

**PRACTITIONERS SELLING CONTROLLED SUBSTANCES
INSPECTION REPORT**

Name _____ Location No. 0224 _____

Street _____ City _____ State _____ Zip _____

Telephone No _____ Fax No _____ Hours of Operation _____

Practitioners at this location:

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Inspection Type: New Routine Change of Location Remodel Other _____

DESIGNATIONS: C MEANS COMPLIANT, NC MEANS NON-COMPLIANT

18 VAC 110-30-90 PHYSICAL STANDARDS

Attach pictures and a diagram of the controlled substance selling area including locations of alarm sensors for new, remodel and change of location inspections.

C	NC	
_____	_____	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.
_____	_____	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.
_____	_____	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.
_____	_____	The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner.
_____	_____	A sink with hot and cold running water shall be available within the immediate vicinity of the selling and storage area.
_____	_____	The entire area shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage. (Controlled room temperature 68F – 77F with excursions between 59F – 86F).

18 VAC 110-30-100 ACCESS TO SELLING AREA

C	NC	
_____	_____	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.

18 VAC 110-30-110 MINIMUM EQUIPMENT

C	NC	
_____	_____	Current dispensing information reference source, either hard copy or electronic. Reference _____
_____	_____	Refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained (36F – 46F). Observed Temperature _____
_____	_____	Equipment consistent with requirements of 54.1-3410.2 and USP-NF standards if sterile products are to be prepared.
_____	_____	Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in dispensing activities that require weighing of components.
_____	_____	Other equipment, supplies, and references consistent with the practitioner's scope of practice and with the public safety.

18 VAC 110-30-120

SAFEGUARDS AGAINST DIVERSION

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:

Device Tested: Yes No Monitored By: _____

C NC

The device meets the following requirements:

- Sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
- Maintained in operating order.
- 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.
- Has an auxiliary source of power.
- 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.
- Controlled only by the licensee.

18 VAC 110-30-130

SELLING ENCLOSURES

C NC

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.

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

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.

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

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.

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

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 OR other method approved by the Executive Director of the Board.

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..

18 VAC 110-30-140

PRESCRIPTIONS AWAITING DELIVERY

C NC

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.

18 VAC 110-30-150

SECURITY OF EXPIRED CONTROLLED SUBSTANCES

C NC

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.

18 VAC 110-30-160

DISPOSAL OF SCHEDULE II - VI CONTROLLED SUBSTANCES

C NC

Unwanted Schedule II through VI controlled substances are disposed of by either transfer the drugs to another person or entity authorized to possess Schedule II through VI drugs or by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations.

18 VAC 110-30-170
C NC

SIGN AND WRITTEN PRESCRIPTION REQUIREMENTS

____ 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.
____ 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.

If the patient chooses to purchase the controlled substance from the licensee, the licensee shall EITHER

____ 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 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.

OR

____ 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 may not be kept in the patient's chart.

18 VAC 110-30-180
C NC

INVENTORY RECORDS

____ Inventories and records of all controlled substances listed in Schedules II shall be maintained separately from all other records of the licensee.

____ 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.

____ 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 data base shall be retrieved and made available for inspection within 48 hours of a request by the Board or an authorized agent.

____ Theft or any other unusual loss of any controlled substance have been reported to the Board in accordance with

§ 54.1-3404. An inventory of all Schedule II – V controlled substances has been taken if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss. 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, the inventory shall be used as the opening inventory within the current biennial period.

Has any theft of unusual loss occurred since the last inspection? Yes No

____ Inventories are signed and dated by the person taking the inventory and indicate whether the inventory was taken prior to the opening or after the close of business.

____ All records required by this section shall be filed chronologically.

§ 54.1-3404 BIENNIAL INVENTORY

____ Biennial Inventory performed within two years of previous biennial inventory.
Inventory date _____ opening or Closing of business

18 VAC 110-30-190.
C NC

RECORDS FOR SCHEDULE II THROUGH VI CONTROLLED SUBSTANCES

Hard copy prescription

____ Placed on file for every new prescription dispensed and maintained for two years from the date of last refill.

____ Filed chronologically from date of initial dispensing

____ If an alternate record of all drugs sold is used:

- the record is maintained for two years from date of dispensing or refilling
- chronological order by date of initial dispensing with refills listed with dispensing information OR
- by date of dispensing.

The hard copy prescription or records of sale for Schedule II controlled substances shall:

____ Be maintained separately from other records and in chronological order.

____ 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.

The hard copy prescription or records of sale for Schedule III through VI controlled substances shall:

- ___ ___ Be maintained separately from other records and in chronological order.
- ___ ___ 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.
- ___ ___ 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.

18 VAC 110-30-200 AUTOMATED DATA PROCESSING RECORDS OF SALE

C NC

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:

- ___ ___ Provides 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.
- ___ ___ If the system provides a printout of each day's selling activity, the printout shall be verified, dated and signed by the licensee. 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.
- ___ ___ 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 by an authorized agent.

18 VAC 110-30-210. REPACKAGING, RECORDS & LABELING REQUIREMENTS.

C NC

- ___ ___ 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.
- ___ ___ Repackaged or reconstituted units contain 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 .

18 VAC 110-30-220 LABELING OF PRESCRIPTION AS TO CONTENT AND QUANTITY.

C NC

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

- ___ ___ Name and address of the practitioner and the name of the patient.
- ___ ___ Date of the dispensing.
- ___ ___ Drug name and strength, when strength is applicable.
- ___ ___ Number of dosage units, or if liquid, the number of millimeters dispensed.
- ___ ___ For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label.
- ___ ___ 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 also contain the generic's brand name or the manufacturer or distributor of the drug dispensed.

18 VAC 110-30-240 SPECIAL PACKAGING

C NC

- ___ ___ 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.
- ___ ___ If nonspecial packaging is requested, a release of such request shall be obtained from the patient or patient's authorized agent and maintained for two years from the date of dispensing.

18 VAC 110-30-255 PURCHASE OF DRUGS

C NC

- ___ ___ 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.

ACTS TO BE PERFORMED BY THE LICENSEE

____ One person may be present in the storage and selling area to assist in performance of pharmacy technician tasks who is either registered pharmacy technician or nurse or physician assistant who has received training.

• **Training Requirements for Nurse or Physician Assistant**

____ Board approved Pharmacy Technician training course OR Training Manual developed by the licensee
____ Documentation that the nurse or physician assistant has successfully completed general training is maintained.

• **Training Requirements for Pharmacy Technician, Nurse or Physician Assistant**

____ Site specific training program and manual is available.
____ Documentation of successful completion of the site specific training program is maintained for two years from the date of termination of employment.
____ Documentation for current employees is on site or readily retrievable. After termination, documentation may be stored at an off-site location where it is retrievable upon request.

____ Conducts a prospective drug review and offers to counsel the patient in accordance with 54.1-3319.
____ 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.
____ 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.
____ Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

COMMENTS:

This facility has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions have been deemed by the inspector as not being in compliance and have been explained to me and that I have received a copy of the inspection report.

Signature of Inspector Date
Practitioners Selling Controlled Substances

Signature of Licensee Date