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Automated Pharmacy System

INSPECTION

☐ Opening ☐ Random

INFORMATION

Pharmacy Name: _____ Date: _____

Pharmacy License Number: _____ Expiration Date: _____

Controlled Substance License Number: _____ Expiration Date: _____

DEA Registration Number: _____ Expiration Date: _____

Pharmacist-in-Charge (PIC): _____

Pharmacist-in-Charge License Number: _____ Expiration Date: _____

58-17b-621. Automated pharmacy systems

Automated pharmacy systems can be utilized in licensed pharmacies, remote locations under the jurisdiction of the Utah State Board of Pharmacy, and licensed health care facilities where legally permissible, as approved by the division in collaboration with the board, and described in rule.

	Yes	No	
1.	☐	☐	Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained on site in the pharmacy for review upon request of the Division. Such documentation shall include: [UAC R156-17b-620(1)]

- ☐ Name and address of the pharmacy or licensed health care facility where the automated pharmacy system is being used
- ☐ Manufacturer's name and model
- ☐ Description of how the device is used
- ☐ Quality assurance procedures to determine continued appropriate use of the automated device
- ☐ Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction

2.	☐	☐	Automated pharmacy systems should be used only in settings where there is an established program of pharmaceutical care that ensures that before dispensing, or removal from an automated storage and distribution device, a pharmacist reviews all prescription or medication orders unless a licensed independent practitioner controls the ordering, preparation and administration of the medication; or in urgent situations when the resulting delay would harm the patient including situations in which the patient experiences a sudden change in clinical status. [UAC R156-17b-620(2)]
3.	☐	☐	All policies and procedures must be maintained in the pharmacy responsible for the system and, if the system is not located within the facility where the pharmacy is located, at the location where the system is being used. [UAC R156-17b-620(3)]
4.	☐	☐	Automated pharmacy systems shall have: [UAC R156-17b-620(4)]

- ☐ Adequate security systems and procedures to, prevent unauthorized access, comply with federal and state regulations, and prevent illegal use or disclosure of protected health information.
- ☐ Written policies and procedures in place prior to installation to ensure safety, accuracy, security, training of personnel, and patient confidentiality, and to define access and limits to equipment and medications.

5.	☐	☐	Records and electronic data kept by automated pharmacy systems shall meet the following requirements: [UAC R156-17b-620(5)]

- ☐ All events involving the contents of the automated pharmacy system must be recorded electronically
- ☐ Records must be maintained by the pharmacy for a period of five years and must be readily available to the Division. Such records shall include:

- ☐ Identity of system accessed
- ☐ Identity of the individual accessing the system
- ☐ Type of transaction
- ☐ Name, strength, dosage form and quantity of the drug accessed
- ☐ Name of the patient for whom the drug was ordered
- ☐ Any additional information the PIC may deem necessary

6. ☐ ☐ Access to and limits on access to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations. [UAC R156-17b-620(6)]

7. ☐ ☐ The PIC or pharmacist designee shall have the sole responsibility to: [UAC R156-17b-620(7)]
   - ☐ Assign, discontinue or change access to the system
   - ☐ Ensure that access to the medications comply with state and federal regulations
   - ☐ Ensure that the automated pharmacy system is filled and stocked accurately and in accordance with established written policies and procedures.

8. ☐ ☐ The filling and stocking of all medications in the automated pharmacy system shall be accomplished by qualified licensed healthcare personnel under the supervision of a licensed pharmacist. [UAC R156-17b-620(8)]

9. ☐ ☐ A record of medications filled and stocked into an automated pharmacy system shall be maintained for a period of five years and shall include the identification of the persons filling, stocking, and checking for accuracy. [UAC R156-17b-620(9)]

10. ☐ ☐ All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations. [UAC R156-17b-620(10)]

11. ☐ ☐ All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations. [UAC R156-17b-620(11)]
    N/A ☐

12. ☐ ☐ The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, all in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system remain unused and must be secured and accounted for. [UAC R156-17b-620(12)]

13. ☐ ☐ The automated pharmacy system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law. Written policies and procedures shall address situations in which medications removed from the system are wasted or discarded and must be secured. [UAC R156-17b-620(13)]

COMMENTS

(Use an additional sheet if necessary)

☐ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: Date:

Name of Responsible Party (Print):

Signature of Division Investigator: Date:

Name of Division Investigator (Print):

Revised 3/2025