

Project 7968 - Proposed

Board of Pharmacy

Requirements for use of central fill pharmacy and remote database access

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time, except as provided in 18VAC110-20-276 and 18VAC110-20-277.

B. In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

18VAC110-20-276. Central or remote processing.

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or

8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;

2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties that are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;

3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and

4. The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a nondispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription

processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and ~~permit/registration~~ permit or registration numbers of all pharmacies involved in central or remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records that show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record

showing each processing task, the identity of the person performing each task, and the location where each task was performed.

2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist or registered as a pharmacy technician or pharmacy intern performing the duties of a pharmacy technician in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

G. A pharmacist may only supervise a maximum of six pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians accessing the employer pharmacy's database from a remote location as provided in subsection F of this section, with a maximum of four of the six on site at the employer pharmacy. The supervising pharmacist shall be readily available to the pharmacy technicians and pharmacy interns, and technology shall be available for adequate supervision of pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians.

18VAC110-20-277. Central fill pharmacy.

A. Notwithstanding activities authorized in 18VAC110-20-275, 18VAC110-20-276, and 18VAC110-20-515, a pharmacy located in the Commonwealth or out of state may outsource tasks associated with dispensing a prescription drug, including verification for accuracy by a pharmacist and alternate delivery to the originating pharmacy that received the prescription, to a central fill pharmacy permitted in the Commonwealth as a pharmacy or registered as a nonresident pharmacy.

B. A central fill pharmacy may operate if:

1. Sufficient automation is employed to safely support the practice of pharmacy and limit distractions for pharmacy personnel;
2. The central fill pharmacy does not accept prescriptions or communications directly from patients or providers; and
3. Dispensing is restricted to Schedule VI drugs.

C. Notwithstanding § 54.1-3321 of the Code of Virginia, an unregistered or unlicensed person may perform the following non-dispensing functions at a central fill pharmacy:

1. The movement of sealed manufacturer bottles from an inventory shelf to a pharmacy technician's workspace for the purpose of filling a canister when the filling of the canister is completed by a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee who barcode scans or uses other technology to verify each individual bottle or package of medication prior to filling the canister.
2. Manually bagging prepared prescriptions when barcode scanning or use of other technology is used to verify the prescription product vial, prescription medication leaflet, and prescription bag label.
3. Loading an automated robotic dispenser with the pharmacist-verified and sealed canister when barcode scanning or other technology is used to verify accurate placement of each canister.
4. Performing monthly cycle counts of sealed manufacturer-packaged products and sealed canisters; however, the opening of a sealed manufacturer-packaged product or canister and the counting of an unsealed manufacturer-packaged product or canister is not permitted.

D. A pharmacist practicing at a central fill pharmacy may supervise up to 12 licensed or registered persons, to include pharmacy technicians, pharmacy technician trainees, and pharmacy interns, and may supervise up to 12 unregistered or unlicensed persons performing non-dispensing functions authorized in this subsection. Each pharmacist shall determine the number of persons the pharmacist can safely and competently supervise at one time.

E. Notwithstanding 18VAC110-20-270 B, pharmacist verification of a canister of medication after it is filled and sealed but prior to being loaded into a barcoded automated robotic dispenser serves as the final product verification of a prescription. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of the contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards. This provision shall not constitute a waiver of the requirement for a pharmacist to verify the accuracy of data entry of the prescription.

F. A central fill pharmacy shall ensure that each pharmacy receiving dispensed drugs from the central fill pharmacy shall provide a one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public as its notification of the dispensing and delivery process. 18VAC110-20-275 B 2 h shall not apply to central fill pharmacies and those pharmacies receiving dispensed drugs from central fill pharmacies.

G. A written policy and procedure must be maintained by the central fill pharmacy and complied with and shall include, at minimum, procedures for ensuring:

1. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes and the method for ensuring pharmacist verification of all packaged and repackaged drugs compliant with this section and assigned barcodes;

2. Accurate stocking and restocking of the robotic pharmacy system;

3. Removing expired drugs;

4. Proper handling of drugs that may be dropped by the robotic pharmacy system;

5. Performing routine maintenance of the robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

6. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

7. Maintaining quality assurance reports.

H. All manual picks for dispensing at a central fill pharmacy shall be verified for accuracy by a pharmacist.

I. If it is identified that the robot at a central fill pharmacy selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operation of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

J. One prescription per automated dispensing device per quarter shall be redirected to a pharmacist to audit for prescription product accuracy in all components. Quarterly quality assurance records related to these audits shall be maintained for two years from the date the audit is performed.

K. A central fill pharmacy may deliver the dispensed drug to the patient's residence or the originating pharmacy that received the prescription pursuant to § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-275.

L. An out-of-state pharmacy solely returning a drug that was not delivered to the patient to the central fill pharmacy that dispensed the drug as authorized in § 54.1-3411.1 of the Code of Virginia shall be exempt from obtaining registration as a nonresident pharmacy.

M. The transfer of the prescription between the originating pharmacy that received the prescription and the central fill pharmacy shall not be required if the pharmacies share a common electronic file or have technology that allows sufficient information necessary for dispensing the prescription.