

Virginia Board of Pharmacy

Pharmacy New, COL, Remodel Inspection

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 | |
|--------------------------------------|--|---|--|
| Pharmacy Permit Number: | | Inspection Type: | |
| Legal Business Name: | | Inspection Results: | |
| Address: | | Inspection Date: | |
| | | 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): | |
| FEIN: | | Inspection Emailed To (email address): | |
| Pharmacy Email: | | | |
| 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 | | | |
|-----------------------------|-----------------------|-------------------|----------------------------------|--------|
| | | Ор | en | Closed |
| | Start Time: (24-ho | our format hh:mm) | End Time: (24-hour format hh:mm) | |
| Sunday | , | | | |
| Monday | , | | | |
| Tuesday | , | | | |
| Wednesday | , | | | |
| Thursday | , | | | |
| Friday | | | | |
| Saturday | r. | | | |

| | | | Pharmacy | Personnel | | | |
|------------------------------|-----------------------------------|---------------------------------------|--|------------------------------------|-------------------|---------------------------------------|-----|
| Fotal Pharmacists: | Pharmacists: To | | Total Registered Pharmacy Technicians: | | | | |
| Total Registered Pharmacy In | otal Registered Pharmacy Interns: | | Number of Pharmacy Technic | cian Trainees: | | | |
| Ratio Tech:Pharmacist preser | nt at time of inspection: | | | Number of Compounding Technicians: | | | |
| | | Business L | icensure Information f | or State of Residence ar | nd Federal | | |
| | | (boar | rd of pharmacy, state contr | olled substance, DEA, FDA, | etc.) | | |
| License/Regist | tration Agency | Business Name on License/Registration | | License Type/Number | | Expiration Date | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | Type(s) of Practice - Ty | pe "X" for all that apply | | | |
| | | Investigational Drugs, | | | | Central or Remote | |
| Chain - Community | | Clinical Trials/Research | | Central Fill/ Shared Services | | Processing | |
| Independent - Community | | Hospital/Institutional | | Specialty Pharmacy | | Outsourcing Facility | |
| FQHC-Health Dept/Free | | nospitaly institutional | | opecially manuacy | | | |
| Clinic/ CSB | | Long-Term Care | | Pilot Program | | Nonsterile Compounding | |
| | | Narcotic Treatment | | | | Nonsterile Hazardous Drug | |
| Home Health/Infusion | | Program (NTP) | | Nuclear Pharmacy | | Compounding | |
| Vail Order (only) - closed | | | | | | | |
| loor | | Internet Pharmacy (New Rx) | | Manufacturer | | Sterile Compounding | |
| Mail/Deliver | | Internet Pharmacy (Refill | | | | Sterile Hazardous Drug | |
| out-of-state list below) | | Rx) | | Wholesale Distributor | | Compounding Pharmacists initiating | |
| Veterinary Pharmacy | | Telepharmacy | | Freestanding ED | | treatment | |
| reterinary Pharmacy | | | | , | | treatment | l . |
| | | States to which th | he pharmacy mails/del | ivers compounded steri | le drug products: | | |
| | | | | | | | |
| | | | Com | ments | | | |
| | | | Collin | iiciito | | | |

| New Pharmacy Permit | Result | Note | 25 | | |
|--|---------------------|---------------------------------|-----------------|--|--|
| 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 Equipmen | nt & Monitoring | | |
| his 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 n 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, | | Was the security system tested? | | | |
| and shall be subject to the following conditions: The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted | | Primary connection: | | | |
| and suitable device. The device shall: | | | | | |
| 1. have at least one hard-wired communication method | | Secondary connection: | | | |
| 2. be monitored in accordance with accepted industry standards | | Maniferral Inv | | | |
| 3. be maintained in operating order | | Monitored by: | | | |
| 4. have an auxiliary source of power | | Primary verified by: | | | |
| 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 | | Secondary vernied by. | | | |
| breaking by any means when activated. | | Senso | | | |
| 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 | | 90 degree 180 degree | | | |
| accordance with 18VAC110-20-190 B 2. | | 360 degree | | | |
| The system shall be activated whenever the prescription department is closed for business. | | Contact | | | |
| The alarm system shall include a feature by which any breach in the alarm shall be communicated | | Other | | | |
| by the monitoring entity to the PIC or a pharmacist working at the pharmacy. | | Cameras | | | |
| S | ecurity System Note | 25 | | | |
| | | | | | |

| Pharmacy New, Change 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. | | notes |
| 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.PN.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. | | |

| Enclosures 18VAC110-20-190 | | Result | Not | es |
|--|--|--------|--|----|
| 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 ti | imes when a pharmacist is not on duty. | | | |
| The enclosure shall be capable of being locked in a duty is not present in the prescription departmen | , , | | | |
| 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 18 | | | 4.1-3410.2 | |
| Nonsterile Compounding | | | | |
| Does the pharmacy engage in nonsterile compour | nding? | | Types of nonsterile dosage forms: | |
| Does the pharmacy engage in nonsterile hazardous drug compounding? | | | Is there a separate negative pressure storage area for HD? | |
| Comments: | | | | |
| Sterile Compounding | | | | |
| Does the pharmacy engage in sterile compoundin | g? | | Categories of Sterile compounding: | |
| Does the pharmacy engage in sterile hazardous drug compounding? | | | Is there a separate negative pressure storage area for HD? | |
| Comments: | | | | |
| Name of certification company | | | Cleanroom meets USP requirements? | |
| Does the pharmacy utilize a segregated compoun | ding area (SCA)? | | Not | es |
| Does the pharmacy utilize a CAI or CACI (RABS) in | | | 1 | |
| Does a demarcation line or barrier separate the b | uffer area from the ante area? | | | |
| Does the pharmacy engage in immediate use com | pounding? | | | |

| | | Primary Eng | ineering Controls (P | EC) | | |
|--|---------------------------------------|---|---|---------------|--------------------|--|
| Number of Nonsterile Compounding powder hoods: | | Number of Nonsterile HD Compounding BSC/CACI hoods: | | | | |
| Number of | Sterile Compounding LAFW hoods/areas: | | Number of Sterile HD Compounding of BSC hoods: | | | |
| Number of | Sterile Compounding BSC hoods: | | Number of Sterile HD Compounding of CACI hoods: | | | |
| Number of | Sterile Compounding CAI/CACI hoods: | | Other (explain): | | | |
| | РЕС Туре | Make | Model | Serial Number | Certification Date | |
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| | | | | | | |
| | | | Buffer & Ante Area | | | |
| | Area | Certification Date | | Notes | | |
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Virginia Board of Pharmacy

Pharmacy New, Change of Location, Remodel Inspection Form

| USP <800> HAZARDOUS DRUGS | HANDLING IN | HEALTHCARE SETTINGS | | | |
|--|-----------------|---------------------|--|--|--|
| | | | | | |
| | | | | | |
| Compounding | 18VAC110-20-321 | & §54.1-3410.2 | | | |
| 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. | | | | | |
| Maximum BUD as described in USP<797> | | | | | |
| Unclassified C-SCA | | | | | |
| 1. Containment Primary Engineering Control (C-PEC) | | 4 | | | |
| a. Externally vented. • Examples: Class II BSC or CACI | | | | | |
| 2. Containment Secondary Engineering Control (C-SEC) | | | | | |
| a. Externally vented | | 4 | | | |
| b. 12 Air Changes Per Hour (ACPH) | | 4 | | | |
| 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. | | | | | |