Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy

Select Facility Type

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Facility License or Permit Number:		**Inspection Type:**	
Facility Name:		**Inspection Results:**	
Special or Limited Use?		**Inspection Date:**	
Controlled Substances Registration Number (CSR): (If applicable)		**Inspector Name:**	
CSR Inspection conducted concurrent with this inspection:		**Responsible Party:**	
Address:		**Responsible Party License Number:**	
City:		**Responsible Party Email Address):**	
State:		**Individual on Duty:**	
Zip Code:		**Inspection Emailed To (person):**	
Telephone number:		**Inspection Emailed To (email address):**	
Fax number:			
Email address:			
Drug Schedules (Select all that apply):			
Type of Products (Select all that apply):			

Hours of Operation		**Is facility open 24/7?**		**State & Federal Licensure Information**		
	Start Time (hh:mm)	**End Time (hh:mm)**	**Closed**	**License/Registration Agency**	**License/Registration Number**	**Name on License/Registration**
Sunday						
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						

Inspector Comments

Virginia Board of Pharmacy
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	General	Result	Notes
54.1-3430	Permits issued under the provisions of this chapter shall be displayed in a conspicuous place in the factory or other place of business for which issued.		
18VAC110-50-30	A license, permit, or registration shall not be issued to any wholesale distributor, manufacturer, warehouser, or third-party logistics provider to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license, permit, or registration is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.		
	If a wholesale distributor, manufacturer, warehouser, or third-party logistics provider engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedules II through V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances.		
	A licensee or permit holder proposing to change the location of an existing license or permit, or make structural or security system changes to an existing location, shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.		
	The proposed location, structural changes, or security system changes shall be inspected by an authorized agent of the board prior to issuance of a license or permit.		
	Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.		
	Security of Drugs	**Result**	**Notes**
18VAC110-50-40	The holder of the license or permit shall restrict access to 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.		
18VAC110-50-40	The holder of the license, permit, or registration, **except for those distributors of only medical gases other than nitrous oxide**, shall install a 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.		
	2. One communication line installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards to include wireless motion sensors.		
	3. The device shall be maintained in operating order, shall have an auxiliary source of power, and shall be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		
	4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.		
	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.		
	6. The system shall be activated whenever the drug storage areas are closed for business.		

Security Alarm System							**Was alarm tested?**		**Notes**
Mode of Communication		**Security Company**							
Primary:		**Test Verified By:**							
Secondary:		**Test Verified By:**							
Describe if Other:									
Number of Sensors		**90**	**180**	**360**	**Contact**	**Other**	**Camera**		

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	Safeguards Against Diversion of Drugs	**Result**	**Notes**
18VAC110-50-40	Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.		
	1. The holder of the license, permit, or registration 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.		
	2. The holder of the license, permit, or registration 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 wholesale distributor, manufacturer, warehouser, third-party logistics provider, nonresident wholesale distributor, nonresident warehouser, nonresident third-party logistics provider, or nonresident manufacturer 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.		
	Storage	**Result**	**Notes**
18VAC110-50-50	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.		
	Any facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices as set forth in this section.		
	Disposal of Drugs by Authorized Collectors	**Result**	**Notes**
18VAC110-50-51	Any **manufacturer, wholesale distributor, or reverse distributor** wishing to accept for return a previously dispensed drug in Schedules II through V for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent's property, shall first be authorized by the DEA as a collector. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with federal and state law. 1. Prior to collecting drugs, an authorized collector shall submit in writing to the board: a. The name, address, and license number, if applicable, of the facility. b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and c. Signature of the responsible party. 2. If an authorized collector chooses to cease acting as a collector, the responsible party shall notify the board within 30 days.		
	Records of Drugs in Schedules I, II, III, IV & V	**Result**	**Notes**
§54.1-3404	Except as set forth in subsection G, every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory. An inventory taken by use of an oral recording device shall be promptly reduced to writing and maintained in a written, typewritten or printed form. Such inventory shall be made either as of the opening of business or as of the close of business on the inventory date.		

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§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.		
	The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture. The record shall in every case show the proportion of morphine, cocaine, or ecgonine contained in or producible from crude opium or coca leaves received or produced.		
	The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the 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, and the 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 keeping of a record required by or under the federal laws, containing substantially the same information as is specified above, shall constitute compliance with this section, except that every such record shall contain a detailed list of any drugs lost, destroyed or stolen, the kind and quantity of such drugs, and the date of the discovery of such loss, destruction or theft. The form of records shall be prescribed by the Board.		
	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.		
	All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded.		

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		Result	Notes
	Storage, Handling, Transport, and Shipment of Prescription Drugs		
18VAC110-50-90	All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:		
	1. 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.		
	2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;		
	3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.		
	4. 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.		
	5. Be maintained in a clean and orderly condition.		
	6. 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.		
	Examination of Drug Shipments and Accompanying Documents		
18VAC110-50-100	Upon receipt, each shipping container shall be visually examined for identity to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit, or damaged drugs, or drugs or devices that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents.		
	Upon receipt of drugs, a wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider involved.		
	Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.		
	Returned, Damaged and Counterfeit Drugs		
18VAC110-50-110	Any drug or device returned to a manufacturer, another wholesale distributor, or a third-party logistics provider shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer, wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider to which the drugs are returned.		
	Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition.		

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		Result	Notes
18VAC110-50-110	When a drug or device is adulterated, misbranded, counterfeited, or suspected of being counterfeit, or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider shall:		
	1. Provide notice to the board and the manufacturer, wholesale distributor, or third-party logistics provider from which such drug or device was acquired within three business days of that determination.		
	2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities.		
	Policies and Procedures		
18VAC110-50-120	All wholesale distributors, nonresident wholesale distributors, third-party logistics providers, or nonresident 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, nonresident wholesale distributors, third-party logistics providers, or nonresident third-party logistics providers shall include in their policies and procedures at least the following:		
	1. A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate authorities.		
	2. 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;		
	3. A procedure for handling recalls and withdrawals of prescription drugs and devices.		
	4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider.		
	5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs.		
	6. A procedure to ensure initial and ongoing training of all employees;		
	7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a violation of a drug law or any law related to wholesale distribution of prescription drugs or to third-party logistics providers.		
	8. 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.		

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		Result	Notes
	Recordkeeping		
18VAC110-50-130	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. 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 or third-party logistics provider shall establish and maintain the following:		
	1. 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.		
	2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50;		
	3. 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.		
	4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;		
	5. 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 or nonresident third-party logistics provider.		
	6. Copies of the mandated report of thefts or unusual losses of Schedules II through 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.		
	Due Diligence		
18VAC110-50-140	Prior to the initial purchase of prescription drugs from another wholesale distributor or third-party logistics provider not residing and licensed in Virginia, a wholesale distributor or third-party logistics provider shall obtain, and update annually, the following information from the selling wholesale distributor or third-party logistics provider:		
	1. A copy of the license to wholesale distribute or act as a third-party logistics provider from the resident state. If the resident state does not require licensure as a third-party logistics provider, documentation confirming active registration with the U.S. Food and Drug Administration is acceptable.		
	2. The most recent facility inspection report, if available;		
	3. A list of other names under which the wholesale distributor or third-party logistics provider is doing business, or was formerly known as.		
	4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any nonpublicly held corporation.		
	5. A list of all disciplinary actions by state and federal agencies.		
	6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution or for the legal acts of a third-party logistics provider.		
	7. A listing of any manufacturers for whom the wholesale distributor or third-party logistics provider is an authorized distributor of record.		

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		Result	Notes
18VAC110-50-140	If the selling wholesale distributor's or third-party logistics provider's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor or third-party logistics provider may conduct an inspection of the wholesale distributor's or third-party logistics provider's facility prior to the first purchase of drugs or devices from another wholesale distributor or third-party logistics provider to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor or third-party logistics provider.		
	Prior to the first purchase of drugs from another wholesale distributor or third-party logistics provider not residing in and licensed in Virginia, the purchasing wholesale distributor or third-party logistics provider shall secure a national criminal background check of all of the wholesale distributor's or third-party logistics provider's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.		

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	Delivery of Medical Devices on Behalf of a Medical Equipment Supplier	Result	Notes
Complete if the Medical Equipment Supplier utilizes a permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor for delivery.			
§54.1-3415.1	A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user or consumer **on behalf of a medical equipment supplier**, provided that:		
	1. Such delivery occurs at the direction of a medical equipment supplier that has received a valid order from a prescriber authorizing the dispensing of such prescription device to the ultimate user or consumer.		
	2. The manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider has entered into an agreement with the medical equipment supplier for such delivery.		
18VCA110-50-55 (A)	**In accordance with provisions of subsection A of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third party logistics provider, nonresident third party logistics provider, warehouser, or nonresident warehouser licensed, permitted or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier.** **1. Such delivery shall only occur in accordance with an agreement between a delivering entity named in subsection A of this section and a medical equipment supplier in compliance with law and regulation.** **2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and an individual medical equipment supplier or multiple medical equipment suppliers under shared ownership. The agreement shall be applicable to all ultimate users or consumers receiving services from the medical equipment supplier who require delivery of Schedule VI prescription devices.** **3. The medical equipment supplier shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a valid order from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of orders of prescribers shall be the responsibility of the medical equipment supplier, upon request of the board or delivering entity.**		
§54.1-3415.1	A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence **to be administered by persons authorized to administer such devices**, provided that:		
	1. Such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence.		
	2. The medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.		
18VAC110-50-55 (B)	**B. In accordance with provisions of subsection B of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third party logistics provider, nonresident third party logistics provider, warehouser, or nonresident warehouser permitted, licensed, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence to be administered by persons authorized to administer such devices, provided that:** **(i) such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence and** **(ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.** **1. Such delivery shall only occur in accordance with an agreement between a delivering entity authorized in subsection B of this section and a medical director of a home health agency, nursing home, assisted living facility, or hospice, and in compliance with law and regulation.** **2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and the medical director of an individual home health agency, nursing home, assisted living facility, or hospice, or multiple such entities under shared ownership. The agreement shall be applicable to all ultimate users or consumers of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI prescription devices.** **3. The home health agency, nursing home, assisted living facility or hospice shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a request from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of the request from a prescriber shall be the responsibility of the home health agency, nursing home, assisted living facility or hospice, upon request of the board or delivering entity.**		
18VAC110-50-55 (C)	**The agreement, as required by A. 1 and B. 1, shall be in written or electronic format and shall be retained in a format available upon request to the board at all times the agreement is in effect, and for two years after the date the agreement is terminated or concluded.**		
18VAC110-50-55 (D)	**An agreement shall not contain any patient specific or patient health information that would be subject to the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)**		