REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES.

18 VAC 110-30-10 et seq.

PART I.
GENERAL PROVISIONS.

18 VAC 110-30-10. Definitions.

The following words and terms when used in this chapter shall have the following meaning 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" ~~as used in this chapter shall mean~~ 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 rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" ~~as used in this chapter shall mean~~ means a doctor of medicine, osteopathy or podiatry who possesses a current ~~unrestricted~~ 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.

18 VAC 110-30-15. 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.

2. The application fee for reinstatement of a license, which has been revoked or suspended indefinitely, shall be $300.

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

1. The annual fee for renewal of a license shall be $50.

2. The annual fee for renewal of an inactive license shall be $35.

3. The late fee for renewal of a license within 60 days after the expiration date is $25 in addition to the annual renewal fee.

4. The delinquent fee for reinstatement of a lapsed license is $50 in addition to all unpaid renewal fees.

PART II

LICENSURE REQUIREMENTS

18 VAC 110-30-20. Application for licensure.

A. ~~In order to engage in the sale of controlled substances as defined in § 54.1-3401 of the Code of Virginia and as provided for in § 54.1-2914 B of the Code of Virginia, a practitioner who possesses a current unrestricted license issued by the Board of Medicine shall make application to~~

~~the Board of Pharmacy on a form provided by the Board. A fee of $200 shall be remitted with the application for licensure.~~ 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.

~~B.~~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.

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.

18 VAC 110-30-30. Renewal of license.

A. A license so issued shall be valid until December 31 of the year of issue. ~~A renewal~~ Renewal of the license shall be made on or before December 31 of each year. ~~The annual renewal fee shall be $50.~~

~~1. Between January 1, 1994 and January 1, 1995, the annual renewal fee shall be $25.~~

B. If a practitioner fails to renew his license to sell within the Commonwealth by the renewal date, he must pay the ~~back~~ renewal fee ~~and~~ plus ~~a $25~~ the late fee ~~within 60 days of expiration.~~ He may renew his license by payment of these fees for 60 days from the date of expiration.

C. Failure to renew the license to sell within 60 days 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. 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 ~~a~~ the delinquent fee ~~of $50~~.

~~D. The annual fee for renewal of an inactive license to sell shall be $35.~~

18 VAC 110-30-31. Inactive status.

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.

18 VAC 110-30-40. 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.

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.

B. Prior to the dispensing, the licensee shall 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 18 VAC 110-30-200, 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.

18 VAC 110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who ~~desires~~ intends to cease selling controlled substances shall notify the Board 10 days prior to cessation and his license will be placed on an inactive 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 ~~practitioner~~ 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.

18 VAC 110-30-60. ~~Inactive status~~. (Repealed.)

~~Any licensee who elects to take an inactive status shall not engage in the sale of controlled substances. To reactivate his license, he shall apply to the Board and shall pay the fee charged for license renewal. Engaging in the sale of controlled substances with an inactive license may subject the licensee to disciplinary action by the board.~~

PART III.

INSPECTION REQUIREMENTS, STANDARDS AND SECURITY FOR STORAGE AREA.

18 VAC 110-30-70. Maintenance of a common stock of controlled substances.

Any two or more licensees who elect to maintain a common stock of controlled substances for dispensing shall:

1. Designate a licensee 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 Schedule II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Drug Control Act 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.

18 VAC 110-30-80. 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 ~~a~~ 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 18 VAC 110-30-90 , 18 VAC 110-30-100, 18 VAC 110-30-110, 18 VAC 110-30-120, and 18 VAC 110-30-130 of this chapter.

E. 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.

18 VAC 110-30-90. 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 60 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, dispensing, and record-keeping related to the sale of controlled substances. The workspace 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 ~~the effective date of this chapter~~ 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 the immediate vicinity of the selling and storage area; 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.

18 VAC 110-30-100. 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 which is exclusively used by the licensee and to which only the licensee has access provided the portion of the office used exclusively for controlled substances storage and preparation is at least 60 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 18 VAC 110-30-90, 18 VAC 110-30-120, and 18 VAC 110-30-130.

18 VAC 110-30-110. Minimum equipment.

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

~~1.~~ A current ~~copy of the United States Pharmacopeia Dispensing Information Reference Book~~ 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 copy of the current Virginia Drug Control Act and board regulations;

4. A current copy of the Virginia Voluntary Formulary;

5. A laminar flow hood if sterile products are to be prepared;

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

18 VAC 110-30-160. Disposal of Schedule II through ~~V~~ VI controlled substances.

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

~~1. Return the drugs to the Drug Enforcement Administration (DEA) by delivery to the nearest DEA office; or~~

~~2~~ 1. Transfer the drugs to another person or entity authorized to possess Schedule II through ~~V~~ VI drugs; or

~~3.~~ 2. Destroy the drugs ~~according to the following procedures~~ 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:

~~a~~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:

(~~1~~a.) Date, time, manner, and place of destruction;

(~~2~~b.) The names of the licensees who will witness the destruction process.

~~b~~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 ~~office as set forth above in this~~ ~~subsection~~;

~~c. The DEA Drug Destruction Form No. 41 shall be used to make a record of all controlled substances to be destroyed;~~

~~d. The controlled substances shall be destroyed in accordance with all applicable local, state, and federal laws and regulations by burning in an incinerator or by other methods approved in advance by the board~~.

~~e~~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 ~~practitioner~~ licensee conducting the destruction.

~~f. Each form shall show the following information:~~

~~(1) Legible signatures of the licensee and the witnessing person.~~

~~(2) The license number of the licensee and other licensed person destroying the controlled substances~~.

~~(3) The date of destruction.~~

~~g~~ 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.

~~(1) Three copies of the completed destruction form shall be sent to: Drug Enforcement Administration, Washington Field Division, Room 2558, 400 6th Street, S.W., Washington, DC 20024, Attn: Diversion Control Group~~.

~~(2) A copy of the completed destruction form shall be sent to the office of the board.~~

~~(3) A copy of the completed destruction form shall be retained with the inventory records~~.

PART IV.

WRITTEN PRESCRIPTION AND RECORD KEEPING STANDARDS.

18 VAC 110-30-170. 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. The licensee shall ~~provide~~ conspicuously display a sign in the public area of the office~~. The sign must be legible to the public with normal vision and must advise the public that the controlled substances may be obtained from him or from a pharmacy~~ advising patients of their right to choose where they have their prescriptions filled.

C. 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.

D. If the patient chooses to purchase the controlled substance from the licensee, the written prescription shall be returned 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 18 VAC 110-30-190. 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.

18 VAC 110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold.

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

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

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 which 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.

18 VAC 110-30-200. 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 record keeping 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.

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.

PART V

PACKAGING, REPACKAGING AND LABEL STANDARDS

18 VAC 110-30-210. ~~Repacking~~ 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 shall appear on any subsequently repackaged 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.

18 VAC 110-30-220. Labeling of prescription as to content and quantity.

A. 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; ~~and~~

~~3. The controlled substance name, and strength when applicable.~~

~~a. If a trade name controlled substance is sold, the trade name of the controlled substance or the generic name of the controlled substance.~~

~~b. If a generic controlled substance is sold in place of a trade name controlled substance, in addition to the requirements of § 32.1-87 (A) of the Code of Virginia, one of the following methods shall be used:~~

~~(1) The generic name; or~~

~~(2) name for the product sold which appears on the generic manufacturer's label; or~~

~~(3) The generic name followed by the word "generic for" followed by the trade name of the controlled substance for which the generic controlled substance is substituted.~~

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 ~~f~~llowed 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)~~ 4. The number of dosage units, or if liquid, the number of millimeters dispensed.

18 VAC 110-30-240. 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. ~~If nonspecial packaging is requested, documentation of such request shall be maintained for two years from the date of dispensing.~~

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 and maintained for two years from the date of dispensing.

PART VI

PATIENT'S CHOICE OF SUPPLIERS AND RETURN OF CONTROLLED SUBSTANCES

18 VAC 110-30-255. 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.

18 VAC 110-30-260. 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, ~~and~~ have not been stored under conditions whereby ~~it~~ they may have become contaminated, and provided such return or exchange is consistent with federal law and regulation.

PART VII

GROUNDS FOR REVOCATION OR SUSPENSION

18 VAC 110-30-270. Grounds for ~~revocation or suspension~~ disciplinary action.

In addition to those grounds listed in § 54.1-3316 of the Code of Virginia, the ~~Board of Pharmacy~~ 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 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.

~~1. Has been negligent in the sale of controlled substances;~~

~~2. Has become incompetent to sell controlled substances because of his mental or physical condition;~~

~~3. Uses drugs or alcohol to the extent that he is rendered unsafe to sell controlled substances;~~

~~4. Has engaged in or attempted any fraud or deceit upon the patient or the Board in connection with the sale of controlled substances;~~

~~5. Has assisted or allowed unlicensed persons to engage in the sale of controlled substances;~~

~~6. Has violated or cooperated with others in violating any state or federal law or any regulation of the Board relating to the sale, distribution, dispensing or administration of controlled substances;~~

~~7. Has had his federal registration to dispense controlled substances revoked or suspended; or~~

~~8. Has been convicted of violating any federal drug law or any drug law of Virginia or of another state or has had his license to practice medicine, osteopathy or podiatry suspended or revoked in Virginia or in any other state.~~

Certification

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

_____

Elizabeth Scott Russell
Executive Director
Virginia Board of Pharmacy

Date:_____