COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Amended Agenda of Regulation Committee
Meeting *November 12, 2024*
9AM

TOPIC	PAGES

Call to Order: Ling Yuan, PharmD, Committee Chairman

- Welcome & Introductions

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.

Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh

- Chart of current regulatory actions **2-6**
- Adopt recommendation for guidance document for accessible prescription labels **7-11**
- Consideration of potential changes to crisis stabilization unit emergency regulations prior to Board adoption of proposed stage **12-39**
- Consideration of public comments to emergency medical services emergency regulations prior to Board adoption of proposed stage **40-76**
- Discuss request to recognize pharmacy inspection report performed by Gates Healthcare Associates **77-182**

Adjourn

Board of Pharmacy
Current Regulatory Actions
As of October 26, 2024

In the Governor's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	3/29/2017	2348 days; 7.9 years since submission for executive branch review	Addresses a patient safety concern.

In the Secretary's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	937 days 2.6 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	937 days 2.6 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians
18VAC110-21	Fast-Track	Repeal of outdated sections	4/18/2023	437 days	Repeals outdated regulations regarding pharmacy

					technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	4/18/2023	428 days	Implements changes identified during the periodic review process
18VAC110-20	Fast-Track	Amendment to clarify application of 18VAC110-20-735	6/21/2023	424 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable formulations of naloxone
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	9/29/2023	201 days	Changes reference from nurse practitioner to advanced practice registered nurse pursuant to legislation
18VAC110-20	Final	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	7/8/2024	89 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals
18VAC110-20	Emergency/ NOIRA	Requirements for use of central fill pharmacy and remote database	7/8/2024	46 days	Implements requirements of Chapter 407 of the 2024 Acts of Assembly.
18VAC110-20	Final	Exemption of ADDs stocked solely with emergency or stat-use medications from certain	10/1/2024	17 days	Response to a petition for rulemaking to allow certain ADDs exemption from

		requirements of 18VAC110-20-555			requirements under regulations
18VAC110-20 18VAC110-21 18VAC110-30 18VAC110-50	Proposed	Increase in fees	7/9/2024	11 days	Necessary for continued operation of the Board.

In the Department of Planning and Budget

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	NOIRA	Exclusion of private dwellings or residences from operating locations of CSRs	10/1/2024	16 days	Excludes private residences from operating locations of CSRs, similar to pharmacy permit exclusions.

In the Office of the Attorney General

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-21	Proposed	2023 pharmacists initiating treatment	4/4/2024	205 days	Implements legislation from 2023 Session regarding pharmacists initiating treatment
18VAC110-20	Fast-track	Replacement of analytic lab regulation for pharmaceutical processors	5/15/2024	164 days	Replaces the former 18VAC110-60-300(A) into Board of Pharmacy regulations as required by Virginia Code § 4.1-1602
18VAC110-15	Fast-track	Amendment to allow agency subordinates to hear credentials cases	10/1/2024	25 days	Conforms regulatory language to changes in the Virginia Code.

18VAC110-20	Exempt/ Final	September 2024 scheduling of chemicals in Schedule I	10/1/2024	25 days	Implements scheduling as recommended by DFS.
18VAC110-20	Exempt/ Final	Accessible prescription labels	10/1/2024	25 days	Implements legislation from the 2024 General Assembly Session.
18VAC110-20	Exempt/ Final	September 2024 action to conform state schedules to federal schedule changes	10/1/2024	25 days	Coordinates state regulatory schedules with federal regulatory changes.

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date/ next steps
18VAC110-20	Emergency/ NOIRA	Crisis stabilization services and use of automated dispensing systems and remote dispensing systems	8/26/2024	Emergency regulations effective 8/12/2024 – 2/11/2026; public comment period 8/26/2024 – 9/25/2024. Proposed stage will be before the December Board meeting.
18VAC110-20	Emergency/ NOIRA	Allowances for emergency drugs by EMS agencies	9/9/2024	Emergency regulations effective 8/20/2024 – 2/19/2026; public comment period 9/9/2024 – 10/9/2024. Proposed stage will be before the December Board meeting.
18VAC110-21	Final	2022 pharmacists initiating treatment	10/21/2024	Effective 11/20/2024 (replaces

				emergency regulations)
18VAC110-20	Proposed	Pharmacy working conditions	11/18/2024	Public comment period 11/18/2024 – 1/17/2024. Board will vote on final regulations at March 2025 meeting.

Agenda Item: Adopt recommendation for guidance document for accessible prescription labels

Included in your agenda package:

- HB 516
- Draft of guidance document addressing accessible labels as approved by the workgroup.
- Public comment received from National Federation of the Blind, Virginia Chapter

Staff notes: Enactment clause 3 of HB516 requires the Board to adopt a guidance document identifying appropriate technologies, packaging, labeling, and counseling for dispensing medications to blind or low-vision patients.

Actions needed:

- Discuss comment received and consider if amendments to draft Guidance Document 110-14 are needed;
- Motion to recommend to full board to adopt draft Guidance Document 110-14 as presented or amended.

CHAPTER 725

An Act to amend the Code of Virginia by adding a section numbered 54.1-3410.3, relating to prescription drugs; labels; blind and disabled users.

[H 516]

Approved April 8, 2024

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-3410.3 as follows:

§ 54.1-3410.3. Accessible prescription labels.

A. For the purposes of this section, "prescription reader" means a device that is designed to audibly identify the prescription drug contained on the label of a prescription drug.

B. A pharmacy shall notify each person who identifies themselves or a patient as blind, visually impaired, or otherwise print disabled to whom a prescription drug is dispensed that an accessible prescription label or alternate accommodation is available to the person upon request at no additional cost.

C. If a person informs the pharmacy that he is blind, visually impaired, or otherwise print disabled, and the person requests an accessible prescription label or accommodation, as determined between the pharmacist and the patient, the pharmacy shall:

1. Upon request of a person for an accessible prescription label, provide the person, either at the pharmacy or through mail order, an accessible prescription label fixable to the bottle or container that:

a. Is available to the person in a timely manner comparable to other patient wait times and will remain available for at least the duration of the prescription;

b. Utilizes audible or large print labels or enclosures that are appropriate to the disability and preference of the person making the request;

c. Seeks to attain best practice standards established by the U.S. Access Board; and

d. Is compatible with a prescription reader; or

2. As determined between the pharmacist and patient, provide appropriate counseling and accommodation to the patient and dispense the medication in suitable packaging with sufficient labeling and other information.

2. That the Board of Pharmacy shall adopt initial regulations to implement the provisions of this act no later than December 31, 2024. The Board of Pharmacy's initial adoption of regulations necessary to implement the provisions of this act shall be exempt from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board of Pharmacy shall consult with organizations of blind or low-vision consumers and other individuals who are blind, community pharmacists, and other pharmacy stakeholders to assist in the development of necessary regulations and shall provide an opportunity for public comment on the regulations prior to adoption.

3. That the Board of Pharmacy shall issue a guidance document identifying appropriate technologies, packaging, labeling, and counseling for dispensing medications to blind or low-vision patients. In developing guidance documents, the Board of Pharmacy shall consider best practices and formatting suggestions as published and revised by the U.S. Access Board.

Virginia Board of Pharmacy

Dispensing Medications to Blind or Low-Vision Patients

In addition to complying with Virginia Code § 54.1-3410.3 and 18VAC110-20-351, pharmacists should refer to the United States Access Board at **https://www.access-board.gov/rx.html** for information regarding various delivery methods for providing accessible prescription drug container labels, best practices to use for all formats, and format-specific best practices such as for audible, braille, and large print labels. Pharmacists should ensure patients are counseled in compliance with Virginia Code § 54.1-3319 and in a manner that identifies and aids their understanding of how to properly use the accessible label or other accommodation provided. To assist the pharmacist and patient in determining the appropriate accommodation, a collaborative communication should occur. Additionally, the Board recommends that the pharmacy record the accommodation provided to each patient to ensure that all pharmacy personnel are aware of how to consistently provide patient care to each accommodated patient.

References

Va. Code § 54.1-3319
Va. Code § 54.1-3410.3
18VAC110-20-351

United States Access Board: **https://www.access-board.gov/rx.html**

NATIONAL FEDERATION OF THE BLIND
VIRGINIA

Live the life you want.

Caroline Juran, RPh, Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
caroline.juran@dhp.virginia.gov
September 20, 2024

Dear Dr Juran and Members of the Board:

We offer these comments as President and Legislative Chair of the largest organization of blind and low vision individuals, the National Federation of the Blind of Virginia. Our members throughout the state enable us to understand the barriers blind and low vision individuals face in using prescription medication. It is important that the regulations and guidance documents the Board of Pharmacy develops go beyond what is simply stated in the law. We request that the Board provide some specificity and guidance to pharmacists as to how the new law should be implemented. With their busy schedules and limited time, pharmacists will undoubtedly be unfamiliar with the various options for providing accessible prescription labeling. Pharmacists may not take the time to wade through the U.S. Access Board's Best Practices report and recommendations. I am also concerned that the guidance offered by the Access Board is over 10 years old and badly out of date.

We have held several meetings with pharmacists and their representatives, and all agreed that some guidance from the Board's regulations and guidance documents would be helpful. The Board of Pharmacy can augment implementation of the law by providing some specificity in the following areas on its website and through communication with pharmacists:

- What information must and should be provided in an Audio label?
    - The Access Board Best Practices Report states that "all required information contained on the print drug container label should be provided on the accessible label in the same sequence as the print label." Please state this directly in the Board's regulations or guidance.
- What information must and should be provided on a large print label?
    - All information as specified above should be provided on the large print label and should be stated directly in the regulations or guidance.
- What are commercially available options for providing audio labels since both pharmacies and patients will be unfamiliar with the options?
    - We suggest that the guidance document provides some options that pharmacists can use to produce accessible labels. We have provided information and links to labeling devices in the attachment.
- What are available options and requirements for providing large print labels including details on font size since both pharmacies and patients will be unfamiliar with the options?

    - The Access Board states that the label should be printed in 18-point bold font on non-glossy paper with black text on a white or pale-yellow background. Please state this in the text of the Board's regulations or guidance.
- Your draft regulations state that the accessible label should be affixed to the bottle and should be provided in the same timeframe as prescriptions are provided to other patients. The regulations or guidance should answer other questions, such as:
    - What are reasonable expectations between pharmacists and patients reuse/return of the equipment?
    - Can the pharmacy require that the patient pay for any recording devices or time to record the information?
    - When can the pharmacist require use of mail order or refuse to serve a patient?

With regard to counseling the pharmacist may provide, the regulations or guidance documents should state that the counseling should be provided in a private place where Protected Health Information (PHI) cannot be overheard by others, as required in HIPAA Regulations.
Your thoughtfulness in going beyond what the law states to address these issues will greatly assist pharmacies in implementing the legislation and enable blind and low vision patients to safely take their medication.
Finally, please let us know how the Virginia Board of Pharmacy will be communicating the law, regulatory requirements and guidance documents to pharmacies and the public. We would be happy to work with you to share any materials and resources you develop with our membership.

Cordially,

Tracy Soforenko
President
National Federation of the Blind of Virginia
202-285-4595
president@nfbv.org
CC: Bonnie O'Day, Legislative Chair

Agenda Item: Consideration of potential changes to CSU emergency regulations prior to Board adoption of proposed stage

Included in your agenda package:

- Draft proposed stage regulations with inclusion of changes to 18VAC110-20-700 for discussion by the Committee; and

- Town Hall summary page showing no comments on the emergency/NOIRA stage.

Action needed:

- Discussion of 18VAC110-20-700(C) and consideration of whether the Board should add amendments to that section to the proposed regulations;

- Consideration of whether language in 18VAC110-20-490(B)(3) regarding maintenance of a key to access an ADD or RDS should be added to 18VAC110-20-555 for consistency; and

- Recommendation to the full Board regarding proposed regulations.

Project 7883 - Proposed

Board of Pharmacy

Crisis Stabilization Services and Use of Automated Drug Dispensing Systems and Remote Dispensing Systems

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. 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. 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 that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. 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, date of delivery, and signature of the person receiving the prescription. Such log shall be maintained for a period of one year. Notwithstanding the provisions of this subsection, prescriptions prepared for delivery to the patient may also be secured in an area outside of the prescription department in a remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490.

B. 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 or maintained in a manner that combines the two methods for storage. The cabinet, drawer, or safe

may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug that 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. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner~~,~~ or 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.

2. 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:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. 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 and subsection A of 18VAC110-20-490, if applicable.

C. 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 authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided 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~~ ensuring 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. The procedure for ~~assuring~~ ensuring confidentiality of patient information; and

e. The 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, remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490, or other device that cannot be easily moved and that shall be locked at all times when not in use. 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.

D. 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.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably ~~assured~~ ensured.

F. The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm. However, the pharmacy and alternate delivery site shall comply with following requirements:

1. To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to

where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this requirement may be made for patients with inherited bleeding disorders who may require therapy to prevent or treat bleeding episodes.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital, state facility as defined in § 37.2-100 of the Code of Virginia that is established pursuant to Title 37.2 of the Code of Virginia, facility as defined in § 37.2-100 of the Code of Virginia that is licensed by the Department of Behavioral Health and Developmental Services and provides site-based crisis stabilization services, or other facility authorized by the board may use automated ~~devices~~ drug dispensing systems and remote dispensing systems for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 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. Unless prohibited under federal law, a remote dispensing system that solely stores drugs labeled and verified by the provider pharmacist for patients to obtain medication may be placed within close proximity of a permitted pharmacy or at a location issued a controlled substance registration pursuant to § 54.1-3420.2 of the Code of Virginia in a secure area under constant surveillance to ensure security of drugs, confidentiality of protected health information, and appropriate recordkeeping.

B. Policy and procedure manual; access codes.

1. Proper use of the automated drug dispensing ~~devices~~ system and remote dispensing system and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated drug dispensing ~~device~~ system and remote dispensing system shall have a specific access code ~~that records~~ or other means to record 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.

3. If a key may be used to access the automated drug dispensing system or remote dispensing system and the provider pharmacy is not located within the facility, a key may be maintained in the possession of the director of nursing or an individual designated by the director of nursing who is licensed to administer medications.

C. Distribution of drugs from the pharmacy.

1. Except when the automated drug dispensing system or remote dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside

of the hospital or facility it services shall first obtain a controlled substance registration issued in the name of the pharmacy at the address of the hospital or facility and a registration from the Drug Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through VI.

2. Drugs authorized pursuant to § 54.1-3434.02 of the Code of Virginia may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Pharmacies using a remote dispensing device that only stores patient-specific dispensed drugs for patients to obtain medication may place pharmacist-verified dispensed drug into the device.

3. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing ~~device~~ system or remote dispensing system. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital or facility unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated drug dispensing ~~device~~ system or remote dispensing system; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

~~2.~~ 4. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated drug dispensing ~~device~~ system or remote dispensing system 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 ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution and dispensing of drugs from the device.

1. Automated drug dispensing ~~devices in hospitals~~ and remote dispensing systems shall be capable of producing a hard-copy record of distribution that 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 or maintained electronically.

2. If an automated drug dispensing ~~device~~ system or remote dispensing system 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.

3. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope.

4. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 B on the label, medication envelope, or the medication run report.

5. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug placed in the bulk bin that is placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug.

E. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or ~~his~~ the PIC's 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.

F. Reviews and audits.

1. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with § 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing ~~devices~~ system and remote dispensing system, to include procedures for timely termination of access codes when applicable, accuracy of distribution and dispensing from the device, and proper recordkeeping.

2. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution and dispensing of Schedules II through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through 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.

3. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system as follows:

a. The audit shall include a review of administration and dispensing records, if applicable, for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered and dispensed for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution, dispensing, 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~~ the PIC's designee shall be exempt from requirements of this audit if reconciliation software that 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 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.

4. The PIC or ~~his~~ the PIC's designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections. Automated drug dispensing ~~devices~~ systems and remote dispensing systems 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~~ the PIC's 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:

1. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

2. 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;

3. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to ~~their~~ the expiration date; and

4. 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.

H. Records.

1. 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 or facility 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.

2. 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.

3. Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution, dispensing, and administration records that are printed and reviewed in conducting required audits may be maintained at an ~~off-site~~ offsite 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 drug dispensing ~~device~~ system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-555. Use of automated dispensing devices and remote dispensing devices in nursing homes.

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 and remote dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system or remote dispensing system in a nursing home shall be under the control of the pharmacy providing services to the

nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A pharmacy that is not located within the nursing home ~~without an in-house pharmacy~~ it services shall obtain a controlled substances registration issued in the name of the pharmacy at the address of the nursing home and a registration from the Drug Enforcement Administration, if required, prior to ~~using an automated dispensing system~~ stocking drugs in Schedules II through VI, unless the automated drug dispensing system or remote dispensing system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. ~~For facilities not required to obtain a controlled substance registration, access~~ Access to the automated drug dispensing ~~device~~ system or remote dispensing system shall be restricted to a licensed nurse, pharmacist, or prescriber~~,~~ or a registered pharmacy technician ~~for the purpose of stocking or reloading~~ pursuant to designation by the PIC or pharmacist on duty.

4. Removal of drugs from any automated drug dispensing system or remote 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:

a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated drug dispensing ~~device~~ system or remote dispensing system 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 online 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 drug dispensing ~~devices~~ systems and remote dispensing systems shall be capable of producing a hard-copy record of distribution and dispensing, if applicable, that shall show patient name, drug name and strength, dose or quantity withdrawn, dose to be administered, if applicable, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated drug dispensing ~~devices~~ systems 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.

6. Drugs authorized pursuant to § 54.1-3434.02 of the Code of Virginia may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

7. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing ~~device~~ system and remote dispensing system, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

~~7.~~ 8. 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.

~~8.~~ 9. At the time of loading, the delivery record for all Schedules 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.

~~9.~~ 10. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated drug dispensing ~~device~~ system or remote dispensing system 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 the proper reporting of a loss.

~~10.~~ 11. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope and is not self-administered.

12. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 on the label, medication envelope, or the medication run report.

13. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug placed in the bulk bin that is placed in the device and the device incorporates sufficient technology assistance to ensure accuracy of the dispensed drug.

14. The PIC of the provider pharmacy or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution ~~and~~, administration, and dispensing, if applicable, of Schedules II through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system as follows:

a. The audit shall reconcile records of all quantities of Schedules 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~~ the PIC's 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 and dispensing records, if applicable, from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered and dispensed 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 or dispensed.

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, dispensing, 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.

~~11.~~ 15. Automated drug dispensing ~~devices~~ systems and remote dispensing systems 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.

~~12.~~ 16. Personnel allowed access to an automated drug dispensing ~~device~~ system or remote dispensing system shall have a specific access code ~~which~~ that records the identity of the person accessing the device.

~~13.~~ 17. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and ~~assure~~ ensure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system and remote 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~~ ensuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

~~14.~~ 18. 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. Schedules II through V distribution and delivery records may only be stored ~~offsite~~ off site or electronically as described in subdivisions ~~14~~ 18 a and ~~14~~ 18 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution ~~and,~~ administration, and dispensing records that are printed and reviewed in conducting required audits may be maintained ~~offsite~~ 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 drug dispensing ~~device~~ system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs that may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation; or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train

individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated drug dispensing ~~devices~~ systems or remote dispensing systems, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. ~~Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.~~

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply for and obtain a controlled substances registration in order to maintain a stock of ~~Schedule~~ Schedules II through VI controlled substances for immediate treatment of patients in crisis. ~~Schedule II through V controlled substances shall not be stocked.~~ The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to ~~Schedule VI controlled substances and only~~ those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:

a. Name of patient;

b. Date and time of administration;

c. Drug name, strength, and quantity administered;

d. Name or initials of person administering; and

e. Prescriber name.

3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an ~~off-site~~ offsite database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past

two years. It shall also have the capacity of producing a printout of any data ~~which~~ that the registrant is responsible for maintaining.

4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

Agency Department of Health Professions

Board Board of Pharmacy

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action: Crisis Stabilization Services and Use of Automated Drug Dispensing Systems and ...

Emergency/NOIRA Stage

Action 6460 / Stage 10323

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	6/27/2024 1:03 pm	Sync Text with RIS
Agency Background Document	5/15/2024	Upload / Replace
Attorney General Certification	6/27/2024	
Governor's Review Memo	8/6/2024	
Registrar Transmittal	8/11/2024	

Status	
Public Hearing	Will be held at the **proposed** stage
Governor's Review Needed By	12/10/2024
Emergency Authority	2.2-4011(B)
Attorney General Review	Submitted to OAG: 5/15/2024 Review Completed: 6/27/2024 Result: Certified
DPB Review	Submitted on 6/27/2024 Policy Analyst: Cari Corr Review Completed: 7/18/2024
Secretary Review	Secretary of Health and Human Resources Review Completed: 7/24/2024
Governor's Review	ORM Review: ORM Approved 8/6/2024 Governor Review Completed: 8/6/2024 Result: Approved
Virginia Registrar	Submitted on 8/11/2024 The Virginia Register of Regulations Publication Date: 8/26/2024 Volume: 41 Issue: 1
Comment Period	Ended 9/25/2024 0 comments

Effective Date	8/12/2024
Expiration Date	2/11/2026

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, VA 23233-1463
Email Address:	**caroline.juran@dhp.virginia.gov**
Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

This person is the primary contact for this chapter.

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Part XVI. Controlled Substances Registration for Other Persons or Entities

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs that may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation; or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the

registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

Statutory Authority

§ 54.1-2400 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 15, Issue 26, eff. October 13, 1999; amended, Virginia Register Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009; Volume 28, Issue 23, eff. August 15, 2012; Volume 32, Issue 14, eff. April 21, 2016; Volume 35, Issue 9, eff. January 23, 2019.

Agenda Item: Consideration of public comments to EMS emergency regulations prior to Board adoption of proposed stage

Included in your agenda package:

- Draft proposed stage regulations identical to emergency regulations regarding EMS providers;

- Public comments received following the publication of the emergency/NOIRA stage of the regulatory process.

Action needed:

- Discussion of public comments and consideration of whether the comments warrant changes in the draft proposed regulations; and

- Recommendation to the full Board regarding proposed regulations.

Project 7873 - Proposed

Board of Pharmacy

Allowances for emergency drugs by EMS agencies

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Acquisition" of an existing entity permitted, registered, or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any

recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be ~~assured~~ ensured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or the prescriber's designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Designated location" means a station, EMS agency substation or satellite location, or other location approved by the DEA, if applicable, and designated by an EMS agency or regional EMS council.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug:

1. Variation from the prescriber's prescription drug order, including:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300.

"Emergency medical services provider" or "EMS provider" means the same as defined in 12VAC5-31-10.

"Emergency medical services vehicle" or "EMS vehicle" has the same meaning prescribed in § 32.1-111.1 of the Code of Virginia.

"EMS agency" ~~means emergency medical services~~ has the same meaning as prescribed in § 32.1-111.1 of the Code of Virginia.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Faxed prescription" means a written prescription or order that is transmitted by an electronic device that sends over telephone lines the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Hospital-owned" means, with respect to an EMS agency, owned by a hospital.

"Initials" means the first letters of a person's name or other unique personal identifier.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Other EMS vehicle" means a vehicle used by the EMS agency or regional EMS council for the purpose of providing or facilitating emergency medical care or transporting controlled substances to and from the registered and designated locations. Such vehicles must be either owned by or registered to an EMS agency, regional EMS council, or jurisdiction and operated by an EMS agency or regional EMS council.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing, and storage of all Schedules II through VI drugs and devices and any Schedule I investigational drug.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts

that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Regional EMS council" means an organization designated by the State Board of Health pursuant to § 32.1-111.4:2 of the Code of Virginia.

"Registered EMS agency headquarters" means the principal office and primary business location of an EMS agency that maintains a controlled substances registration issued by the board or a hospital-owned EMS agency that is covered by the registration of a hospital.

"Registered location" means, for the purposes of emergency medical services, a location that appears on a DEA certificate of registration or controlled substances registration issued to an EMS agency or regional EMS council, which shall be the location at which the agency or council receives Schedules II through VI controlled substances from those entities authorized to distribute controlled substances.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration

of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children younger than five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Station" means an enclosed structure that houses one or more EMS vehicles or other EMS vehicles in the state in which the EMS agency is registered that is actively and primarily being used for emergency response by the EMS agency.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is controlled between -25° and -10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20°C (-4°F), the temperature of the storage location should be controlled to plus or minus 10 degrees.

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for ~~his~~ that person's own use or for the use of a member of ~~his~~ that person's household or for an animal owned by ~~him~~ that person or a member of ~~his~~ that person's household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-500. ~~Licensed emergency medical services (EMS) agencies.~~ (Repealed.)

~~A. The pharmacy may prepare a kit for a licensed EMS agency provided:~~

~~1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. Except as authorized in 18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.~~

~~2. The 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 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.

3. 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.

4. 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.

5. 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.~~

~~6. 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.~~

~~7. 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.~~

~~8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.~~

~~9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.~~

~~10. 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.~~

~~B. 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.~~

~~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.~~

18VAC110-20-505. Use of radio-frequency identification.

A. A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for ~~licensed~~ emergency medical services pursuant to ~~18VAC110-20-500~~ 18VAC110-20-591 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of ~~a~~ an RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A pharmacy technician may place the RFID tag on the drugs, and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist, verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355.

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

B. A registered EMS agency headquarters, regional EMS council, or designated location of the EMS agency or regional EMS council may use RFID to verify the accuracy of drugs placed into a kit for emergency medical services under the following conditions:

1. An EMS supervising practitioner or responsible party shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of an RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A person authorized to administer drugs or a pharmacy technician may place the RFID tag on the drugs, and the EMS responsible party or designee authorized to administer drugs shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A person authorized to administer drugs or a pharmacy technician may remove RFID-tagged drugs from the EMS inventory whose RFID tags have been previously verified for accuracy by the EMS responsible party or designee authorized to administer drugs and place the drugs into the kit's container. A person authorized to administer drugs may then place the container into the device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. An EMS responsible party or designee authorized to administer drugs shall perform a weekly random check for verification of the accuracy of 5.0% of all kits prepared that week utilizing RFID technology. A manual or electronic record from which information can be readily retrieved shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of the EMS responsible party or designee authorized to administer drugs verifying the accuracy of the process.

5. All records required by this subsection shall be maintained for a period of one year from the date of verification by the EMS responsible party or designee authorized to administer drugs.

18VAC110-20-591. Allowances for emergency medical services agencies to obtain drugs.

A. This section contains specific provisions by which an EMS agency may obtain drugs for administration.

B. Unless prohibited by federal law, a pharmacy may prepare a kit for an EMS agency, provided:

1. The PIC of the pharmacy shall be responsible for all prescription drugs contained in this kit. Except as authorized in 18VAC110-20-505, a pharmacist shall (i) check each kit after filling and (ii) initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit containing drugs in Schedules II through V is sealed, secured, and stored in such a manner that will deter theft or loss of drugs and aid in detection of theft or loss. Kits containing only drugs in Schedule VI are not required to be sealed but must be secured in a manner to deter theft or loss.

a. The 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.

3. 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 administered to a patient.

4. 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.

5. 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 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.

6. 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.

7. The record of the drugs 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.

8. Intravenous and irrigation solutions provided by a pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by a 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, prescriber, or pharmacy technician if the kit contents include Schedule II, III, IV, or V drugs.

11. Drug kits shall be secured on the EMS vehicle or other EMS vehicle at all times, unless the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service. The EMS agency is not required to obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia to participate in a pharmacy kit exchange in accordance with this section unless the EMS agency needs to temporarily store a secured drug kit within the EMS building when a vehicle is incapable of maintaining appropriate drug storage temperature or is out of service and the EMS agency does not otherwise serve as a designated location of a current, active controlled substances registration. An alarm system consistent with requirements in 18VAC110-20-710 is not required under these conditions.

C. An EMS agency or regional EMS council that has been issued a controlled substances registration pursuant to 18VAC110-20-690 G and a registration from DEA in accordance with federal law may receive drugs in Schedules II through VI and deliver or transfer the drugs to any designated location of the registered EMS agency headquarters or regional EMS council. Delivery of the drugs shall not constitute wholesale distribution.

D. For sites that are not designated locations of the entity providing the drug, nothing shall preclude a hospital, EMS agency, or regional EMS council from transferring or distributing drugs in Schedule VI to another EMS agency, regional EMS council, or a designated location of either entity during a shortage of drugs or in an emergency.

E. A hospital, EMS agency, regional EMS council, and designated locations may deliver drugs in Schedules II through V to each other consistent with federal law in the event of shortages of such drugs, a public health emergency, or a mass casualty event. All entities transferring, delivering, and receiving drugs shall comply with recordkeeping requirements listed in 18VAC110-20-721.

F. In compliance with federal law, a hospital pharmacy may provide drugs to a hospital-owned EMS agency operating as an extension of the hospital pharmacy's DEA registration.

G. If an EMS agency that is not hospital owned has obtained a controlled substances registration and a DEA registration in accordance with federal law, a pharmacy may provide that EMS agency drugs for restocking an EMS vehicle or other EMS vehicle, provided all of the following criteria are met:

1. The registered or designated location of the agency operating the EMS vehicle or other EMS vehicle maintains the record of receipt of drugs in accordance with state and federal law.

2. The pharmacy maintains a record of the delivery to the EMS agency in accordance with state and federal law.

3. If the EMS vehicle or other EMS vehicle is primarily situated at a designated location of an EMS agency, the designated location notifies the registered location of the agency within 72 hours of the EMS vehicle or other EMS vehicle receiving drugs in Schedules II through V.

4. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs from an automated drug dispensing device.

5. If such drugs 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 the drug, name of the EMS agency and provider receiving the drug, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

6. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs, such Schedule VI drugs shall remain in a separate container.

H. Schedule VI drugs stored on an EMS vehicle or other EMS vehicle are not required to be stored in a sealed kit, but must be stored in a manner to deter theft or loss. Drugs in Schedules II through V stored on a ground EMS vehicle, other EMS vehicle, or EMS vehicle that is a licensed fixed-wing aircraft shall be stored in a sealed, secured kit or device within a locked cabinet that is accessible from the patient compartment of the vehicle. Drugs in Schedules II through V stored on an EMS vehicle that is a licensed rotary aircraft shall be stored in a sealed, secured kit or device to deter theft or loss.

1. The method of sealing the kits shall ensure that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

2. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The EMS registered agency headquarters, regional EMS council, or designated location sealing and resealing the kit shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

3. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by EMS personnel may be used.

I. Registered EMS agency headquarters, regional EMS councils, and designated locations of the registered EMS agency headquarters or regional EMS councils shall implement a process to review expiration dates no less often than every three months to ensure drugs are not administered beyond the expiration date.

J. Registered EMS agency headquarters, regional EMS councils, and designated locations of the registered EMS agency headquarters or regional EMS councils shall perform drug inventories and report drug theft or unusual loss to the board in accordance with § 54.1-3404 of the Code of Virginia.

K. Registered EMS agency headquarters and regional EMS councils shall audit the security of the drug storage location and perform a random audit of Schedules II through V drugs and required recordkeeping for accuracy at least every six months at each designated location under the controlled substances registration. Documentation verifying the completion of the audit for each designated location shall be maintained at the registered EMS agency headquarters or regional EMS council for two years from the date performed.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity that maintains or intends to maintain a supply of Schedules II through ~~Schedule~~ VI controlled substances, other than ~~manufacturers'~~ manufacturer samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities that may be registered by the board shall include hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, ~~and~~ emergency medical services agencies, and regional EMS councils, provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date or requests that are received after the application is filed shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedules II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

G. The board may issue a controlled substances registration to an EMS agency or regional EMS council to receive controlled substances in Schedules II through VI from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy. The EMS agency or regional EMS council shall identify to the board any designated location to which the EMS agency or regional EMS council may deliver controlled substances. The EMS agency or

regional EMS council shall also obtain a registration from DEA in accordance with federal law prior to delivery of Schedules II through V drugs. The EMS agency or regional EMS council shall identify on the controlled substances registration application the name and physical address of the designated locations and attest that each designated location of the EMS agency or regional EMS council complies with the storage and security requirements of 18VAC110-20-710. Any changes to the designated locations shall be submitted to the board in advance of delivering or ceasing to deliver controlled substances to that location and the designated locations must be approved sites under federal law.

H. An EMS agency receiving only Schedule VI drugs from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy or temporarily storing a secured drug kit within the EMS building when the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service shall obtain a controlled substance registration or operate as a designated location of a registered EMS agency headquarters.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions that meet USP-NF specifications or ~~manufacturers'~~ manufacturer's suggested storage for each drug.

B. Any drug that has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedules II through VI drugs, ~~he~~ the controlled substances registrant shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device, or other area that shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. A registered EMS agency headquarters or regional EMS council may store controlled substances in an automated dispensing device that is located at a secured site at the registered location or designated location of the EMS agency or regional EMS council that is (i) installed and operated by the EMS agency or regional EMS council, (ii) not used to directly dispense controlled substances to an ultimate user, and (iii) is in compliance with the requirements of state law.

F. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet, or area that has a security device for the detection of breaking that meets the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers~~,~~; animal control officers~~,~~; humane societies~~,~~; alternate delivery sites as provided in 18VAC110-20-275~~, emergency medical services agencies~~; registered EMS agencies or regional EMS councils, or designated locations of registered EMS agency headquarters or regional EMS councils stocking only ~~intravenous fluids with no added drug,~~ Schedule VI drugs or temporarily securing a secured drug kit that may contain Schedules II through VI drugs when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service; persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal~~,~~; and teaching institutions possessing only Schedule VI drugs.

G. A registered EMS agency headquarters or regional EMS council may store controlled substances at any of the following secured locations:

1. A registered location of the EMS agency or regional EMS council;

2. A designated location of the EMS agency or regional EMS council of which the board has been notified and DEA has granted approval if stocking drugs in Schedules II through V;

3. In an EMS vehicle or other EMS vehicle situated at a registered location or designated location of the EMS agency or regional EMS council; or

4. In an EMS vehicle or other EMS vehicle used by the EMS agency that is traveling from or returning to a registered location or designated location of the EMS agency or EMS council in the course of responding to an emergency or otherwise actively in use by the EMS agency.

H. Drugs secured in an EMS agency, regional EMS council, EMS vehicle, or other EMS vehicle shall be stored at an appropriate temperature pursuant to manufacturer's directions at all

times. If the EMS vehicle or other EMS vehicle cannot maintain appropriate temperature or is out of service, the drug kit may be temporarily maintained within the building of the EMS agency. The drug kit shall be stored in compliance with this section.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for ~~Schedule~~ Schedules II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia to include the reporting of any drug theft or unusual loss and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. ~~All~~ Except as provided in subdivision 9 of this section, all records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An entity ~~which~~ that is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

4. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data ~~which~~ that the registrant is responsible for maintaining under the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia).

5. The Department of Forensic Science may exclude from any inventory quantities of controlled substances used to conduct chemical analyses and controlled substances received for analyses as evidentiary material as provided in § 54.1-3404 G of the Code of Virginia.

6. Documents that describe the conditions and extent of the responsible party's authorization to dispense controlled substances for each EMS provider employed by or practicing at an EMS agency holding a controlled substances registration. Such documents shall be maintained in a readily retrievable manner and be available for inspection and copying by authorized agents of the board. Examples of such documentation include protocols, practice guidelines, or practice agreements.

7. Records of all controlled substances that are received, administered, or otherwise disposed of, records of deliveries of controlled substances between all locations of an EMS agency or regional EMS council pursuant to the controlled substance registration, and record of the standing or verbal orders issued or adopted.

8. Documentation verifying the completion of audit for each designated location pursuant to 18VAC110-20-591 K.

9. Records required to be maintained by an EMS agency or regional EMS council shall be maintained, whether electronically or otherwise, pursuant to subdivision 2 of this section or at each registered location, designated location of the EMS agency, or regional EMS

council where the controlled substances involved are received, administered, or otherwise disposed of for two years from the date of execution of the record.

18VAC110-20-721. Additional recordkeeping requirements for EMS agencies.

A. Each EMS agency holding a controlled substances registration or serving as a designated location of an EMS agency or regional EMS council, including a hospital-owned EMS agency operating under a hospital registration, responsible for administering a drug must maintain written standing protocols signed by the operational medical director for the EMS agency that authorize the administration. Oral orders authorizing the administration shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner and maintained by the EMS entity responsible for administering the drug.

B. A record for each dose of drug in Schedules II through VI administered and destruction of partially administered drug in the course of providing emergency medical services must also be maintained. 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. Except as indicated in 18VAC110-20-591 for emergency drug kits provided by a pharmacy, documentation shall be maintained in the EMS agency or the designated location of an EMS agency or regional EMS council for a period of two years from the date of destruction.

C. The following records shall be maintained for each acquisition of a drug in Schedules II through VI from another registrant of the board or each distribution of a drug in Schedules II through VI to another registrant of the board:

1. For each acquisition of a drug from another registrant:

a. Name of the drug;

b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

d. Number of commercial containers acquired;

e. Date of the acquisition;

f. Name, address, and registration number of the person from whom the substance was acquired; and

g. Name and title of the person acquiring the drug.

2. For each distribution of drug in Schedules II through VI to another registrant:

a. Name of the drug;

b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

d. Number of commercial containers distributed;

e. Date of the distribution;

f. Name, address, and registration number of the person to whom the substance was distributed; and

g. Name and title of the person in receipt of the distributed drugs.

3. For each delivery of drug in Schedules II through VI between a designated location and a registered location:

a. Name of the drug;

b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

d. Number of units or volume of finished form in each commercial container and number of commercial containers delivered (e.g., 100-tablet bottle or 3-milliliter vial);

e. Date of the delivery;

f. Name and address of the designated location to which the substance was delivered; and

g. Name and title of the person in receipt of the controlled substances.

4. For destruction of a drug in Schedules II through VI, unless otherwise authorized under federal law, expired or unwanted drugs shall be transferred to another person or entity authorized to possess or provide for proper disposal of such drugs.

D. A designated location of an EMS agency that receives drugs in Schedules II through V must notify the EMS agency's registered location within 72 hours of receipt of the drugs in the following circumstances:

1. An EMS vehicle or other EMS vehicle primarily situated at a designated location of the EMS agency acquires drug from a hospital while restocking following a response; or

2. The designated location of the EMS agency receives drugs from another designated location of the same agency.

E. To the extent permitted by federal law, registered EMS agency headquarters, regional EMS councils, or designated locations of the EMS agency or regional EMS council in which the

repackaging or prepackaging of over-the-counter drugs is performed shall maintain adequate control records for a period of one year or until the expiration of the drugs, whichever is greater.

1. The records shall show the name of the drugs used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist, EMS responsible party, or designee authorized to administer drugs verifying the process; the assigned lot or control number; the manufacturer or distributor name and lot or control number; and an expiration date.

2. Any subsequently repackaged units shall show the name of the drug; strength, if any; the assigned lot or control number or the manufacturer or distributor name and lot or control number; and an appropriate expiration date determined by the pharmacist, EMS responsible party, or designee authorized to administer drugs in accordance with USP guidelines.

3. Repackaging of drugs shall be performed in compliance with USP-NF standards.

Action: Allowances for emergency drugs by EMS agencies [6452 / 10312]			
Commenter	**Title**	**Comment**	**Date/ID**
Bolar Volunteer Rescue Squad	Drugbox on Rapid Response Unit	Iam writing this comment because Iam Rescue Captain of Bolar Volunteer Rescue Squad in Bolar Virginia. We cover Southeren Highland and Northern Bath Counties. I live 14 minutes from on Station. I keep a VAOEMS Certified First Responder Unit at my house locked up and shore line plugged in. Where we live we have no cellular service and our radios are limited on the power that our repeaters can transmit on because of the NARO over in Greenbank, WVA. We are trying to get the board to realize the importance of saving lives, if our First Responder Unit could be equipped with a BLS Schedule 6 box. We have the temperature controlled unit, on Responder 9. When it is 45 minutes to 60 minutes before an epipen can be administered to a patient, and yes I have been in this situation before this ruling could save countless lives. Please help us help our community Matthew Ratcliffe Bolar Volunteer Rescue Squad Chief	10/3/24 6:06 pm CommentID:228049
Ryland Kendrick, Stafford County Fire & Rescue	Medication storage	The transition away from hospital-supplied sealed drug kits (and especially sealed narcotics kits) is a great challenge but also may have some benefits going forward. My own experience has been that sealing all the controlled medications in one catch-all bag has had some unintended negative consequences due to the inevitable out of sight/out of mind effect. Clinicians were not able to handle and inspect the vials, and there were measurable decreases in pain medication use based on the less accessible nature (and increased restocking time) of the multiple-medicine kits. 18VAC110-20-591 section 6H refers to keeping Schedules II-V drugs in "sealed, secured kit or device" but does not provide further detail and the terms are not in the Definitions section. Our goal is to track at the individual vial level, and also make sure the medications are easy to account for (to identify any problems as soon as possible). Under the old system when we carried all our controlled meds in a single sealed bag provided by the hospital, it prevented us from tracking except at the bag level, and also made close examination of each vial difficult if not impossible. We consulted a DEA Diversion Investigator and a pharmacist and proposed storing all medications in a single box, with each Sched II-V drug vial separately sealed in its own individual bar-coded tamper-evident bag (clear so we can monitor each vial), with the entire drug box locked in our access-controlled compartment in the EMS vehicle? We were trying to set up functional controlled medication kits, i.e. seizure kit, sedation kit, pain kit, to help our clinicians and increase medication accountability, and for regulatory purposes each kit would be both sealed and secured. Both the DEA Investigator and the pharmacist agreed these were compliant and secure solutions	10/8/24 5:45 pm CommentID:228077

		(although not the same as the traditional all-in-one solution). Our goal was to keep the controlled medications secure but easier to visually access, inspect, and verify/account for by sealing and storing them individually, which would also coincidentally reduce barriers to use to benefit patients, and reduce medication error potential by separating the often very similar vials. Could the language in the regulations be revised to provide more clarity on this aspect of storage?	
John M. Montgomery, President, Highland County Volunteer Rescue Squad	Drug Boxes on Quick Response Vehicles in Rural Areas	The Highland County Volunteer Rescue Squad ("HCVRS") has been operating two Quick Response Vehicles ("QRV's") in Highland County for a number of years to try to speed response times in our rural and very mountainous county. The County is one of the largest counties in Virginia by land mass, but is the least populated county, with a population of around 2000 residents. Additionally, the County has several mountain ranges with valleys in between, making cross-county transport time-consuming and difficult. Accordingly, it poses a great challenge to HCVRS and the Highland Emergency Medical Service ("HEMS") to reach remote citizens with challenging medical needs. Each of our QRV's is equipped with full drug boxes to address the most critical patients. Each QRV has the full capability of our ambulance units, with the single exception of the ability to transport patients. The QRV's are located in Blue Grass and in McDowell, and the main transport units are located in Monterey, the county seat. It has come to our attention that the Board of Pharmacy has expressed concern about the storage of drug boxes on the QRV units. With respect, if the Board of Pharmacy disallows the drug boxes on our QRV units, it will significantly increase response times and puts patients' lives in danger. The QRV units are locked at all times, and are equipped with auxiliary power connections to maintain the temperature of the drug boxes on the QRV units. The drug boxes within the QRV units are also locked. Accordingly, the units are double-locked and secured with power connections, as they would be in any of our EMS bays. HCVRS is prepared to register the locations of the QRV units as contemplated by the proposed regulations, but wishes to convey how critical these QRV units are to the response times in our rural area, and for our ability to meet the emergency medical needs of our community.	10/8/24 9:16 pm CommentID:228080
Anonymous	Reduction of Fire Station Security Requirements	I recommend reducing the stringent security requirements for the storage of Schedule II-V controlled substances by updating regulations to explicitly allow DEA-compliant storage systems, such as Automated Dispensing Machines (ADM). Including ADM and other DEA-compliant technologies in the approved methods for storage and exchange would streamline operations,	10/9/24 12:31 pm CommentID:228085

		enhance efficiency, and maintain the necessary safeguards to prevent diversion and unauthorized access. The current security requirements for SII-V are cost prohibitive for agencies and reduce EMS access for medication exchange in both urban and rural communities.	
Debbie Trible, Highland County Vol Rescue Squad	QRV	Highland County is 416 square miles of rugged mountainous terrain with a ridge and valley topography. A location five miles away can easily be a thirty-minute drive. Our volunteer rescue squad has developed a fleet of Quick Response Vehicles parked at a volunteer home. Each unit has the same equipment as an ambulance, with the exception of a stretcher. These units, all equipped with a drug box, respond locally while an ambulance responds from a more distant central location. A trained volunteer arriving quickly on scene can provide lifesaving/stabilizing medications...IF THEY HAVE A DRUG BOX IN THE UNIT. Removing the drug box from our QRV units will completely undo years of hard work creating a best result Emergency Services System and ***will result in a significantly elevated risk of death, serious injury, or complications for our local residents and visitors***. This is unacceptable. One size does not fit all. We are well over an hour to the nearest suitable hospital. Our QRV fleet allows our providers to stabilize a patient earlier in the process while the ambulance is on the way. Our county has a small population and cannot afford to fund and staff Emergency Services stations throughout the county. Instead, we utilize volunteers and FULLY EQUIPPED QRV's to produce good outcomes for our residents.	10/9/24 4:59 pm CommentID:228089

Agenda Topic: Request from Gates Healthcare Associates, Inc. to recognize its inspection report as an acceptable alternative to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Background: Currently inspection reports from the National Association of Boards of Pharmacy that satisfy the inspection report requirements of §54.1-3434.1 are the only deemed acceptable alternative. Refer to Guidance Document 110-38. This agenda topic was referred by the full board in September to the Regulation Committee for further consideration.

Included in Agenda Packet:

- Background on Gates' inspection process and example of inspection report (Ernest Gates, President & CEO, Gates Healthcare Associates, granted permission to share publicly)
- Commonly Cited Deficiencies by Gates
- Bios or resumes of three inspectors performing inspections for Gates
- Link to Board Inspection Report at https://www.dhp.virginia.gov/media/dhpweb/docs/pharmacy/forms/Inspection/PharmacyRoutineInspection.pdf
- Guidance Document 110-38

Actions Needed:

Discuss request.

Motion to recommend that full board accept request and amend Guidance Document 110-38 or deny request.

Gates Healthcare Associates, Inc.
Compounding Pharmacy USP <797> Inspections
Common Deficiencies

Sterile Compounding USP <797> Inspections		
Deficiency	**Category**	**Description**
Cleanroom Certification—Dynamic Conditions	Facility Management	• Certification testing not be conducted under dynamic conditions • No description of dynamic condition within the report • Certifier being counted as the only person in the room • Pharmacy not having the maximum number of individuals simulating compounding while being tested • Reports not indicating the max number of individuals allowed in the room while maintaining room parameters
Cleanroom Certifications—Smoke Study Testing	Facility Management	• No video of smoke study testing • Not tested under both static and dynamic conditions
Cleanroom Certifications—Certification Day Checklist	Facility Management	• PIC/DP not utilizing a checklist during the certification testing • Lack of communication between the certifier and DP

Viable Sample Reports	Environmental Monitoring	• Lack of documentation on follow-up for actionable items or review of report
Sampling Plans	Environmental Monitoring	• Pharmacy uses sampling plan provided by certification company • Not sampling high-traffic areas, doors, or random sites to validate cleaning procedures
Certificates of Analysis	Products and Components	• Facility lacks a COA review process and documentation
Missing SOPs & Competencies	Policies & Procedures Training Documentation	• Equipment SOPs/Training • Formulation SOPs/Training • Designated Person SOP
Compounding Observations	Hand Hygiene/Garbing	• Long nails, fake nails • Hair sticking out from bonnets • Lack of beard covers • Ankles exposed • Allowing sterile garb to touch the floor • Not using a bench to assist with garbing • Line of demarcation not in the correct place for optimal garbing practices • No mirror or clock in anteroom • Not using healthcare approved hand soap or extended-release sanitizer

Compounding Observations	Aseptic Technique	• Technician leaning into the hood while compounding • Placing elbows on the PEC while compounding • Not re-sanitizing gloves when performing lengthy batch fills • Moving in and out of the hood too frequently without proper hand sanitization
Validation Testing	Media Fills	• Media fill test does not match most complicated and lengthy compounding procedure/batch
Internal Auditing	Quality Management	• No internal auditing, random validation testing, or random staff competencies being conducted as part of a Quality Management Program.
Out of Specification Results Quality Control	Quality Management	• No tracking or trending of OOS from in-process checks, final product testing, or QC results
Annual Reporting	Quality Management	• Lack of an annual quality report, track and trending, PI/CAPAs

Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

Application for Board Approved Inspectors

Bid Number:

Submitted to
Bureau of Health Care Safety and Quality

Submitted on
April 12, 2024

Prepared by
Gates Healthcare Associates Inc.

Location
1 Meeting House Square
Middleton, MA 01949

Contact
Ernie Gates, CEO
978-646-0091
Email: ernie.gates@gatesconsult.com
https://gateshealthcareassociates.com/

Confidential

Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

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Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

REQUEST FOR APPROVAL

STATE BOARD OF REGISTRATION IN PHARMACY

Gates Healthcare Associates (GHA) appreciates the opportunity to present our application for Approved Board Inspections to the State Board of Registration in Pharmacy.

We are requesting to be approved as a third-party entity to provide regulatory inspections of general pharmacy operations (retail pharmacy, including mail-order pharmacy), nonsterile compounding pharmacies to USP Chapter <795>, sterile compounding pharmacies to USP Chapter <797>, compounding hazardous drugs (sterile and nonsterile) to USP Chapter <800>, and nuclear pharmacies to USP Chapter <825>.

ABOUT GATES HEALTHCARE REGULATORY INSPECTIONS

Gates Healthcare Associates (GHA) is a pharmaceutical and healthcare consulting firm that is well equipped with a proven track record of providing compliance and regulatory standards guidance and monitoring services to pharmacies across the country in support of State Boards of Pharmacy.

GHA has conducted our services since 1994, providing compliance and regulatory inspections, auditing, remediation, and monitoring services in all 50 United States as well as Canada, GHA has worked with all State Boards of Pharmacy.

Since 2018, starting with the Michigan State Board of Pharmacy, we began to provide inspection services as an Approved Board Inspector for State Boards of Pharmacy and currently we are an approved 3rd party inspection vendor for 9 states with more in process.

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APPLICATION SUMMARY

A. What type(s) of inspections does Gates Healthcare Associates (GHA) perform for State Boards in Pharmacy?

- General Pharmacy Operations (retail pharmacy, including mail-order pharmacy)
- Nonsterile Compounding Pharmacies to USP Chapter <795>
- Sterile Compounding Pharmacies to USP Chapter <797>
- Compounding Hazardous Drugs (sterile and nonsterile) to USP Chapter <800>
- Nuclear Pharmacies to USP Chapter <825>

B. What experience in providing pharmacy inspectional services and types of inspections does GHA perform.

Gates Healthcare Associates (GHA) is a pharmaceutical and healthcare consulting firm that is well equipped with a proven track record of providing compliance and regulatory standards guidance and monitoring services to pharmacies across the country in support of State Boards of Pharmacy.

GHA has conducted our services since 1994, providing compliance and regulatory inspections, auditing, remediation, and monitoring services in all 50 United States as well as Canada.

Since 2018, starting with the Michigan State Board of Pharmacy, we began to provide inspection services as an Approved Board Inspector for State Boards of Pharmacy and currently we are an approved 3rd party inspection vendor for 9 states with more in process.

C. What is the GHA process that is undertaken to conduct pharmacy inspections from the request to the "closing out" of an inspection including any involvement with the correction of identified deficiencies.

The inspector, using detailed inspection tools, will perform the inspection(s). After performing the inspection(s) needed, the inspector will review items of partial compliance or noncompliance with the staff at the facility and discuss a plan of correction, if applicable.

The inspector will prepare a report with findings that includes the plan of correction and submit to GHA for a quality review before being supplied to the client/pharmacy. The client/pharmacy will then submit a copy of this inspection to the Board of Pharmacy for licensure or renewal of licensure. If the Board of Pharmacy requests a copy of the inspection report, GHA will provide both the client/pharmacy and Board of Pharmacy with report copies.

The State Board of Pharmacy will then use these detailed inspection reports and any plan of correction to assess compliance for the purpose of licensure or license renewal.

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1 Meeting House Square
Middleton, MA 01949
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GHA is also available to perform these inspections and any periodic mandated monitoring of facilities for compliance subsequent to a disciplinary action or to ensure remediation of noncompliant items for licensure or renewal.

D. What is GHA's vetting process for pharmacist inspectors and how they meet qualification and experience requirements.

For compliance and licensure inspections we send a fully trained, licensed pharmacist to perform the inspection(s) on-site. Inspectors are chosen based on experience, training, and oversight of the specific inspection.

GHA inspectors have years of experience and additionally are trained initially and annually on the specific inspections they perform. Initial training includes online training on the tools and on-site training in the inspection process.

E. Attachments are included of the inspection forms/tools to be utilized.

Attachments: 2 and 3. USP 797 and USP 800 Inspection Reports.
Example of actual inspections performed.

Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

INSPECTION OVERVIEW

For compliance and licensure inspections we send a fully trained, licensed pharmacist to perform the inspection(s) on-site. Inspectors are chosen based on experience, training, and oversight of the specific inspection. GHA inspectors have years of experience and additionally are trained initially and annually on the specific inspections they perform. Initial training includes online training on the tools and on-site training in the inspection process. Depending on the number or type(s) of inspections needed, inspections are typically 1 to 2 days in length.

The inspector, using detailed inspection tools, will perform the inspection(s). After performing the inspection(s) needed, the inspector will review items of partial compliance or noncompliance with the staff at the facility and discuss a plan of correction, if applicable.

The inspector will prepare a report with findings that includes the plan of correction and submit to GHA for a quality review before being supplied to the client/pharmacy. The client/pharmacy will then submit a copy of this inspection to the Board of Pharmacy for licensure or renewal of licensure. If the Board of Pharmacy requests a copy of the inspection report, GHA will provide both the client/pharmacy and Board of Pharmacy with report copies.

The State Board of Pharmacy will then use these detailed inspection reports and any plan of correction to assess compliance for the purpose of licensure or license renewal.

GHA is also available to perform these inspections and any periodic mandated monitoring of facilities for compliance subsequent to a disciplinary action or to ensure remediation of noncompliant items for licensure or renewal.

Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
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Inspection Content outlines

GENERAL PHARMACY INSPECTION

Sections:

- General Operations and Licensure
- Crisis Plans
- Personnel including training.
- Compliance Plan
- Facility and Security
- Product Ordering, Receipt and Inventory
- Prescription Processing
- Billing Practices
- Privacy and Confidentiality including nondiscrimination.
- Dispensing, Mail and Delivery
- Off-Site Processes
- Off-Site Inventory
- Patient Counseling and Communication
- Patient Care Programs
- Quality Program

Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

USP CHAPTER 795 NONSTERILE COMPOUNDING INSPECTION

Sections:

- General Compounding Operations
- Component Selection, Use, and Handling
- Animal Compounding
- Environment and Equipment
- Cleaning and Sanitizing
- Training and Competency
- Personal Hygiene and Garbing
- Master Formula Record (MFR) and Compounding Record (CR)
- Beyond-Use Dating (BUD)
- Compounding Procedures
- Finished Preparation Release Checks and Tests
- Labels and Labeling
- Quality Assurance and Quality Control
- Recalls, Complaints, and Adverse Event Reporting
- Documentation
- Dispensing and Patient Consultation

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1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

USP CHAPTER 797 STERILE COMPOUNDING INSPECTION

Sections:

- Section I: General Operations
- Section II: Component Selection, Use, and Handling
- Section III: Animal Compounding
- Allergenic Extract Sets
    - Section IV: Environment and Equipment
    - Section V: Cleaning and Sanitizing
    - Section VI: Training and Competency
    - Section VII: Personal Hygiene and Garbing
    - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)
    - Section IX: Beyond Use Dating (BUD)
    - Section X: Compounding Procedures
    - Section XI: Finished Preparation Release Checks and Tests
    - Section XII: Labels and Labeling
- Immediate-Use CSPs
    - Section IV: Environment and Equipment
    - Section V: Cleaning and Sanitizing
    - Section VI: Training and Competency
    - Section VII: Personal Hygiene and Garbing
    - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)
    - Section IX: Beyond Use Dating (BUD)
    - Section X: Compounding Procedures
    - Section XI: Finished Preparation Release Checks and Tests
    - Section XII: Labels and Labeling
- Category 1 CSPs Compounded in a Segregated Compounding Area (SCA)
    - Section IV: Environment and Equipment
    - Section V: Cleaning and Sanitizing
    - Section VI: Training and Competency
    - Section VII: Personal Hygiene and Garbing

  - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)
  - Section IX: Beyond Use Dating (BUD)
  - Section X: Compounding Procedures
  - Section XI: Finished Preparation Release Checks and Tests
  - Section XII: Labels and Labeling
- Category 1 or 2 CSPs Compounded in a Compounding Suite (anteroom and buffer room)
  - Section IV: Environment and Equipment
  - Section V: Cleaning and Sanitizing
  - Section VI: Training and Competency
  - Section VII: Personal Hygiene and Garbing
  - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)
  - Section IX: Beyond Use Dating (BUD)
  - Section X: Compounding Procedures
  - Section XI: Finished Preparation Release Checks and Tests
  - Section XII: Labels and Labeling
- Compounding Category 3 CSPs
  - Section IV: Environment and Equipment
  - Section V: Cleaning and Sanitizing
  - Section VI: Training and Competency
  - Section VII: Personal Hygiene and Garbing
  - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)
  - Section IX: Beyond Use Dating (BUD)
  - Section X: Compounding Procedures
  - Section XI: Finished Preparation Release Checks and Tests
  - Section XII: Labels and LabelingEnvironment
- Section XIII: Quality Assurance and Quality Control
- Section XIV: Recalls, Complaints, and Adverse Event Reporting
- Section XV: DOCUMENTATION
- Section XVI: Dispensing and Patient Consultation

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1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

USP CHAPTER 800 HAZARDOUS DRUG HANDLING INSPECTION

Sections:

I. General Operations for Handling HDs
II. General Pharmacy Activities in Handling HDs
III. Garbing for General Pharmacy
IV. Nonsterile Compounding HDs
V. Garbing for Non-sterile Compounding HDs
VI. Sterile Compounding HDs
VII. Garbing for Sterile Compounding HDs
VIII. Environmental sampling
IX. Training
X. Medical Surveillance

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1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

USP CHAPTER 825 RADIOPHARMACEUTICALS INSPECTION

Sections:

1. General Operations
2. RADIATION SAFETY CONSIDERATIONS
3. IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS
4. PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE
5. FACILITIES AND ENGINEERING CONTROLS
6. MICROBIOLOGICAL AIR AND SURFACE MONITORING
7. CLEANING AND DISINFECTING
8. ASSIGNING BUD
9. DOCUMENTATION
10. PREPARATION
11. COMPOUNDING
12. DISPENSING
13. REPACKAGING
14. QUALITY ASSURANCE AND QUALITY CONTROL

Gates Healthcare Associates, Inc.
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

Attachment 1: Sterile Compounding Inspection Tool

Sterile Compounding (USP <797>) Inspection

Conducted for

Client Name

Conducted on

March 6, 2024

Prepared by

Denise Frank

Location

Client street

Client City, NY Client zip

Confidential

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1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

USP Chapter <797> Sterile Compounding Inspection

Client Name	**Complete**
Inspection Date	3/6/2024
Conducted By	Denise Frank
Facility Name	Client Name
Location Address	2657 Client street Rd Client City, NY Client zip
Pictures of Facility	

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1 Meeting House Square
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Facility Information

1. Pharmacist-in-Charge (PIC)	Susan Smith

2. Designated Person(s) Name(s) and Title(s)

Lisa Smith, PharmD, CCO
Trainers (managers)

3. Facility and equipment description (PECs, SCAs, SECs):

ISO 7 ante room leading to iso 7 positive pressure and ISO 7 negative pressure HD.
Anteroom: 2 four-foot CVE with redundant HEPA filters. HD has a BSC, and a CVE for weighing and mixing (during which no compounding occurs). Positive pressure has 2 LAFW.

4. Pictures

5. Sterile preparations compounded:	
a. Injections, infusions	Yes
b. Irrigations for internal body cavities	No
c. Ophthalmic dosage forms	No
d. Aqueous preparations for pulmonary inhalation.	No
e. Baths and soaks for live organs and tissues Implants	No
f. Implants	No
g. REPACKAGING sterile products	No
g. Other (describe in notes)	No
6. Types of compounding performed:	
a. Immediate Use CSPs	No
b. Category 1 CSPs	No
c. Category 2 CSPs	Yes
d. Category 3 CSPs	No
e. Allergenic Extract Sets	No

Note: This inspection does not apply to:
• Hazardous drug compounding (see USP Chapter <800>)
• Radiopharmaceuticals (see USP Chapter <825>)
• Preparation per approved labeling if a single dose for an individual patient and the labeling includes the diluent, resultant strength, container-closure system, and storage time.
• Docking of proprietary bag and vial systems according to the labeling for immediate administration to an individual patient. (Docking for future activation is considered compounding, BUD does not exceed time specified in labeling).
• Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.

NOTE: The use of technologies, techniques, materials, and procedures other than those described in USP Chapter <797> is not prohibited as long as they are noninferior to those described in USP Chapter <797> and validated for the intended purpose (see USP Chapter <1223> Validation of Alternative Microbiological Methods and <1225> Validation of Compendial Procedures).

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1 Meeting House Square
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Executive Summary & Plan of Correction

Section I: General Operations

1.a. and b. The facility has a designated person(s) but the person(s) identity and specific duties are not detailed in the SOPs.
4.a. Patient profiles are not complete. Inconsistent data. Of particular concern are allergy and disease state information. Also missing are other medications taken by the patient. Allergy information is missing and there is no hard stop to gather the information.
5.a. and b. Batch preparations are made; they are not of an appropriate volume (30 days or less) based on current volume and evaluated and documented each time a batch is prepared.
8. The pharmacy does not have the USP Compounding Compendium and so does NOT have appropriate USP reference chapters (including those cited by 797).
10. Only one person (maybe) has access to SDS. ALL employees need ready access.

Section II: Component Selection, Use, and Handling

3.d. No documentation that a COA is received for each lot of sterile, depyrogenated containers and container-closure systems received showing conformance with sterility and depyrogenation requirements.

Category 1 or 2 CSPs - Section IV: Environment and Equipment

Environment

6. The anteroom does NOT have a line of demarcation (LOD).
12. Unused outlets are not covered.
16. The light fixtures in the positive pressure buffer room are not sealed and flap up when the door is opened.
17. The sink in the anteroom is unacceptable. The sink is too small, and the faucet is too close to the sink making it impossible to wash and rinse hands keeping your hands above your elbows unless your elbows are outside the sink spilling water everywhere. Garb (gloves) are stored next to the sink and splashed with water.
24. Particle-generating appliance (oven) is not located next to an air return so particles may be entering and persisting in the clean room. No documentation that airflow around the placement and operation has been confirmed by airflow testing or that the appliance is part of the surface sampling program.
27. The immediate area around the door into the anteroom from the unclassified areas and the pass-through door contains particle-generating materials (cardboard).
28.b.-c. Differential air pressure is not measured from outside areas to the anteroom. Unknown pressure differential. Observed door being held open for long periods of time.
28.f. There is no prevention of doors from the general pharmacy to the anteroom and the anteroom to the buffer room from being held open at the same time. At a minimum, signage, and training.
28.i. No documentation that pressure monitoring equipment is periodically inspected and verified or calibrated.
29.b.-d., g. The temperature in the anteroom is not monitored, recorded, equipment validated or calibrated. Unknown if the temperature is kept at or below 20°C. The humidity in the anteroom is not monitored, recorded, equipment validated or calibrated. Unknown if the humidity range is maintained below 60%. Or if drug products that require storage in a “dry place” are used, the humidity does not exceed 40% OR there is an SOP that describes the steps to protect the opened product from being exposed to higher humidity. Records not available.

Equipment

8. No documentation that equipment (oven) is periodically inspected and verified as accurate or calibrated.
10.b. The ACD (repeater pump) is not used as part of media fill testing.

Environmental Monitoring

1.The most recent certification reports are not available. Dates provided for when certification is performed but unable to produce or obtain the certification reports for nonviable tests.
6. Unable to review testing to determine if the PIC/PR is familiar with the tests, performance of tests, or results.
10.-23. Noncompliant. No report. Unable to verify that environmental testing was performed correctly, documented, and reported correctly. Or if any tests failed.

Viable Air Sampling

2. Air sampling performed in-house by staff needs to be validated.

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11. Unknown (not documented) that the testing was performed dynamically. No record of the number of staff present and the activities they were performing during the testing. Unknown maximum capacity.
14.-15. Testing results are not evaluated against previous results to detect trends even if action levels have not been exceeded. If action levels are exceeded, no SOP detailing an action plan based on results, location, and identity of CFUs including when and if compounding must cease until remediated.

Viable Surface Sampling

2. Surface sampling performed in-house by staff needs to be validated.
13. Unknown (not documented) that the testing was performed dynamically. No record of the number of staff present and the activities they were performing during the testing. Unknown maximum capacity
16.-17. Testing results are not evaluated against previous results to detect trends even if action levels have not been exceeded. If action levels are exceeded, no SOP detailing an action plan based on results, location, and identity of CFUs including when and if compounding must cease until remediated.

Category 1 or 2 CSPs - Section V: Cleaning and Sanitizing

4. Products (including cleaning and disinfecting agents, packages of wipers, etc.) are not marked with the date opened or first used and the date after which they should not be used once opened (beyond use date).

Category 1 or 2 CSPs - Section VI: Training and Competency

3.a.b. Initial training and competencies are not performed or documented. No documentation of core skills and SOP training that includes a written test. Initial gloved-fingertip testing is not performed three times in succession.
4.a. Annual core skills and SOPs written test not performed/documented.
5.a.b. Personnel performing tasks but not performing compounding must also be trained, training details, competencies, frequency and documentation must be detailed in the SOPs. Includes those performing in-process checks, final verification, and dispensing of CSPs. Also anyone that does not compound but performs cleaning activities.

Category 1 or 2 CSPs - Section VII: Personal Hygiene and Garbing

11. Gloves are stored near the sink and are splashed.
16. Donning garb is noncompliant. No mirror present to check all hair is covered, personnel observed with hair outside head cover. There is no line of demarcation so booties are donned and traverse over clean and dirty side of floor.
17. Hand hygiene is noncompliant. There are no disposable nail picks – reusing a single pick then sanitizing at the end of the day. Sink is inadequate for washing – hands are not kept above elbows through the process, there is splashing.
19. Did not observe staff using alcohol-based hand rub before donning gloves.
20. Gloves. Using nonsterile gloves and later covering with sterile gloves. Technique sloppy - careful when handling cuffs.

Category 1 or 2 CSPs - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)

4. MFR is incomplete. Does not include specific equipment or step-by-step directions.

Category 1 or 2 CSPs - Section IX: Beyond Use Dating (BUD)

Multiple-Dose CSPs

10. No antimicrobial effectiveness testing was performed or documented. Does not have USP Compounding Compendium for Chapter <51>.
11. Container-closure testing not performed or documented. Does not have USP Compounding Compendium for Chapter <1207>.

Sterilization and Depyrogenation

2.a. The MFR does not contain information about the types, sizes, and quantities of filters to be used for filter sterilization of the specific CSP or the parameters for testing sterilization filters, including bubble point, if the filter is tested using the bubble point method.
2.b. Unknown/undocumented if and when using a prefilter to remove excessive particulate matter prior to sterilization by filtration.
2.c. Filter is not of adequate size to have the sterilization process completed WITHOUT replacing the filter during the process.

Category 1 or 2 CSPs - Section XI: Finished Preparation Release Checks and Tests

Endotoxin Testing

1.b.c.d. Unknown if endotoxin testing performed appropriately. Missing SOP, no documentation. Does not have USP

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Compounding Compendium for Chapter <85>.

Category 1 or 2 CSPs - Section XII: Labels and Labeling

3.-4. Labels and labeling are incomplete.

Section XIV: Recalls, Complaints, and Adverse Event Reporting

Recalls

1.- 7. There is no recall procedure for internal recalls. The recall procedure does not include all the detail required in the performance and documentation of a recall/internal recall, including reporting, and quality issues are documented on the CR.

Complaint Handling

5. The SOP does not contain all the details required for documentation of a complaint.

Adverse Event Reporting

1.-2. SOPs do not address reporting of adverse events or how other patients/providers are informed if the investigation reveals an issue that may affect other patients.

Section XV: DOCUMENTATION

2.-4. Record retention SOPs lacks detail in the retention times of documents, legibility, and how/where they are stored.

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Inspection

Section I: General Operations

1. The pharmacy has a designated person or persons in charge of sterile compounding operations.	Compliant
a. The designated person(s) is identified in the facility's SOPs. Attachment	Unknown/Partially Compliant
b. The responsibilities of the designated person(s) are included in the SOPs.	Unknown/Partially Compliant
2. The pharmacy makes copies of approved commercial products.	Yes
a. Products are verified as appearing on the FDA Drug Shortage List or ASHP Shortage List at the time of compounding, distribution, and dispensing.	Compliant
b. The Drug Shortage List(s) 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.	Compliant
3. The pharmacy compounds essential copies of commercially available products NOT on the Drug Shortage List.	Yes
a. The compounded preparation produces a clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner.	Compliant
4. The pharmacy dispenses compounded preparations pursuant to a patient- specific prescription.	Yes
a. There is a complete patient profile including demographics, disease states or conditions, allergies, and DUR information including other prescription and OTC medications the patient is taking. Missing disease state/condition, allergy information, other medications.	Noncompliant
b. If the pharmacy uses more than one prescription processing system (such as a billing system and a separate clinical management system), appropriate data is entered into each for performing DUR.	Compliant
5. They pharmacy performs anticipatory (batch) compounding.	Yes

a. Batch preparations (in anticipation of prescriptions) are of an appropriate volume (interpreted as 30 days or less). NOTE: Issue with FDA 503A vs 503B Watch quantities.	Unknown/Partially Compliant
b. Volume to prepare in a batch is evaluated each time the batch is compounded by looking at the most recent history, evaluation is documented.	Unknown/Partially Compliant
c. Batch products in stock are all within their BUD (not outdated).	Compliant
6. The pharmacy does not distribute compounded preparations to health care providers or other pharmacies for office use or stock.	Compliant
7. There are no compounded preparations that leave the pharmacy that are not dispensed pursuant to a prescription and labeled for a specific patient. (Note if the facility provides veterinary compounds for office use)	Compliant
8. The pharmacy has appropriate current references for compounding. At a minimum, USP Compounding Compendium and State regulations. Also, may include compatibility references, formula and stability references, references for specific types of compounding and clinical dosage/toxicology for the patient base (veterinary, geriatric, pediatric, etc.), access to formulas from vendors, etc. No USP Compounding Compendium. Has vendor information and ASHP guidance.	Unknown/Partially Compliant
9. There are no preparations compounded that present demonstrable difficulties for compounding as identified by the FDA.	Compliant
10. The pharmacy staff has access to Safety Data Sheets (SDS) for APIs, components, and chemicals used for compounding and cleaning. Not readily available for staff. One person maybe can access.	Unknown/Partially Compliant
11. The pharmacy has policies and procedures/standard operating procedures for compounding. (Note that we will not evaluate all the SOPs)	Yes
a. The SOPs address all aspects of the compounding operation.	Compliant
b. The type(s) of compounds that are prepared.	Compliant

c. All personnel who conduct or oversee compounding activities are trained in the facility's SOPs and are responsible for ensuring that they are followed. Training addresses:	Compliant
d. Training addresses: **• Recognizing potential problems, deviations, failures, or errors (equipment, facilities, materials, personnel, process, or testing) that may contaminate the CSP or otherwise adversely affect the quality of the CSP.** **• Reporting any problems, issues, deviations, failures, or errors to the designated person(s).**	Compliant
e. The designated person(s) ensures that SOPs are fully implemented, and that follow-up occurs if there are any problems, deviations, or errors identified including documentation of corrective actions.	Compliant
f. SOPs are reviewed at least every 12 months by the designated person. The review is documented.	Compliant
g. Any changes or alterations to an SOP is made only by a designated person(s) and is documented.	Compliant
h. Revisions to SOPs are communicated to all personnel involved in these processes and procedures and documented (training documentation or acknowledgement).	Compliant
Section II: Component Selection, Use, and Handling	
1. The facility uses commercially manufactured products for compounding.	No
2. The pharmacy compounds using bulk powder APIs.	Yes
a. Obtains APIs from FDA-registered facility in the US, either directly from the manufacturer/repackager or from a wholesaler that purchases directly from the manufacturer/repackager.	Compliant

b. Active Pharmaceutical Ingredients (APIs), bulk drug substances used are: **• Compliant with the standards of an applicable USP or NF monograph, if one exists; or** **• A component of an FDA-approved human drug product; or** **• On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation.** **• 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.**	Compliant
c. Certificates of analysis (COAs) are obtained for all bulk APIs used for compounding. COA is from the originating manufacturer and if not manufactured in the US, the COA from the importer, repackager, or distributor in US.	Compliant
d. The COA includes specifications (e.g., compendial requirements for quality) and test results for the component that show the API meets expected quality.	Compliant
e. The COA for an API is reviewed upon receipt of the API to verify the quality of the API before being used for compounding and kept on file.	Compliant
3. The pharmacy purchases other compounding components and container-closure systems.	Yes
a. Components must comply to USP-NF monograph, if one exists.	Compliant
b. Must be accompanied by documentation (COA, labeling) that verifies that the component meets the criteria in the USP–NF monograph, if one exists, and any additional specifications for the component.	Compliant
c. In the United States, should be manufactured by an FDA-registered facility (If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select a component that is suitable for the intended use and establish identity, strength, purity, and quality.)	Compliant
d. A COA is received for each lot of sterile, depyrogenated containers and container-closure systems received showing conformance with sterility and depyrogenation requirements.	Unknown/Partial Compliant

4. The facility purchases nonsterile containers or container-closure systems.	No
5. The facility imports APIs or other components directly from foreign sources.	No
6. There are no preparations 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.	Compliant
7. Component (including APIs) receipt information is documented and includes receipt date, quantity received, supplier name, lot number, expiration date, and results of any in-house or third-party testing performed.	Compliant
a. For all components that lack a vendor expiration date, the date of receipt is clearly and indelibly marked on each package. The component (APIs and added substances) must not be used by the compounding facility after 1 year from the date of receipt. A shorter expiration date must be assigned if the ingredient is known to be susceptible to degradation. Best practice is to label all APIs with date received and date first opened.	Compliant
b. Components and APIs are visually examined upon receipt for damage, evidence of deterioration, or other elements such as temperature indicators that show the product experienced a temperature extreme.	Compliant
c. All APIs and other components used are evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" (unless used for veterinary compounding), "for research purposes only" or an equivalent statement must not be used to compound for these purposes. No APIs or components in stock have handwritten or typed labels from another pharmacy.	Compliant
d. Any component found to be of unacceptable quality is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from the same vendor are examined to determine whether the other lots have the same defect.	Compliant
8. The pharmacy repackages APIs into smaller containers for ease of use.	No

Section III: Animal Compounding

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1. The pharmacy compounds CSPs for animals.	No

Note: The following are addressed in each section by the type of compounding performed.

Section IV: Environment and Equipment
Section V: Cleaning and Sanitizing
Section VI: Training and Competency
Section VII: Personal Hygiene and Garbing
Section VIII: Master Formula Record (MFR) and Compounding Record (CR)
Section IX: Beyond Use Dating (BUD)
Section X: Compounding Procedures
Section XI: Finished Preparation Release Checks and Tests
Section XII: Labels and Labeling

Does the pharmacy compound Allergenic Extract Sets?	No

Immediate Use CSPs

Does the pharmacy compound CSPs for Immediate Use?	No

Category 1 CSPs Compounded in a Segregated Compounding Area (SCA)

Does the pharmacy compound Category 1 CSPs in an SCA?	No

Category 1 or 2 CSPs Compounded in a Compounding Suite (anteroom and buffer room)

Does the pharmacy compound Category 1 or 2 CSPs in a compounding suite?	Yes

Category 1 or 2 CSPs - Section IV: Environment and Equipment

1. If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.	Compliant
2. The facility performs compounding using blood products or other biological materials.	No
3. Entry into the sterile compounding areas is limited to task critical employees (limited to only trained and authorized pharmacy personnel). At a minimum, signage indicating authorized personnel only.	Compliant
4. The compounding suite has ISO Class 7 or 8 anteroom(s) leading to ISO Class 7 buffer room(s).	Compliant
Describe:	

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ISO 7 ante room leading to iso 7 positive pressure and ISO 7 negative pressure HD.
Anteroom: 2 four-foot CVE with redundant HEPA filters. HD has a BSC, and a CVE for weighing and mixing (during which no compounding occurs). Positive pressure has 2 LAFW.

5. If the facility has a negative pressure buffer room (for HDs), the anteroom is ISO Class 7.	Compliant
6. 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 buffer room.	Noncompliant
7. Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation. All products in and out through pass through.	N/A
8. Carts used in the clean room/buffer room are kept on the clean side of the line of demarcation.	N/A
9. 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.	Compliant
10. Equipment, carts, tables, PECs are free from any rust or corrosion.	Compliant
11. Walls painted with epoxy-based paint or comprised of an impermeable surface and are seamless or have sealed seams where panels meet and in corners.	Compliant
12. There are no unsealed holes or cracks in the walls. Unused outlets have plugs or covers. Unused outlets not covered.	Noncompliant
13. The ceiling tiles are composed of a vinyl surface or other impermeable material, with the tiles caulked and sealed and the seams where the walls meet the ceiling are caulked and sealed.	Compliant
14. The clean room and anteroom are free from dust collecting overhangs, such as ceiling utility pipes, or ledges. If there are ledges, doorframes, etc. that have horizontal surfaces, care is taken to specifically clean these areas as they may collect dust.	Compliant
15. Sprinkler heads are flush with the ceiling and covered. Covers are easily cleanable.	Compliant

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16. The exposed surfaces of the light fixtures are smooth, mounted flush, and sealed. Not sealed, flaps up when door opened.	Noncompliant
17. The sink used for hand hygiene and the eyewash station may be placed either inside or outside of the anteroom. **• If the sink is located outside of the anteroom, it is located in a clean space to minimize the risk of bringing contaminants into the anteroom.** **• If the sink is located inside the anteroom, it may be placed on either the clean side or the dirty side of the anteroom. The order of hand washing and garbing depends on the placement of the sink.** **• The sink is at least 1 meter away from the door into a negative pressure HD buffer room.** **• The sink is of the appropriate size and configuration to allow for washing of hands and arms up to the elbows while keeping hands above the level of the elbows.** **• Garb and compounding supplies are not stored adjacent to the sink to prevent being splash contaminated.**	Noncompliant
18. The buffer room does not contain plumbed water sources (sink, eyewash, floor drains).	Compliant
19. The anteroom does not contain a floor drain.	Compliant
20. All air ducts controlling air flow into the cleanroom suite are on or near the ceiling and equipped with HEPA filtered air.	Compliant
21. Air returns in the cleanroom suite must be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow.	Compliant
22. There are no other sources of air coming into the anteroom or clean room such as blowers, fans, air conditioning units, etc. Free-standing air conditioners, humidifiers, and dehumidifiers must not be used within the classified area.	Compliant
23. If there is particle generating equipment in the clean room or anteroom (such as computers and printers), the equipment is 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 particle counts and smoke testing performed while the equipment was in use.	Compliant

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24. If there are particle generating appliances in the clean room or anteroom (such as a refrigerator), the equipment 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 particle counts and smoke testing performed while the equipment was in use and appliances are also part of the viable surface sampling program.	Unknown/Partially Compliant
25. 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.	Compliant
26. Pre-sterilization procedures that may generate particles (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.	Compliant
27. 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, bathroom door, food preparation areas, etc.) to limit potential contamination from being brought in through the entry. Required (by some states) a minimum distance of 10 feet. Cardboard. May use plastic sheeting.	Unknown/Partially Compliant
28. Maintaining Room Separation with Differential Air Pressure	
a. The anteroom and clean room are completely enclosed with doors and are equipped with monitors or gauges to measure differential pressure.	Compliant
b. The ante room is at least 0.02" w.c. positive pressure to general pharmacy areas. Note that some states have a maximum pressure limit.	Unknown/Partially Compliant
c. The buffer room is at least 0.02" w.c. positive pressure to the anteroom. Note that some states have a maximum pressure limit.	Unknown/Partially Compliant
d. Pressures are read and recorded each shift (minimum of once daily) or are continuously recorded. Continuously records with alerts.	Compliant
e. There is a plan in place to detect and react to pressure differentials outside of limits.	Compliant

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f. The doors into the anteroom from the general pharmacy area and from the anteroom into the clean room are prevented from both being open at the same time. By interlocking, or training of personnel and signage. Need signage/training to prevent.	Unknown/Partially Compliant
g. The inside and outside doors of a pass-through are prevented from both being open at the same time. By interlocking, or training of personnel and signage.	Compliant
h. Pass-throughs are located between outside areas and the anteroom, or between the anteroom and the buffer room. The pass-through is NOT between the buffer room directly to unclassified general pharmacy space (some states do not allow). This circumvents the stepped level of air quality. Allowed if the pass-through has HEPA filtered air and maintains at least ISO Class 8 air quality (ISO Class 7 if in negative pressure HD buffer room).	Compliant
i. Pressure differential monitoring equipment (gauges, probes) are periodically inspected, and verified as accurate or calibrated yearly or in accordance with the equipment manufacturer guidelines.	Noncompliant

29. Temperature and Humidity in the Cleanroom Suite:	
a. Temperature and humidity in the cleanroom suite must be controlled through a heating, ventilation, and air conditioning (HVAC) system.	Compliant
b. The cleanroom suite is maintained at a temperature of 20° or cooler and a relative humidity of 60% Buffer room, unknown anteroom	Unknown/Partially Compliant
c. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. Buffer room, unknown anteroom	Unknown/Partially Compliant
d. The results of the temperature and humidity readings must be documented at least once daily or stored in the continuous recording device and must be retrievable. Not in anteroom.	Noncompliant

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e. The temperature and humidity readings must be reviewed as described in the facility's SOPs. Address "dry place".	Unknown/Partially Compliant
f. There is a procedure for responding to excursions that includes evaluating the effect of the excursion on drug product integrity. Excursions are documented.	Compliant
g. Temperature and humidity monitoring devices must be calibrated or verified for accuracy at least every 12 months or as required by the manufacturer.	Unknown/Partially Compliant
30. Does the pharmacy store APIs and other components in an area outside the compounding suite?	No
31. Trash is disposed of in a safe, sanitary, and timely manner including hazardous waste. Waste of any component is disposed of in accordance with laws and regulations (EPA, state, locality). Watch process, don't tamp down or squeeze air out of bag.	Compliant
Compounding Equipment	
1. PECs are appropriately located in the compounding suite with regard to airflow and potential contamination (proximity to doors, etc.)	Compliant
2. Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.	Compliant
3. There is a procedure if a PEC is turned off (e.g., for maintenance) that includes when the unit will be turned back on, how long it must run before compounding, and that the interior must be fully cleaned and disinfected before compounding occurs.	Compliant
4. PEC pre-filters are checked and replaced regularly and documented. Documented on a log if replaced by staff or documented by the certification company.	Compliant
5. If the facility uses a Pharmaceutical Isolator for compounding, it must be placed in ISO Class 8 or better room (with or without an anteroom) and may be used for Category 2 CSPs.	N/A
6. The pharmacy uses a lyophilizer (freeze dryer).	No

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7. Scales, balances, or other equipment used for measurement are regularly calibrated, and validated at least annually. *If scales are NOT validated and sealed by a state or local weights and measures agency, describe procedure used.	Compliant
8. Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and verified as accurate or calibrated yearly or in accordance with the equipment manufacturer guidelines.	Unknown/Partially Compliant
9. Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) should be of suitable composition such that the surfaces that contact components are not reactive or sorptive. Supplies in direct contact with the CSP must be sterile and depyrogenated.	Compliant
10. The pharmacy uses Automated Compounding Devices (ACDs) for sterile compounding (such as repeater pumps).	Yes
a. There is an SOP for the use and calibration, and documentation of the ACD tubing being changed or discarded every 24 hours. Need to document.	Compliant
b. The ACD is used when performing media fill testing. Will add.	Unknown/Partially Compliant
c. Before using ACDs or other similar equipment, compounding personnel must conduct an accuracy assessment before the first use and again each day the equipment is used to compound CSPs.	Compliant
d. The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification.	Compliant
11. Robotics are used for sterile compounding and there is an SOP for the use, calibration, cleaning, and maintenance. Robotics are located in an ISO Class 5 PEC or enclosure.	N/A
Environmental Monitoring	
1. The most recent PEC and SEC certification reports is available.	Noncompliant

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2. Date of last certification:	November 3, 2023, July 31, 2023.
3. All ISO Class 7 and 8 SECs (buffer rooms, anterooms) have been certified every 6 months (view dates of last 2 or 3 certifications).	Compliant
4. All ISO Class 5 PECs have been certified every 6 months (view dates of last 2 or 3 certifications).	Compliant
5. Certification is performed whenever a device or room is moved, or major work is done to the space.	Compliant
6. The PIC 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.	Unknown/Partially Compliant
7. Certification of the rooms is performed to a standard such as (most common) the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted in the report. The designated person(s) is responsible for determining if the standards used are appropriate.	Compliant
8. The certification technician appropriately garbed and washed when entering clean rooms and appropriately cleaned and sanitized equipment then bringing into the SCA or compounding suite, transferring to a clean cart on the clean side of the line of demarcation, and again when introduced into the ISO Class 5 PEC.	Compliant
9. Certification technician performs viable testing first, to reduce contamination introduced by certification process.	Compliant
10. The certification report includes information about the equipment used for performing certification testing including identification of the equipment used by model, serial number, and last calibration date (or date when next calibration is due). Has air sampler equipment info.	Noncompliant
a. The equipment used had not exceeded its calibration date at the time of certification.	Unknown/Partially Compliant

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11. Testing that is required to be performed under "DYNAMIC" conditions are performed with the maximum number of staff that would be working in that area at one time. The certification technician does not count as one of the people. Document personnel.	Noncompliant
a. It is documented for the tests how many staff were present and what they were doing (donning garb, compounding in the hood using the repeater pump, etc.)	Noncompliant
12. ISO Class 5 pre-filter (if applicable) is inspected, indicated in the report if the pre-filter is replaced.	Noncompliant
13. HEPA filter air velocity measured.	Noncompliant
14. HEPA filter integrity test performed, if leaks found they are fixed, or the filter is replaced, and the filter retested.	Noncompliant
15. Particle counts performed to a plan. **• DYNAMIC test: Documentation of personnel and activity during test.** **• If there is equipment within the ISO 5 PEC, particle counts are performed while the equipment is running and in use (repeater pump, etc.)** **• Particles measured are those that are ≥0.5 µm in size.** **• ISO Class 5 PEC must not exceed 3,520 particles per cubic meter of air.**	Noncompliant
16. Smoke pattern testing was performed to confirm unidirectional flow at DCA. **• DYNAMIC test: Documentation of personnel and activity during test.** **• Smoke pattern testing is video recorded (required in some states) or the smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, and the approximate area of the DCA (e.g., turbulent 3 inches from the back, 6 inches from the front, 2 inches from the sides and the equipment in the hood).** **• If there is equipment within the ISO 5 PEC, smoke testing is performed while the equipment is running and in use (repeater pump, etc.)**	Noncompliant
17. ISO Class 7 or 8 SEC ceiling HEPA filter(s) air velocity measured to calculate ACPH.	Noncompliant
18. Ceiling HEPA filter integrity test performed, if leaks found they are fixed, or the filter is replaced, and the filter retested.	Noncompliant

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19. Particle counts performed to a plan. **• DYNAMIC test: Documentation of personnel and activity during test.** **• Particle counts performed around particle generating equipment while running (printers printing, prop the door open on refrigerator so compressor kicks on, etc.)** **• Particles measured are those that are ≥0.5 µm in size.** **• ISO Class 7 SEC must not exceed 352,000 particles per cubic meter of air.** **• ISO Class 8 SEC must not exceed 3,520,000 particles per cubic meter of air.**	
20. Smoke pattern testing was performed around all openings to confirm air flow. **• DYNAMIC test: Documentation of personnel and activity during test.** **• Smoke pattern testing is video recorded (required in some states) or the smoke flow is described in the report** **• Smoke pattern testing performed around particle generating equipment while running (printers printing, prop the door open on refrigerator so compressor kicks on, etc.)**	Noncompliant
21. Air pressure differentials are measured. **• DYNAMIC test: Documentation of personnel and activity during test.** **• Positive pressure measured from the buffer room to the anteroom must be ≥ 0.020”wc.** **• Positive pressure measured from the anteroom to unclassified space must be ≥ 0.020”wc.** **• Magnahelic air pressure differential gauges, or electronic equipment/probes are calibrated or verified as accurate and adjusted if needed.**	Noncompliant
22. Smoke studies and viable environmental (viable) monitoring is repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, change of HEPA filter units).	Noncompliant
23. Failed testing is evaluated by the designated person(s) and corrective action taken which may include suspending compounding until the issue is remediated.	Unknown/Partially Compliant
Viable Air Sampling	
1. If viable air sampling is outsourced, the designated person ensures the sampling is performed to the requirements of USP <797>, state regulations, and the facility SOPs.	Compliant

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2. If viable air sampling is performed in house, personnel have been appropriately trained and the process has been validated. Needs to validate self-testing.	Unknown/Partially Compliant
3. Volumetric active air sampling of all classified areas using an impaction air sampler are conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions.	Compliant
4. Each classified area, PEC, and SEC must be sampled for viable airborne particles to assess microbiological air quality in all classified areas.	Compliant
5. For entities compounding Category 1 and Category 2 CSPs, this must be completed at least every 6 months.	Compliant
6. Viable air sampling of PECs and SECs must also occur: **• In conjunction with the certification of new facilities and equipment** **• After any servicing of facilities or equipment** **• In response to identified problems (e.g., positive growth in sterility tests of CSPs)** **• In response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination)** **• In response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents)**	Compliant
7. Sampling is performed using a volumetric active air impaction sampling device, testing at least 1000 L of air (1 cubic meter) at each sampling location.	Compliant
8. Sampling is detailed in the SOP and can be accomplished one of three ways: **• Sample with a TSA plate. Samples are incubated at 30 - 35ºC for no less than 48 hours and then incubated at 20 - 25ºC for no less than 5 additional days (to grow fungal contamination** **• Sample with two TSA plates. The first sample is incubated at 30 - 35ºC for no less than 48 hours and concurrently, the second sample is incubated at 20 - 25ºC for no less than 5 days. This cuts down the total time.** **• Sample with a TSA plate and an MEA or SDA plate incubating the TSA at 30 - 35ºC for no less than 48 hours and the MEA or SDA plate incubated concurrently at 20 - 25ºC for no less than 5 days.** Single TSA at two temps	Compliant

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9. Sampling flows from clean to dirty areas (PECs, then ISO Class 7 buffer room, then ISO Class 7 or 8 anteroom).	Compliant
10. A sampling plan or map is developed and followed that includes: **• The interior of the PEC** **• Both chambers of a CAI or CACI, all chambers of a pharmaceutical isolator.** **• Specific areas within the anteroom** **• Specific areas within the buffer room** **• The interior of any passthrough chambers.**	Compliant
11. Sampling must occur during dynamic conditions, meaning that personnel are working in the areas to be sampled, this is documented. Typically performed towards the end of the shift but before cleaning and sanitizing activities are performed. Record personnel present and activity.	Unknown/Partially Compliant
12. Sampling is documented including the identity, lot numbers, and expiration dates of media used, media COAs or other documentation to show the media is sterile, and that it will support growth.	Compliant
13. Action levels: **• ISO Class 5 PEC Action Level: >1 CFU/plate** **• ISO Class 7 SEC Action Level: >10 CFUs/plate** **• ISO Class 8 SEC Action Level: >100 CFUs/plate**	Compliant
14. The designated person(s) also evaluates CFU counts against previous data to identify trends even if the action level has not been exceeded.	Unknown/Partially Compliant

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15. If action levels are exceeded: **• The cause must be investigated, and corrective action must be taken.** **• An attempt must be made to identify any microorganisms recovered to the genus level.** **• Investigation includes other monitoring documentation (temperature, humidity, differential pressure, certification reports, cleaning records, equipment maintenance logs, etc.) and includes personnel performance and competency.** **• The extent of the investigation should be consistent with the deviation and should include an evaluation of trends.** **• The corrective action plan must be dependent on the CFU count and the microorganism recovered. Corrective action may include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair. The plan may require compounding to be limited or cease until remediated. The corrective action plan is be documented.** **• Data collected in response to corrective actions is reviewed to confirm that the actions taken have been effective. For example, after the corrective action, the air is sampled weekly and is below action limits three times in succession.**	Unknown/Partially Compliant
Viable Surface Sampling	
1. If viable surface sampling is outsourced, the designated person ensures the sampling is performed to the requirements of USP <797>, state regulations, and the facility SOPs.	Compliant
2. If viable surface sampling is performed in house, personnel have been appropriately trained and the process has been validated.	Unknown/Partially Compliant
3. Media must be incubated at the two different temperatures (not appropriate to leave at "room temperature"). The facility has two incubators or has a way to specifically schedule all viable samples for the lengths of time they are to be incubated at the two different temperatures.	Compliant
4. Incubators are NOT located within the ISO Classified space.	Compliant
5. Each classified area, PECs and SECs, must be sampled for microbial contamination. Sampling occurs at the end of the shift before cleaning and sanitizing is performed.	Compliant

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6. Performed monthly for compounding Category 1 and 2 CSPs	Compliant
7. Surface sampling of PECs and SECs must also occur: **• In conjunction with the certification of new facilities and equipment** **• After any servicing of facilities or equipment** **• In response to identified problems (e.g., positive growth in sterility tests of CSPs)** **• In response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination)** **• In response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents)**	Compliant
8. Surface sampling of the DCA within the PEC occurs: **• After completing a media-fill test as part of the aseptic compounding competency before gloves or work surfaces are cleaned or sanitized.** **• With every Category 3 CSP compounded, at the end of each batch before gloves or work surfaces are cleaned or sanitized.** **• If an enclosed robotic device is used for compounding Category 3 CSPs, at least once daily at the end of compounding operations before cleaning and disinfection occurs.**	Compliant
9. Surface sampling media used includes additives (such as lecithin and polysorbate 80) to neutralize cleaning product residue.	Compliant
10. Sampling is detailed in the SOP and can be accomplished one of three ways: **• Sample with a TSA plate. Samples are incubated at 30 - 35ºC for no less than 48 hours and then incubated at 20 - 25ºC for no less than 5 additional days (to grow fungal contamination** **• Sample with two TSA plates. The first sample is incubated at 30 - 35ºC for no less than 48 hours and concurrently, the second sample is incubated at 20 - 25ºC for no less than 5 days. This cuts down the total time.** **• Sample with a TSA plate and an MEA or SDA plate, incubating the TSA at 30 - 35ºC for no less than 48 hours and the MEA or SDA plate incubated concurrently at 20 - 25ºC for no less than 5 days.** Single plate at two temps	Compliant

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11. Sampling flows from clean to dirty areas (PECs, then ISO Class 7 buffer room, then ISO Class 7 or 8 anteroom).	Compliant
12. A sampling plan or map is developed and followed that includes: **• The DCA in the interior of the PEC** **• Equipment within the PEC** **• Both chambers of a CAI or CACI, all chambers of a pharmaceutical isolator.** **• Staging or work areas near the PEC – tables, counters, etc.** **• Frequently touched areas in the SEC – door jamb, shelving, etc.** **• The interior of any passthrough chambers.**	Compliant
13. Sampling must occur during dynamic conditions, meaning that personnel are working in the areas to be sampled, this is documented. Typically performed towards the end of the shift but before cleaning and sanitizing activities are performed. Needs to document personnel.	Unknown/Partially Compliant
14. Sampling is documented including the identity, lot numbers, and expiration dates of media used, media COAs or other documentation to show the media is sterile, and that it will support growth.	Compliant
15. Action levels: **• ISO Class 5 PEC Action Level: >3 CFUs/plate** **• ISO Class 7 SEC Action Level: >5 CFUs/plate** **• ISO Class 8 SEC Action Level: >50 CFUs/plate**	Compliant
16. The designated person(s) also evaluates CFU counts against previous data to identify trends even if the action level has not been exceeded.	Unknown/Partially Compliant

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17. If action levels are exceeded: **• The cause must be investigated, and corrective action must be taken.** **• An attempt must be made to identify any microorganisms recovered to the genus level.** **• Investigation includes other monitoring documentation (temperature, humidity, differential pressure, certification reports, cleaning records, equipment maintenance logs, etc.) and includes personnel performance and competency.** **• The extent of the investigation should be consistent with the deviation and should include an evaluation of trends.** **• The corrective action plan must be dependent on the CFU count and the microorganism recovered. Corrective action may include process or facility improvements, personnel training, cleaning, and disinfecting, or HEPA filter replacement and/or repair. The plan may require compounding to be limited or cease until remediated. The corrective action plan is documented.** **• Data collected in response to corrective actions is reviewed to confirm that the actions taken have been effective. For example, after the corrective action, the air is sampled weekly and is below action limits three times in succession.**	Unknown/Partially Compliant

Category 1 or 2 CSPs - Section V: Cleaning and Sanitizing	
1. All personnel performing cleaning observe appropriate personal hygiene, hand hygiene and are appropriately garbed. If working overhead, goggles are worn.	Compliant
2. Supplies: **a. All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads) are low lint.** **b. Mop handles and tool handles are not made of wood. Handles are cleaned and disinfected before and after each use.** **c. Cleaning tools will be stored in the room in the cleanroom suite in which they are used and not removed from the areas unless they are being disposed of.**	Compliant

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3. Agents: **a. Appropriate cleaning and sanitizing agents are used that are effective for bacteria, viruses, fungi, and spores.** **b. Surfaces are cleaned prior to being disinfected with an EPA-registered disinfectant or an EPA-registered one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step. Note: Alcohol is NOT a cleaning agent.** **c. A sporicidal disinfectant is also used. Some EPA-registered one-step disinfectant cleaners may have sporicidal properties.** **d. If cleaning and sanitizing agents are not premixed, there are formulas and instructions for mixing or diluting the agents prior to use, and for documentation.**	Compliant
4. Products (including cleaning and disinfecting agents, packages of wipers, etc.) must be marked with the date opened or first used and the date after which they should not be used once opened (beyond use date).	Noncompliant
5. Cleaning proceeds from the cleanest to dirtiest, and top to bottom. Floors are cleaned last.	Compliant
6. Cleaning activities and application of a sporicidal are documented.	Compliant
7. PEC: Cleaning the PEC interior including equipment: **• Cleaning and disinfection: daily on days of compounding and if contaminated.** **• Sporicidal monthly (Category 1 and 2)**	Compliant
8. PEC: Cleaning the PEC removable work tray: **• Surface cleaning and disinfection: daily on days of compounding.** **• Underneath the tray cleaned and disinfected monthly.** **• Sporicidal monthly (surface and underneath) (Category 1 and 2)**	Compliant

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9. PEC: All items entering the PEC must be sterile. **• Cleaning and disinfecting supplies used in the PEC must be sterile.** **• Tool handles and holders are cleaned and disinfected prior to use in a PEC.** **• Cleaning and disinfecting agents used in the PEC must be sterile. If they are not premixed, sterile water must be used in preparing the agents.**	Compliant
10. PEC: Cleaning steps are observed: **• Clear the PEC of trash and supplies.** **• Clean the surface with sterile water or a detergent with surfactant to remove soil and residues.** **• Disinfect using an appropriate agent. Observe dwell times.** **• Apply sporicidal agent. Observe dwell times.** **• Sterile 70% IPA is then applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue and allowed to dry.**	Compliant
11. PEC: When compounding in the PEC, wipe down the horizontal work surface in the PEC including the removable work tray with sterile 70% IPA: **• Before starting compounding** **• At least every 30 minutes if compounding takes 30 minutes or less.** **• Immediately after compounding** **• These cleaning activities during compounding do not need to be documented on the cleaning log.**	Compliant
12. SEC: Daily cleaning and disinfecting on days of compounding or if contaminated: **• Pass through chamber** **• Work surfaces outside the PEC** **• Reusable garb (goggles, etc.)** **• Sink surfaces** **• Floors** Add reusable garb.	Compliant
13. SEC: Monthly cleaning and disinfecting: **• Walls, doors, doorframes, exterior of PECs** **• Ceilings in ISO Class 7 or 8 SEC** **• Storage shelving, bins, tables** **• Other equipment (carts, stools, trash bins, refrigerators etc.)**	Compliant

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14. SEC: Monthly sporicidal applied to: **• Pass through chamber** **• Work surfaces outside the PEC** **• Sink surfaces** **• Floors** **• Walls, doors, doorframes, exterior of PECs** **• Ceilings in ISO Class 7 or 8 SEC** **• Storage shelving, bins, tables** **• Other equipment (carts, stools, trash bins, refrigerators, etc.)**	Compliant
15. If fatigue mats are used, they are cleaned, disinfected and sporicidal applied on the same schedule as the floors. Must clean and let mats dry on both sides, and the area underneath is cleaned.	N/A
16. The tacky mat is located outside of the ISO spaces (anteroom and clean room). There is a procedure for placement of a tacky mat, and frequency of replacement.	Compliant
17. Sufficient time is allocated and scheduled for cleaning activities.	Compliant
18. There is a waste disposal system in place.	Compliant
Category 1 or 2 CSPs - Section VI: Training and Competency	
1. Personnel performing compounding and personnel who have direct oversight of compounding personnel must successfully complete training and competencies before performing compounding or supervising compounding.	Compliant
2. If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements.	N/A
3. Initial training and competencies are performed and documented.	Unknown/Partially Compliant
a. Core Skills and SOP training **• Written test**	Unknown/Partially Compliant
b. Garbing and Hand Hygiene training and competencies **• Observational Competency** **• Gloved Fingertip and Thumb Sampling (GETS), 3 times in succession** 3 initial.	Unknown/Partially Compliant

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c. Aseptic Technique training and competencies **• Observational Competency** **• Media Fill Test** **• Surface sampling** **• Gloved Fingertip and Thumb Sampling**	Compliant
4. Ongoing training and competencies are performed and documented.	Compliant
a. Core Skills and SOPs, written test: Every 12 months	Unknown/Partially Compliant
b. Garbing and Hand Hygiene competencies (with single GFTS test): **• Every 12 months – direct oversight, no compounding** **• Every 6 months – Compounding Category 1 or 2 CSPs**	Compliant
c. Aseptic Technique competencies (with media fill, GFTS, and surface sample) **• Every 12 months – direct oversight, no compounding** **• Every 6 months – Compounding Category 1 or 2 CSPs**	Compliant
5. Training and competency is required for others involved in compounding. If using other folks.	Unknown/Partially Compliant
a. Persons performing in-process checks, final verification, and dispensing of CSPs. **• Initial and annual for items that apply to their position, detailed in SOPs (Core skills, SOPs, USP, compounding documentation, final release checks and tests, etc.)**	Unknown/Partially Compliant
b. Persons performing cleaning and disinfecting of sterile compounding areas (may be compounding personnel, or personnel dedicated to cleaning activities), and others that enter the classified compounding areas (performing stocking, etc.) receive the training appropriate for their duties. **• Initial and annual for items that apply to their position, detailed in SOPs.** **• Includes hand hygiene and garbing, cleaning, and disinfection.**	Unknown/Partially Compliant
6. If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. View documentation.	N/A

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7. Core skills training includes: **• Hand hygiene Garbing** **• Cleaning and disinfection** **• Calculations, measuring, and mixing.** **• Aseptic technique** **• Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)** **• Use of equipment** **• Documentation of the compounding process (e.g., master formulation and compounding records)** **• Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area PEC** **• Proper use of PECs** **• Principles of movement of materials and personnel within the compounding area**	Compliant
8. Gloved Fingertip and Thumb Sampling Procedures are detailed in the SOP. Includes:	Compliant
a. Using one sampling media device (e.g., plates, paddles, or slides) per hand.	Compliant
b. Using general microbial growth agar (e.g., trypticase soy agar [TSA]) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) as this agar supports both bacterial and fungal growth.	Compliant
c. Sampling occurs BEFORE gloves are sanitized with sterile 70% IPA.	Compliant
d. Collect samples from all gloved fingertips and thumbs from both hands by rolling fingertip pads and thumb pad over the agar surface.	Compliant
e. Incubate the media device at 30°–35° for no less than 48 h and then at 20°–25° for no less than 5 additional days. Samples must be inverted and incubated in an incubator.	Compliant
f. Record the number of CFU per hand (left hand, right hand). **• Determine whether the CFU action level is exceeded by counting the total number of CFU from both hands.** **• Action Level for Garbing Competency: > 0 CFU total from both hands** **• Action Level for Aseptic Technique Competency: > 3 CFU total from both hand**	Compliant

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g. A test failure will require the test to be repeated. The designated person(s) will determine if any remediation may be required (training, etc.) before the test is repeated.	Compliant
h. The personnel that failed the test will not be allowed to compound, or supervise compounding, until remediation is completed, and a successful gloved fingertip and thumb test is achieved.	Compliant
9. Media Fill Testing Procedures are detailed in the SOP. Includes:	Compliant
a. If all of the starting components are sterile to begin with, manipulate them in a manner that simulates sterile-to-sterile compounding activities, and transfer the sterile soybean–casein digest media into the same types of container closure systems commonly used at the facility. Do not further dilute the media unless specified by the manufacturer.	N/A
b. If some of the starting components are nonsterile to begin with, dissolve a commercially available nonsterile soybean–casein digest powder in nonbacteriostatic water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities.	Compliant
c. The media fill test includes the most complex compounding performed, in the appropriate volume, and using any equipment or automation.	Compliant
d. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.	Compliant
e. Once the compounding simulation is completed and the final containers are filled with the test media, perform a gloved fingertip and thumb sample on each hand and surface sample of the direct compounding area inside the PEC. Take the samples prior to disinfecting gloves and PEC. Handle and store samples to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the CFU reading (e.g., invert containers).	Compliant

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f. Incubate the final containers at 20°–25° and 30°–35° for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the SOPs (recommend higher temperature first, then lower temperature). Final containers must be incubated in an incubator.	Compliant
g. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.	Compliant
h. A test failure (media fill, GFTS, and/or surface sampling) will require the test to be repeated. The designated person(s) will determine if any remediation may be required (training, etc.) before the test is repeated.	Compliant
i. The personnel that failed the test will not be allowed to compound, or supervise compounding, until remediation is completed, and a successful test is achieved.	Compliant
Category 1 or 2 CSPs - Section VII: Personal Hygiene and Garbing	
1. Personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections must report to the designated person(s) who will evaluate whether the person is excluded from compounding until the condition resolves.	Compliant
2. No food (including mints, gum, etc.) or drinks are allowed in the anterooms, buffer rooms, or segregated compounding areas.	Compliant
3. Personnel remove items that are not easily cleanable or are not necessary for compounding. At a minimum, individuals must: **• Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)** **• Remove all cosmetics because they shed flakes and particles (including false eyelashes)** **• Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection)** **• Cover any jewelry that is permanent and cannot be removed (if it can be removed, it should be removed).**	Compliant
4. Shoes and socks must be worn. Socks are tall enough, so no skin is exposed at the ankle	Compliant

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5. No earbuds or headphones allowed.	Compliant
6. No electronic devices that are not necessary for compounding or other required tasks into the compounding area.	Compliant
7. Fingernails are clean, short, and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails, and extenders) must not be worn.	Compliant
8. Eyeglasses and hearing aids are cleaned or wiped down with sterile 70% IPA, if worn.	Compliant
9. The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected	Compliant
10. Garb is available and includes: **• Low-lint knee-length garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall)** **• Low-lint covers for shoes** **• Low-lint cover for head that covers the hair and ears,** **• Low-lint cover for facial hair** **• Low-lint face mask** **• Sterile powder-free gloves**	Compliant
11. Garb is not stored near the sink to avoid contamination by splashing water. Move gloves.	Unknown/Partially Compliant
12. Personnel do not don garb at the same time another is doffing garb.	Compliant
13. The order of donning garb is dependent on the location of the handwashing sink and the line of demarcation. The order must be detailed in the SOP.	Compliant
14. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.	N/A
15. Disposable soap containers must not be refilled or topped off.	Compliant

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16. Donning garb. • **Don a bouffant cap to cover all hair and ears. Check in the mirror to ensure all hair is contained and covered.** • **Don a surgical mask.** • **Don a facial hair cover if appropriate for facial hair, or sideburns that extend beyond the bouffant cap. This applies to males and females. Note that the beard cover may be worn over or under the surgical mask.** • **Don a shoe cover over each shoe while stepping over the line of demarcation (LOD), taking care that the shoe does not touch the floor on the clean side of the LOD and the covered shoe does not touch the floor on the dirty side of the line of demarcation.** • **Repeat with the other shoe.** Mirror. All hair covered. Needs LOD.	Noncompliant
17. Perform hand hygiene: • **Clean underneath fingernails under warm running water using a disposable nail cleaner.** • **Keeping your hands above the level of your elbows, wash hands starting at the fingers and working down the forearms to the elbows with soap and water for at least 30 seconds. Time the washing using a clock or timer located near and visible when at the sink.** • **Do not use a brush to scrub your skin, this will create more skin shedding.** • **Do not shake water off your hands. Keep hands above the level of your elbows so water does not run down and drip off your fingers.** • **Using low-lint disposable towels or wipers, dry completely from your hands down to elbows.** Need disposable nail picks. Sink not big enough or faucet tall enough.	Noncompliant
18. Don the gown, taking care that no part of the gown or sleeves touches the floor.	Compliant
19. Apply alcohol-based hand rub to one hand and rub hands together, covering all surfaces of hands and fingers until hands are dry. Allow hands to dry thoroughly before donning sterile gloves.	Unknown/Partially Compliant

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20. Gloves: • **Select the appropriate size of sterile gloves.** • **Open the package of sterile gloves on a flat surface and inspect for defects.** • **Don sterile gloves using aseptic technique.** • **Gloves must NOT be donned or doffed inside the ISO Class 5 primary control engineering exposing bare skin.** • **Enter the buffer room.** • **If using a RABS PEC, sterile gloves must be donned over the gloves on the gauntlets inside the RABS. This is in addition to the gloves worn on your hands inside the gauntlets.** • **Apply sterile 70% IPA to gloves immediately after donning is completed, and regularly throughout the compounding process and whenever nonsterile surfaces (e.g., vials, counter tops, chairs, or carts) are touched, or the gloves leave and re-enter the ISO Class 5 PEC.** Using nonsterile gloves and later covers with sterile gloves. Technique sloppy - careful when handling cuffs.	Unknown/Partially Compliant
21. Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Gloves are changed if torn, punctured or contaminated.	Compliant
22. Doffing garb • **When personnel exit the compounding area, gowns may be hung up in the anteroom and used during the same shift before being discarded.** • **All other disposable garb is discarded.** • **Shoe covers remain on the shoes while on the clean side of the LOD and may be removed and discarded once on the dirty side of the LOD.** • **Shoe covers are not worn outside the compounding area to prevent tracking residue into other areas.** • **Non-disposable garb such as goggles, full face masks, or shields, must be placed in an area or bin marked for used garb and cleaned and sanitized during the daily cleaning at the end of the day.**	Compliant
23. 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.	Compliant
24. Pharmacists or other personnel do NOT enter the clean room without fully washing and garbing (wearing just a mask to check technician's	Compliant

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Category 1 or 2 CSPs - Section VIII: Master Formula Record (MFR) and Compounding Record (CR)

Creating Master Formulation Records - A master formulation record (MFR) is a detailed record of procedures that describes how the CSP is to be prepared.

1. An MFR must be created for all CSPs prepared from nonsterile ingredient(s)	Compliant
2. An MFR must be created for CSPs prepared for more than one patient.	Compliant
3. Any changes or alterations to the MFR must be approved and documented according to the facility's SOPs.	Compliant
4. The MFR must include at least the following information: **• Name, strength or activity, and dosage form of the CSP** **• Identities and amounts of all ingredients; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility)** **• Type and size of container closure system(s)** **• Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions.** **• Physical description of the final CSP** **• BUD and storage requirements** **• Reference source to support the stability of the CSP** **• Quality control (QC) procedures (e.g., pH testing, filter integrity testing)** **• Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter)** Specific equipment.	Unknown/Partially Compliant

Creating Compounding Records - A CR documents the compounding of each CSP.

1. A CR is created for all Category 1 and Category 2 CSPs.	Compliant
2. A prescription or medication order or label may serve as the CR. The CR information may be kept electronically. An MFR can serve as the basis for preparing the CR.	Compliant

3. CRs must include at least the following information: **• Name, strength or activity, and dosage form of the CSP** **• Date and time of preparation of the CSP** **• Assigned internal identification number (e.g., prescription, order, or lot number)** **• A method to identify the individuals involved in the compounding process and individuals verifying the final CSP** **• Name of each component** **• Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s)** **• Weight or volume of each component** **• Strength or activity of each component** **• Total quantity compounded.** **• Final yield (e.g., quantity, containers, number of units)** **• Assigned BUD and storage requirements.** **• Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing)**	Compliant
4. If applicable, the CR must also include: **• MFR reference for the CSP** **• Calculations made to determine and verify quantities and/or concentrations of components.**	Compliant
Category 1 or 2 CSPs - Section IX: Beyond Use Dating (BUD)	
1. Establishing BUDs. BUDS are established and assigned based on stability and sterility. Factors considered include: **• The chemical and physical properties of the drug and/or its formulation, and if any starting components are nonsterile.** **• The compatibility of the container–closure system with the finished preparation (e.g., leachable, interactions, storage conditions (e.g., if freezing will damage the closure), degradation of the container-closure system)** **• Environmental conditions in which the CSP is prepared, storage conditions (colder temperatures have longer BUDs as microbial growth is slowed), and packaging.** **• Aseptic processing and sterilization method(s) used and whether sterility testing is performed.**	Compliant

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2. Storage Conditions. CSPs may be stored under different storage conditions before they are used (e.g., CSPs may first be frozen, then thawed in the refrigerator, and finally kept at controlled room temperature before administration). **• The CSP must be thawed in appropriate conditions. Do not heat in a microwave.** **• Once the CSP is thawed, the CSP must not be refrozen.** **• The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage condition.** **• BUDs must NOT be additive. For example, an aseptically processed CSP prepared from one or more nonsterile starting component(s) cannot be stored for 45 days in a freezer, then 4 days refrigerated, and then 24 h at controlled room temperature for a total of 50 days.** **• Once a CSP has been stored under a condition that would require a shorter BUD (e.g., controlled room temperature), the CSP must be used within the time frame for THAT storage condition (in the previous example, 24 h).** **• The CSP formulation must remain chemically and physically stable, and its packaging must maintain its integrity for the duration of the BUD.**	Compliant
3. BUDs for Category 1 CSPs **• Controlled Room Temperature (20°–25°): BUD ≤12 h** **• Refrigerator (2°–8°): BUD ≤24 h**	N/A

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4. BUDs for Category 2 CSPs **a. Aseptically processed, made from one or more NONSTERILE starting components, no sterility testing** **• Controlled Room Temperature (20°–25°): 1 day** **• Refrigerator (2°–8°): 4 days** **• Freezer (−25° to −10°): 45 days** **b. Aseptically processed, made from only STERILE starting components, no sterility testing** **• Controlled Room Temperature (20°–25°): 4 days** **• Refrigerator (2°–8°): 10 days** **• Freezer (−25° to −10°): 45 days** **c. Aseptically processed, sterility testing performed and passed** **• Controlled Room Temperature (20°–25°): 30 days** **• Refrigerator (2°–8°): 45 days** **• Freezer (−25° to −10°): 60 days** **d. Terminally sterilized, no sterility testing performed** **• Controlled Room Temperature (20°–25°): 14 days** **• Refrigerator (2°–8°): 28 days** **• Freezer (−25° to −10°): 45 days** **e. Terminally sterilized, sterility testing performed and passed** **• Controlled Room Temperature (20°–25°): 45 days** **• Refrigerator (2°–8°): 60 days** **• Freezer (−25° to −10°): 90 days**	Compliant
5. Shorter BUD **• A shorter BUD must be assigned when the stability of the CSP or its components is less than the USP BUDs** **• The BUD must not exceed the shortest remaining expiration date of any of the commercially available starting components.** **• For CSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions).** **• If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP is not be negatively impacted.**	Compliant

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Phone: 978-646-0091

6. Longer BUD **• Category 1 CSPs may not be assigned longer BUDs. Category 1 CSPs may be prepared in a cleanroom suite. The BUDs in the table are the maximum BUDs permitted.** **• Category 2 CSPs may not be assigned longer BUDs. Category 2 CSPs must be prepared in a cleanroom suite. The BUDs in the table are the maximum BUDs permitted.**	Compliant
8. Multiple-Dose CSPs	
Does the pharmacy compound multiple-dose CSPs?	Yes
Multiple-dose CSP containers are designed to include more than one dose and be entered/penetrated multiple times.	
a. Compounded as a Category 2 CSP with appropriate BUDs assigned.	Compliant
b. After a multiple-dose CSP container is initially entered or punctured, the multiple-dose container must not be used for longer than the assigned BUD or 28 days if supported by antimicrobial effectiveness testing results on the CSP, whichever is shorter.	Compliant
9. Preservatives **• Used to inhibit growth of microorganisms and minimize contamination risk.** **• Must be appropriate for the CSP formulation (e.g., not inactivated by the other ingredients in the CSP, appropriate for intended patient such as neonates)** **• Must be appropriate for the route of administration (e.g., intrathecal, ophthalmic injection)** **• Preservatives are not a substitute for aseptic technique.**	Compliant

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10. Antimicrobial Effectiveness Testing **Aqueous multiple dose CSPs must pass antimicrobial effectiveness testing (USP Chapter <51>). You may use testing:** **• Conducted (or contracted for) once for each formulation in the particular container closure system in which it will be packaged.** **• Results from an FDA-registered facility or published in peer-reviewed literature sources, provided that the CSP formulation and container closure system are exactly the same as those tested.** **• Results of a bracketing study from an FDA-registered facility or published in peer-reviewed literature. Antimicrobial effectiveness testing is on a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives), as well as the container closure system used.**	Noncompliant
11. Container-Closure Testing **• Performed once per formulation and fill volume in the specific container-closure system in which the multiple-dose CSP will be packaged. Must conform to container closure integrity to the end of the BUD. USP <1207> "Package Integrity Evaluation – Sterile Products".**	Noncompliant
12. The facility compounds multiple-dose, non-preserved, aqueous topical, and topical ophthalmic, CSPs	No
13. Vial and Bag Docking **• Docking and activation of proprietary bag and vial systems for immediate administration to a single patient is not considered sterile compounding and the BUD used is supplied by the manufacturer (on the label or in the labeling) as long as the manufacturer instructions are followed.** **• Docking of the proprietary bag and vial systems for future activation and administration IS considered compounding and must be performed in an ISO Class 5 environment in accordance with this chapter, with the exception of BUDs. Beyond-use dates (BUDs) for proprietary bag and vial systems must be the lesser of USP per appropriate Category, or as specified in the manufacturer's labeling.**	N/A
Category 1 or 2 CSPs - Section X: Compounding Procedures	
1. The appropriate components and supplies are gathered, examined for damage or other signs the quality has been compromised, and positively identified as correct.	Compliant

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2. Category 1 and Category 2 CSPs can be compounded by using only sterile starting ingredients, or by using some or all nonsterile starting ingredients. **• If all components used to compound are sterile from the start, the sterility of the components must be maintained during compounding to produce a CSP.** **• If one or more of the starting components being used to compound is not sterile, the sterility of the compounded preparation must be achieved through a sterilization process (e.g., terminal sterilization in the final sealed container) or sterilizing filtration, and then sterility must be maintained if the CSP is subsequently manipulated.**	Compliant
3. If preparing Category 2 CSPs from nonsterile component(s), presterilization procedures, such as weighing and mixing, must be completed in an ISO Class 8 or better environment (e.g., anteroom or buffer room). **• Presterilization procedures that may generate airborne particles are performed in single-use containment glove bags, containment ventilated enclosures (CVEs), BSCs, or CACIs to minimize the risk of airborne contamination. CVEs, BSCs, or CACIs used for presterilization procedures are be certified at least every 6 months.** **• If not performed under containment, there is a process evaluation carried out and documented according to the SOPs.** **• Presterilization procedures must not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions.** **• Personnel must follow the hygiene and garbing requirements and garbing during presterilization procedures.**	Compliant
4. Compounding is performed according to the MFR/CR (if used).	Compliant
5. Appropriate information is documented on the compounding record including any in-process checks.	Compliant
6. Moving materials and supplies into the sterile compounding suite and PEC: **a. Ensure that materials exposed in patient care and treatment areas are never introduced into areas where components and ingredients for CSPs are present.**	N/A

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b. Ensure that the cart or conveyance that is used to transport components of CSPs or materials from the non-ISO controlled areas do not cross the Line of Demarcation separating the "Clean" side of the Ante area from the "Dirty" side.	N/A
c. Ensure that the clean cart or conveyance that is used to transport components of CSPs or materials from the Buffer areas do not cross the Line of Demarcation separating the "Clean" side of the Ante area from the "Dirty" side.	N/A
d. Immediately before any item or equipment is introduced into the clean side of the anteroom or placed into pass-throughs, supplies are decontaminated by wiping with a non-linting wipe saturated in a sporicidal agent, EPA-registered disinfectant, or sterile 70% IPA. Ensure minimum contact time of the disinfectant shall be followed according to the manufacturers' directions, validation studies or published data.Personnel performing this task must be aware of the agent currently in use and gloves must be worn.	Compliant
e. Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for scheduled operations during a shift may be decontaminated and stored on shelving in the anteroom (No hazardous drugs may be stored in the anteroom).	Compliant
f. Ensure that nonessential objects that shed particles are not brought into the buffer area, including but not limited to pencils, cardboard cartons, dry erase pens or boards, paper towels, and cotton items (e.g. gauze pads).	Compliant
g. Ensure that compounding Records are contained in a protective sleeve and are wiped down.	Compliant
h. Immediately before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low lint wipers and allowed to dry. • Wiping must not render labels unreadable. • Sterile items in sealed containers designed to keep them sterile until opening, may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA.	Compliant

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7. When working in a PEC, the following should be avoided: **• Leaning into or over the work area** **• No bare skin enters the PEC (head when reaching to clean, donning gloves in the PEC, etc.)** **• Blocking "First Air" between sanitized and/or open containers.** **• Resting hands or forearms on the work area.** **• Coughing over the work area.** **• Placing objects against the back or side wall of the PEC.** **• Rapid movement in the direct compounding area (DCA).** **• Using a PEC as a storage space when not in use.** **• Storing personal items in the sterile compounding suite.** **• Performing any activities unrelated to compounding.**	Compliant
8. Aseptic Technique in the PEC **• Objects placed in the PEC should be positioned to allow sufficient airflow with minimal obstruction. A direct path must be maintained between the HEPA filter and the area inside the PEC where manipulations are being performed. Avoid placing large objects in the back of the PEC.** **• Always minimize clutter in the PEC.** **• Items unrelated to compounding should never enter the PEC.** **• Work should always be performed approximately in the center of the work surface in the DCA.** **• Gloves are sanitized with sterile 70% IPA every time the hand leaves the ISO Class 5 PEC and re-enters. Gloves are allowed to dry before commencing or resuming compounding.**	Compliant

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9. Syringes and Needles **• Commercially sterilized, disposable, and latex-free syringes with a locking mechanism for needles should be used to compound sterile preparations.** **• To maximize accuracy, the smallest syringe that can hold a desired amount of solution shall be used.** **• After proper sanitizing of the exterior package of the syringe, the syringe shall be removed from the protective syringe package in the PEC.** **• Needles shall be selected and opened following the same procedure for selecting/opening syringes.** **• To maintain sterility, two parts of the needle shall never be touched or swabbed with alcohol: (1) the hub and (2) the shaft.** **• Critical sites must be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA must be allowed to dry before entering or puncturing stoppers/septum or breaking the necks of ampules.** **• Used needles shall be placed in an appropriate medical sharps container. Once the medical sharps container has reached the maximum fill limit, it shall be discarded in accordance with local regulation.**	Compliant
10. Sterile Compounding Equipment and Materials **• Check the expiration dates when using autoclaved equipment.** **• Ensure the color indicator (if applicable) has changed to the proper color indicating sterilization has occurred.** **• When removing the autoclave wrapping, handle the material with gloved hands and with minimal manipulations.** **• Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) should be of suitable composition such that the surfaces that contact components are not reactive or sorptive.** **• Supplies in direct contact with the CSP must be sterile and depyrogenated.**	Compliant
11. Use of certain sterile products as components of CSPs:	
a. A conventionally manufactured single-dose container is a container–closure system that holds a sterile medication for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements. If a single-dose vial is entered or punctured only in an ISO Class 5 or cleaner air, it may be used up to 12 hours after initial entry or puncture as long as the storage requirements during that 12-hour period are maintained.	N/A

b. Opened single dose ampules must not be stored for any time period.	N/A
c. A conventionally manufactured pharmacy bulk package is a container of a sterile product for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the sterile preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile containers. The pharmacy bulk package must be used according to the manufacturer's labeling. The pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC.	N/A
d. A conventionally manufactured product in a multiple-dose container is intended to contain more than 1 dose of a drug product. Once initially entering or puncturing the multiple-dose container, the multiple-dose container must not be used for more than 28 days unless otherwise specified by the manufacturer on the labeling.	N/A
e. A multiple-dose CSP is designed to contain more than 1 dose of medication, intended to be entered or punctured multiple times, and usually contains a preservative. Multiple-dose CSPs must be stored under the conditions upon which its BUD is based (e.g., refrigerator, controlled room temperature). After a multiple-dose CSP is initially entered or punctured, the multiple-dose CSP must not be used for longer than the assigned BUD or 28 days, whichever is shorter.	N/A
f. When a compounded single-dose CSP or a CSP stock solution is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured in ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based (e.g., refrigerator, controlled room temperature). The component CSP may be used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder must be discarded.	Compliant
Sterilization and Depyrogenation	
1. The pharmacy sterilizes CSPs by filtration	Yes

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Middleton, MA 01949
Phone: 978-646-0091

a) Filters used for sterilization are: i) Sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and include labeling for pharmaceutical use. Sterilizing filters with labeling that states "for laboratory use only" or an equivalent statement must not be used for compounding CSPs.	Compliant
ii) Certified by the manufacturer to retain at least 10-7 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (i.e., pressure, flow rate, and volume filtered).	Compliant
iii) are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity).	Compliant
iv) are chemically stable at the pressure and temperature conditions that will be used; and	Compliant
v) have enough capacity to filter the required volumes.	Compliant
2. a) The Master Formulation Record (when required) or the compounding record must contain: • The types, sizes and quantities of filters to be used for filter sterilization of the specific CSP. • The parameters for testing sterilization filters, including bubble point, if the filter is tested using the bubble point method.	Noncompliant
b) When CSPs are known to contain excessive particulate matter, a prefiltration step must be performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of the sterilizing filter to remove gross particulate contaminants.	Unknown/Partially Compliant
c) The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process. • Exception: When sterilization by filtration is part of the media fill test, the media does not filter easily, and more than one filter may be needed to complete the task. Filter integrity (bubble point test) must be performed on filters used for sterilization during a media fill test.	Unknown/Partially Compliant
d) Filtration of the CSP must occur inside the ISO Class 5 PEC using aseptic technique.	Compliant

e) The CSP is passed through the filter (or prefilter then filter) The CSP will be filtered before placing into the final containers, maintaining aseptic technique inside the PEC.	Compliant
f) The filter brand, lot number and expiration date of filters used must be documented on the compounding record.	Compliant
g) A filter integrity test (bubble test) is performed for every filter used to sterilize a CSP. **• Results are documented on the CR.** **• The filter has failed the test if the pressure at which bubbling starts is lower than the manufacturer's stated pressure.** **• CSPs filtered with failed filters are not released for dispensing.**	Compliant
The pharmacy performs terminal sterilization and/or depyrogenation.	No
Category 1 or 2 CSPs - Section XI: Finished Preparation Release Checks and Tests	
a. Visual Inspection: CSP physical appearance is as expected. **• No particulates, filaments, or other foreign matter such as cores. Check against a light and a dark color background.** **• No signs of incompatibility such as cloudiness, precipitation, broken emulsion, etc.** **• No discoloration or other defects**	Compliant
b. Container integrity **• No leaks** **• The container is not cracked or broken.** **• Seals are intact.**	Compliant
c. CSP label and labeling inspected. **• Confirm the CSP matches the order or prescription.** **• Confirm the label and labeling are complete** **(a) Patient-specific label contains all elements and is complete.** **(b) Batch label contains all elements and is complete.**	Compliant

d. Compounding Record is inspected. **• All calculations accurate and complete, in-process checks appropriately documented.** **• Any alterations or deviations from the Master Formula Record (if required) or the compounding record are evaluated and documented.** **• Results of quality checks and tests are recorded and within specifications (pH, etc.).** **• Sterilization appropriate and validated (biological indicators, filter integrity tests, etc.)**	Compliant
e. If the CSP is dispensed at a later date (not the date it was compounded); the physical appearance and container integrity must be conducted immediately upon release or dispensing to ensure precipitation, cloudiness, leakage, etc. have not developed during storage.	Compliant
Sterility Testing	
The pharmacy uses sterility testing.	Yes
Sterility testing: • Is not required for Category 1 CSPs • Is required for Category 2 CSPs only if the CSP is assigned a BUD that requires sterility testing.	
1. Sterility testing must be performed according to USP Chapter <71>, or a validated alternative method that is not inferior to USP Chapter <71> testing. **• CSPs requiring sterility testing are quarantined until it is documented that they have passed a sterility test.** **• CSPs are released for use or dispensing before the sterility tests are received only if there is a recall process that is activated immediately if results of the sterility tests indicate failure.**	Compliant
2. Method Suitability Testing: Sterility testing performed according to USP Chapter <71> requires that a Method Suitability Test be performed to ensure that contamination can be recovered. **• Method suitability testing is to USP Chapter <71> Membrane Filtration method is the method of choice when the CSP formulation permits.** **• The preferred alternative is the USP Chapter <71> Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium method.**	Compliant
3. If an alternative method is used for sterility testing, the method must be validated (see USP Chapter <1223>) and demonstrated to be suitable for that CSP formulation.	Compliant

4. The designated person(s) will ensure that documentation is obtained that the method suitability test has been performed. For example, the laboratory test results may document that the testing was performed in accordance with a specific method suitability test.	Compliant
5. Number of units to be tested: The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units.	Compliant
6. The appropriate number of units is tested per batch. **i. Parenteral preparations** **• 1 to 39 containers, test 10% rounded up to the next whole number** **• 40 to 100 containers, test 10% or 4 containers, whichever is the greater** **• 101 to 250 (max) containers, test 10 containers** **ii. For large volume parenteral preparations,** **• Test 2% or 10 containers, whichever is less** **iii. Ophthalmic and other noninjectable preparations** **• 1 to 200 containers, test 5% or 2 containers, whichever is the greater** **• 201 to 250 containers, test 10 containers** **iv. If the product is presented in the form of single-dose containers, apply the scheme shown above for preparations for parenteral use.**	Compliant
7. Failed sterility tests must be addressed by the designated person(s) including: **• Investigation for possible causes** **• Identification of the microorganism** **• Evaluation of the sterility testing procedure, the compounding facility, process, and/or personnel that may have contributed to the failure.** **• The source(s) of the contamination, if identified, must be corrected, and the designated person(s) must determine whether the conditions causing the sterility failure affect other CSPs.** **• The investigation and resulting corrective actions must be documented.**	Compliant

Endotoxin Testing	
The pharmacy uses endotoxin testing.	Yes

1. a. Endotoxin testing:
   • Is not required for Category 1 CSPs
   • Is required for Category 2 CSPs if compounded from one or more nonsterile components AND assigned a BUD that requires sterility testing.
   • Is recommended (not required) for Category 2 CSPs compounded from one or more nonsterile components that are not assigned a BUD that requires sterility testing.

b. Endotoxin testing must be performed according to USP Chapter <85>, or a validated alternative method that is not inferior to USP Chapter <85> testing.	Unknown/Partially Compliant
c. The CSP does not exceed the endotoxin limits required by the type of CSP. See USP Chapter <1085> Guidelines on the Endotoxins Test for specific calculations to determine the limits of endotoxins based on route of administration, dose of CSP per kg of body weight, and duration of administration. **• Must not exceed the endotoxin limit in an official USP-NF monograph, or other CSP formula source.** **• Must not exceed the endotoxin limit calculated as described in USP Chapter <85> for the appropriate route of administration for humans.** **• CSPs for nonhuman species must not exceed the endotoxin limit calculated as described in USP Chapter <85> based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species unless a different limit is scientifically supported.** **• CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.**	Unknown/Partially Compliant
d. Endotoxin tests resulting in failures must prompt an investigation by the designated person(s) including: **• An evaluation of the depyrogenation process for any materials used in preparing the CSP.** **• The endotoxin content of any of the components, storage of utensils and components, compounding facility, process, and/or personnel that may have contributed to the failure.** **• The source(s) of the contamination, if identified, must be corrected, and the designated person(s) must determine whether the conditions causing the endotoxin contamination affect other CSPs.** **• The investigation and resulting corrective actions must be documented.**	Unknown/Partially Compliant

Category 1 or 2 CSPs - Section XII: Labels and Labeling

Label: designates that part of the labeling that is on the immediate container.
Labeling: all labels and other written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed, except the outer shipping container.

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Phone: 978-646-0091

1. All Category 1 and 2 CSPs are labeled with appropriate, legible identifying information to prevent errors during storage, dispensing, and use.	Compliant
2. Labels and labeling must additionally be compliant to state regulations, detailed in the SOPs.	Compliant
3. The label on each immediate container of the CSP must, at a minimum, display prominently and legibly the following information: **• Assigned internal identification number (e.g., barcode, prescription, order, or lot number)** **• Active ingredients and their amounts, activities, or concentrations.** **• Storage conditions if other than controlled room temperature.** **• BUD (does not say exp. or expiration date)** **• Dosage form** **• Total amount or volume if it is not obvious from the container.** **• If it is a single-dose container, a statement (if there is space) such as "SINGLE USE ONLY".** **• If it is a multiple-dose container, a statement (if there is space, otherwise include in labeling) such as "MULTIPLE DOSE CONTAINER" and "Discard 28 days after first opening/puncture." Or similar.**	Unknown/Partially Compliant
4. The labeling on the CSP must display the following information, as applicable: **• Route(s) of administration** **• Special handling instructions** **• Warning statements** **• Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.** **• The labeling on the CSP should indicate that the preparation is compounded. Note: required by some states.**	Unknown/Partially Compliant
5. The label of the CSP must be verified to ensure that it conforms with the **• Prescription or medication order** **• MFR, if required, and the CR** **• State regulations of the state(s)**	Compliant

6. PATIENT SPECIFIC – INPATIENT **a. Information needed in addition to the information above, such as other elements as required by the state regulations** **• Name of the patient** **• Location of the patient (room number, etc.)**	N/A
7. PATIENT SPECIFIC – OUTPATIENT/COMMUNITY **a. Information needed in addition to the information above, such as other elements as required by the state regulations:** **• Patient name** **• Prescriber name** **• Pharmacy name, location and phone number** **• Prescription number** **• A reference or established name, or a distinct common name, dosage form and potency** **• Quantity** **• Directions for use.** **(1) The directions for prescription use must follow the prescriber written instructions.** **(2) The pharmacist will encourage prescribers to follow current standards and contact the prescriber if directions for use are ambiguous or lacking clarity.** **(3) Use of native language and/or larger type if needed to accommodate specific patient needs.** **• Date filled.** **• May be required to contain the initials of the compounder and/or the pharmacist performing final verification (required by some states)** **• May be required to contain the physical description of the product (required by some states)** **• Auxiliary labels (if applicable)**	Compliant
Compounding Category 3 CSPs	
Does the pharmacy compound Category 3 CSPs?	No
Section XIII: Quality Assurance and Quality Control	
Quality assurance (QA) is a system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards. Quality control (QC) is the sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP. See USP Chapter <1163>.	
1. The QA and QC program is formally established to ensure all aspects of the preparation of CSPs are conducted in accordance with USP Chapter <797> and state regulations	Compliant

2. The designated person(s) responsible for the QA program has the training, experience, responsibility, and authority to perform these duties.	Compliant
3. The facility has formal, written QA and QC programs that establish a system of: **• Adherence to procedures.** **• Prevention and detection of errors and other quality problems (deviations, action levels, etc.).** **• Evaluation of complaints and adverse events.** **• Appropriate investigations and corrective actions.**	Compliant
4. The SOP describes the roles, duties, and training of the personnel responsible for each aspect of the QA program.	Compliant
5. The QA and QC program is reviewed at least once every 12 months by the designated person(s). The results of the review are documented, and appropriate action is taken if needed.	Compliant
Section XIV: Recalls, Complaints, and Adverse Event Reporting	
Recalls	
1. The policy and procedure include determining when recalls must be initiated. Needs internal recall procedure.	Unknown/Partially Compliant
2. If a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (e.g., sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Unknown/Partially Compliant
3. Recall includes any unused dispensed CSPs and the quarantine of any stock remaining in the pharmacy.	Unknown/Partially Compliant
4. Other lots that may be affected are investigated and recalled if necessary.	Unknown/Partially Compliant

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5. The SOP for recall of dispensed CSPs must contain: **• Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall.** **• Procedures to determine the distribution of any affected CSP, including the date and quantity of distribution.** **• Procedures to identify patients who have received the CSP.** **• Procedures for disposal and documentation of the recalled CSP.** **• Procedures to investigate and document the reason for recall.** **• The recall system includes communication with both the patient and the physician/prescriber regarding the affected compounded sterile preparations.** **• Implementation of the recall procedures is documented.**	Unknown/Partially Compliant
6. The recall must be reported to the Board of Pharmacy or other agencies if required.	Unknown/Partially Compliant
7. Quality issues with compounded preparations are also appropriately documented on the compounding record for the corresponding lot.	Unknown/Partially Compliant
Complaint Handling	
1. There is an SOP for handling complaints.	Compliant
2. Complaints include (but are not limited to) concerns or reports on the quality, labeling, or possible adverse reactions related to a specific CSP.	Compliant
3. The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP. **• If it does, a thorough investigation into the cause of the problem is initiated and completed.** **• The investigation considers if the quality problem extends to other CSPs.** **• Corrective action, if necessary, must be implemented for all potentially affected CSPs.** **• The designated person(s) considers whether to initiate a recall of potentially affected CSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected.**	Compliant
4. A readily retrievable written or electronic record of each complaint must be kept by the facility, regardless of the source of the complaint (e.g., email, telephone, or mail).	Compliant

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5. The record must contain: **• Name of the complainant or other unique identifier.** **• If known, the name and strength of the CSP and identification number (prescription, order, lot number)** **• Date the complaint was received.** **• Nature of the complaint.** **• Response to the complaint.** **• The findings of any investigation and any follow-up.**	Unknown/Partially Compliant
6. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained.	Compliant
7. A CSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction.	Compliant
Adverse Event Reporting	
1. Adverse events potentially associated with the quality of CSPs are reported if required in accordance with the facility's SOPs and state regulations.	Unknown/Partially Compliant
2. If the investigation into an adverse event reveals a quality problem with a CSP that is likely to affect other patients, those patients and prescribers potentially affected must be informed.	Unknown/Partially Compliant
Section XV: DOCUMENTATION	
1. All facilities where CSPs are prepared have and maintain written or electronic documentation to demonstrate compliance that includes the following.	Compliant
2. The facility has a document retention policy. All required records for a particular CSP (e.g., MFR, CR, and release inspection and testing results) must be readily retrievable for at least 2 years, or longer if required by state regulations or accreditation standards. NY 5 years. SOP says archived 10 years.	Compliant
3. Indicate how long the following records are kept by the facility:	Unknown/Partially Compliant
a. Personnel training, competency assessments, and qualification records including corrective actions for any failures.	
b. Certification reports, including corrective actions for any failures	

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c. Environmental air and surface monitoring procedures and results	
d. Equipment records (e.g., calibration, verification, and maintenance reports)	
e. COAs and all documentation required for components not conventionally manufactured.	
f. Receipt of components	
g. SOPs, required MFRs, and CRs	
h. Release inspection and testing records	
i. Information related to complaints and adverse events including corrective actions taken.	
j. Results of investigations and corrective actions	
k. Records of cleaning and sanitizing the designated compounding area	
l. Logs: temperature, humidity, pressure differential	
m. Accommodations to personnel compounding CSPs	
n. Any required routine review (e.g., yearly review of QA and QC programs, yearly review of chemical hazard and disposal information)	
4. Documentation and records are legible and stored in a manner that prevents their deterioration and/or loss.	
Section XVI: Dispensing and Patient Consultation	
1. Patient training and materials contain information and precautions regarding the handling, storage and disposal of medications.	Compliant
2. Required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) are provided for the compounded preparations.	Compliant
3. Patients are 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.	Compliant
4. The pharmacy delivers, sends, mails, or ships CSPs.	Yes

a. The SOPs describe the processes and techniques for handling, storing, packaging, and transporting CSPs. Personnel are trained and training documented.	Compliant
b. The mode of transportation is appropriate and does not adversely affect the sterility and stability of the CSP. For example, products that may be damaged by shaking are not delivered by pneumatic tube systems. Undue exposure to heat, cold, and light is considered.	Compliant
c. Packaging materials protect CSPs from damage, leakage, contamination, and degradation, while protecting persons from exposure. If the CSP is sensitive to light, light-resistant packaging materials must be used. In some cases, the CSP must be packaged in a special container (e.g., a cooler) to protect it from temperature fluctuations.	Compliant
d. Packaging is tamper-evident, where required.	Compliant
e. Packages are tracked.	Compliant
f. Special handling instructions are included on the exterior of the container, as appropriate	Compliant
g. Packaging materials maintain the physical and chemical integrity, and stability of the CSPs for the length of time spent in transport. Verified by data from the packaging material manufacturer or validated by the pharmacy during weather extremes (heat, and cold to protect from freezing).	Compliant
h. If packaging is not validated, the SOP describes how temperature monitoring devices or indicators are used including instructions to the patient or recipient on what to do if the indicator is activated.	N/A

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Attachment 2: Hazardous Compounding Inspection Tool

Hazardous Compounding (USP <800>) Inspection

Conducted for

Client Pharmacy

Conducted on

March 6, 2025

Prepared by

Denise Frank

Location

Client street
Client city, NY Climate Zone

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USP Chapter <800> Hazardous Drugs Inspection

Client Pharmacy **Complete**

Inspection Date	3/6/2024
Conducted By	Denise Frank
Facility Name	Client Pharmacy
Location Address	2657 Client street Rd Client city, NY Client zip

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Section I: General Operations for Handling HDs
2. The pharmacy does not have or could not locate the appropriate references for handing hazardous drugs.
4.- 5. There is no complete list of HDs handled in the pharmacy or any Assessment of Risk (AOR).
9. The SOPs for handling HDs are incomplete, missing sections.

Section II: General Pharmacy Activities in Handling HDs
3. Appropriate spill kits need to be available where HDs are received and handled.
5. Storage of products to be dispensed without manipulation is not addressed in the AOR.
8. Unknown if specific equipment is dedicated for use with HDs and decontaminated after every use.

Section IV: Nonsterile Compounding HDs
5. Storage of HDs and HD APIs are NOT stored in a negative-pressured room with at least 12 air changes per hour. There are holes/gaps in the ceiling tiles open to the area above the dropped ceiling that will make consistent pressure difficult if not impossible to achieve.
14. The C-SEC is NOT negatively pressured between 0.01 and 0.03 inches water column to adjacent areas. Pressures not monitored or recorded, no crisis plan to maintain containment during a power outage.

Section V: Garbing for Non-sterile Compounding HDs
1.Shoe covers. Inadequate space to don (at the top of the stairs, door held open), no LOD box inside door, staff/students observed avoiding floor inside of door (stepping over).
2.- 3. Covers and gowns of unknown composition to be used with HDs. Gowns may NOT close in the front and must resist permeability.
5. Using safety glasses and not goggles (safety glasses or shields do NOT protect the eyes from splashes or contamination from above or the sides.
8. Removal of HD garb is not complete before traveling outside the HD room. No LOD box clearly marked or used inside the door to the HD room.

Section VI: Sterile Compounding HDs
8. No assessment of risk was performed, no instructions on alternative containment of stored HDs.
17. The HD buffer room is NOT adequately pressured. The gauge reads in “mba”, DR and staff did not know what that translates to in inches of water column and had no idea what the actual pressure is. 0.2 “mba” is equivalent to 0.08 “wc (from Google search on site). Too high pressure in the HD buffer room, contaminated air pulled in.
21. HD clean room lacks LOD box inside the buffer room door to ensure garb and contaminated booties are removed before entering the shared anteroom.

Section VII: Garbing for Sterile Compounding HDs
1.Shoe covers not appropriately donned when entering shared anteroom and second set not donned/doffed appropriately to minimize contamination of the floor from outside the anteroom or HD contamination from inside the HD buffer room or shared anteroom from the outside areas. NO LOD in shared anteroom or LOD box inside HD buffer room.
3. Gowns not chemo gowns that resist permeability and close in the back.
4. Using nonsterile, non HD gloves covered by sterile chemo gloves. Both pair for HD compounding must be chemo gloves (ASTM 6978 or better) and sterile.
5. Using safety glasses and not goggles (safety glasses or shields do NOT protect the eyes from splashes or contamination from above or the sides.
8. PPE not appropriately doffed when leaving HD buffer room and entering shared anteroom. There is no LOD box inside the HD buffer room door.

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I. General Operations for Handling HDs	
1. The pharmacy has a qualified designated person for hazardous drugs.	Compliant
2. The pharmacy has appropriate references for handling hazardous drugs. *USP <800>, NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings (most recent copy) at a minimum.	Unknown or Partially Compliant
3. The pharmacy handles hazardous drugs with the full containment requirements of USP <800>. Required for HD APIs and those used in compounding. Required for all HDs if no assessment of risk is performed.	N/A
4. The pharmacy has a list of all hazardous drugs and has performed an assessment of risk for those hazardous drugs in the pharmacy that are not manipulated and do not require full containment.	Non-Compliant
5. The assessment of risk includes: • Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only) • Dosage form • Risk of exposure • Packaging • Manipulation • Alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure.	Non-Compliant
6. There is a procedure in place to review and revise the list and to review entire list and assessment of risk for changes and updates at least every 12 months and document the review.	Compliant
7. The assessment of risk is available to staff.	Compliant
8. There is appropriate signage of areas where hazardous drugs are stored or handled.	Compliant

9. The pharmacy has appropriate policies and procedures/standard operating procedures for handling and compounding hazardous drugs that includes but is not limited to addressing the recommended SOPs in USP <800>. **• Hazard communication program** **• Occupational safety program** **• Designation of HD areas** **• Receipt** **• Storage** **• Compounding** **• Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs)** **• Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)** **• Deactivation, decontamination, cleaning, and disinfection** **• Dispensing** **• Transport** **• Administering** **• Environmental monitoring (e.g., wipe sampling)** **• Disposal** **• Spill control** **• Medical surveillance**	Unknown or Partially Compliant
10. The SOPs are reviewed by the designated person, and the review documented, at least every 12 months. Any revisions in SOPS, forms or records must be made as needed and communicated to all personnel handling HDs.	Compliant
II. General Pharmacy Activities in Handling HDs	
1. Receiving and unpacking is performed in a designated area that is neutral or negative pressure to surrounding areas.	Compliant
2. The policy and procedure for the receiving and unpacking process addresses: appropriate PPE, decontaminating packages with wipes (sprays not allowed), and transporting the HDs to storage areas.	Compliant
3. There is a policy and procedure for the handling of damaged product, leaks, or spills and there is an appropriate spill kit available. Policy. No spill kit available.	Unknown or Partially Compliant
4. PPE and other materials are appropriately disposed of as contaminated or trace-contaminated waste. Note that wipes used to decontaminate product when unpacking HDs are considered contaminated (not trace).	Compliant

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5. Storage of products used in the general pharmacy, to be dispensed without any manipulation, is addressed in the assessment of risk. Products may or may not be segregated. Products must be clearly marked.	Unknown or Partially Compliant
6. Products are stored to prevent spilling or breakage if the container falls. Products are not stored on the floor.	Compliant
7. There is a process in place for preparing and dispensing HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms. (Process does not need to require further containment unless required by the manufacturer.)	Compliant
8. Equipment is be dedicated for use with HDs and decontaminated after every use. Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines. NIOSH Table 2 and Table 3 HDs are not placed in automated counting or packaging machines unless thorough assessment of risk is performed addressing residues and procedure including decontamination.	Unknown or Partially Compliant
9. Appropriate PPE is available and used by personnel when preparing HDs for dispensing as indicated on the assessment of risk.	Compliant
10. Patients are given appropriate information on the handling and disposal of HDs.	Compliant
III. Garbing for General Pharmacy	
1. Policies and procedures are in place that address PPE. Includes appropriate types and characteristics of PPE specifically used for HDs.	Compliant
2. Policies and procedures address at a minimum: Receipt of HDs into stock and storage, transportation of HDs (as appropriate), filling prescriptions/orders, manipulation of dosage forms including compounding, administration (if appropriate to your setting), all cleaning activities (deactivation, decontamination, cleaning, and disinfecting), spill control, waste disposal. May be addressed in one policy or PPE addressed in the individual policies for these tasks.	Compliant
IV. Nonsterile Compounding HDs	
Does the pharmacy compound nonsterile preparations using HDs?	Yes

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1. Receiving and unpacking is performed in a designated area that is neutral or negative pressure to surrounding areas.	Compliant
2. There is a policy and procedure for the receiving and unpacking process that addresses: appropriate PPE, decontaminating packages with wipes (sprays not allowed), and transporting the HDs to storage areas.	Compliant
3. There is a policy and procedure for the handling of damaged product, leaks, or spills and there is an appropriate spill kit available.	Compliant
4. PPE and other materials are appropriately disposed of as contaminated or trace-contaminated waste. Note that wipes used to decontaminate product when unpacking HDs are considered contaminated (not trace).	Compliant
5. Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API are stored separately from non-HDs in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).	Unknown or Partially Compliant
Getting fixed. There are holes/gaps in the ceiling tiles open to the area above the dropped ceiling that will make consistent pressure impossible to achieve.	
6. Non-antineoplastic, reproductive risk only, HDs may be stored with other inventory if permitted by the assessment of risk. Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.	Compliant
7. Refrigerated antineoplastic HDs requiring manipulation must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH	Compliant
8. Nonsterile compounding using HDs must follow USP <795> including the assignment of BUDs.	Compliant
9. There must be a sink available and an eyewash station. Eyewash station must be plumbed to provide continuous flow of water. Eyewash stations with bottled solutions may be used immediately then person moved to a plumbed station. If bottled eyewash stations used, solutions are not expired.	Compliant
10. Water sources and drains must be at least one meter away from the C-PEC	Compliant

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11. The C-PEC is a CVE, Class I or II BSC, or CACI that is externally vented (preferred, and required if volatiles) or has redundant HEPA filters in series. Common antineoplastic HDs that are known to volatilize include cisplatin, cyclophosphamide, and fluorouracil. The volatilization characteristics for many HDs is not known, so caution is advised.	Compliant
12. The C-PEC is operated continuously if it supplies some or all of the negative pressure for the room. There is a procedure for loss of power, or if the unit must be repaired or moved.	Compliant
13. The C-SEC (or C-SCA) is enclosed, externally vented and maintains at least 12 ACPH.	Compliant
14. The C-SEC is negatively pressured between 0.01 and 0.03 inches of water column to adjacent areas. Pressure is monitored and recorded. Crisis plans include maintaining power to HVAC in the event of an outage.	Unknown or Partially Compliant
15. C-PECs and C-SECs are certified regularly (at least annually).	Compliant
16. Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.	Compliant
17. There is a cleaning procedure available that includes deactivation, decontamination, cleaning and sanitization steps with appropriate cleaning products. Cleaning is documented including the mixing of any cleaning solutions (if not using ready-to-use products). Appropriate garb is used when cleaning. No sprays are used. Cleaning agent is not alcohol (increases permeation of HDs through skin). Alcohol may be used as final sanitization after deactivation/decontamination and cleaning performed.	Compliant
18. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process. Certification of the buffer room must confirm that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity.	N/A

V. Garbing for Non-sterile Compounding HDs

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1. Shoe covers: Shoe covers are donned when entering HD compounding areas. Two sets of shoe covers are donned across the line of demarcation in a shared anteroom. *May not have reusable garb such as dedicated shoes when performing hazardous compounding.* May don one set of covers in the ante-room and the second set when entering the hazardous drug buffer room.	Unknown or Partially Compliant
Inadequate space to don (at the top of the stairs, door held open), no LOD box inside door, staff/students observed avoiding floor inside of door (stepping over).	
2. Head, hair, and facial hair covers are available and used when required. Sleeve covers, if used, are coated to resist permeability by HDs.	Unknown or Partially Compliant
3. Gowns: Disposable and shown to resist permeability by HDs. Gowns close in the back (i.e., no open front or bunny suits), are long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through. Gowns are changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, changed 2–3 hours or immediately after a spill or splash.	Unknown or Partially Compliant
4. Gloves: Chemotherapy gloves are appropriately donned. *Chemo gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. *Chemotherapy gloves must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor), or better. Gloves are powder-free.	Compliant
5. Goggles are used when eye protection is needed. Eye glasses alone or safety glasses with side shields are not acceptable as they do not protect the eyes adequately from splashes. Face shields alone do not provide full eye and face protection. *Face shields may be used in combination with goggles to provide a full range of protection against splashes to the face and eyes. Also, a full-facepiece respirator provides eye and face protection.	Unknown or Partially Compliant
6. Respirators are used when appropriate: unpacking HDs not contained in plastic bags, working on HD spills larger than the spill kit can contain, cleaning underneath the work surface of a C-PEC, other known or suspected exposure to airborne particles or vapors. Employees have had a medical evaluation and respirators are fit tested. Surgical masks are not acceptable for respiratory protection.	Compliant

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7. Appropriate disposal of PPE. Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. Biohazard card Bonn	Compliant
8. PPE is removed after handling the HD and BEFORE traveling to other areas where the PPE may spread HD contaminants. For example, after filling a prescription for an HD, gloves are removed and discarded appropriately before answering the phone or handling other items in the pharmacy. When compounding, the outer set of shoe covers are removed as you leave the compounding area to prevent tracking trace HD residue into the ante room or around other areas of the pharmacy. No LOD box clearly marked or used inside the door to the HD room.	Unknown or Partially Compliant
VI. Sterile Compounding HDs	
Does the pharmacy compound sterile preparations with HDs?	Yes
1. Sterile compounding using HDs must follow USP <797>.	Compliant
2. Sterile compounded preparations containing hazardous drugs are appropriately identified and defined according to USP Chapter <797> Category for determining BUD.	Compliant
3. Receiving and unpacking is performed in a designated area that is neutral or negative pressure to surrounding areas.	Compliant
4. There is a policy and procedure for the receiving and unpacking process that addresses: appropriate PPE, decontaminating packages with wipes (sprays not allowed), and transporting the HDs to storage areas.	Compliant
5. There is a policy and procedure for the handling of damaged product, leaks, or spills and there is an appropriate spill kit available.	Compliant
6. PPE and other materials are appropriately disposed of as contaminated or trace-contaminated waste. Note that wipes used to decontaminate product when unpacking HDs are considered contaminated (not trace). Using biomedical red bags inside, HD bins outside	Compliant

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7. Antineoplastic HDs requiring manipulation and any HD API are stored separately from non-HDs in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).	Compliant
8. Non-antineoplastic, reproductive risk only, HDs may be stored with other inventory if permitted by the assessment of risk. Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. Need assessment of risk.	Non-Compliant
9. Refrigerated antineoplastic HDs requiring manipulation must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH	Compliant
10. There must be a sink available and a plumbed eyewash station. Eyewash station must be plumbed to provide continuous flow of water. Eyewash stations with bottled solutions may be used immediately then person moved to a plumbed station. If bottled eyewash stations used, solutions are not expired.	Compliant
11. Water sources and drains must be at least one meter away from the C-PEC.	Compliant
12. The C-PEC is a Class II or III BSC, or CACI that maintains an ISO Class 5 or better air quality. The C-PEC must be externally vented.	Compliant
13. The C-PEC is located in a C-SEC that is an unclssified C-SCA. The C-SCA is enclosed, externally vented and maintains at least 12 ACPH. Must follow USP <797> for types of compounding allowed outside an ISO-classified compounding suite. BUDs assigned per USP <797> for CSPs prepared in a segregated compounding area.	N/A
14. The C-SCA is negatively pressured between 0.01 and 0.03 inches of water column to adjacent areas. Pressure is monitored and recorded.	N/A
15. The C-PEC is located in a C-SEC that is an ISO Class 7 buffer room with an ISO Class 7 ante room.	Compliant
16. The HD buffer room is enclosed with fixed walls is maintained with at least 30 ACPH	Compliant

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17. The HD buffer room is negatively pressured between 0.01 and 0.03 inches of water column to adjacent areas. Pressure is monitored and recorded. .2 mba (.08 "wc)	Non-Compliant
18. The anteroom adjacent to the HD buffer room is maintained with at least 30 ACPH.	Compliant
19. The anteroom is positively pressured to adjacent non-classified rooms with at least 0.02 inches of water column. Pressure is monitored and recorded.	Compliant
20. C-PECs and C-SECs are certified regularly as required by USP <797>.	Compliant
21. The hazardous drug clean room has a designated area inside the door to indicate where removal and disposal of trace and contaminated garb occurs before entering a shared anteroom.	Non-Compliant
22. The hand-washing sink must be placed in the ante-room at least 1 meter away from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room.	Compliant
23. Due to the difficulty of cleaning and sanitizing, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer room and ante room must be smooth, impervious, free from cracks and crevices, and non-shedding. (USP <797> requirements)	Compliant
24. There is a cleaning procedure available that includes deactivation, decontamination and cleaning steps with appropriate cleaning products. Cleaning is documented including the mixing of any cleaning solutions (if not using ready-to-use products). Appropriate garb is used when cleaning. No sprays are used.	Compliant
25. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process. Certification of the buffer room must confirm that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity.	N/A
VII. Garbing for Sterile Compounding HDs	

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1. Shoe covers: Shoe covers are donned across the LOD when entering then anteroom or C-SEC. Two sets of shoe covers are donned across the line of demarcation in a shared ante-room. *May not have reusable garb such as dedicated shoes when performing hazardous compounding.* May don one set in ante-room and the second set when entering the hazardous drug buffer room. Need LOD in HD room	Unknown or Partially Compliant
2. Head, hair, and facial hair covers are available and used. Sleeve covers, if used, are coated to resist permeability by HDs.	Compliant
3. Gowns: Disposable and shown to resist permeability by HDs. Gowns close in the back (i.e., no open front or bunny suits), are long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through. Gowns are changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, changed 2–3 hours or immediately after a spill or splash.	Non-Compliant
4. Gloves: Two pairs of sterile chemotherapy gloves are appropriately donned. Chemo gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. Chemo gloves must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor), or better. Gloves are powder-free.	Unknown or Partially Compliant
5. Goggles are used when eye protection is needed. Eye glasses alone or safety glasses with side shields are not acceptable as they do not protect the eyes adequately from splashes. Face shields alone do not provide full eye and face protection. *Face shields may be used in combination with goggles to provide a full range of protection against splashes to the face and eyes. Also, a full-facepiece respirator provides eye and face protection.	Unknown or Partially Compliant
6. Respirators appropriate for sterile compounding are used (such as N-95 surgical masks). Respirators are also used when unpacking HDs not contained in plastic bags, working on HD spills larger than the spill kit can contain, cleaning underneath the work surface of a C-PEC, other known or suspected exposure to airborne particles or vapors. Employees have had a medical evaluation and respirators are fit tested. A regular surgical mask is NOT appropriate respiratory protection.6.	Compliant

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7. Appropriate disposal of PPE. Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations.	Compliant
8. PPE is removed after handling the HD and BEFORE traveling to other areas where the PPE may spread HD contaminants. Removing outer set of gloves when finished in the C-PEC. The inner set must remain on until completely doffing garb that may be contaminated. The HD gown and outer set of shoe covers are removed when leaving the HD buffer room to prevent tracking trace HD residue into the ante room, or around other areas of the pharmacy. Need LOD inside HD buffer room door	Unknown or Partially Compliant
VIII. Environmental sampling (Note: recommended not required by USP Chapter 800)	
1. Wipe sampling performed initially and at least every 6 months thereafter to verify containment.	N/A
2. Sites of sampling include the PEC and antechamber, surfaces of work areas or counters adjacent to the PEC, floor in the HD buffer room, and areas immediately outside the HD buffer room or segregated compounding area (anteroom, general pharmacy, receiving area, etc)	N/A
3. If any measurable contamination is found, the designated person will identify, document, and contain the cause of contamination. Such action may include reevaluating work practices, re-training personnel, performing thorough deactivation, decontamination, cleaning, and improving engineering controls. Repeat wipe sampling performed to validate that the deactivation/decontamination and cleaning steps have been effective.	N/A
IX. Training	
1. There is documentation that all personal working with or around HDs are appropriately trained including policies and procedures, documentation and handling of hazardous drugs. *Note this includes personnel performing receiving, dispensing activities, compounding and supervising.*	Compliant

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2. The training content for handling hazardous drugs includes: **Overview of the pharmacy's list of HDs and the risk assessment,** **Review of all policies and procedures related to HDs,** **Proper use of personal protective equipment (PPE),** **Proper use of equipment and containment devices,** **How to handle an exposure to an HD,** **How to handle a spill including the use of spill kits and handling the receipt of damaged HDs,** **Proper disposal of HDs,** **Proper disposal of trace-contaminated materials such as used PPE**	Compliant
3. 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 including teratogenicity, carcinogenicity, and reproductive issues. *Recommended for ALL personnel.*	Compliant
4. There is documentation that all personnel (including housekeeping or other outside personnel) that perform cleaning activities or trash removal in the hazardous drug compounding areas are appropriately trained in HD garbing, cleaning, and in the handling of contaminated and trace-contaminated waste.	N/A
5. There is documentation that all personnel handling HDs have passed an initial written exam, and subsequent annual written exams that include handling of NIOSH hazardous drugs and the facility's hazardous drugs list and risk assessment.	N/A
6. There is documentation that all personnel handling HDs have passed an initial and subsequent annual competency assessments of handling and compounding hazardous drugs using observational audit tools. HD handling skills evaluation to include use of equipment.	Compliant
X. Medical Surveillance (Note: recommended not required by USP Chapter 800)	
1. The pharmacy has a documented medical surveillance program. Needs only follow up for acute exposure.	N/A
2. The program includes initial baseline assessment, monitoring by periodic surveillance, and a follow up plan for employees when health changes suggesting toxicity are found or when employees experience an acute exposure.	N/A

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3. The program has a quality plan to assess sources of exposure including primary preventative measures, environmental sampling, and a plan for improvement to prevent or limit future exposures.	N/A

L. Rad Dillon, R.Ph., ASQ SSGB, ASQ CQA, is a Gates Healthcare Associate. He graduated from the University of Texas College of Pharmacy in 1981, and shortly thereafter entered the new home infusion industry, working for numerous national and regional providers in various managerial and corporate leadership roles.

Beginning in 2000 he attained a series of American Society for Quality certifications, including Certified Manager of Quality and Organizational Excellence (CMQ/OE), Certified Quality Auditor (CQA), and Certified Six Sigma Green Belt (CSSGB).

His career focus has included the creation and maintenance of policies and procedures, internal auditing programs, quality management programs, internal and external benchmarking initiatives, and educational and training offerings. The latter included complete training programs on hazardous drug handling, sterile compounding, and a set of commercially available policies and procedures on these topics.

Professional support activities have included six years as a member of ACHC's Board of Commissioners, continued involvement in NHIA including being a faculty member of its Sterile Compounding Clinic and numerous articles for Infusion Magazine, and current membership in APC.

Following a ten-year period of contractual and full-time employment with ACHC / PCAB, he has returned to private consulting practice, concentrating on sterile and nonsterile and hazardous drug compliance, auditing, and policy and procedure maintenance assignments.
He recently attained the credentials of GMPro upon completing a certification program in cGMP.

Ken Speidel RPh, BS – Pharm., PharmD., FIACP., FACA.
Career Overview

Dr. Speidel is known for his innovative and broad perspective on pharmaceutical and pharmacy practices. In addition to his experience as a clinician and medical executive, Ken is a lecturer, consultant and educator to physicians, and other practitioners, specialty medical practices, medical and pharmacy students, pharmaceutical manufacturers and distributors on a variety of pharmacy and health related subjects.

Professor Speidel is internationally known for his experience in pharmacy practice and medical education including his national recognition as a pharmacotherapeutic specialist in endocrinology and pain management, as well expertise in sterile and non-sterile compounding processes and USP Standards of Practice. Ken has over 30 years of clinical and operational experiences in specialty pharmacy practice including sterile and non-sterile compounding. He has been a consultant to the development of national standards for pharmacy compounding practices and has been a consultant to many companies and provider organizations across north America.

Dr. Speidel has experience in many aspects of pharmacy from acute care/alternate site infusion/long term care/specialty infusion/community pharmacy/palliative care/hospice and home care. He serves as a valued and expert consultant to other pharmacists, physicians, health systems, pharmaceutical companies, chemical companies, business owners and as a pharmacy college faculty member, preceptor, and instructor to doctorial pharmacy students. Professor Speidel was previously the course developer, coordinator, and principle faculty member for Findlay Universities College of Pharmacy non-sterile and sterile practice curriculum as well as an advanced compounding course. Ken's student team won the 2012 Compounding Classic Skills Competition at the University of Florida an event which he first proposed the conceptual model which was later developed by Medisca Pharmaceuticals. Ken is an author of a text on sterile and non-sterile pharmaceutical compounding in the NAPLEX examination study guide. His knowledge in compounding formulation and evaluation led to the development of PharmaCare Rx., Inc a specialty only compounding pharmacy. His professional accolades and achievements are reflective in his extensive involvement and membership in various pharmacy and infusion therapy organizations. Most notably he is the past multi-term president of the National Home Infusion Association (NHIA).

Ken was a primary developer and advisor to the development of the nation's first third party accreditation organization designed to accredit pharmacy compounding facilities known as the Pharmacy Compounding Accreditation Board (PCAB). He was appointed to a select committee that drafted the initial national pharmacy compounding standards. Ken was previously involved with the Joint Commission in several capacities including the JCAHO PTAC Advisory Panel. He presents at numerous hospital grand round lecture forums as well as national audiences and has published numerous articles related to compounding, home infusion pharmacy and specialty therapeutics. Ken has assisted in the development, writing, researching of several nationally recognized educational programs through the University of Florida (UF) and the University of Southern California (USC). These courses include: *The Essential Elements of Compounded Sterile Preparations* (home study and practical course); *The Science of Pharmaceutical Compounding* – non-sterile (home study and practical course); *Essential Elements of Personalized Analgesic Medications* and *Functional and Personalized Hormone Restoration Therapy*. Ken is also a keynote speaker for Sterile, Non-Sterile, Pain Management and Endocrine programs. He also takes pride in being a past two-term president of a community-based hospice program and facilitated its purchase and association within a healthcare system. Dr. Speidel has been awarded Fellowship status with the International Academy of Compounding Pharmacists as well as the American College of Apothecaries.

Education (abbreviated)

1981 Ohio Northern University, Ada, Ohio. BS Pharmacy
1997 Ohio Northern University, Ada, Ohio. Doctor of Pharmacy
Additional clinical experience in nutritional support, pediatric intensive care and geriatric medicine
Additional training and education in endocrinology, aseptic compounding, extemporaneous compounding, functional medicine, pain management

- Additional post-graduate education available upon request

Professional Experience (abbreviated)

Vice President Compounding Compliance Gates HealthCare Associates (present)

Responsible for 503a and 503b compounding services provided by Gates HealthCare Associates.

- *Lead Associate on compounding compliance related services.*
- *Directs all educational offerings provided by GHA*
- *Coordinates cGMP consultative activities.*
- *Senior advisor to the Executive Team*

Professor Pharmacy Practice University of Findlay College of Pharmacy (retired)

Responsible for several on-campus courses in Pharmacy Practice

- *Course Coordinator Lead Professor/Instructor in the Non-sterile and Sterile skills labs*
- *Faculty in Numerous Pharmacology Courses*
- *Course Coordinator, curriculum developer Veterinary Pharmacy Course*
- *Contributor to senior capstone program*
- *Consultant to pharmacy practice standards*
- *Hub Site Preceptor for APPE Program*
- *Member Faculty Affairs Committee*

Surveyor & Accreditation Expert Pharmacy Compounding Accreditation Board/Accreditation Commission for HealthCare (ACHC) (current)

- Developed Surveyor Training Program
- A third-party accreditation organization located in Washington DC
- Appointed to an eight-member national standards committee responsible for the drafting, support and submittal of the initial standards of practice for the compounding pharmacy accreditation process. www.pcab.org
- Developed and led an accreditation and standards improvement initiative that resulted in an improved and more objective accreditation process as well as improvements in surveyor competency.
- Member of the Standards Review Committee.
- Provides on-site surveyor activities nationwide including consultation to organizations that have applied and prepared for third party accreditation for organizations involved in sterile and non-sterile compounding. Review and critique organizational SOPs and confirmation of operational performance while on-site.

Consultant and Senior Associate Health System Consulting Group (current)

- Assists compounding organizations in improving compliancy with Standards of Practice
- Develop and support organizational standard operation procedures
- Design and monitor organizations quality improvement plans
- Support organizational preparation for 3rd party accreditation
- Implement staff competency programs in non-sterile and aseptic compounding practices

PharmaCare RX Inc. (2005-2011)
A compounding pharmacy and consulting organization

- *President and clinical director.*
    - *Responsible for clinical consultations, business development, student education, compounding formulation and evaluation, quality assurance and performance improvement*
- *Clinical Preceptor/Instructor Ohio State College of Pharmacy and Ohio Northern University*
- *Chief Pharmacy Consultant*
    - *Responsible for physician education, patient consultations, functional medicine review*
- *Quality and Risk Management Coordinator*
    - *Responsible for third party accreditation activities, continuous quality improvement and standards of practice*
- *Primary pharmacy consultant to Active Infusion Services Akron area branch*

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NorthCoast HealthCare Management/NorthCoast Infusion Network (2007-2011)
A healthcare management company and network of pharmacy and home health organizations throughout Ohio.

- *Vice-President*
    - *Responsible for pharmacy consultation and liaison with network pharmacy and home healthcare organizations throughout Ohio.*
    - *Supported the cultivation and maintenance of network pharmacy providers locally and nationally.*
    - *Review and consultation on clinical pharmacy to nursing staff*
    - *Review, interpret and report pooled clinical dispensing data from network providers.*
    - *Pharmacy liaison to drug manufacturers and managed care payers.*
    - *Provided primary surveillance and educational support on pharmaceutical investigational pipeline*

NorthCoast Infusion Therapies Ltd. (2007-2009)
An MSO based infusion therapy provider serving Northeast Ohio. Provides complex parenteral therapy to clients based in the alternate site care setting.

- *Vice President of Specialty Pharmacy Services*
    - Accountable for all business & clinical operations, management, consulting
    - Responsible for accreditation and quality management
    - Liaison to physician community

Additional Past Experiences

- Vice President of a large regional retail chain of community pharmacies including specialty pharmacies; i.e., compounding and infusion and also integrated natural products with traditional medication.

- *Vice President of Specialty Pharmacy Services*
    - Accountable for all business & clinical operations, management, consulting & new business
    - Supported two private label infusion operations owned by large hospital program
    - Served on the Executive Leadership Team of Pharmacy Corporation
    - Participated at the Director Level on hospitals Home Care Management Team (P&T and Nutritional Support Committees)
    - Reengineered (including relocation) compounding lab and processes that exceeded standards of practice
    - Member of numerous strategic planning committees on healthcare, infusion, home care, business management and integrated delivery systems

- Preceptor/instructor to doctoral pharmacy students
- A.C.E. Instructor to Medical School
- Managed specialty compounding pharmacy as well as a JCAHO accredited infusion operation
- Member of several Pharmacy and Therapeutics Committees

- *Executive Director of hospital-based Home Infusion Company*
  - Led the start-up and business/operational development of a full-scale infusion joint venture of an Acute Care Hospital, Community Pharmacy and Nursing Agency

- *General Manager – professional medical center pharmacy*
  - Responsible for the P&L of a community pharmacy with prescription averages > 200/day
  - Marketed and maintained prescriber relationships
  - Maintained hospital employee prescription program

- Founder, *owner, President & managing pharmacist*, community pharmacy
  - Founded and developed a new start community pharmacy competing and overtaking the daily volume of a local store of a national chain pharmacy
  - Created innovative healthcare screening and disease management activities
  - Health-center based pharmacy specializing in outpatient medication counseling and support
  - Created first Home Infusion Pharmacy in County

- *Pharmacis*t, community county hospital
  - Supported pharmacy operations, aseptic technician as well as parenteral product preparation for a 200+ bed acute care facility. Consulted with medical staff on pharmacotherapy issues

- *Consultant pharmacist* to 600 extended care patients
  - Developed first medication review process for all facilities
  - Presented numerous lectures and in-services on medication related topics
  - Member of several patient care committees
  - Staffed distribution pharmacy

Professional Activities (abbreviated)

- Member Faculty Affairs Committee University of Findlay
- Member Pharmacy Accreditation Compounding Board Standards Committee
- Member Robinson Memorial Hospital Visiting Nurse Professional Advisory Committee
- Member of Select Committee for Ohio State Board of Pharmacy
- Multi-Term Past President of the National Home Infusion Association
- Multi-term President of Portage County Hospice Program
- Board Member The National Home Infusion Association
- Hospice on call clinical team member

Professional Membership

- Member International Academy Compounding Pharmacists (IACP)
- Member National Community Pharmacists Association (NCPA)
- Member American Society of Health System Pharmacists (ASHP)
- Member the National Home Infusion Association (NHIA)
- Member National Hospice and Palliative Care Organization

Presentations/Publications (abbreviated)

Numerous Articles, Courses Authored, Grand Round, Lecture Presentations, Publications:
** Abbreviated and non-inclusive **

Author NAPLEX Review Text 2013; Chapter Author NAPLEX Non-sterile Compounding, Chapter Author NAPLEX Sterile Compounding Publisher Jones and Bartlett

Course Coordinator and Developer Phar449/549 Veterinary Pharmacy University of Findlay College of Pharmacy Fall 2012

Subcutaneous Immune Globulin Therapy in the Alternate Site Setting-Infusion Journal May/June 2006

Contributor

Basu Sarkar, A, Dudley R, Melethil S, Speidel J, Markandakumar G, "Chemical Stability of Hydrocortisone in Topical preparation in Proprietary Cream Base", Innovations in Pharmacy, 2011, 2(3):1-3.

Basu Sarkar, A, Speidel J, Bhatt,G. "Stability Studies on Compounded Topical Local Anesthetic Preparations", J. Amer. Pharm. Assoc., March/April, 2011.

Basu Sarkar, A, Speidel J and Bhatt, G. "Stability Studies on Compounded Topical Local Steroid Preparations", J. Amer. Pharm. Assoc., March/April, 2011.

Received 'Postgraduate Best Paper Award' in the Basic Sciences section in APhA Annual Meeting and Exposition, 2011 held at Seattle, for the presentation "Stability Studies on Compounded Topical Local Steroid Preparations", Basu Sarkar, A , Speidel J, Bhatt G..

Presentations (Abbreviated and Non-inclusive)

Essential Elements of Personalized Analgesic Medications	Vancouver	Canada
Functional and Personalized Hormone Restoration Therapy	Auckland Manila	NZ Philippines
The Science of Pharmaceutical Compounding: Non-Sterile Training	Sydney	Australia
Essential Elements of Personalized Analgesic Medications	Sydney	Australia
Essential Elements of Personalized Analgesic Medications	Melbourne	Australia
Essential Elements of Personalized Analgesic Medications	Toronto	Canada
Essential Elements of Compounded Sterile Preparations	Aventura	FL
Functional and Personalized Hormone Restoration Therapy	Kuala Lumpur	Malaysia
Essential Elements of Personalized Analgesic Medications	Aventura	FL
The Science of Pharmaceutical Compounding: Non-Sterile Training	Aventura	FL
Essential Elements of Personalized Analgesic Medications	Las Vegas	NV
Functional and Personalized Hormone Restoration Therapy	Toronto	Canada
Essential Elements of Compounded Sterile Preparations	Aventura	FL
The Science of Pharmaceutical Compounding: Non-Sterile Training	Montreal	Canada
The Science of Pharmaceutical Compounding: Technician Training	Aventura	FL
The Science of Pharmaceutical Compounding: Non-Sterile Training	Aventura	FL
The Science of Pharmaceutical Compounding: Non-Sterile Training	Sydney	Australia
Functional and Personalized Hormone Restoration Therapy	Sydney	Australia
Functional and Personalized Hormone Restoration Therapy	Melbourne	Australia
Functional and Personalized Hormone Restoration Therapy	Las Vegas	NV
Personalizing Pharmacotherapy Through Compounding Pharmacy	San Diego	CA
Compliance Requirements for Traditional Compounding (503A) and Outsourcing Facilities (503B)	Oklahoma City	OK

Misc Prior Presentations (Abbreviated and Non-inclusive)

The Science of Pharmaceutical Compounding: Non-Sterile Training University of Florida Gainesville and Vancouver Canada – Presenter and Lab Faculty

Essential Elements of Compounded Sterile Preparations: University of Florida – Presenter and Lab Faculty

Essential Elements of Prescription Analgesic Compounding: Las Vegas, NV; Boston MA., Cardinal RBC Orlando Florida; Calgary, Alberta Canada

Vision Ready: Business, Marketing and Sales for the Successful Compounding Pharmacist, Cardinal Retail Business Conference; Orlando Florida.

Developing Compounding Services, Pain Management Cardinal Retail Business Conference; Orlando Florida.

Regulatory Guidelines, Standards of Practice and Quality First Initiatives, Cardinal Retail Business Conference; Orlando Florida.

Essential Elements of Prescription Hormone Compounding San Diego CA; Toronto, Ontario Canada; Phoenix, AZ; Miami, FL

Advanced Concepts in Pain Management Dallas

Endocrinology for compounding Pharmacists Ontario Canada

Advanced Concepts in Sterile Product Preparation; Gainesville Florida

Pharmacology Review Workshop for Midwives-ACNM Annual Clinical Meeting
Infusion Therapy Niche for Community Pharmacy-NCPA Annual Meeting,

Subcutaneous Immune Globulin Therapy in the Alternate Site Setting-Infusion Journal

Clinical Perles in the Management of Specialty Biotherapies-The National Home Infusion Association Annual Meeting,

ASHP Midyear December Subcutaneous Immune Globulin Therapy,

Infused Biotherapies Wellpoint-Anthem,

Specialty Pharmacy Trends and Future NHIA National Conference,

Home Infusion Therapy and Beyond,

Pharmacology for Rehabilitation Specialists Children's Hospital Akron, Ohio

Hormone Replacement Therapy…is there hope after the WHI trial?

MICHELLE WOOSLEY, PHARMD, MBA

Phone: 502-558-3365 ~ E-mail: michelle@pharmcorerx.com

LinkedIn: https://www.linkedin.com/in/michelle-woosley-pharmd-mba/

EXECUTIVE SUMMARY

Innovative, strategic, and visionary pharmacy leader with experience in a wide variety of pharmacy settings including community pharmacy, outpatient infusion services, specialty pharmacy, hospital pharmacy, sterile compounding, nonsterile compounding, veterinary pharmacy, and hazardous drug handling. Leadership experience encompasses fifteen years in pharmacy operations, business growth and development, creation of new service lines, new builds and remodels, and team management. Additional areas of focus and expertise include ten years in compounding practice and regulatory compliance management, ten years as a quality assurance and accreditation specialist, and five years of experience conducting pharmacy audits and inspections.

AREAS OF EXPERTISE

- State and Federal Regulatory Compliance
- USP Compliance Chapters <795>, <797>, <800>
- Pharmacy Accreditation (ACHC, URAC, etc.)
- Quality Assurance & Quality Improvement
- New Pharmacy Expansion & Construction
- Virtual Wholesalers & Third-Party Logistics
- On-Site Facility Gap Analysis
- Pharmacy Compliance Assessment
- Policy & Procedure Development
- Team Training & Education
- Inspection Response & Remediation
- Pharmacy Operations & Standardization

WORK EXPERIENCE

PHARMCORE, LLC Remote, USA
Founder, Principal Consultant, Certified Executive Coach-- *July 2022 – Present*

- Provide consulting services on compounding pharmacy business operations, regulatory compliance, compounding compliance, quality management, and accreditation readiness for pharmacies.
- Conduct on-site facility assessments to ensure compliance with applicable laws, regulations, and standards.
- Prepare pharmacies for inspection programs, regulatory inspections, and accreditation surveys.
- Assist with regulatory agency post-inspection findings and advise on any needed remediation.
- Serve as a subcontractor for pharmacy industry consulting agencies.
    - **Frank Consulting, LLC**
        - Provide consulting services in the areas of pharmacy practice, community pharmacy, compounding, accreditation, and regulatory compliance including monitoring.
    - **Gates Healthcare Associates, Inc.**
        - Part of a team of expert consultants and subject matter experts on a wide variety of healthcare settings and industry standards. Provide pharmacy inspection and accreditation readiness services for clients.
    - **National Coalition for Drug Quality and Security (NCDQS)**
        - Provide inspection services for wholesale distributors and third-party logistics companies handling prescription drugs and devices.

COLD BORE CAPITAL/OPTIO RX, LLC, Remote, USA
Corporate Director, Compliance and Quality *– Jan. 2021 – May 2022*

- Responsible for a large, multi-state, private equity owned portfolio of nonsterile and sterile compounding pharmacies, veterinary pharmacies, retail pharmacies, specialty and fertility pharmacies, and hospice pharmacies.
- Served as the subject matter expert on compounding standards, pharmacy regulations, and industry best practices**.**
- Consulted on external third-party audits, Boards of Pharmacy, and FDA/DEA inspections.
- Conducted on-site audits of pharmacy facilities, nonsterile compounding labs, and sterile cleanrooms.
- Standardized quality assurance and quality control procedures across all pharmacies.
- Streamlined compliance monitoring processes for FWA, OIG checks, and license verifications.
- Authored and managed all corporate, administrative, and compliance policies and procedures for the organization**.**
- Provided guidance on pharmacy accreditations, accreditation project plans, and needed corrective action**.**
- Evaluated and directed quality management initiatives, process improvement, and incident reporting processes.
- Participated in the acquisition process of new pharmacies and due diligence procedures.

MICHELLE WOOSLEY, PHARMD, MBA

Phone: 502-558-3365 ~ E-mail: michelle@pharmcorerx.com

LinkedIn: https://www.linkedin.com/in/michelle-woosley-pharmd-mba/

WORK EXPERIENCE- CONT.

COMPREHENSIVE PHARMACY SERVICES
Director of Accreditation, Specialty and Ambulatory Pharmacy Services *– Jan. 2020 – Dec 2020* Remote, USA
Specialty Pharmacy Manager, U of L Health Specialty Pharmacy (CPS contract) *– Oct. 2017 – Dec. 2019* Louisville, KY

- Directed the development of the Specialty Pharmacy Division for Comprehensive Pharmacy Services.
- Met with C-Suite executives, senior leaders, and stakeholders regarding start-up goals and initiatives.
- Provided guidance on pharmacy accreditation standards and regulatory requirements.
- Conducted site visits to assess operational workflow, clinical practices, and to monitor the project plan.
- Developed client-specific pharmacy implementation plans for pharmacy operations and accreditation readiness.
- Performed mock accreditation surveys in advance of the client's scheduled survey date.
- Wrote, implemented, and revised policies and procedures to meet URAC and ACHC accreditation standards.
- Collaborated with health system marketing teams to design new marketing materials for the specialty pharmacy.
- Created specialty pharmacy quality management programs to integrate with the health system's quality program.
- Recruited, trained, coached, and supervised pharmacists, technicians, interns, and pharmacy residents.
- Hired as a contract site leader for new specialty pharmacy start up at University of Louisville Hospital in October '17.
    - Baseline revenue from specialty prescriptions was $2.64 million in EBITDA annually at contract initiation.
    - In December 2019, annual revenue from specialty prescriptions was $30 million in EBITDA.
    - The UofL Specialty Pharmacy also achieved URAC Accreditation in December 2019.

AMERIMED INFUSION/JEWISH HOSPITAL, Louisville, KY
Director of Operations *– Aug. 2011 – Oct. 2017*

- Supervised pharmacy operations and the clinical practice of a health-system owned, 340B home infusion pharmacy.
- Baseline annual revenue upon hire as the Director of Operations in August 2011 was $12.5 million in EBITDA.
- Annual revenue in 2016 was $21 million in EBITDA; Budget projects for 2018 were set at $23 million.
- Therapy mix included traditional infusion therapies, hemophilia, and specialty pharmacy injectables.
- Responsible for meeting all performance metrics and customer service goals of the infusion pharmacy.
- Managed drug procurement, preparation, labeling, packaging, proper disposal, and security of medications.
- Oversaw medication dispensing by planning, implementing, and maintaining standard operating procedures.
- Assisted with investigations and documentation of any medication error, compliant, or adverse drug event.
- Complied with state and federal drug laws as regulated by the Board of Pharmacy, FDA, and DEA.
- Maintained compliance with USP <797> sterile compounding standards and procedures.
- Ensured quality management, medication safety, and regulatory compliance of all aspects of the pharmacy.
- Responsible for ACHC and Joint Commission accreditations and for ongoing compliance with applicable standards.

NORTON SUBURBAN HOSPITAL, Louisville, KY
Clinical Staff Pharmacist *– Sept. 2007 – Aug. 2011*

- Supported daily workflow functions and clinical pharmacy initiatives within a 250-bed hospital.
- Conducted medication reconciliation on all new admissions and discharges.
- Participated in daily rounds of medical surgical floors and ICU/CCU areas with the medical team.
- Compounded sterile IV orders and nonsterile compounds for adult and pediatric patients.
- Residency and student preceptor on medical-surgical floors.
- Managed remote orders during off-hours for a critical access hospital.
- Performed clinical chart reviews for renal dosing adjustments and therapeutic interchanges.
- Provided pharmacy consults on TPNs, vancomycin, aminoglycosides, and anticoagulants.
- Preceptor pharmacy students and PGY1 residents.

CVS PHARMACY, Louisville, KY –- **Staff Pharmacist*, Floater PRN*** –-2022-2023
WAL-MART PHARMACY, Louisville, KY — ***Staff Pharmacist, Floater PRN*** — 2007-2017
KROGER PHARMACY, Nashville/Knoxville, TN **– *Pharmacy Manager*** —2002-2007
RITE AID PHARMACY — Birmingham, AL — ***Pharmacy Manager*** — *2001-2002*

- Managed multiple pharmacy teams ranging from 2-20 staff members for retail pharmacy chains.
- Processed and accurately dispensed prescription orders and administered immunizations.
- Supervised daily operations of the pharmacy and promoted teamwork.
- Ensured compliance with all regulatory and pharmacy practice policies and procedures.
- Effectively addressed customer complaints and worked to resolve any issues.
- Conducted oversight of inventory management procedures, inventory counts, and reconciliation.

MICHELLE WOOSLEY, PHARMD, MBA

Phone: 502-558-3365 ~ E-mail: michelle@pharmcorerx.com

LinkedIn: https://www.linkedin.com/in/michelle-woosley-pharmd-mba/

PROFESSIONAL AFFILIATIONS/TEACHING EXPERIENCE/PRESENTATIONS

Professional Development

- ASHP Mid-Year Meeting, Dec. 2022
- American Society of Pharmacy Law Annual Conference, Nov. 2022
- DEA Virtual Diversion Pharmaceutical Awareness Training, Aug. 2022
- American Society of Pharmacy Law Annual Conference, Nov. 2021.
- Healthcare Compliance Corporation of America—Compliance Essentials Workshop, Oct. 2021.
- Healthcare Compliance Corporation of American Annual Meeting, March 2022.
- Professional Compounding Centers of America (PCCA)—USP Implementation Training, March 2021.
- Professional Compounding Centers of American (PCCA)—Core Compounding Training, April 2021.
- Accreditation Commission for Health Care (ACHC) Certified Consultant Training, 2020.

Memberships/Professional Organizations

- M&A Source, 2024--current
- International Business Broker Association (IBBA), 2024—current.
- Kentucky Pharmacists Association (KPhA), 2024—current.
- American College of Veterinary Pharmacy (ACVP), 2024—current.
- Alliance for Pharmacy Compounding (APC), 2021—current.
- American College of Apothecaries (ACA), 2021—current.
- American Society of Pharmacy Law (ASPL), 2021—current.
- Controlled Environmental Testing Association (CETA), 2021—current.
- American Society of Health-System Pharmacists (ASHP), 2015—current.

Presentations

- AbbVie, Meetings and Events International Speakers Bureau, 2019
  Learn About AbbVie's Growing Portfolio and AbbVie's Continued Commitment to Patient Care (Immunology Portfolio)
  Learn About AbbVie's Growing Portfolio and AbbVie's Continued Commitment to Patient Care (Rheumatology Portfolio)

LICENSE/CERTIFICATES/EDUCATION

Licenses

- Kentucky Pharmacist License, Active, *2002 - Present*

Certifications

- Center for Executive Coaching Certified Executive Coach, *2024*
- ACHC Hazardous Drug Designated Persons (HDDP) Certification, *2022*
- ASHP Advanced Sterile Compounding Preparation Training Certification, *2017*
- ASHP Immunization Certification, *2000*

Education

- Master of Business Administration, Healthcare Administration, Sullivan University, *2019*
- Doctor of Pharmacy, Samford University McWhorter College of Pharmacy, *2001*
- B.S. Biology with Minor in Chemistry, Murray State University, *1997*

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

...

As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

...

For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

An application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of §54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

An "opening" inspection report for a newly opened pharmacy or a new location for an existing pharmacy indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies performing non-sterile compounding, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an "operational" inspection report shall be provided during the subsequent renewal of the registration. An "opening" inspection report for

a newly opened pharmacy or a new location for an existing pharmacy performing sterile compounding shall not satisfy the requirements for obtaining initial registration or renewal as a nonresident pharmacy. Submission of an "operational" inspection report indicating compliance with USP-NF standards for sterile compounding shall be required for consideration for obtaining initial registration or renewal as a nonresident pharmacy.