

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

Date _____
Hours _____

WHOLESALE DISTRIBUTOR
INSPECTION REPORT

Name _____ License No. _____ Exp Date _____

Street _____ City _____ State _____ Zip _____

Telephone No _____ Fax No _____ Hours of Operation _____

Responsible Party _____

CSRC License No. _____ Exp Date _____ DEA No. _____ Exp Date _____

TYPE OF FACILITY

WHOLESALE DISTRIBUTOR Prescription Drugs Oxygen Other Medical Gases
(Describe in Comments)

INSPECTION TYPE

New Routine Change of Location Remodel Other _____

DESIGNATIONS: C MEANS COMPLIANT, NC MEANS NON-COMPLIANT

FACILITY

	C	NC	
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	
__	__		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__	__		Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or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

C NC

- — The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
- — The installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards.
- — The device shall be operable, centrally-monitored, and 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.
- — Prescriptions 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 wholesale distributor, manufacturer, or warehouse, 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

- — All prescription drugs 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 in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
- — If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected. 21CFR205.50(c)(1)
- — Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs 21CFR205.50(c)(1)
- — Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secured area in accordance with DEA security requirements and standards.
- — Facility is 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

- — All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor.
A wholesale distributor shall establish and maintain the following:
- — Inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition;

C NC

- — 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;
- — 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 be 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 WHOLESALERS OF ONLY GASES)

C NC

- 54.1-3404 — — 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)
- 54.1-3404 — — The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.
- 54.1-3404 — — Date of last inventory performed: _____
- 54.1-3404 — — Opening or Closing of Business
- 54.1-3404 — — Inventories and records of Schedule II are maintained separately from all other records
CFR 1304.04(f)(1)
- 54.1-3404 — — 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)
- 54.1-3404 — — 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
- 54.1-3404 — — 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

All wholesale distributors 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;

