



PRACTITIONERS SELLING CONTROLLED SUBSTANCES INSPECTION REPORT

		<input type="checkbox"/> No Deficiency	<input type="checkbox"/> Deficiency	<input type="checkbox"/> Waivers Requested
Facility Name:			Permit No:	0224-
Street:	City:	State:	VA	Zip:
Telephone:	Fax:	Email:		
Hours of Operation:				
Designated Responsible Practitioner:			License No:	0213-
Inspector:			Date:	

Inspection Type: New Routine Change of Location Remodel Focused Compliance
 Other (Describe):
 Compounding: Does not compound Nonsterile Sterile

DESIGNATIONS: C MEANS COMPLIANT * NC MEANS NON-COMPLIANT * NA MEANS NOT APPLICABLE

18 VAC 110-30-90 PHYSICAL STANDARDS

New, remodel and change of location inspections - attach pictures and a diagram of the controlled substance selling area including locations of alarm sensors.

- | | | | |
|--------------------------|--------------------------|--------------------------|---|
| C | NC | NA | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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 the 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 workspace used in preparation of the drugs shall be contained within the enclosed area. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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 | NA | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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. |

18 VAC 110-30-110 MINIMUM EQUIPMENT

C NC NA

- Current dispensing information reference source, either hard copy or electronic.
 - Reference Used: _____
- 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 NA

- 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 NA

- 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 locked and alarmed at all times when the licensee is not on duty.
- 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.
- 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:
 - 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.
 - 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 the seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.
- 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 NA

- 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 NA

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 NA

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 NA

- 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.

INVENTORY RECORDS

C NC NA

§ 54.1-3404 BIENNIAL INVENTORY

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

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

18 VAC 110-30-180 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.

C NC NA

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

18 VAC 110-30-190. RECORDS FOR SCHEDULE II THROUGH VI CONTROLLED SUBSTANCES

C NC NA

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 in lieu of a hard copy prescription:
- 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
- Maintained 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
- Maintained 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 NA

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 NA

- 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 NA

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 PACKAGING STANDARDS

- 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.

18 VAC 110-30-240 SPECIAL PACKAGING

C NC NA

- 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 NA

- 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 110-30-255 RETURNING OF CONTROLLED SUBSTANCES

C NC NA

- 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.

