Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy

Pharmacy New, COL, Remodel Inspection

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Pharmacy Permit Number:		Inspection Type:	
FEIN:		Inspection Results:	
Legal Business Name:		Inspection Date:	
Address:		Inspector Name:	
City:		Pharmacist-in-Charge:	
State:		Pharmacist-in-Charge License Number:	
Zip Code:		Pharmacist-in-Charge Email:	
Telephone number:		Pharmacist on Duty:	
Toll free number:		Pharmacist on Duty License Number:	
Fax number:		Inspection Emailed To (person):	
E-Profile ID:		Inspection Emailed To (email address):	
Pharmacy Email:		Guidance Document 110-27 left with:	
Does the pharmacy have a PMP waiver?		If yes, does the pharmacy dispense a "covered substance"?	

§ 54.1-2519 "Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. "Covered substance" also includes cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.

Pharmacy Hours of Operation	Is pharmacy open 24/7		
	Open		Closed
	Start Time: (24-hour format hh:mm)	End Time: (24-hour format hh:mm)	
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Pharmacy Personnel

Total Pharmacists:		Number of Compounding Technicians:	
Total Registered Pharmacy Interns:		Number of Pharmacy Technician Trainees:	
Total Registered Pharmacy Technicians:		Ratio Tech:Pharmacist present at time of inspection:	

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc.)			
License/Registration Agency	**Business Name on License/Registration**	**License Type/Number**	**Expiration Date**

Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail		Investigational Drugs, Clinical Trials/Research		Central Fill/ Shared Services		Central or Remote Processing	
Open to the Public		Hospital/Institutional		Specialty Pharmacy		Outsourcing Facility	
Closed Door		Long-Term Care		Handles Medical Marijuana		Nonsterile Compounding	
Drive-through window		Narcotic Treatment Program (NTP)		Nuclear Pharmacy		Nonsterile Hazardous Drug Compounding	
Mail/Deliver (in state)		Internet Pharmacy (New Rx)		Manufacturer		Sterile Compounding	
Mail/Deliver (out-of-state list below)		Internet Pharmacy (Refill Rx)		Wholesale Distributor		Sterile Hazardous Drug Compounding	
Veterinary Pharmacy		Telepharmacy		Provide products for "Office Use"		Pharmacists initiating treatment	

States to which the pharmacy mails/delivers compounded sterile drug products:							
State		**State**		**State**		**State**	
AK		ID		MT		RI	
AL		IL		NC		SC	
AR		IN		ND		SD	
AZ		KS		NE		TN	
CA		KY		NH		TX	
CO		LA		NJ		UT	
CT		MA		NM		VA	
DC		MD		NV		VT	
DE		ME		NY		WA	
FL		MI		OH		WI	
GA		MN		OK		WV	
HI		MO		OR		WY	
IA		MS		PA		Other:	

Comments

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New Pharmacy Permit	Result	Notes
18VAC110-20-140 (F) - Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.		
18VAC110-20-140 (G) - If the pharmacy is not operational within 90 days from the date the permit is issued, the board shall rescind the pharmacy permit unless an extension is granted for good cause shown.		

Comments
Enter comments referencing scope of changes

Security 18VAC110-20-180	Result	Security Equipment & Monitoring	
This section shall not apply to pharmacies that are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 (A), and have installed prior to closing a security system that meets the requirements of 18VAC110-20-180 (A)(1) through (A)(4).			
A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:		Was the security system tested?	
The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		Primary connection:	
The device shall:		Secondary connection:	
1. have at least one hard-wired communication method			
2. be monitored in accordance with accepted industry standards		Monitored by:	
3. be maintained in operating order			
4. have an auxiliary source of power		Primary verified by:	
5. be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		Secondary verified by:	
The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.		**Sensors**	
Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2.		90 degree	
		180 degree	
The system shall be activated whenever the prescription department is closed for business.		360 degree	
		Contact	
The alarm system shall include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy.		Other	
		Cameras	

Security System Notes

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Physical Standards 18VAC110-20-150		Result	Notes
	The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.		
	Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department		
	A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public.		
	The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.		
	The entire area of the location of the pharmacy practice, including all areas where drugs are stored shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet U.S.P.-N.F. specifications for drug storage.		
	The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.		
	A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.		
	Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs. A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is controlled between -25° and -10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20°C (-4°F), the temperature of the storage location should be controlled to plus or minus 10 degrees. **(18VAC110-20-10)**		
	A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.		
Sanitary Conditions 18VAC110-20-160		**Result**	**Notes**
	The entire area of any place bearing the name of a pharmacy shall be maintained in a clean and sanitary manner and in good repair and order.		
	Adequate trash disposal facilities and receptacles shall be available.		
Required Equipment 18VAC110-20-170		**Result**	**Notes**
	A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy.		
	A set of Prescription Balances, sensitive to 15 milligrams, and weights or an electronic scale if the pharmacy engages in dispensing activities that require the weighing of components.		
	Other equipment, supplies, and references consistent with the pharmacy's scope of practice and with the public safety.		

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Enclosures 18VAC110-20-190	Result	Notes
The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.		
The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.		
The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.		
The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions in 18VAC110-20-190 (B)(1) & (B)(2))		

Compounding			
Does the pharmacy engage in nonsterile compounding?		**Risk Levels:**	
Does the pharmacy engage in sterile compounding?		**Risk Levels:**	

Sterile Compounding 18VAC110-20-321 & §54.1-3410.2			
		Cleanroom meets USP requirements?	
Name of certification company		**Notes**	
Does the pharmacy utilize a segregated compounding area?			
Does the pharmacy utilize a CAI or CACI in a non-ISO 7 area?			
Does a demarcation line or barrier separate the buffer area from the ante area?			
Does the pharmacy engage in immediate use compounding?			

Primary Engineering Controls

Number of PECs

Nonsterile Compounding powder hoods number:		**Nonsterile HD Compounding BSC/CACI hoods number:**	
Sterile Compounding Number LAFW hoods/areas:		**Sterile HD Compounding Number of BSC hoods:**	
Sterile Compounding Number BSC hoods:		**Sterile HD Compounding Number of CACI hoods:**	
Sterile Compounding Number CAI/CACI hoods:			

PEC Type	Make	Model	Serial Number	Certification Date

Buffer & Ante Area

Area	Certification Date	Notes

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USP <800> HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS

This section is for educational purposes only. The Board will not enforce compliance with USP<800> prior the effective date of revised USP <795> and USP<797>

Deficiency Number	General Requirements	Result	Notes
	Pharmacy has identified if it stocks any hazardous drugs (HDs) on the NIOSH list.		
	Assessment of risk has been performed.		
	Pharmacy has identified a 'designated person' who is responsible for continuing to evaluate the fundamental practices and precautions for handling HDs.		
	If the pharmacy performs non-sterile HD compounding, the engineering controls comply with USP Chapter <800>.		
	1. Containment Primary Engineering Control (C-PEC)		
	a. Externally vented (preferred) or redundant–HEPA filtered in series Examples: CVE, Class I or II BSC, CACI		
	2. Containment Secondary Engineering Control (C-SEC)		
	a. Externally vented		
	b. 12 air changes per hour (ACPH)		
	c. Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas		
	d. Fixed walls		
	If the pharmacy performs sterile HD compounding, the engineering controls comply with USP Chapter <800>.		
	ISO Class 7 buffer room with an ISO Class 7 ante-room		
	1. Containment Primary Engineering Control (C-PEC)		
	a. Externally vented. • Examples: Class II BSC or CACI		
	2. Containment Secondary Engineering Control (C-SEC)		
	a. Externally vented		
	b. 30 Air Changes Per Hour (ACPH)		
	c. Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.		
	3. Maximum BUD as described in USP<797>		
	Unclassified C-SCA		
	1. Containment Primary Engineering Control (C-PEC)		
	a. Externally vented. • Examples: Class II BSC or CACI		
	2. Containment Secondary Engineering Control (C-SEC)		
	a. Externally vented		
	b. 12 Air Changes Per Hour (ACPH)		
	c. Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.		
	3. Maximum BUD as described in USP<797> for CSPs prepared in a segregated compounding area.		