

CONTROLLED SUBSTANCE REGISTRATION - INSPECTION REPORT B

Department of Health Professions
 Perimeter Center
 9960 Mayland Drive, Suite 300
 Henrico, VA 23233-1463

Permit No. 0220-	Expiration Date	Date	Time	Days & Hours of Operation
Name of Entity		Telephone No	Fax No.	
Street Address		City	State	ZIP
Responsible Party	License No.	Supervising Practitioner	License No.	DEA No.
<input type="checkbox"/> New <input type="checkbox"/> Routine <input type="checkbox"/> Reinspection <input type="checkbox"/> Other (Describe)	Controlled Substance		<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> VI	
<input type="checkbox"/> Ambulatory Surgery Center (1) <input type="checkbox"/> Correctional Facility (1,2) <input type="checkbox"/> EMS Agency (1) <input type="checkbox"/> Hospital (1) <input type="checkbox"/> Out-Patient Clinic (1) <input type="checkbox"/> Other (1,2)				
(1) Must have a supervising practitioner. See application for details		(2) Must submit a protocol with application.		

		C – Compliant	NC – Not Compliant	NA – Not Applicable
GENERAL		C	NC	NA
54.1-3422 (D)	Controlled substances are manufactured, distributed, or dispensed at location on CSRC application/certificate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.1-3423	Responsible party on CSR identified and correct.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-700 (E)	Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.13423(C)	Evidence of federal registration provided for Schedule I substances. Write DEA No here:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-690 (C)	The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-700 (B)	The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-700 (C)	Access to the controlled substances shall be limited to the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, or to other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-700 (D)	The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
STORAGE		C	NC	NA
110-20-710 (A)	Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug. Refrigerator temperature (36° - 46°F) Actual _____ Freezer temperature (-4° - +14°F) Actual _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (B)	Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (C)	If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (D)	Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SECURITY		C	NC	NA
If the facility is not staffed 24 hours a day				
110-20-710 (E)	Drugs are stored in a fixed and secured room, cabinet or area with a security device for the detection of breaking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (E)	Device is microwave, photoelectric, ultrasonic or other generally accepted and suitable device. The installation and device shall be based on accepted alarm industry standards.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (E)	The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, & be maintained in operating order	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (E)	Capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational Describe and note how verified:	<input type="checkbox"/>	<input type="checkbox"/>	
110-20-710 (E)	<input type="checkbox"/> Check if security system was tested at time of inspection. Security system monitored by: Test verified by:	<input type="checkbox"/>	<input type="checkbox"/>	

SECURITY		C	NC	NA
110-20-710 (E)	The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-710 (E)	Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RECORDS		C	NC	NA
110-200-720	Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-720	All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-720	Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining under the Drug Control Act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.1-3404	Records of receipt of CII-V drugs includes A) Date of receipt B) Name & address of person from whom received C) Kind and quantity of drug.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.1-3404	Distribution record includes A) Date of selling, administering, dispensing, disposal or waste B) Name and address of person (or owner & species) to whom sold, administered or dispensed C) Name, strength and quantity of drug D) Signature of individual selling, administering, dispensing or disposing. Entries are chronological.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.1-3404	Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs. Within 30 days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.1-3404	After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-720	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 or after the close of business on that date. An entity which is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-720	Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Requirements For Correctional Facilities Only		C	NC	NA
110-20-590	All prescription drugs at any correctional facility shall be obtained only on an individual prescription basis from a pharmacy and subject to the following conditions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-590	All prepared drugs shall be maintained in a suitable locked storage area with the only person responsible for administering the drugs having access	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-590	All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record. Such drugs shall be returned to the provider pharmacy or to a secondary pharmacy along with the drug administration record, a copy of the drug administration record, or other form showing substantially the same information, within thirty days of discontinuance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-590	An emergency box and a Stat-drug box may be prepared for a correctional facility served by the pharmacy pursuant to 18VAC110-20-540 and 18VAC110-20-550 provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, or physician assistants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
110-20-590	Prescription drugs, including but not limited to vaccines, may be floor-stocked only at a medical clinic or surgery center which is part of a correctional facility and which is staffed by one or more prescribers during the hours of operation provided the clinic first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, and 18VAC110-20-720	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Signature of Applicant/Title of Applicant

Date