

ARTICLE XXXIX AUTOMATED PHARMACY SYSTEMS

1. Automated pharmacy systems include, but are not limited to, mechanical systems that perform operations or activities relative to the storage, packaging, delivery, or distribution of medications, and which collects, controls and maintains all transaction information. Every pharmacy that utilizes any such automated medication delivery system shall comply with the following.

2. PERSONNEL

The pharmacist-in-charge shall have the following responsibilities:

- A. Assuring that the automated pharmacy system is in good working order and accurately delivers the correct strength, dosage form, and quantity of the medication prescribed while maintaining appropriate record-keeping and security safeguards; and
- B. Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed by the pharmacy; and
- C. Providing the Board with prior written notice of the installation or removal of any automated pharmacy system. Such notice must include the name and address of the pharmacy, the location of the automated equipment, and the identification of the responsible pharmacist.

3. PHARMACY PRACTICE

Automated pharmacy systems can be utilized in permitted pharmacies, remote locations wherein patients are receiving pharmaceutical care by the pharmacist and/or pharmacy responsible for the automated pharmacy system, and other health care facilities, provided they are under the jurisdiction of the Board. The pharmacist-in-charge shall be responsible for the following:

- A. Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained onsite in the pharmacy for review by the Board. Such documentation may include, but is not limited to:
 - (1) Name and address of the pharmacy and/or licensed health care facility where the automated pharmacy system(s) is being used; and
 - (2) Manufacturer's name and model; and
 - (3) Description of how the device is used; and
 - (4) Quality assurance procedures to determine continued appropriate use of the automated device; and
 - (5) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction.
- B. Automated pharmacy systems should be used only in settings where there is a program of pharmaceutical care which provides that medication orders are reviewed by a pharmacist in accordance with established policies and procedures. The delivery of a "first dose" or an "emergency dose" may take

place without prior order review by a pharmacist, provided appropriate security and patient medication management controls are in place.

- C. All policies and procedures must be maintained in the pharmacy responsible for the system. If the system is not within the facility where the pharmacy is located, policies and procedures must be maintained at the location where the system is being used.
- D. Automated pharmacy systems shall have adequate security systems and procedures, evidenced by written policies and procedures, to:
 - (1) Prevent unauthorized access and to comply with federal and state regulations; and
 - (2) Maintain patient confidentiality.
- E. Records and/or electronic data kept by automated pharmacy systems shall meet the following requirements:
 - (1) All events involving the contents of the automated pharmacy system must be recorded electronically; and
 - (2) Records must be maintained by the pharmacy and must be readily available to the Board. Such records shall include:
 - (a) Identity of system accessed; and
 - (b) Identification of the individual accessing the system; and
 - (c) Type of transaction; and
 - (d) Name, strength, dosage form, and quantity of the drug accessed and/or removed; and
 - (e) Name of the patient for whom the drug was ordered and a record in the automated pharmacy system or other readily retrievable system of the name of the prescriber; and
 - (f) Such additional information as the pharmacist-in-charge may deem necessary.
- F. Access to, and limits on access (e.g. security levels) to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations.
- G. The pharmacist-in-charge shall be responsible for:
 - (1) Assigning, discontinuing, or changing access to the system; and
 - (2) Ensuring that access to the medications comply with state and federal regulations; and
 - (3) Ensuring that the automated pharmacy system is filled/stocked/replenished accurately and in accordance with established written policies and procedures.
- H. The filling/stocking/replenishing of all medications in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a pharmacist licensed by the Board.
- I. A record of the medications filled/stocked/replenished in an automated pharmacy system shall be maintained for a period of two (2) years and shall include identification of the persons filling/stocking/replenishing and checking for accuracy.
- J. All containers of medications stored in an automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and

regulations.

- K. The automated pharmacy system must have the capability to produce a hard copy printout of the utilization of controlled substances maintained in each automated pharmacy system. All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.
- L. The automated pharmacy systems shall provide a mechanism for securing and accounting for medications removed from and subsequently returning to the equipment, all in accordance with existing state and federal law.
- M. The automated pharmacy system shall provide a mechanism for securing and accounting for wastage of medications or discarded medications in accordance with state and federal law and/or regulations.