Commonwealth of Virginia
Department of Health Professions
Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Date_____

Hours_____

THIRD-PARTY LOGISTICS PROVIDER
INSPECTION REPORT

Name_____ Permit No. 0239-_____Exp Date_____

Street_____City_____State_____Zip_____

Telephone No_____ Fax No_____ Email_____

Responsible Party _____Hours of Operation_____

CSRC No. _____ Exp Date_____ DEA No. _____ Exp Date _____

CSRC Schedules ☐ II ☐ III ☐ IV ☐ V

FACILITY ENGAGES IN DISTRIBUTION OF:

☐ Prescription Drugs ☐ Devices ☐ Oxygen ☐ Nitrous Oxide ☐ Other Medical Gases (Describe in comments)

INSPECTION TYPE

☐ New ☐ Routine ☐ Change of Location ☐ Remodel ☐ Reinspection ☐ Other _____

DESIGNATIONS: C - COMPLIANT, NC - NON-COMPLIANT, NA - NOT APPLICABLE

FACILITY

C	NC	NA	§54.1-3430
__	__	__	Permit is displayed in a conspicuous place.

18VAC 110-50-90
All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

C	NC	NA	
__	__	__	Be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with the labeling of such drugs and devices or with official USP-NF compendium standards;
__	__	__	Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;
__	__	__	Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
__	__	__	Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;
__	__	__	Be maintained in a clean and orderly condition;
__	__	__	Be free from infestation of any kind.
__	__	__	The facility shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.
__	__	__	The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

SECURITY- 18VAC 110-50-40

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:

☐ **Alarm was tested at time of inspection**

Monitored By _____ Verified By _____

C	NC	NA	
__	__	__	The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
__	__	__	The installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards.
__	__	__	The device shall be maintained in operating order and shall have an auxiliary source of power.
__	__	__	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.
__	__	__	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.
__	__	__	The system shall be activated whenever the drug storage areas are closed for business.
			Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.
__	__	__	The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.
__	__	__	The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.
__	__	__	Prescription drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the third-party logistics provider and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient or patients.

STORAGE - 18VAC 110-50-50

C	NC	NA	
__	__	__	All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements of USP-NF.
__	__	__	If no specific storage requirements are established for a drug or a device, it may be held at controlled room temperature, as defined in USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.
__	__	__	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, or logs shall be utilized to document proper storage of prescription drugs.
__	__	__	Packaging of the prescription drugs should be in accordance with USP-NF standards.
__	__	__	Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards.
__	__	__	Facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices.

RECORDS – 18VAC 110-50-130

C	NC	NA	
__	__	__	All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying upon request by an authorized agent of the board for a period of three years following the date the record was created or received by the third-party logistics provider.
__	__	__	If records are not maintained on premises at the address of record, they shall be made available within 48 hours of such request
			A wholesale distributor, nonresident wholesale distributor, or third-party logistics provider shall establish and maintain the following:
__	__	__	Unless otherwise indicated in federal law, inventories and records of all transactions, including the dates of receipt and distribution or other disposition or provision, and records related to the federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed;
__	__	__	Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50
__	__	__	Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection;
__	__	__	Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;
__	__	__	An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs or provides prescription drugs as a third-party logistics provider;
__	__	__	Copies of the mandated report of thefts or unusual losses of Schedule II-V controlled substances in compliance with the requirements of §54.1-3404 of the Code of Virginia.
__	__	__	Records shall either (i) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or (ii) if kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board.
__	__	__	All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

Records of Drugs in Schedules I, II, III, IV & V (NOT APPLICABLE TO DISTRIBUTORS OF ONLY GASES)

C	NC	NA	§54.1-3430
__	__	__	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)
__	__	__	The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.
__	__	__	Date of last inventory performed: _____ ☐ Opening or ☐ Closing of Business
__	__	__	Inventories and records of Schedule II are maintained separately from all other records CFR 1304.04(f)(1)
__	__	__	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)
__	__	__	The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the 1) date of selling, administering, or dispensing, 2) 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, 3) 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
__	__	__	The record of such drugs received shall in every case show the 1) date of receipt, 2) name and address of the person from whom received 3) kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture 4) date of such production or removal from process of manufacture

POLICIES & PROCEDURES 18VAC 110-50-120

C	NC	NA	
			All third-party logistics providers shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors shall include in their policies and procedures at least the following:
__	__	__	A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate persons;
__	__	__	A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution;
__	__	__	A procedure for handling recalls and withdrawals of prescription drugs and devices;
__	__	__	Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the third-party logistics provider;
__	__	__	A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs;
__	__	__	A procedure to ensure initial and ongoing training of all employees;
__	__	__	A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to wholesale distribution of prescription drugs or that of a third-party logistics provider;
__	__	__	A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies.

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 Licensee	Date
Printed Name	Date	Printed Name	Date