Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy

Medical Equipment Supplier

9960 Mayland Drive, Suite 300
Henrico, VA 23233

www.dhp.virginia.gov/pharmacy
Email: pharmbd@dhp.virginia.gov

Main: 804.367.4456
Fax: 804.527.4472

Facility Permit Number:		Inspection Type:	
Facility Name:		Inspection Results:	
Address:		Inspection Date:	
Address:		Inspector Name:	
City:		Responsible Party:	
State:		Responsible Party Email Address):	
Zip Code:		Individual on Duty:	
Telephone number:		Inspection Emailed To (person):	
Toll-free Nmber:		Inspection Emailed To (email address):	
Fax number:		FacilityEmail Address:	
Products distributed by this facility:			
Does this facility utilize another entity for delivery?			

License Number	Name of Facility	License Number	Name of Facility

Hours of Operation	Is facility open 24/7?		Does this facility hold other licenses?		
	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						

Comments

Virginia Board of Pharmacy
Medical Equipment Supplier Inspection Report

	Medical Equipment Supplier		
"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.			
	Permit	**Result**	**Notes**
§54-1-3430	Permits shall be displayed in a conspicuous place in the factory or other place of business for which issued.		
§54-1-3435.2 (A)	It shall be unlawful for any person to act as a medical equipment supplier, as defined in 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board.		
	Application	**Result**	**Notes**
18VAC110-20-630 (A)	Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board.		
18VAC110-20-630 (A)	An application shall be filed for a new permit or for acquisition of an existing medical equipment supplier.		
18VAC110-20-630 (A)	The application shall designate the hours of operation the location will be open to service the public.		
18VAC110-20-630 (A)	The application shall be signed by a person who works at the location address on the application and will act as a responsible party for that location.		
18VAC110-20-630 (B)	Any change in the hours of operation expected to last for more than one week shall be reported to the board in writing and a notice posted, at least 14 days prior to the anticipated change, in a conspicuous place to the public.		
18VAC110-20-630 (C)	Within 14 days of a change in the responsible party assigned to the permit, the outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name of the new responsible party.		
18VAC110-20-630 (D)	A permit holder proposing to change the location of an existing license or permit or make structural 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.		
	Facility	**Result**	**Notes**
18VAC110-20-630 (E)	A permit shall not be issued to any medical equipment supplier 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 or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.		
18VAC110-20-680 (A)	A medical equipment supplier's location shall be inspected by the board prior to engaging in business.		
§54-1-3435.2 (B)	Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water and saline for irrigation.		
18VAC110-20-680 (A)	The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.		
18VAC110-20-680 (B)	Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items.		
18VAC110-20-680 (B)	No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.		

Virginia Board of Pharmacy
Medical Equipment Supplier Inspection Report

	Order & Records	Result	Notes
§54-1-3435.2 (C)	Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a prescriber authorized to prescribe such drugs and devices.		
18VAC110-20-680 (C)	A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.		
18VAC 110-20-680 (D)	Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include: 1. Name and address of patient. 2. Item dispensed and quantity, if applicable. 3. Date of dispensing.		
18VAC110-20-680 (E)	A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer shall be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, by facsimile machine, or by electronic transmission. 1. The transferring medical equipment supplier shall: a. Record the word "VOID" on the face of the invalidated order. b. Record on the reverse side of the invalidated order the name and address of the medical equipment supplier to which it was transferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information. 2. The receiving medical equipment supplier shall: a. Write the word "TRANSFER" on the face of the transferred prescription. b. Provide all information required to be on a valid order to include: (1) Date of issuance of original order. (2) Original number of refills authorized on the original order. (3) Date of original dispensing if applicable. (4) Number of valid refills remaining and date of last dispensing. (5) Medical equipment supplier name and address from which the order information was transferred. (6) Name of transferring individual if transferred orally.		
18VAC110-20-680 (E)	3. Both the original and transferred order shall be main-tained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for the storage and retrieval of dispensing information.		

Virginia Board of Pharmacy
Medical Equipment Supplier Inspection Report

	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)**		