; or

2. Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations.

B. If Schedule II through V drugs are to be destroyed, the following additional procedures shall apply:

1. At least 14 days prior to the destruction date, the licensee shall provide a written notice to the board office. The notice shall state the following:

a. Date, time, manner, and place of destruction;

b. The names of the licensees who will witness the destruction process.

2. If the destruction date is to be changed or the destruction does not occur, a new notice stating the information required in subdivision 1 of this subsection shall be provided to the board;

3. The actual destruction shall be witnessed by the licensee conducting the destruction and another licensee of the board who is not employed by the licensee conducting the destruction;

4. At the conclusion of the destruction of the controlled substance stock, the DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the practitioner's office with other inventory records.

# Part IV. Written Prescription and Record Keeping Standards.

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

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.

B. The licensee shall 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 and return it to the licensee. 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.

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.

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; and

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.

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.

## 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 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.

## 18VAC110-30-230. Packaging standards for controlled substance sold.

A controlled substance shall be sold only in packaging approved by the current U.S.P.-N.F. for the controlled substance. In the absence of such packaging standard for the controlled substance, it shall be dispensed in a well-closed container.

## 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 release of such request shall be obtained 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.

## 18VAC110-30-250. Choice of controlled substance supplier.

A licensee shall neither interfere with the patient's right to choose his supplier of medication nor cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

## 18VAC110-30-255. Purchase of drugs.

Except for an emergency purchase from another licensee or pharmacy, a licensee may only purchase Schedule II through VI drugs from a wholesale distributor licensed or registered by the board.

## 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 been stored under conditions in which official compendium storage requirements can be assured, 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, osteopathic medicine or podiatry 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.