

MANUFACTURER

0207 RESTRICTED & 0208 NON-RESTRICTED
 DEPARTMENT OF HEALTH PROFESSIONS
 Perimeter Center
 9960 Mayland Drive, Suite 300
 Henrico, VA 23233
 Web Site: www.dhp.virginia.gov

DATE	TIME	INSPECTION HOURS	OFFICE USE
FACILITY TYPE <input type="checkbox"/> 0207 Restricted <input type="checkbox"/> 0208 Non-Restricted			
<input type="checkbox"/> Devices <input type="checkbox"/> Oxygen <input type="checkbox"/> Prescription Drugs			

NAME	LICENSE NO.	EXPIRATION DATE
STREET ADDRESS	CITY	STATE ZIP
RESPONSIBLE PARTY	TELEPHONE NO.	FAX NO.
HOURS OF OPERATION	DEA NO. <input type="checkbox"/> Check if applied for	EXPIRATION DATE
CONTROLLED SUBSTANCE SCHEDULES <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> VI	CSRC NO. <input type="checkbox"/> Check if applied for	EXPIRATION DATE
INSPECTION TYPE: <input type="checkbox"/> NEW <input type="checkbox"/> CHANGE OF LOCATION <input type="checkbox"/> REMODEL <input type="checkbox"/> ROUTINE <input type="checkbox"/> OTHER – DESCRIBE		

C indicates in compliance with law or regulation **NC** indicates not in compliance with law or regulation **NA** indicates does not apply

AREA / REQUIREMENT		C	NC	NA
54.1-3430 LICENSE				
Permit is displayed in a conspicuous place.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18VAC110-50-30 LOCATION & INSPECTION				
Facility does not operate from a private dwelling or residence.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prescription drugs are not stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Possesses a Controlled Substance Registration and is registered with the DEA if the facility engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of Schedule II – V controlled substances. <input type="checkbox"/> CSRC Applied For <input type="checkbox"/> DEA Applied For		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18VAC110-50-40 SAFEGUARDS AGAINST DIVERSION OF DRUGS				
The holder of the license or permit shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution or quality control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking subject to the following conditions:				
1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The device shall be operable, centrally-monitored, and have an auxiliary source of power.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The system shall be activated whenever the drug storage areas are closed for business.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Check if security system was tested at time of inspection. Security system monitored by:				
Test verified by:				
Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized person.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18VAC110-50-50 STORAGE	C NC NA
Drugs and devices are stored 1) at appropriate temperature and under appropriate conditions in accordance with labeling of the drug or USP-NF requirements or 2) at controlled room temperature, as defined in the USP-NF, if no specific storage conditions are established. <ul style="list-style-type: none"> Controlled Room Temperature is a temperature maintained thermostatically of 68°F – 77°F (20°C – 25°C) that allows for excursions between 59°F – 86°F (15°C – 30°C). 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs are utilized to document proper storage of prescription drugs.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Packaging of drugs is in accordance with USP-NF standards.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Schedule II-V controlled substances are separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Facility is of adequate size and construction and has proper equipment necessary for the proper storage of prescription drugs and devices.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

AREA / REQUIREMENT	C NC NA
54.1-3404 RECORDS OF DRUGS IN SCHEDULES II, III, IV & V	C NC NA
Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to Sec. 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. CFR 1304.04(a)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory. Date of inventory: _____ <input type="checkbox"/> Opening or <input type="checkbox"/> Closing of Business	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Inventories and records of Schedule II are maintained separately from all other records CFR 1304.04(f)(1)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. CFR 1304.04(f)(2)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the <ul style="list-style-type: none"> date of selling, administering, or dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, kind and quantity of drugs. Any person selling, administering, dispensing or otherwise disposing of such drugs shall make and sign such record at the time of each transaction	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
The record of such drugs received shall in every case show the <ul style="list-style-type: none"> date of receipt, name and address of the person from whom received kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture date of such production or removal from process of manufacture	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

ACKNOWLEDGEMENT: 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 that have been deemed by the inspector as not being in compliance have been explained to me and that I have received a copy of this inspection report.

SIGNATURE OF INSPECTOR

SIGNATURE OF LICENSEE