

**PRACTITIONERS SELLING CONTROLLED SUBSTANCES  
INSPECTION REPORT**

Name \_\_\_\_\_ License No. 0213 \_\_\_\_\_ Exp Date \_\_\_\_\_

Street \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Telephone No \_\_\_\_\_ Fax No \_\_\_\_\_ Hours of Operation \_\_\_\_\_

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 _____
_____	_____	Copy of the current Virginia Drug Control Act and board regulations.
_____	_____	Laminar flow hood if sterile products are prepared.
_____	_____	Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in extemporaneous compounding..

**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 shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
_____	_____	The device shall be maintained in operating order.
_____	_____	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.
_____	_____	The alarm system must have an auxiliary source of power.

\_\_\_\_\_ 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.  
\_\_\_\_\_ The alarm system is 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 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 and the 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.  
\_\_\_\_\_ 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 be separated from the stock used for selling and may be maintained in a designated area with the unexpired stock 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                    SIGN AND WRITTEN PRESCRIPTION REQUIREMENTS**

**C                    NC**  
\_\_\_\_\_ The licensee shall provide the patient with a written prescription whether or not he intends to sell the controlled substance to the patient.  
\_\_\_\_\_ The licensee shall conspicuously display a sign in the public area of the office advising patients of their right to choose where they have their prescriptions filled.  
\_\_\_\_\_ 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 110-30-180                    INVENTORY RECORDS**

**C                    NC**  
\_\_\_\_\_ 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 report 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  
\_\_\_\_ 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. RECORDS FOR SCHEDULE II THROUGH VI CONTROLLED SUBSTANCES**

C NC

**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.  
\_\_\_\_ A hard copy prescription shall be placed on file chronologically and maintained for a period of two years.  
\_\_\_\_ 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.

**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 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.  
\_\_\_\_ Expiration date for U.S.P.-N.F. Class B or better packaging material does 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 unless it can be documented that the repackaged unit has a stability greater than six months.

**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 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.

**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.

**18 VAC 110-30-40                      ACTS TO BE PERFORMED BY THE LICENSEE**

**C                      NC**

\_\_\_\_\_      \_\_\_\_\_      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.  
\_\_\_\_\_      \_\_\_\_\_      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

**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