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64B16-28.141 Requirements for use of an Automated Pharmacy System by a Community Pharmacy.

(1) Definitions:

(a) "Automated pharmacy system (APS)" means a mechanical system that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(b) "Establishment" means one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings.

(c) "Pharmacist" means a pharmacist as defined by section 465.003, FS.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The automated pharmacy system is located within the prescription department, adjacent to the prescription department, or is located on the establishment of the licensed pharmacy, and the operation of the automated pharmacy system is under the supervision of a pharmacist. An automated pharmacy system that is not located within the prescription department shall be operated as an extension of the licensed pharmacy and the automated pharmacy system shall not require an independent and separate community pharmacy permit. An automated pharmacy system that is not located within the prescription department shall have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit number of the community pharmacy that is responsible for the operation of the automated pharmacy system.

(b) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.
2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.
3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.
4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.
5. Compliance with a Continuous Quality Improvement Program.
6. A method to ensure that patient confidentiality is maintained.
7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(c) The system ensures that each prescription is dispensed in compliance with the definition of dispense as defined by section 465.003, F.S., and the practice of the profession of pharmacy. The system shall include a mechanism to ensure that the patient or an authorized agent of the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product. The means of communication may include in person, electronic, digital, or telephonic.

(d) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(e) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) The requirements in subsection (2), above, are met.

(b) Except as provided in paragraph (d), below, the stocking or restocking of a medicinal drug shall only be completed by the following:

1. A pharmacist;
2. A pharmacy intern under the direct and immediate personal supervision of a pharmacist; or
3. A registered pharmacy technician under the direct supervision of a pharmacist.

(c) Access to the Automated Pharmacy System in the absence of a pharmacist for purposes of servicing and maintenance by non-pharmacy licensed personnel shall be permitted provided that the system is capable of tracking individual access and preventing unauthorized access, and the system employs user based access or other technology that will prevent access to areas of the dispensing cabinet where drugs are stored. If the system does not employ such technology, access to the system for servicing and maintenance is permitted only under the direct supervision of a pharmacist.

(d) If the automated pharmacy system uses removable cartridges or containers to store the drug or uses unit of use packages, the stocking or restocking of the cartridges, containers or unit of use packages may occur at a licensed repackaging facility and may be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A pharmacist verifies the cartridge, container or unit of use packages have been properly filled and labeled.

2. The individual cartridge, container or unit of use package is transported to the provider pharmacy in a secure, tamper-evident container.

3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge, container or unit of use package is accurately loaded into the automated pharmacy system.

4. The pharmacist verifying the filling and labeling retains responsibility if the cartridge, container or unit of use package is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(e) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), visual verification or similar process to ensure that the proper medication is being dispensed from the automated system.

(f) The medication shall bear a patient specific label that complies with rule 64B16-28.108, F.A.C.

(g) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.
2. Name, strength, and dosage form of the drug product dispensed.
3. Quantity of drug dispensed.
4. Date and time of dispensing.
5. Name of provider pharmacy.
6. Prescription number.
7. Name of prescribing practitioner.
8. Identity of the pharmacist who approved the prescription or order.
9. Identity of the person to whom the drug was released.

(4) The pharmacist responsible for filling, verifying, loading or supervising the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History - New 11-29-04, Amended 12-30-07, 1-1-10, 7-5-18.