

REGULATION 12 —AUTOMATION

12-00-0001—AUTOMATED AND ROBOTIC PHARMACY SYSTEMS

(a) Purpose and Scope:

The purpose of this regulation is to recognize the use of automated pharmacy systems and or robotic pharmacy systems in community or institutional pharmacy settings.

(b) Definitions:

(1) “Automated pharmacy systems” include, but are not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medications—and which collects, controls, and maintains all transaction information.

(2) “Robotic pharmacy system” means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, and dispensing—and collects, controls, and maintains all transaction information.

(c) General requirements for automated pharmacy systems and robotic pharmacy systems:

(1) Duties and responsibilities of the permit holder

(A) Providing the Board prior written notice of the installation, removal, or substantive change of the automated or robotic pharmacy system. Such notice must include, but is not limited to:

- (i) the name, address, and permit number of the pharmacy,
- (ii) the identification of the responsible pharmacist,
- (iii) the manufacturer’s name and model of the system, and
- (iv) the policies and procedures for the system operation (for initial installations)

(B) Obtaining written approval and authorization from the Board of Pharmacy prior to implementation.

(C) Developing and implementing an ongoing quality assurance program that monitors performance of the system, which is evidenced by written policies and procedures developed by the pharmacy and include the following:

- (i) Method of ensuring accurate packaging and loading of the system,
- (ii) Procedures for conducting quality control checks of final dispensing for accuracy,
- (iii) Manufacturer’s schedules and recommendations for maintenance of the device, and
- (iv) Plan for maintenance of all related documentation for a minimum of two years.

(D) Assuring that the system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

(2) Pharmacy Practice

(A) The automated/robotic pharmacy system can be utilized in licensed pharmacies and licensed health care facilities where legally permissible and shall comply with the following provisions:

- (i) documentation, as to type of equipment, serial numbers, content, policies and procedures, and location, shall be maintained on-site in the pharmacy for review by an agent of the Board of Pharmacy, and
- (ii) the system shall be used only in settings where there is an established program of pharmaceutical care that ensures medication orders or prescriptions are reviewed by

a pharmacist in accordance with established policies and procedures and good pharmacy practice.

- (3) The system shall have adequate security systems and procedures, evidenced by written policies and procedures, to:
 - (A) prevent unauthorized access;
 - (B) comply with federal and state regulations, and;
 - (C) maintain patient confidentiality.
- (4) The filling/stocking of all medications in the system, shall be accomplished by qualified personnel under the supervision of a licensed pharmacist. An electronic or hard copy record of medications filled into the system shall be maintained and include identification of the person filling the device.
- (5) 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. Proper identification and access control, including electronic passwords, biometric identification, or other coded identification, must be limited and authorized by the pharmacist-in-charge. The pharmacist in charge must:
 - (A) be able to stop or change access at any time, and
 - (B) maintain a current and retrievable list of all persons who have access and the limits of that access.
- (6) The pharmacist in charge shall have the sole responsibility to:
 - (A) assign, discontinue, or change access system;
 - (B) ensure that access to the medications comply with state and federal regulations and;
 - (C) ensure that the system is filled/stocked accurately and in accordance with established, written policies and procedures. (10/2001)