COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Ad Hoc Committee Meeting regarding Routine Pharmacy Inspection Process

June 20, 2018

1:00PM

TOPIC **PAGE**

Call to Order: Jody H. Allen, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

Topics: Sammy Johnson/Caroline Juran

- Overview of revised inspection report 1-83
- Amend Guidance Document 110-9 84-99

Adjourn

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

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

9960 Mayland Drive, Suite 300
Henrico, VA 23233

Main: 804.367.4456
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Pharmacy Permit/ e-Profile ID:			Inspection Information
Legal Business Name:		Day 1:	
Doing Business As (DBA):		Start Time: 24-hour format (13:00)	
Address:		End Time: 24-hour format (13:00)	
City:		Day 2:	
State:		Start Time: 24-hour format (13:00)	
Zip Code:		End Time: 24-hour format (13:00)	
Telephone number:		Inspector Name:	
Toll free number:		Inspection Performed by (NABP, State, etc):	Virginia Board of Pharmacy
Fax number:		Observer Name/Affiliation (if applicable):	
Website:		Observer Name/Affiliation (if applicable):	

Areas reviewed:						
	General Pharmacy	☐	Long Term Care	☐	Automated Drug Dispensing System - Hospital	☐
	Nonsterile Compounding	☐	Hospitals	☐	Automated Drug Dispensing System - LTC	☐
	Sterile Compounding	☐	Central or Remote Processing	☐	Unit Dose	☐
	Alternate Delivery	☐	Remote Processing - Hospital or LTC	☐	Robotic	☐

Pharmacy Hours of Operation — Check if 24/7 ☐

	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Key Pharmacy Personnel	Name	License Number	Email
Pharmacist in Charge			

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
Inspector Notes:			

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		Institutional		Specialty Pharmacy		Outsourcing Facility	
Closed Door		Long-Term Care		Handles Medical Marijuana		Nonsterile Compounding	
Drive-through window		HMO/PBM only		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"			

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:		Sterile HD Compounding Number of CACI hoods:	

Personnel

Total Pharmacists:		Of technicians, how many are certified?	
Total Student Interns:		Of technicians, how many are techs-in-training?	
Total Technicians:		Ratio #tech:#RPh present at time of inspection:	
Number of Compounding Technicians			

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

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:	

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

USP <800> HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS

Y - Compliant N - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		Y	N	UI	NA	Notes
	USP <800> HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS					
	The effective date of USP Chapter <800> is December 1, 2019. For more information on USP Chapter <800>, refer to USP-NF frequently asked questions published by USP at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings and Board of Pharmacy Guidance Document 110-36 available at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm					
	Has the pharmacy identified if it stocks any hazardous drugs (HDs) on the NIOSH list?					
	Has an assessment of risk been performed?					
	Has the pharmacy 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, do 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, do 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					

Deficiency Number	Y - Compliant N - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		Y	N	UI	NA	Notes
	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					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

General Pharmacy Inspection

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	General Pharmacy & Staffing					
4	Pharmacist, Pharmacy Technician, or Pharmacy Intern license or registration current active. **[18VCA110-20-40] 18VAC110-20-80] [18VAC110-20-105]**					
1	The pharmacist-in-charge (PIC) is in full and actual charge and fully engaged in the practice of pharmacy at this location. **[§54.1-3434]**					
1	PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. **[18VAC110-20-110]**					
5	Acts restricted to a pharmacist are performed only by a pharmacist or a directly monitored pharmacy intern. **[§54.1-3320]**					
102	Pharmacy exceeds scope of special or limited-use pharmacy permit. **[18VAC110-20-120]**					
7	Drugs shall not be stocked in a remodeled location or moved to a new location until approval is granted by the inspector or board staff. **[18VAC110-20-140]**					
2, 14	An application for a permit designating the new PIC filed within 14 days of original date of termination or resignation of previous PIC, or as permitted by Executive Director of Board. Deficiency 2 – PIC in place, inventory taken, application not filed with board within required timeframe. Deficiency 14 – No incoming PIC inventory, Inventory taken or over 5n days late, inventory substantially incomplete. **[§54.1-3434] [18VAC110-20-110] [18VAC110-20-240]**					
108	For emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with pharmacist's signature across the seal in a safe or vault or other secured place. **[18VAC110-20-190]**					
6, 143	Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more than four pharmacy technicians at one time. **[§54.1-3320]**					
3	No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. **[§54.1-3321]**					
	Drug Receipt & Storage	**C**	**NC**	**UI**	**NA**	**Notes**
12a, 146	Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty. **[18VAC110-20-200]**					
35	Except for an emergency purchase from another pharmacy, a pharmacist may only purchase Schedule II through VI drugs from a wholesale distributor or warehouser licensed or registered by the board. **[18VAC110-20-395]**					
109	Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. **[18VAC110-20-200] [§54.1-3457]**					
109	A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions: **[18VAC110-20-355]**					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.					
	2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.					
	3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.					
111	Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. **[18VAC110-20-200]**					
	1. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy which detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia.					
	2. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription.					
	3. Such log shall be maintained for a period of one year.					
110	Controlled paraphernalia and Schedule VI medical devices shall be placed in an area in the prescription department where the pharmacist can exercise reasonable supervision and control. **[18VAC110-20-200]**					
	Enclosure & Access	**C**	**NC**	**UI**	**NA**	**Notes**
12	All drugs are stored in the prescription department approved by the Board. **[18VAC110-20-190]**					
11, 145	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. **[18VAC110-20-190]**					
9	The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty. **[18VAC110-20-190]**					
11, 145	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. **[18VAC110-20-190]**					
10	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. **[18VAC110-20-180] [18VAC110-20-190]**					
	Physical Standards, Sanitary Conditions, Equipment & Resources	**C**	**NC**	**UI**	**NA**	**Notes**

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
104	A sink with hot and cold running water shall be within the prescription department. **[18VAC110-20-150]**					
106	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. **[18VAC110-20-160]**					
8, 105	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. Refrigerator (2° and 8°C) (36° and 46°F): Freezer (-20° and -10°C) (-4° and 14°F). **[18VAC110-20-150]**					
107	A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy. **[18VAC110-20-170]**					
	Security	**C**	**NC**	**UI**	**NA**	**Notes**
	18VAC110-20-180 *This section shall not apply to pharmacies which are open and staffed by pharmacists 24 hours a day. If approved prior to November 4, 1993, the security system will be deemed to meet the requirements of subdivisions A 1, 2, and 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur.*					
9, 9a, 144	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: **[18VAC110-20-180]**					
	1. Device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device					
	2. Monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power					
	3. Capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational					
	4. Fully protect the prescription department and shall be capable of detecting breaking by any means when activated					
9	The alarm system shall be activated whenever the prescription department is closed for business or a pharmacist is not on duty. **[18VAC110-20-180] 18VAC110-20-190]**					
10	Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy. **[18VAC110-20-180] [18VAC110-20-190]**					
	Counseling & Prospective Review	**C**	**NC**	**UI**	**NA**	**Notes**
121	A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. Such review shall include: **[§54.1-3319]**					
	1. Screening for potential drug therapy problems due to therapeutic duplication					
	2. Drug-disease contraindications					
	3. Drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs					
	4. Incorrect drug dosage or duration of drug treatment					
	5. Drug-allergy interactions					
	6. Clinical use or abuse					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
120	A pharmacist shall offer to counsel any person who presents a new prescription for filling. The offer to counsel may be made in any manner the pharmacist deems appropriate in his professional judgment. **[§54.1-3319]**					
	Compliance Packaging	C	NC	UI	NA	Notes
125	Drugs may be dispensed in compliance packaging for self-administration when requested by the patient or for use in hospitals or long-term care facilities provided: **[18VAC110-20-340]**					
	1. Packaging meets all current U.S.P.-N.F. standards for packaging, labeling and recordkeeping					
	2. Compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, shall comply with USP-NF standards for customized patient medication packages to include:					
	a. If the packaging allows for the separation of the individual containers, the labels for each individual container shall be labeled with the identity of each of the drug products contained within; and					
	b. The main packaging label shall contain all the required elements for any outpatient prescription label and shall contain a physical description identifying each solid dosage form contained within the individual containers.					
	Special Packaging	C	NC	UI	NA	Notes
126	Each drug dispensed to a person in a household shall be dispensed in special packaging except when otherwise directed in a prescription by a practitioner, when otherwise requested by the purchaser, or when such drug is exempted. **[18VAC110-20-350]**					
	If nonspecial packaging is requested, a notation shall be made on the dispensing record or other retrievable record. **[18VAC110-20-350]**					
	Biennial Inventory	C	NC	UI	NA	Notes
13, 112	Biennial inventory taken 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. **[§54.1-3404]**					
13	No biennial inventory or inventory taken over 30 days late or substabntially incomplete.					
112	Inventory available but taken late within 30 days of date due					
113	Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. **[18VAC110-20-240]**					
	Biennial inventory shall include the following information:					
	1. Drugs listed in Schedules I and II shall be maintained separately from all other records **[18VAC110-20-240]**					
	2. Indicate whether the inventory was taken prior to the opening of business or after close of business **[§54.1-3404]**					
	3. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. **[18VAC110-20-240]**					
	4. Signed and dated by the person taking the inventory **18VAC110-20-240**					
	Maintained completely and accurately for two years from the date of the transaction recorded **[§54.1-3404]**					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	Change of Pharmacist-in-Charge	C	NC	UI	NA	Notes
14	PIC CHANGE: The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date. **[§54.1-3434]**					
113	Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. [18VAC110-20-240]					
	Inventory shall include the following information:					
	1. Drugs listed in Schedules I and II shall be maintained separately from all other records **[18VAC110-20-240]**					
	2. Maintained completely and accurately for two years from the date of the transaction recorded **[18VAC110-20-240]**					
	3. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. **[18VAC110-20-240]**					
14	All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction. **[18VAC110-20-240]**					
	Perpetual Inventory	C	NC	UI	NA	Notes
15	Perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly **[18VAC110-20-240]**					
	All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction. **[18VAC110-20-240]**					
	Drug Loss or Theft	C	NC	UI	NA	Notes
16	Whenever any registrant or licensee discovers a theft or any other unusual loss of any Schedule II, III, IV or V controlled substance, he shall immediately report such theft or loss to the Board. **[§54.1-3404]**					
16	Within 30 days after the discovery of a loss of any Schedule II, III, IV or V drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost. **[§54.1-3404]**					
16	All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded. **[§54.1-3404]**					
	Prescriptions	C	NC	UI	NA	Notes
17	A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. NOTE: See 18VAC110-20-250 Electronic Image **[18VAC110-20-240]**					
17	All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy. **[18VAC110-20-240]**					
17	Prescriptions for Schedule II drugs shall be maintained in a separate prescription file. **[18VAC110-20-240]**					
17	Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. **[18VAC110-20-240]**					
17	**NOTE:** A chart order may serve as the hard-copy prescription for those patients in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia **[18VAC110-20-240]**					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:					
	a. This information is contained in other readily retrievable records of the pharmacy; and					
	b. The pharmacy maintains a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.					
	Requirements for filing of chart orders.					
	a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.					
	b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.					
	Automated Data Processing System	C	NC	UI	NA	Notes
18	An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions: **[18VAC110-20-250]**					
	A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:					
	a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription 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. Storing electronic images of prescriptions for Schedule II through V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.					
	b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.					
	c. For Schedule II through V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.					
	Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.					
	Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) and any data entry of on-hold prescriptions. Such printout shall be provided within 48 hours of a request of an authorized agent.					
	Records of Receipt & Invoices	**C**	**NC**	**UI**	**NA**	**Notes**
114	Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. **[18VAC110-20-240]**					
	Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.					
	All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.					
	Invoices or other records showing receipts of Schedule VI drugs shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.					
	All records shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.					
	Records - Partial Dispensing	**C**	**NC**	**UI**	**NA**	**Notes**
119	The pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found. **[§54.1-3412]**					
119	The partial filling of a prescription for a drug listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and he makes a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing; however, if the remaining portion is not or cannot be dispensed within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription. **[18VAC110-20-310]**					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
119	Prescriptions for Schedule II drugs written for patients in long-term care facilities may be dispensed in partial quantities, to include individual dosage units. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II drugs in all partial dispensing shall not exceed the total quantity prescribed. Schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug. **[18VAC110-20-310]**					
119	Information pertaining to current Schedule II prescriptions for patients in a long-term care facility may be maintained in a computerized system if this system has the capability to permit: **[18VCA110-20-310]**					
	1. Output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, identification of the long-term care facility, identification of drug authorized (to include dosage form, strength, and quantity), listing of partial dispensing under each prescription, and the information required in subsection B of this section.					
	2. Immediate (real time) updating of the prescription record each time a partial dispensing of the prescription is conducted.					
119	The pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found. **[§54.1-3412]**					
119	A prescription for a Schedule II drug may be filled in partial quantities to include individual dosage units for a patient with a medical diagnosis documenting a terminal illness under the following conditions: **[18VAC110-20-310]**					
	1. The practitioner shall classify the patient as terminally ill, and the pharmacist shall verify and record such notation on the prescription.					
	2. On each partial filling, the pharmacist shall record the date, quantity dispensed, remaining quantity authorized to be dispensed, and the identity of the dispensing pharmacist.					
	3. Prior to the subsequent partial filling, the pharmacist shall determine that it is necessary. The total quantity of Schedule II drugs dispensed in all partial fillings shall not exceed the total quantity prescribed.					
	4. Schedule II prescriptions for terminally ill patients may be partially filled for a period not to exceed 60 days from the issue date unless terminated sooner.					
	5. Information pertaining to partial filling may be maintained in a computerized system under the conditions set forth in 18VAC110-20-320 subsection C.					
	A prescription for a Schedule II drug may be filled in partial quantities if the partial fill is requested by the patient or by the practitioner who wrote the prescription provided:					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	1. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;					
	2. The prescription is written and filled in accordance with state and federal law; and					
	3. The remaining portions are filled not later than 30 days after the date on which the prescription is written.					
119	A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times. **[18VAC110-20-320]**					
	1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with §54.1-3414 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.					
	2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:					
	a. Each partial dispensing is recorded in the same manner as a refilling;					
	b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and					
	c. No dispensing occurs after six months after the date on which the prescription order was issued.					
119	Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with 54.1-3412 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed. **[18VAC110-20-320]**					
119	The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that: **[18VAC110-20-320]**					
119	1. Each partial dispensing is recorded in the same manner as a refilling;					
	2. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and					
	3. No dispensing occurs after six months after the date on which the prescription order was issued.					
	Any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. **[18VAC11-20-255]**					
119	A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting **[18VAC110-20-255]**					
119	1. Procedures for using the record					
	2. How the record is integrated into the total dispensing record system					
	3. How the data included in the record shall be interpreted					
	Prescription Labeling	**C**	**NC**	**UI**	**NA**	**Notes**

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
124	Whenever a pharmacist dispenses any drug listed within Schedule II through VI on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing **[§54.1-3410]**					
	1. Prescription serial number or name of the drug					
	2. Date of initial filling *Do not cite if label inlcudes date of dispensing reather that date of initial filling.*					
	3. His name and address, or the name and address of the pharmacy					
	4. 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					
	5. Name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a char order					
	6. Directions as may be stated on the prescription					
	7. Drug name and strength, when strength is applicable					
	8. Number of dosage units or, if liquid, the number of milliliters dispensed					
	For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label. **[18VAC110-20-330]**					
124	NOTE: Does not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.					
	If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed. **[18VAC110-20-330]**					
124	NOTE: Does not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.					
	Prescription Order	C	NC	UI	NA	Notes
116	A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription. NOTE: See 18VAC110-20-285 for faxing of prescription orders for Schedule II drugs. **[§54.1-3410]**					
116	A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription. **[§54.1-3410]**					
116	The agent of the prescriber on his behalf may orally transmit a prescription. The written record of the prescription specifies the full name of the agent of the prescriber.					18VAC110-20-280 3. An authorized agent, as defined in §54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription. 18VAC110-20-220 2. Orders for radiopharmaceuticals may be transmitted orally, by fax, or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature, but must include the name of the agent.
116	A written prescription shall be written with ink or individually typed or printed and shall contain: **[§54.1-3408.01]**					
116	1. Name, address, and telephone number of the prescriber.					
	2. First and last name of the patient for whom the drug is prescribed.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	3. Address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. NOTE: If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription.					
	4. Dated and signed by the prescriber on, the day when issued					
	5. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber					
	Electronic Transmitted Prescription	**C**	**NC**	**UI**	**NA**	**Notes**
	Effective July 1, 2020 - Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription. **§54.1-3408.02**					
116	Unless otherwise prohibited by law, an electronic prescription may be transmitted from the prescriber or an authorized agent as defined in § 54.1-3408.01 C of the Code of Virginia directly to the dispensing pharmacy. Electronic prescriptions of Schedule II-V controlled substances shall comply with any security or other requirements of federal law. All electronic prescriptions shall also comply with all security requirements of state law related to privacy of protected health information. **[18VAC110-20-285]**					
	A pharmacy receiving an electronic prescription shall maintain such prescription record in accordance with 18VAC110-20-250 A.					
	Faxed Prescription	**C**	**NC**	**UI**	**NA**	**Notes**
116	Unless otherwise prohibited by federal law, prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions: **[18VAC110-20-280]**					
	1. The prescription shall be faxed only to the pharmacy of the patient's choice					
	2. A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's signature.					
	3. An authorized agent may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription					
116	A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations: **[18VAC110-20-280]**					
	1. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice					
	2. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or					
	3. Forwarding a written prescription by an authorized agent from a long-term care facility, provided					
	a. The provider pharmacy maintains written procedures for such transactions					
	b. The original prescription is obtained by the provider pharmacy within seven days of dispensing					
	c. The original prescription shall be attached to the faxed copy					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
116	The following additional information shall be recorded on the faxed prescription: **[18VAC110-20-280]**					
	1. Date that the prescription was faxed					
	2. Printed name, address, phone number, and fax number of the authorized prescriber					
	3. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number					
116	Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for: **[18VAC110-20-280]**					
	1. Orders to be administered to long-term care facility and home infusion patients					
	2. Prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state which may include home hospice					
	3. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's signature					
116	If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality. **[18VAC110-20-280]**					
116	Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes: **[18VAC110-20-280]**					
	1. Patient's name & address					
	2. Drug name and strength, quantity					
	3. Directions for use,					
	4. Prescriber's name, prescriber's signature or agent's name					
	5. Date of authorization					
	Emergency Prescription	C	NC	UI	NA	Notes
118	In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that: **[§54.1-3410] [18VAC110-20-290]**					
	1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period					
	2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner					
	3. If the pharmacist does not know the practitioner, he shall make a reasonable effort to determine that the oral authorization came from a practitioner					
	4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist					
	5. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order					
	6. The dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	7. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to him					
	Repackaging	**C**	**NC**	**UI**	**NA**	**Notes**
127	Control records of reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs maintained for a period of one year or until the expiration, whichever is greater. **[18VAC110-20-355]**					
127	Control record includes the following information: **[18VAC110-20-355]**					
	1. Date repackaged					
	2. Name of the drug(s) used & strength of drug, if any					
	3. Quantity prepared					
	4. Assigned lot or control number					
	5. Manufacturer's or distributor's name and lot or control number					
	6. Expiration date					
20	7. Initials of the pharmacist verifying the process **[18VAC110-20-355]**					
127	The following information shall appear on any subsequently repackaged or reconstituted units: **[18VAC110-20-355]**					
	1. Drug name & strength of drug, if any					
	2. Assigned lot or control number or the manufacturer's or distributor's name and lot or control number					
	3. Appropriate expiration determined by the pharmacist in accordance with USP guidelines					
127	Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:					
	A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved, for each bin including: **[18VAC110-20-355]**					
	1. Drug name and strength, if any					
	2. Name of the manufacturer or distributor					
	3. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling					
	4. Any assigned lot number					
	5. An expiration date determined according to USP guidelines for repackaging					
	6. Date of filling					
20	7. Pharmacist's initials verifying the accuracy of the process **[18VAC110-20-355]**					
127	If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines. **[18VAC110-20-355]**					
	Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.					
	In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:					
	a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or					
	b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.					
	An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.					
	Continuous Quality Improvement	**C**	**NC**	**UI**	**NA**	**Notes**
	§54.1-3434.03. Continuous quality improvement program - Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.					
142	Pharmacy Actively Reports to Patient Safety Organization **[18VAC110-20-418]** A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting					
	Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement.					
142	Pharmacy does not actively report to a patient safety organization **[18VAC110-20-418]** A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:					
	(1) Dates the analysis was initiated and completed;					
	(2) Names of the participants in the analysis;					
	(3) General description of remedial action taken to prevent or reduce future errors; and					
	(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days. *Do not cite a deficiency if only the record of zero report is missing.*					
	Nonsterile Compounding - Simple Compounding Only	**C**	**NC**	**UI**	**NA**	**Notes**
	A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of §54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.					
	SIMPLE COMPOUNDING - Making a preparation that has a United States Pharmacopeia (USP) compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.					
	Complete the Nonsterile Compounding report if the pharmacy engages in Moderate or Complex nonsterile compounding					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
29	In accordance with the conditions set forth in §54.1-3410.2 subsections A and B, pharmacists 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; however, a pharmacist may distribute to a veterinarian in accordance with federal law. **[§54.1-3410.2]**					
29	Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. **[§54.1-3410.2]** *A veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.* **[§54.1-3301]**					
29	A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. **[§54.1-3410.2]**					
27	Pharmacists may use bulk drug substances in compounding when such bulk drug substances: **[§54.1-3410.2]**					
	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; or are manufactured by an establishment that is registered by the FDA					
	2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and 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.					
27	Pharmacists shall not engage in the following: **[§54.1-3410.2]**					
	1. The 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. However, this prohibition shall be limited to the scope of the FDA withdrawal					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
28	2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) 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 (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product					
?	3. The compounding of 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					This is not currently addressed in 110-9
130a	Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with: **[§54.1-3410.2]**					
	1. the statement "For Administering in Prescriber Practice Location Only"					
	2. the name and strength of the compounded medication or list of the active ingredients and strengths					
	3. the facility's control number					
	4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
	5. the name and address of the pharmacy					
	6. the quantity					
130a	Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with: **[§54.1-3410.2]**					
	1. the statement "For Administering in Prescriber Practice Location Only"					
	2. the name and strength of the compounded medication or list of the active ingredients and strengths					
	3. the facility's control number					
	4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
	5. the name and address of the pharmacy					
	6. the quantity					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
20a	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product. **[§54.1-3410.2]**					
130	Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method. **[§54.1-3410.2]**					
130	In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the: **[§54.1-3410.2]**					
	1. name and quantity of all components					
	2. the date of compounding and dispensing					
	3. the prescription number or other identifier of the prescription order					
	4. total quantity of finished product					
	5. signature or initials of the pharmacist or pharmacy technician performing the compounding					
20a	6. signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.					
130	In addition to the requirements of §54.1-3410.2 subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: **[§54.1-3410.2]**					
	1. the generic name and the name of the manufacturer of each component or the brand name of each component					
	2. the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown					
	3. the source of acquisition of the component					
	4. the assigned lot number if subdivided					
	5. the unit or package size and the number of units or packages prepared					
	6. the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.					
130	A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product. **[§54.1-3410.2]**					
130a	Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding. **[§54.1-3410.2]**					
130a	A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern. Pharmacists shall label all products compounded prior to dispensing with: **[§54.1-3410.2]**					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	1. the name and strength of the compounded medication or a list of the active ingredients and strengths					
	2. the pharmacy's assigned control number that corresponds with the compounding record					
	3. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
	4. the quantity.					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	General Operations and Information					
29	In accordance with the conditions set forth in §54.1-3410.2 subsections A and B, pharmacists 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; however, a pharmacist may distribute to a veterinarian in accordance with federal law. **[§54.1-3410.2]**					
29	Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. **[§54.1-3410.2]**					
29	A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. **[§54.1-3410.2]**					
27	Pharmacists may use bulk drug substances in compounding when such bulk drug substances: **[§54.1-3410.2]**					
	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; or are manufactured by an establishment that is registered by the FDA					
	2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and 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.					
27	Pharmacists shall not engage in the following: **[§54.1-3410.2]**					
	1. The 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. However, this prohibition shall be limited to the scope of the FDA withdrawal					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
28	2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) 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 (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product					
?	3. The compounding of 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					This is not currently addressed in 110-9
130a	Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with: **[§54.1-3410.2]**					
	1. the statement "For Administering in Prescriber Practice Location Only"					
	2. the name and strength of the compounded medication or list of the active ingredients and strengths					
	3. the facility's control number					
	4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
	5. the name and address of the pharmacy					
	6. the quantity					
130a	Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with: **[54.1-3410.2]**					
	1. the statement "For Administering in Prescriber Practice Location Only"					
	2. the name and strength of the compounded medication or list of the active ingredients and strengths					
	3. the facility's control number					
	4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
	5. the name and address of the pharmacy					
	6. the quantity					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
20a	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product. **[54.1-3410.2]**					
130	Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method. **[54.1-3410.2]**					
130	In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the: **[§54.1-3410.2]**					
	1. name and quantity of all components					
	2. the date of compounding and dispensing					
	3. the prescription number or other identifier of the prescription order					
	4. total quantity of finished product					
	5. signature or initials of the pharmacist or pharmacy technician performing the compounding					
	6. signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.					
130	In addition to the requirements of §54.1-3410.2 subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: **§54.1-3410.2]**					
	1. the generic name and the name of the manufacturer of each component or the brand name of each component					
	2. the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown					
	3. the source of acquisition of the component					
	4. the assigned lot number if subdivided					
	5. the unit or package size and the number of units or packages prepared					
	6. the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.					
130	A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product. **[§54.1-3410.2]**					
130a	Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding. **[§54.1-3410.2]**					
130a	A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern. Pharmacists shall label all products compounded prior to dispensing with: **§54.1-3410.2]**					
	1. the name and strength of the compounded medication or a list of the active ingredients and strengths					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	2. the pharmacy's assigned control number that corresponds with the compounding record					
	3. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
	4. the quantity.					
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?					
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*					
28 1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?					
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?					
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?					
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?					
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?					
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?					
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*					
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?					
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?					
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*					
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*					
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*					
2.06	If yes, are any of these controlled substances? *List compounds provided.*					
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?					
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*					
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*					
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*					
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*					
8.00	Does the pharmacy compound investigational drugs? *Provide List.*					
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*					
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.					
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*					
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*					
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding.* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*					
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*					
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs.* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.					
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*					
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*					
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?					
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.*					
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*					
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources.*					
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*					
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*					
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*					
19.00	Does the pharmacy use scales/balances for nonsterile compounding?					
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*					
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*					
19.03	Describe the pharmacist checks for the measurement of each ingredient					
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**					
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?					
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?					
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?					
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?					
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?					
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?					
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?					
	Component Selection and Use	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)					
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.					
21.02	USP- or NF-grade substances used, if available					
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.					
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*					
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.					
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.					
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*					
21.08	All APIs and components received without an expiration date are labeled with the date they were received.					
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.					
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).					
22.00	Where water is an ingredient, purified or distilled water is used.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.					
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).					
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.					
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.					
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.					
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.					
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.					
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.					
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					
	Beyond Use Dating (BUD)	**C**	**NC**	**?**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
27.00	BUDs are assigned from the day of preparation.					
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.					
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*					
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*					
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.					
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).					
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.					
	Environment	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.					
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.					
35.00	Only one preparation compounded at a time.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.					
37.00	The compounding area is well lit.					
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize. (NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*					
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.					
38.02	RECOMMENDED: Hood prefilters are checked and replaced regularly.					
38.03	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.					
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.					
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).					
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.					
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*					
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.					
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.					
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.					
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.					
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.					
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.					
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.					
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.					
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.					
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.					
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.					
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.					
47.00	All components and packaging containers and closures are properly rotated to use oldest first.					
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel (OSHA regulations and NIOSH Alerts).					
49.00	Trash is disposed of in a safe, sanitary, and timely manner.					
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.					
50.00	**Recommended:** Environmental testing is performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? *Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials or known allergens such as penicillin, not using a hood, or the compounding room not segregated.*					
	Training *-Verify records of all compounding personnel (up to 10).*	C	NC	UI	NA	Notes
	Total Non-Compliant (Includes Unknowns)		**0**			
51.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.					
52.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.					
53.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.					
54.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*					
55.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.					
55.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.					
56.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	Compounding Equipment	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
57.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*					
58.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*					
59.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.					
59.01	Hood filters are checked regularly and replaced when necessary.					
60.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*					
61.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.					
	Documentation	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
62.00	The pharmacy creates a master formulation record the first time before compounding a new preparation.					
62.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.					
62.02	The **master formulation record** includes:					
62.03	Official or assigned name, strength, and dosage form					
62.04	All necessary calculations					
62.05	Description of all ingredients and their quantities					
62.06	Compatibility and stability information including references (when available)					
62.07	Equipment used for the preparation					
62.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)					
62.09	Container used and packaging requirements					
62.10	Assigned BUD information					
62.11	Labeling information including the name of and quantity or concentration of each active ingredient					
62.12	Description of the finished preparation					
62.13	Storage requirements					
62.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).					
63.00	The pharmacy creates a compounding record for each compound prepared					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
63.01	The **compounding record** includes:					
63.02	Official or assigned name, strength and dosage of the preparation					
63.03	Master Formulation Record reference					
63.04	Sources, lot numbers, and expiration dates of all components					
63.05	Total quantity or number of dosage units compounded					
63.06	Person compounding the preparation					
63.07	Person performing the quality control procedures					
63.08	Person who approved the preparation					
63.09	Date of compounding					
63.10	Assigned internal identification number or prescription number					
63.11	Description of the final preparation					
63.12	Assigned BUD					
63.13	Duplicate label					
63.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?					
63.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate.					
	Compounding Procedures	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
64.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.					
65.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.					
66.00	The containers and closures selected meet USP standards (from container supplier).					
67.00	Container selection determined by physical and chemical properties of the preparation.					
68.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.					
69.00	Personnel don appropriate protective garb when performing compounding.					
69.01	If hazardous compounding, personnel don appropriate protective garb when compounding.					
70.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly.*					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
71.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*					
72.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.					
73.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*					
74.00	Personnel are appropriately garbed for protection when cleaning.					
75.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. Compounding MUST be observed, if compounding is not being performed at the time of survey, mark as "Non-Compliant".*					
75.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. List individual who signs the Denial of Authorization*					
	Finished Preparation Release Checks and Tests	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)			**0**		
76.00	The finished preparation is observed to appear as expected in the master formulation record and documented.					
77.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.					
78.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.					
79.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.					
79.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient					
79.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.					
80.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*					
81.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.					
81.01	Labeling contains generic name and quantity or concentration of each active ingredient.					
81.02	Labeling contains assigned BUD.					
81.03	Labeling contains storage and handling information.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
81.04	If hazardous, labeling contains storage and handling information.					
81.05	Labeling contains prescription or control number, whichever is applicable.					
82.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).					
83.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.					
84.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.					
85.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.					
	Patient Counseling and Communication	**C**	**NC**	**UI**	**NA**	**Notes**
	Total Non-Compliant (Includes Unknowns)		**0**			
86.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?					
87.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?					
88.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?					
89.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.					

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
			C	NC	UI	NA	Notes
		Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. *(NA if no sample)*					
		Indicate the areas/rooms of the pharmacy entered to perform the inspection. *If the inspector did not fully garb and enter buffer room(s), indicate reason.*					
		General Operations Information	C	NC	UI	NA	Notes
	21	The pharmacy engages in the compounding of sterile drug products and does not have a clean room that is compliant with USP-NF standards. **[§54.1-3410.2] [18VAC110-20-321]**					
	21a	The pharmacy is erforming sterile compounding outside of a clean room. There is a compliant clean room present that is not utilized for preparation of compounded sterile drug products. **[§54.1-3410.2]**					
	29	In accordance with the conditions set forth in §54.1-3410.2 subsections A and B, pharmacists 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; however, a pharmacist may distribute to a veterinarian in accordance with federal law. **[§54.1-3410.2]**					
	29	Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. **[§54.1-3410.2]**					
	29	A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients. **[§54.1-3410.2]**					
	27	Pharmacists may use bulk drug substances in compounding when such bulk drug substances: **[§54.1-3410.2]**					
		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; or are manufactured by an establishment that is registered by the FDA					
		2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and 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.					
	27	Pharmacists shall not engage in the following: **[§54.1-3410.2]**					
		1. The 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. However, this prohibition shall be limited to the scope of the FDA withdrawal					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	28	2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) 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 (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product					
	?	3. The compounding of 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					This is not currently addressed in 110-9
	130a	Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with: **[§54.1-3410.2]**					
		1. the statement "For Administering in Prescriber Practice Location Only"					
		2. the name and strength of the compounded medication or list of the active ingredients and strengths					
		3. the facility's control number					
		4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
		5. the name and address of the pharmacy					
		6. the quantity					
	130a	Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with: **[54.1-3410.2]**					
		1. the statement "For Administering in Prescriber Practice Location Only"					
		2. the name and strength of the compounded medication or list of the active ingredients and strengths					
		3. the facility's control number					
		4. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
		5. the name and address of the pharmacy					
		6. the quantity					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	20b	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product. **[54.1-3410.2]**					
	130	Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method. **[54.1-3410.2]**					
	130	In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the: **[§54.1-3410.2]**					
		1. name and quantity of all components					
		2. the date of compounding and dispensing					
		3. the prescription number or other identifier of the prescription order					
		4. total quantity of finished product					
		5. signature or initials of the pharmacist or pharmacy technician performing the compounding					
		6. signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.					
	130	In addition to the requirements of §54.1-3410.2 subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: **§54.1-3410.2]**					
		1. the generic name and the name of the manufacturer of each component or the brand name of each component					
		2. the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown					
		3. the source of acquisition of the component					
		4. the assigned lot number if subdivided					
		5. the unit or package size and the number of units or packages prepared					
		6. the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.					
	130	A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product. **[§54.1-3410.2]**					
	130a	Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding. **[§54.1-3410.2]**					
	130a	A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern. Pharmacists shall label all products compounded prior to dispensing with: **§54.1-3410.2]**					
		1. the name and strength of the compounded medication or a list of the active ingredients and strengths					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
		2. the pharmacy's assigned control number that corresponds with the compounding record					
		3. an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding					
		4. the quantity.					
1.00		Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?					
1.01		Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*					
1.02		Are sterile compounded prescriptions picked up at the pharmacy?					
1.03		Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential					
1.04		Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?					
2.00		Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*					
2.01		Does the pharmacy distribute sterile compounded preparations to practitioners for office use?					
2.02		Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?					
2.03		Is the pharmacy registered with the FDA as an Outsourcing Facility?					
2.04		Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*					
3.00		Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?					
3.01		If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations?					
4.00		Which of the following sterile compounds are prepared?					
4.01		Allergen extracts					
4.02		Parenteral solutions					
4.03		Parenteral *suspensions*					
4.04		Preservative-free parenterals					
4.05		Ophthalmic preparations					
4.06		Oral or nasal *inhalation* preparations (not topical sprays)					
4.07		Baths and soaks for live organs and tissues					
4.08		Irrigations for wounds and body cavities					
4.09		Any other sterile preparations (implants, pellets, etc.). *Provide list.*					
5.00		Does the pharmacy compound investigational drugs? *Provide list.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
6.00		Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate name and volume/percent compounded currently.*					
6.01		If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.					
6.02		If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. ***Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.***					
7.00		Does the pharmacy perform **low-risk** compounding? *Indicate percentage of low-risk sterile compounding.*					
7.01	33	Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)?					
7.02		If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.					
7.03	33	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*					
8.00		Does the pharmacy perform **medium-risk** compounding? *Indicate percentage of medium-risk sterile compounding.*					
8.01	33	Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)?					
8.02		If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.					
8.03	33	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*					
9.00		Does the pharmacy perform **high-risk** compounding? *Indicate percentage of high-risk sterile compounding.*					
9.01	25	Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)?					
9.02		If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.					
9.03	25	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*					
10.00		Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?					
11.00		Does the pharmacy perform compounding for **immediate use?** *Indicate percentage of immediate use sterile compounding.*					
12.00		Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous sterile compounding.* ***NIOSH list of hazardous drugs including chemotherapy, hormones, etc.***					
12.01		Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
12.02		Are hazardous drugs segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH?					
12.03		Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?					
13.00		Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*					
14.00		Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*					
15.00		Does the pharmacy compound using any Federally **controlled substances I-V**? *Indicate controlled substances used and percentage of controlled substance sterile compounding.*					
16.00		**APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?					
16.01		Does the pharmacy purchase APIs directly from the manufacturer/repackager? *If not, indicate the source of APIs*					
16.02		Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*					
16.03		Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*					
16.04		Does the computer track on-hand quantities of APIs used for compounding?					
17.00		Does the pharmacy use scales/balances for sterile compounding?					
17.01		If so, what type of scale/balanced is used? *List manufacturer and model number.*					
17.02		If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*					
18.00		Does the pharmacy have a **lyophilizer**?					
18.01		Where is the lyophilizer located? *Indicate location and ISO class of room.*					
18.02		Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer.					
18.03		Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures?					
19.00		Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*					
20.00		Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed*					
21.00		**Quality Assurance/Quality Improvement**: Does the pharmacy continuous quality improvement program include sterile compounding measures? ***Note: If the facility indicates "yes", please ask each question below to verify.***					
21.01		Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
21.02		Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?					
21.03		Does the pharmacy continuous quality improvement program include viable environmental testing?					
21.04		Does the pharmacy continuous quality improvement program include personnel testing and verification?					
21.05		Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?					
21.06		Does the pharmacy continuous quality improvement program include sterilization method testing and validation?					
21.07		Does the pharmacy continuous quality improvement program include end product testing (such as: potency, particulates, sterility, endotoxin, etc.)?					
21.08		Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?					
21.09		Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?					
21.10		Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?					
21.11		Are QREs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA.					
21.12		Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? *Review QA trends.*					
		Component Selection and Use	**C**	**NC**	**UI**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)		**0**			
22.00		**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)					
22.01		Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding.					
22.02		USP- or NF-grade substances used, if available.					
22.03		If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.					
22.04		APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
22.05		If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.					
22.06		All substances and components have a complete label including a batch control or lot number, and an expiration date.					
22.07		For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. *Note: purity and quality testing may be performed to extend.*					
22.08		All APIs are labeled with the date they were received.					
22.09		If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.					
22.10		Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).					
23.00		There are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).					
24.00		There are no preparations compounded that present demonstrable difficulties for compounding as identified by the FDA. *If so, list the name of the products.*					
25.00		When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.					
26.00		For **animal compounding**, does the compounding meet the same standards as compounding for human patients?					
26.01		The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.					
26.02		It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.					
26.03		The pharmacist familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.					
26.04		The facility has a list of drugs and components not allowed when compounding for food-producing animals.					
26.05		The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)					
27.00		If the pharmacy compounds **stock solutions** or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.					
27.01		The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR are assigned on the basis of direct testing or extrapolation from reliable literature sources to support an extended BUD.					
27.02		Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.					
		Environment	C	NC	UI	NA	Notes

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
		Total Non-Compliant (Includes Unknowns)		**0**			
28.00	32	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.					
29.00		If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.					
29.01		Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?					
30.00		Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).					
31.00	32	The anteroom has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.					Need to clarify "may NOT be the doorway"
31.01		Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.					
31.02		Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.					
32.00		All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.					
33.00	32	Walls painted with epoxy based paint or other impermeable surface, and are seamless or have sealed seams where panels meet and corners with no cracks.					
34.00	32	The ceiling tiles are composed of a vinyl surface, with the tiles caulked and sealed and the seams where the walls meet the ceiling are caulked and sealed.					
35.00	32	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.					
36.00		The clean/buffer room or anteroom does not have dust collecting overhangs (eg ceiling utility pipes, ledges, pneumatic tube stations, sprinkler heads, emergency exit signs, etc).					
37.00		The exposed surfaces of:					
37.01		PEC are free of dirt, rust, chips and particulate matter.					
37.02		Light fixtures are smooth, mounted flush, and sealed.					
38.00		A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).					
39.00		There is no sink or drain in the clean/buffer room.					
40.00		Hand drying is with non-linting paper towels, or an electronic or HEPA filtered hand dryer.					
40.01		If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. *(N/A if only using towels)*					
41.00		All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 or 8 environment.					
42.00		Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
43.00		If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g. computers, printers, refrigerators, dishwashers, etc), they are located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while in use.					
44.00		Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.					
45.00		If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.					
45.01	21b	Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.					
46.00		Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.					
46.01		Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.					
46.02		Clean/buffer room is at least 0.02" wc positive pressure to general pharmacy areas.					
46.03		Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.					
46.04		Pressures are continuously monitored and at a minimum read and recorded each shift (minimum of once daily). *View logs*					
46.05		Plan in place to detect and react to pressure differentials outside of limits.					
47.00		If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.					
47.01		The air flow is at least 40 feet per minute across the entire opening.					
47.02		Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*					
47.03		Plan in place to detect and react to air flow measurements outside of limits					
47.04		This area is used only for low- and medium-risk compounding (**High-risk not allowed**).					
48.00		**Temperature:** The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.					
48.01		Temperature in the **compounding area** is maintained to provide comfortable working conditions for compounding personnel of 20° C or cooler (68° F or cooler); Temperature can be more restrictive if warranted by specific drug product storage requirements.					
48.02		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
48.03		Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage.					
48.04		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
48.05	8, 105	Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage.					
48.06		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
48.07	8, 105	Temperature in the **freezer** is maintained to provide controlled frozen temperature of -25° to -10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage.					
48.08		Temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.					
48.09		Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas.					
49.00		**Humidity:** If warranted by specific drug products, humidity in the compounding area is maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place", humidity is not to exceed 40%. (*Generally recommended range is 35-60% for performing sterile compounding* .)					
49.01		If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.					
49.02		If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity.					
49.03		If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).					
50.00		Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.					
51.00		When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces.					
52.00		The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*					
53.00		The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*					
53.01		RECOMMENDED: Pass-throughs are located between outside areas and the anteroom, or between the anteroom and the buffer room (and NOT between the outside areas directly into the buffer room).					
54.00		RECOMMENDED: The immediate area around the doorway or pass-through into the anteroom from the general areas is free of particle generating materials (such as corrugated cardboard, etc.) and is located in an area that limits particles (not next to an outside door or window, etc.) to limit potential contamination from being brought in through the entry.					
55.00	22	**BSC or PEC that is NOT located in an ISO Class 7 clean/buffer room**: BSC or PEC has been certified to maintain ISO Class 5 during compounding activities.					
55.01		Used only for low-risk compounded preparations with a 12-hour or less BUD assigned.					
55.02		All garbing requirements are adhered to.					
55.03		Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.					
55.04		Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas?					
55.05		Has the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent) and an eyewash station.					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
56.00	22	**CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.					
56.01		The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.					
56.02		The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.					
56.03		There is a sink in the compounding area, not directly adjacent to the CAI or CACI, that enables pharmacy personnel to wash hands and an eyewash station.					
56.04		For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH.					
		Cleaning and Disinfection	**C**	**NC**	**UI**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)		**0**			
57.00	132	Are all personnel performing cleaning appropriately garbed?					
58.00		Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*					
59.00		If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?					
60.00		Are reusable tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls.					
61.00		Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?					
62.00		Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present.*					
63.00		Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?					
64.00		Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?					
64.01		If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*					
65.00		Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe?					
66.00		Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?					
67.00		Does daily cleaning include the floors starting from the clean/buffer room and working outwards? Floor cleaning is not to occur during compounding.					
68.00		If fatigue mats are used, are they cleaned daily and let dry on both sides?					
69.00		Is a tacky mat used and if so, is there a procedure in place regarding replacement?					
70.00		Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.) Check inside bins and shelving for dust if you are garbed.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
71.00		Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?					
		Training *-Verify records of all compounding personnel (up to 10).*	**C**	**NC**	**UI**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)		**0**			
72.00		There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, and aseptic technique. ***Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.*** *List number of personnel training files viewed.*					
72.01		All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.					
72.02		All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.					
73.00		All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. ***Teratogenicity, carcinogenicity, reproductive issues.***					
74.00		There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.					
75.00		There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. ***Documentation needs to include training on operation, and troubleshooting***					
76.00		If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. *View documentation.*					
77.00		There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs. *Indicate frequency, if testing more than annually*					
78.00		There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*					
79.00	25a, 26	There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? ***Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations.*** *Indicate frequency, if testing more than annually.*					
80.00	26	There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. ***Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results.*** *Indicate frequency, if testing more than annually.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
81.00	26	There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.* *Indicate frequency, if testing more than annually.*					
82.00		The media-fill testing procedures include:					
82.01		Media selection (including obtaining COAs or growth promotion certificates from suppliers)					
82.02		Fill Volume					
82.03		Incubation time and temperature (30-35°C for a minimum of 7 days then 20-25°C for 7 days)					
82.04		Inspection of filled units					
82.05		Documentation					
82.06		Interpretation of results					
82.07		Action levels set with the corrective actions required					
83.00	25a	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results.* *Indicate frequency, if testing more than every 6 months.*					
84.00	25a	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.* *Indicate frequency, if testing more than every 6 months.*					
85.00	25c, 26a	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.					
85.01		Gloved fingertip tests that have failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination.					
85.02		There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.					
		Garbing	C	NC	UI	NA	Notes
		Total Non-Compliant (Includes Unknowns)		**0**			
86.00		Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.					
87.00		Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
88.00		Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.					
89.00		Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.					
90.00		Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).					
91.00		Garbing includes head and facial hair covers and masks. *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a mirror available to check that all hair is covered.*					
92.00		Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*					
93.00		The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.					
94.00		All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).					
95.00		Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*					
96.00		Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.					
97.00		Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*					
98.00		Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example).					
		Environmental Monitoring	**C**	**NC**	**UI**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)		**0**			
99.00	23	The most recent PEC and room certification report is available.					
99.01	23	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*					
99.02	23	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*					
99.03	23	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is moved or major work is done to the space. *If non-compliant, record the date of the previous certification.*					
99.04		Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
99.05		If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide.					
99.06		The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.					
100.00		The certification report includes information about the equipment used for performing calibration test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).					
100.01		The equipment used had not exceeded its calibration date at the time of certification.					
101.00		The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.					
101.01		ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.*					
101.02		ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.*					
101.03		RECOMMENDED: ISO class 8 anteroom is certified as having a minimum of 20 ACPH.					
101.04		ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically, all of the air will be from outside.*					
101.05		If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.					
102.00	147	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.					
102.01	147	Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate **unidirectional** airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).					
102.02		Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs.					
102.03		Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.					
103.00		Differential air pressure between rooms was measured.					
103.01		The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.					
103.02		The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed.					
104.00		Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
104.01		Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*					
105.00		Particle counts of particles 0.5um and larger were measured under dynamic conditions.					
105.01		ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).					
105.02		ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).					
105.03		ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).					
106.00		HEPA filter tests were performed.					
106.01		All room HEPA filters were leak tested and if leaks found, they were fixed.					
106.02		All PEC HEPA filters were leak tested and if leaks found, they were fixed.					
107.00		PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.					
108.00		Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.*					
108.01		Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*					
108.02		Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*					
108.03		Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and the samples are at least 400 liters in volume? *Note: recommendation in ISO 5 PEC is 1000 liters.*					
108.04		Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.					
108.05		Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3 >5 CFU/plate ISO Class 8 >100 CFU/m3 >100 CFU/plate *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the number of CFUs found must be multiplied by the appropriate factor.*					
108.06		CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are analyzed to determine the organism down to the genus. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
108.07		If the number of CFUs detected **in the rooms** exceeds action levels, begin immediate remediation, including recleaning, retraining and retesting; and conduct investigation into the causes.					
108.08		If the number of CFUs detected **in the PECs** exceeds action levels, begin immediate remediation, including recleaning, retraining and retesting; and conduct investigation into the causes.					
108.09		If any highly pathogenic microbes (ie mold, yeast, coagulase positive staphylococcus, or gram-negative rods) were detected **in the PECs** (whether or not the number of CFUs exceeds action levels), begin immediate remediation, including recleaning, retraining and retesting; and conduct investigation into the causes.					
108.10		RECOMMENDED: The testing report indicates growth promotion testing or documentation and sterility quality control testing of the media plates was performed. *Positive and negative control tests important to validate results of viable testing.*					
108.11		RECOMMENDED: The testing results report includes media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer.					
109.00		Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. *Indicate the outside vendor used to verify procedures and frequency of verifications.*					
		Compounding Equipment	**C**	**NC**	**?**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)		**0**			
110.00		Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*					
111.00		All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.					
112.00		All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.					
113.00		RECOMMENDED: PEC (hood) prefilters are checked and replaced regularly. *View replacement log or documentation of filter check and replacement by certification company.*					
114.00		Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.					
114.01		There is documentation of the ACD tubing being changed or discarded every 24 hours.					
114.02		The ACD is used when performing media fill testing.					
		Compounding Procedures	**C**	**NC**	**UI**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)		**0**			
115.00		Gloves and critical sites are sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a nonlinting wipe.					
116.00		Objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads).					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
117.00		Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.					
118.00		Supplies required for the scheduled operations of the shift are prepared and decontaminated by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.					
119.00		Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). Compounding MUST be observed, if compounding is not being performed at the time of survey mark item as "Non-Compliant".*					
119.01		If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. List individual who signs the Denial of Authorization.*					
120.00		Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.					
121.00		All rubber stoppers of vials and bottles and the neck of ampules are sanitized every time with sterile 70% IPA (and a wait of at least 10 seconds to dry) prior to the introduction of a needle or spike for the removal of product.					
122.00		Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*					
123.00		The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any time period.*					
124.00		Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.					
125.00	130	The compounding record is complete. *View several completed compounding records and answer each of the following questions.*					
125.01		Official or assigned name, strength and dosage of the preparation.					
125.02		Names, lot numbers and expiration dates of all components.					
125.03		Total quantity or number of units compounded.					
125.04		Person compounding the preparation.					
125.05		Person performing the quality control procedures.					
125.06		Person who approved the preparation.					
125.07		Date of compounding.					
125.08		Assigned internal identification number or prescription number.					
125.09		Assigned BUD and reference if extended beyond USP guidelines.					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
125.10		Duplicate label.					
125.11		Sterilization method (if applicable).					
125.12		Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable					
126.00		Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is* ***recommended*** *to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*					
127.00		Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.					
127.01		RECOMMENDED: Labels on batch single-use containers are clearly marked as "Single Use Only".					
128.00		Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include names and quantity or concentration of active ingredients, BUD, total volume, route of administration, storage conditions and other information for safe use.					
128.01		RECOMMENDED: Labels on patient-specific single-use containers are clearly marked as "Single Use Only".					
129.00		Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**					
130.00	33, 25	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen					
131.00	33,25	If extended BUDs are assigned, are they assigned on the basis of stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
132.00		If extended BUDs are assigned, has the facility performed its own stability testing? *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below.* *List the products reviewed.*					
133.00		Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.					
134.00		**Filter sterilization** in an ISO 5 environment and documentation includes:					
134.01		If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.					
134.02		The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling does not indicate "research only" or "laboratory only", for example).					
134.03		Is the appropriate capacity filter being used for the volume being filtered?					
134.04		Filtering is completed rapidly without filter replacement.					
134.05		Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm.					
135.00		**Steam sterilization** documentation includes:					
135.01		The autoclave has been validated for the exposure time and mass of the items to be sterilized.					
135.02		Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices.					
135.03		Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.					
135.04		Heated filtered air is evenly distributed throughout the chamber with a blower.					
135.05		That the CSP will not be adversely affected by the steam and heat.					
135.06		The description of steam sterilization includes conditions and duration for specific CSPs.					
135.07		That the effectiveness of steam sterilization is verified each time using appropriate biological indicators.					
136.00		**Dry heat sterilization** documentation includes:					
136.01		Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture.					
136.02		Sufficient space is left between materials to allow for air circulation.					
136.03		The description of dry heat sterilization includes conditions and duration for specific CSPs.					
136.04		That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators.					
136.05		The oven is equipped with a system for controlling and recording temperature and exposure period.					
137.00		**Depyrogenation by dry heat** documentation includes:					
137.01		Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes.					
137.02		The description of the cycle and duration for specific load items.					
137.03		The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs).					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
137.04		Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins.					
138.00		Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.*					
		Finished Preparation Release Checks and Tests	**C**	**NC**	**UI**	**NA**	**Notes**
		Total Non-Compliant (Includes Unknowns)			**0**		
139.00		Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?					
140.00		Are there checks for container, closure integrity and any other apparent visual defects?					
141.00		Is compounding accuracy documented by verification of steps?					
142.00		Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*					
143.00		Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*					
144.00		**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe.*					
144.01		Sterility testing includes both bacterial and fungal testing.					
144.02		Sterility testing is performed for all CSPs that have extended BUDS.					
144.03		Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers.					
144.04		Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized.					
144.05		The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Less than 100, test 10% or four units, whichever is greater 2. 100 up to 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Less than 200 containers, test 5% or 2 containers, whichever is greater 2. 200 or more containers, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above.					
144.06		For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken.*					
144.07		If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken.*					
145.00		**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe.*					

Deficiency Number		C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
			C	NC	UI	NA	Notes
145.01		Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials).					
145.02		High-risk CSPs prepared in multiple dose vials for administration to multiple patients.					
145.03		High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized.					
145.04		For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.*					
146.00		RECOMMENDED: **Potency testing is performed.** *Describe for which products or circumstances potency testing is performed in.*					
Patient Counseling and Communication			C	NC	UI	NA	Notes
		Total Non-Compliant (Includes Unknowns)		**0**			
147.00		Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?					
148.00		Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?					
149.00		Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?					
150.00		Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.					

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form
Alternate Delivery

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	Alternate Delivery					
	IN ADDITION TO DIRECT HAND DELIVERY TO A PATIENT OR PATIENT'S AGENT OR DELIVERY TO A PATIENT'S RESIDENCE, A PHARMACY MAY DELIVER TO 1) ANOTHER PHARMACY, 2) A PRACTITIONER OF THE HEALING ARTS LICENSED TO PRACTICE PHARMACY OR TO SELL CONTROLLED SUBSTANCES, 3) AN AUTHORIZED PERSON OR ENTITY HOLDING A CONTROLLED SUBSTANCES REGISTRATION ISSUED FOR THIS PURPOSE **[18VAC110-20-275]**					
	DELIVERY TO ANOTHER PHARMACY [18VAC110-20-275]					
122	One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided:					
	1. The two pharmacies have the same owner, ***or***					
	2. Have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law					
	Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:					
	1. A description of how each pharmacy will comply with all applicable federal and state law					
	2. Procedure for maintaining required, retrievable dispensing records to include					
	a. Which pharmacy maintains the hard-copy prescription					
	b. Which pharmacy maintains the active prescription record for refilling purposes					
	c. How each pharmacy will access prescription information necessary to carry out its assigned responsibilities					
	d. Method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient					
	e. How and where this information can be accessed upon request by the board					
	3. Procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process					
	4. Procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription					
	5. Policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information					
	6. Policy and procedure for ensuring accuracy and accountability in the delivery process					
	7. Procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient					
	8. Procedure for informing the patient and obtaining consent for using such a dispensing and delivery process					
	Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	DELIVERY TO A PRACTITIONER OF THE HEALING ARTS LICENSED BY THE BOARD TO PRACTICE PHARMACY OR TO SELL CONTROLLED SUBSTANCES OR OTHER AUTHORIZED PERSON OR ENTITY HOLDING A CONTROLLED SUBSTANCES REGISTRATION. [18VAC110-20-275]					
	A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided					
	1. There is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party					
	2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:					
	a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient					
	b. Procedure for providing counseling					
	c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient					
	d. Procedure for assuring confidentiality of patient information;					
	e. Procedure for informing the patient and obtaining consent for using such a delivery process					
	3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use					
	4. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.					
	5. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Long Term Care

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	Long Term Care					
		Y	N			
	Does this pharmacy provide drugs to a nursing home that utilizes an automated drug dispensing device?			*If yes, complete the Automated Drug Dispensing System - Nursing Home report.*		
	Does the nursing home possess Controlled Substances Registration pursuant to 18VAC 110-20-555 (2)? *If yes, provide Controlled Substances Registration number.*					
	Floor Stock [18VAC110-20-560]	**C**	**NC**	**UI**	**NA**	**Notes**
140,141	Prescription drugs shall not be floor stocked by a LTC facility, except those in the stat drug box or emergency drug box.					
141	In addition to an emergency box or stat-drug box, a long-term care facility in which only those persons licensed to administer are administering drugs may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.					
	Emergency Drug Kit [18VAC110-20-540]	**C**	**NC**	**UI**	**NA**	**Notes**
140	The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.					
	The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL may be included.					
	The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.					
	a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.					
	b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication, resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.					
	c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.					
	The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.					
	Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.					
	Stat Drug Box [18VAC110-20-550]	**C**	**NC**	**UI**	**NA**	**Notes**

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
140	AAn additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:					
	1. The box is sealed in such a manner that will preclude the loss of drugs.					
	a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.					
	b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.					
	c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.					
	2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time and the name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.					
	3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.					
	4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.					
	5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.					
	a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.					
	b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form
Hospital

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	General					
7, 9, 9a, 10, 11, 12, 111, 144	Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening. **[18VAC110-20-440]**					
136	Authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed. **[18VAC110-20-450]**					
	Drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist.					
	A separate record shall be made and left at the location of the stock of drugs that includes the following information:					
	1. Date of withdrawal					
	2. Name of patient					
	3. Name of the drug, strength, dosage form and dose prescribed					
	4. Number of doses removed					
	5. Signature of the authorized nurse					
	Records are maintained within the pharmacy for a period of one year.					
9, 9a, 30	If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times. **[18VAC110-20-180]**					Need to determine which deficiency to cite
	Emergency Medical Services	**C**	**NC**	**UI**	**NA**	**Notes**
139	The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided: **[18VAC110-20-500]**					
	The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this drug kit. A pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.					
	The drug kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of such theft or loss.					
	a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.					
	b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.					
	c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.					
	When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.					
	Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:					
	a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.					
	b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.					
	Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.					
	The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.					
	Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.					
	Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.					
	In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.					
	A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.					
	1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.					
	2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.					
	4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.					
	5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.					
	Floor Stock	C	NC	UI	NA	Notes
137	A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution. **[18VAC110-20-460]**					
	A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock that contains the following information:					
	1. Date					
	2. Drug name and strength					
	3. Quantity					
	4. Hospital unit receiving drug					
	5. Manual or electronic signatures of the dispensing pharmacist and the receiving nurse					
	A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue.					
	The PIC or his designee shall:					
	1. Match returned records with delivery receipts to verify that all records are returned					
	2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned					
	3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded					
	4. Periodically verify that doses documented on administration records are reflected in the medical record					
	5. Initial the returned record					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.					
	Policies & Procedures	C	NC	UI	NA	Notes
134	Policies & procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital. [**18VAC110-20-440**]					
135	Policy and procedure for providing reviews of drug therapy. [**18VAC110-20-440**]					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Central or Remote Processing

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	Central or Remote Processing					
123	Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process: **[18VAC110-20-276]**					
	1. Receiving, interpreting, analyzing, or clarifying prescriptions.					
	2. Entering prescription and patient data into a data processing system					
	3. Transferring prescription information.					
	4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia					
	5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription					
	6. Interpreting clinical data for prior authorization for dispensing;					
	7. Performing therapeutic interventions					
	8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.					
	A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:					
	1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;					
	2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;					
	3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and					
	4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.					
	A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspections. The manual shall include at a minimum:					
	1. The responsibilities of each pharmacy;					
	2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;					
	3. Procedures for protecting the confidentiality and integrity of patient information;					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;					
	5. Procedures for maintaining required records;					
	6. Procedures for complying with all applicable laws and regulations to include counseling;					
	7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and					
	8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.					
	In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.					
	1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.					
	2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Remote Order Prescription Processing - Hospitals & Long Term Care

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	Remote Order Prescription Processing - Hospitals & Long Term Care					
123	Pharmacy does not dispense drugs, but does include any of the following activities related to the dispensing process: **[18VAC110-20-515]**					
	1. Receiving, interpreting, analyzing, or clarifying prescriptions.					
	2. Entering prescription and patient data into a data processing system					
	3. Transferring prescription information.					
	4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication					
	5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order.					
	6. Interpreting or acting on clinical data					
	7. Performing therapeutic interventions					
	8. Providing drug information to the medical or nursing staff of the hospital or long term care facility					
	9. Authorizing the administration of the drug to the patient by appropriate hospital or LTC facility staff					
	The primary pharmacy providing pharmacy services may outsource certain order processing functions to another pharmacy in Virginia or a registered non-resident pharmacy.					
	1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;					
	2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;					
	3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and					
	4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.					
	A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspections. The manual shall include at a minimum:					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	1. The responsibilities of each pharmacy					
	2. A list of the name, address, telephone numbers, and permit /registration numbers of all pharmacies involved in remote processing					
	3. Procedures for protecting the confidentiality and integrity of patient information.					
	4. Procedures for ensuring that pharmacists performing drug reviews have access to appropriate drug information resources					
	5. Procedures for maintaining required records.					
	6. Procedures for complying with all applicable laws and regulations.					
	7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services.					
	8. Procedure for annually reviewing the written policies/procedures for needed modifications and documenting such review.					
	A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.					
	1. The record shall be available by prescription order or by patient name.					
	2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.					
	3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Automated Drug Dispensing System - Hospital

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	Automated Drug Dispensing System - Hospital					
138	Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital **[§54.1-3434.02]**					
	The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for:					
	1. assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system					
	2. ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients					
	3. periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems					
	4. reviewing the operation and maintenance of automated drug dispensing systems.					
	Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber					
	Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for					
	1. preventing unauthorized access,					
	2. complying with federal and state regulations on prescribing and dispensing controlled substances,					
	3. maintaining patient confidentiality,					
	4. assuring compliance with the requirements of §54.1-3434.02					
	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.					
	Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;					
	Filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy.					
	Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy.					

A hospital may use automated devices for the dispensing and administration of drugs pursuant to §54.1-3301 of the Code of Virginia and §§54.3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420 or 18VAC110-20-460 as applicable. The following conditions shall apply: [18VAC110-20-490]

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	Policy & Procedures & Access Codes	**C**	**NC**	**UI**	**NA**	**Notes**
138	Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.					
	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.					
	Distribution of Drugs from the Pharmacy	**C**	**NC**	**UI**	**NA**	**Notes**
138	Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.					
	At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.					
	Distribution of Drugs from the Device	**C**	**NC**	**UI**	**NA**	**Notes**
138	Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue.					
	If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.					
	Discrepancy Reports	**C**	**NC**	**UI**	**NA**	**Notes**
138	A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.					
	Reviews & Audits	**C**	**NC**	**UI**	**NA**	**Notes**
138	The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes, when applicable, and proper recordkeeping.					
	The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedule II through V drugs from each automated dispensing device as follows:					
	a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.					
	The PIC or his designee shall conduct at least a monthly audit to review administration of Schedule II through V drugs from each automated dispensing device as follows:					
	a. The audit shall include a review of administration records from each device per month for possible diversion by fraudulent charting. The review shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.					
	b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.					
	c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:					
	(1) Peer-to-peer comparisons of use for that unit or department; and					
	(2) Monitoring of overrides and unresolved discrepancies.					
	d. The report shall be used to identify suspicious activity which includes, but is not limited to, usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.					
	The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.					
	Inspections	**C**	**NC**	**UI**	**NA**	**Notes**
138	Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:					
	a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;					
	b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;					
	c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and					
	d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	Records	C	NC	UI	NA	Notes
138	All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.					
	Distribution and delivery records and required initials may be generated or maintained electronically provided:					
	a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.					
	b. The records are maintained in a read-only format that cannot be altered after the information is recorded.					
	c. The system used is capable of producing a hard-copy printout of the records upon request.					
	Schedule II through V distribution and delivery records may also be stored offsite or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.					
	Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Automated Drug Dispensing System - Nursing Home

C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable

Deficiency Number		C	NC	UI	NA	Notes
	Automated Drug Dispensing System - Nursing Home					
	Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions: [18VAC110-20-555]					
138	Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.					
	A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system.					
	Distribution of Drugs from the Pharmacy & Device	**C**	**NC**	**UI**	**NA**	**Notes**
138	Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:					
31	a. A drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.					
	b. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.					
	c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.					
	d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.					
	Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.					
	Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.					
	At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.					
	At the time of loading, the delivery record for all Schedule II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.					
	Reviews & Audits	**C**	**NC**	**UI**	**NA**	**Notes**
138	The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:					
	a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.					
	b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.					
	c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.					
	d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.					
	e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.					
	f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.					
	Inspections	**C**	**NC**	**UI**	**NA**	**Notes**
138	Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.					
	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.					
	Policy & Procedures & Access Codes	**C**	**NC**	**UI**	**NA**	**Notes**
138	The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	Records	C	NC	UI	NA	Notes
138	All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:					
	a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.					
	b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:					
	(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.					
	(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.					
	(3) The system used is capable of producing a hard-copy printout of the records upon request.					
	c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 13 a and b of this section if authorized by DEA or in federal law or regulation.					
	d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Unit Dose Dispensing Systems

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	Unit Dose Dispensing Systems					
	A unit dose drug dispensing system may be utilized for the dispensing of drugs to patients in a hospital or long-term care facility. The following requirements shall apply regardless of whether licensed or unlicensed persons administer medications					
128	Any equipment outside the pharmacy used to house drugs to be administered in a unit dose system shall be fitted with a locking mechanism and locked at all times when unattended. **[18VAC110-20-420]**					
	A signed order by the prescribing practitioner shall accompany the requests for a Schedule II drug, except that a verbal order for a hospital patient for a Schedule II controlled substance may be transmitted to a licensed nurse or pharmacist at the hospital who shall promptly reduce the order to writing in the patient's chart. Such an order shall be signed by the prescriber within 72 hours.					
	Properly trained personnel may transcribe the prescriber's drug orders to a patient profile card, fill the medication carts, and perform other such duties related to a unit dose distribution system provided these are done under the personal supervision of a pharmacist.					
	All dosages and drugs shall be labeled with the drug name, strength, lot number and expiration date when indicated.					
	The patient's individual drug drawer or tray shall be labeled in a manner to identify the patient and his location without violating health privacy laws.					
	All unit dose drugs intended for internal use shall be maintained in the patient's individual drawer or tray unless special storage conditions are necessary.					
	A back-up dose of a drug of not more than one dose unit may be maintained in the patient's drawer, tray, or special storage area provided that the dose is maintained in the patient's drawer, tray, or special storage area with the other drugs for that patient.					
	A record shall be made and maintained within the pharmacy for a period of one year showing:					
	1. Date of filling of the drug cart					
	2. Location of the drug cart					
	3. Initials of the person who filled the drug cart					
19	4. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18VAC110-20-270 C. **[18VAC110-20-420] [18VAC110-20-270]**					
128	A patient profile record or medication card will be accepted as the dispensing record of the pharmacy for unit dose dispensing systems only, subject to the following conditions:					
	1. Record of dispensing must be entered on the patient profile record or medication card at the time the drug drawer or tray is filled.					
	2. In the case of Schedule II through V drugs, after the patient profile record or medication card has been completed, the card must be maintained for two years.					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable					
		C	NC	UI	NA	Notes
	3. In the case of the computer-based distribution system, a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs. Records of disposition/administration for floor stock drugs as provided in 18VAC110-20-460 B will be accepted for drugs distributed as floor stock.					
	Hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall not dispense more than a seven-day supply of a drug in a solid, oral dosage form at any one given time.					
	In addition to the requirements listed in subsection A of 18VAC110-20-420, the following requirements apply to those long-term care facilities in which unlicensed persons administer drugs:					
	1. The pharmacy providing medications to such facility shall dispense no more than a 72-hour supply of drugs in a solid, oral dosage form at any one given time.					
	2. The pharmacy shall provide to persons administering medications training specific to the particular unit dose system being used					
	3. The pharmacy shall provide a medication administration record to the facility listing each drug to be administered with full dosage directions to include no abbreviations					
	4. The drugs in a unit dose system shall be placed in slots within a drawer labeled or coded to indicate time of administration					

Virginia Board of Pharmacy
Pharmacy Routine Inspection Form

Robotic Pharmacy System

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
	Robotic Pharmacy Systems					
129	Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in bar-coded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply: **[18VAC110-20-425]**					
	1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.					
	2. The packaging, repackaging, stocking and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.					
	3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system.					
129	a. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A. **[18VAC110-20-425] [18VAC110-20-355]**					
20	b. The verifying pharmacist shall initial the record. **[18VAC110-20-425]**					
129	c. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standard.					
	A written policy and procedure must be maintained and shall include at a minimum, procedures for ensuring:					
	a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter;					
	b. Accurate stocking and restocking of the robotic pharmacy system;					
	c. Removing expired drugs;					
	d. Proper handling of drugs that may be dropped by the robotic pharmacy system;					
	e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;					
	f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;					
	g. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and					
	h. Maintaining quality assurance reports.					
20	Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found. **[18VAC110-20-425]**					

Deficiency Number	C - Compliant NC - Not Compliant UI - Unable to Inspect NA - Not Applicable	C	NC	UI	NA	Notes
20	All manual picks shall be checked by pharmacists. **[18VAC110-20-425]**					
129	If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all doses or compliance packages and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking					
	8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:					
	a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.					
	b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.					
	c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.					
	d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.					
	9. All unanticipated downtime shall be immediately reported to the board.					
	10. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent					

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	2000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		1000
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program	54.1-3321 and 18VAC110-20-111	per individual	First citation = no penalty Repeat = $ penalty 250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	First citation = no penalty Repeat = $ penalty 100
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio ~~First Citation – Deficiency 143 Second Offense – Deficiency 6~~	First citation = no penalty Repeat = $ penalty 100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	First citation = no penalty; drugs may be embargoed Repeat = $ penalty 100 Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	~~Deficiency 9a if a drug loss occurred during the period of non-compliance. Deficiency 144 if no drug loss.~~	First citation and no drug loss = no penalty Drug loss or repeat = $ penalty 250

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190	~~Deficiency 11 if there is evidence that non-compliance contributed to a drug loss. Deficiency 145 if no drug loss.~~	First citation and no drug loss = no penalty Drug loss or repeat = $ penalty 500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		First citation and no drug loss = no penalty Drug loss or repeat = $ penalty 500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	~~Deficiency 12a if there is evidence that non-compliance contributed to a drug loss. Deficiency 146 is no drug loss.~~ Do not cite if stored in a combination method as allowed in Guidance Document 110-40.	First citation and no drug loss = no penalty Drug loss or repeat = $ penalty 250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	Over 30 days late and first citation = no penalty Over 30 days late and repeat = $ penalty 500
14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	Over 5 days late and first citation = no penalty Repeat = $ penalty 500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	Expired drugs not included and first citation = no penalty Repeat = $ penalty 250
16. Theft/unusual loss of drugs not reported to the Board as required ~~or report not maintained~~	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355		1000 per compounded sterile product, up to maximum of 5000 ~~5000~~
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
21b. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better.	54.1-3410.2		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
25b. High-risk compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test or gloved fingertip test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test and gloved fingertip testing was initiated.	500
26a. Documentation that a person who failed a media-fill test or gloved fingertip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		500
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500

Deficiency	Law/Reg Cite	Conditions	$ Monetary Penalty
30. Security of after-hours stock not in compliance	18VAC110-20-450		First citation and no drug loss = no penalty Drug loss or repeat = $ penalty 500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	First citation and no known patient harm = no penalty Repeat = $ penalty 250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Other Deficiencies

If five (5) or more deficiencies in this category are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional deficiency cited in this category, over the initial five.

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold

Deficiency	Law/Regulation Cite	Conditions
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
112. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
114. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
117. Deficiency 117 combined with Deficiency 116 – 6/2011		
118. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320	
120. Offer to counsel not made as required	54.1-3319	
121. Prospective drug review not performed as required	54.1-3319	

Deficiency	Law/Regulation Cite	Conditions
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a Compounded products not properly labeled	54.1-3410.2	
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	

Deficiency	Law/Regulation Cite	Conditions
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	

Deficiency	Law/Regulation Cite	Conditions
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
143. ~~Exceeds pharmacist to pharmacy technician ratio~~	~~54.1-3320~~	~~Per each technician over the ratio First offence - Deficiency 143 Second Offense - Deficiency 6~~
144. ~~Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.~~	~~18VAC110-20-180~~	~~Deficiency 144 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action. Deficiency 9a if drug loss.~~
145. ~~Insufficient enclosures or locking devices~~	~~18VAC110-20-190~~	~~Deficiency 145 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Deficiency 11 if drug loss.~~
146. ~~Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.~~	~~18VAC110-20-200~~	~~Deficiency 146 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Deficiency 12a if drug loss. Do not cite if stored in a combination method as allowed in Guidance Document 110-40.~~
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240	

NOTE: A "repeat" deficiency is a deficiency that was cited during the routine or focused inspection performed immediately prior to the current routine inspection and after July 1, 2018.

Examples:
Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty.
Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/20 – No deficiency.
Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.