

Virginia Board of Pharmacy

Submission of a Current Inspection Report by Nonresident Pharmacies

To comply with §54.1-3434.1 A 3 of the Drug Control Act, the current inspection report, **to include any corrective action taken**, submitted by a nonresident pharmacy upon initial application and renewal should, at a minimum, demonstrate that a review of the applicable information below was performed by the regulatory or licensing agency in the resident state. The inspection report shall be deemed current if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. Inspections performed outside this required timeframe will not meet compliance with Virginia law.

Using this document, review your current inspection report to ensure it demonstrates a review of the information listed below, at a minimum, was performed. The Board will not review inspection reports prior to submission of an initial application or renewal application. Should you determine the pharmacy's current inspection report does not include a review of the information below and/or you are unable to obtain an inspection from the regulatory or licensing agency of jurisdiction which meets these criteria, a Verified Pharmacy Program (VPP) inspection report performed by the National Association of Boards of Pharmacy (NABP) within the required timeframe will be deemed an acceptable alternative. NABP strongly encourages anyone requiring an inspection to submit applications to NABP no later than January 31, 2014 to ensure adequate time for performing the inspection and correcting any possible deficiencies prior to Virginia's April 30th renewal deadline. VPP applications can be obtained from the NABP Web site at www.nabp.net/programs/licensure/verified-pharmacy-program and questions regarding VPP may be directed to vpp@nabp.net. Inspections of compounding pharmacies performed by an entity other than the aforementioned are currently not acceptable alternatives and will not meet compliance with Virginia law.

Inspection Criteria for ALL Pharmacies

- All personnel required to be licensed maintain current licensure
- Pharmacy technicians and pharmacy interns do not exceed authority
- Pharmacy does not share same physical space with another permitted pharmacy
- Alarm access code and means of unlocking prescription department restricted and appropriately maintained
- Expired or otherwise adulterated or misbranded drugs not dispensed or sold are separated from the stock used for dispensing.
- Pharmacy maintained in a clean and sanitary manner and in good repair and order
- Current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy
- Refrigerator/freezer maintained at appropriate temperatures if cold storage necessary
- Pharmacist conducts prospective drug review before each new prescription is dispensed or delivered
- Only valid prescriptions dispensed
- Offer for counseling by pharmacist made on all new prescriptions
- Appropriate packaging used
- Required inventories performed and maintained
- Drug loss or thefts reported to resident regulatory entity and DEA
- Prescriptions appropriately labeled and records maintained as required
- Repackaging appropriately performed and use of compliance packaging

- Automated counting devices, automated dispensing devices, and robotics appropriately used as authorized
- Floorstock provided as authorized
- Delivery of prescriptions to alternate site in compliance
- Remote/central processing performed as authorized

Additional General Compounding Inspection Criteria for Pharmacies Performing Sterile or Nonsterile Compounding

GENERAL COMPOUNDING REQUIREMENTS

- Compounding performed in compliance with USP-NF standards
- Compounding personnel use proper aseptic technique
- Current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy
- Sources of drug product properly licensed
- Pharmacists may use bulk drug substances in compounding when such bulk drug substances:
 1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding ***or***
Are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;
 2. Are manufactured by an establishment that is registered by the FDA ***or***
 3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor ***or*** are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.
- Compounded sterile product (CSP) is appropriately labeled prior to dispensing with information such as:
 - Prescription serial number or name of the drug
 - Date of initial filling
 - Pharmacist name and address, or the name and address of the pharmacy
 - Name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal
 - Name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order
 - Directions as stated on the prescription
 - Drug name and strength, when strength is applicable
 - Number of dosage units or, if liquid, the number of milliliters dispensed
 - Name and strength of the compounded medication or a list of the active ingredients and strengths
 - Pharmacy's assigned control number that corresponds with the compounding record
 - Appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding
 - Quantity
- Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with:
 - Statement "For Administering in Prescriber Practice Location Only"
 - Name and strength of the compounded medication or list of the active ingredients and strengths
 - Facility's control number
 - Appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding
 - Quantity
- Pharmacist shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

- Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check
- Pharmacists shall not engage in the following:
 - Compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. This prohibition is limited to the scope of the FDA withdrawal ***or***
 - Regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. This prohibition shall not include:
 - compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, ***or***
 - compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier ***or***
 - the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage ***or***
 - the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary ***or***
 - the mixing of two or more commercially available products regardless of whether the end product is a commercially available product
- Pharmacist shall not compound inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.
- Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record.
- Compounding records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include information such as:
 - Name and quantity of all components
 - Date of compounding and dispensing
 - Prescription number or other identifier of the prescription order
 - Total quantity of finished product
 - Signature or initials of the pharmacist or pharmacy technician performing the compounding
 - Signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products
- NOTE: In addition to requirements for records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include information such as:
 - Generic name and the name of the manufacturer of each component or the brand name of each component
 - Manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component
 - Assigned lot number if subdivided
 - Unit or package size
 - Number of units or packages prepared
 - Beyond-use date.
 - The criteria for establishing the beyond-use date shall be available for inspection by the Board.

Additional Inspection Criteria for Pharmacies Performing Sterile Compounding

DESCRIPTION OF SERVICES PROVIDED

- Risk level of compounding performed

- Compounding pursuant to prescription and/or provided for office administration only
- Types of facilities provided compounded product
- CSPs are NOT provided as drug samples

CERTIFICATIONS FOR ISO CLASSIFIED AREAS (LOW, MEDIUM, AND HIGH-RISK)

- CSPs are compounded entirely under ISO Class 5 conditions.
- Certification that each ISO classified area is within established guidelines shall be performed no less than every 6 months and whenever the laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACI) are relocated or the physical structure of the buffer area or ante-area has been altered
- Low, medium, or high-risk compounded in ISO Class 5 hood in an ISO Class 7 buffer area with ISO Class 7 or 8 ante area
- CSPs compounded in ISO Class 5 hood in a segregated compounding area NOT located in an ISO Class 7 buffer area are limited to Low-risk CSPs with assigned 12 hour or less Beyond-Use-Date (BUD)
- Hazardous CSPs compounded in ISO Class 5 in ISO class 7 buffer area that is physically separated with ISO Class 7 or better ante area

MEDIA-FILL TESTING (LOW AND MEDIUM-RISK LEVEL)

- Training documentation of initial and annual media-fill tests for low and medium risk compounding maintained for all individuals preparing CSP
- Documentation maintained of a passing media-fill test for any individual preparing CSP within 45 days after receipt of a failed media-fill test.

ENVIRONMENTAL CONDITIONS, GARBING, STORAGE OF CSPs (LOW, MEDIUM, AND HIGH-RISK)

- Demarcation line or barrier identifies separation of the buffer area from the anteroom area.
- Personnel comply with cleansing and garbing requirements
 - no personal outer garment (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests)
 - no artificial nails or visible piercings
 - shall wear shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), face masks, and sterile gloves (all of which may not be reused when reentering compounding area)
 - shall wear nonshedding gown and only nonshedding objects in buffer or clean area
 - appropriate cleaning of rooms, equipment, vials, and bottles
- Drugs are properly stored. In the absence of sterility testing, storage periods shall not exceed the following:

	Low-Risk	Medium-Risk
Controlled Room Temperature	48 hours	30 hours
2° to 8°C (36° and 46°F)	14 days	9 days
-25° to -10°C (-4° and 14°F) or colder	45 days	45 days

OTHER DOCUMENTATION (LOW, MEDIUM, HIGH-RISK)

- Documentation that controlled temperature areas within the pharmacy are monitored at least daily and recorded on a temperature log.
 - Refrigerators 2° to 8°
 - Freezers -20° to -10°
 - Incubators 30° to 35°.
- Documentation maintained for life of equipment indicating that written procedures are followed regarding: required equipment calibration; annual maintenance and routine maintenance; monitoring of proper function; and controlled procedures for use of equipment.
- Documentation of evaluation of airborne microorganisms in the controlled air environment (LAFW, barrier isolators, buffer or clean area, anteroom) at least every six months for low, medium, and high-risk.
- Record of daily accuracy assessment of automated compounding devices.
- Documentation of a formal Quality Assurance Program that provides a mechanism for monitoring, evaluating, correcting, and improving activities and processes.

- Documentation of daily monitoring and documentation of temperature in drug storage refrigerators in patient care settings are maintained between 2° and 8°.
- Documentation of monthly inspection of drug storage areas by pharmacy personnel to confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of multiple-dose containers, avoidance of using single use containers as multiple-dose, and security from unauthorized personnel.
- Specific handling and exposure instructions are included on the exteriors of containers packed with CSP.
- Labels and accessory labeling includes clearly readable beyond-use dates, storage instructions.
- Documentation of a formal training program for home care responsibilities expected of the patient or caregiver, to include storage, handling and administration.

CSP OF HAZARDOUS DRUGS

- Sterile compounding of hazardous drugs performed in an area physically separated from other preparation areas

HIGH-RISK LEVEL CSP

STERILIZATION METHOD, ENDOTOXIN PYROGEN TESTING, MEDIA-FILL TESTING

- Documentation maintained indicating sterilization method and endotoxin pyrogen testing performed per CSP.
- Training documentation of initial and semi-annual media-fill test procedure for CSPs maintained for all individuals preparing high-risk level CSPs
- Individuals who failed a media-fill test have not been permitted to perform high-risk level CSPs after receipt of negative test result until retrained and receipt of passing media-fill test.
- Drugs are properly stored. In the absence of sterility testing, storage periods shall not exceed the following:

	High-Risk
Controlled Room Temperature	24 hours
2° to 8°C (36° and 46°F)	3 days
-25° to -10°C (-4° and 14°F) or colder	45 days

Additional Inspection Criteria for Pharmacies Performing Non-Sterile Compounding

- Types of products compounded, e.g., oral, topical, etc.
- Categories of compounding performed, e.g., simple, moderate, complex, hazardous
- Use of powder hood; if so, appropriately certified
- Compounding pursuant to prescription and/or provided for office administration only
- Types of facilities provided compounded product
- Compounds are NOT provided as drug samples
- Current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy
- Compounds assigned appropriate beyond-use-dates (BUDs)
- Documentation maintained to justify use of any BUDs beyond USP-NF recommendations
- Purified water used as indicated by USP
- Procedures for preventing cross-contamination
- Compounding area is clean
- Compounding formula followed; all deviations recorded
- Proper storage of all drugs
- Quality assurance program in place
- Appropriate packing materials used to maintain stability and purity
- Policies regarding patient caregiver training, handling, storage, and disposal of compounded product