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Board of Registration in Pharmacy

Policy 2022-07: Automated Pharmacy Systems

The Board of Registration in Pharmacy ("Board") authorizes this policy to facilitate patient access to filled Schedule IV through VI prescriptions from automated pharmacy systems. In the case of a licensed healthcare facility, approval for use and placement must be obtained from the facility's licensing body (e.g., Bureau of Health Care Safety and Quality).

Automated Pharmacy System ("APS") means an automated patient-facing device that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information. The APS releases patient medications after correct patient identification and provides patients with the opportunity for a pharmacist consultation.

I. A pharmacy may dispense Schedule IV through VI controlled substances from an APS to a patient or a patient's agent during or after pharmacy hours of operation provided the following requirements are met:

- A. The APS is located within the same building as the pharmacy.
- B. The APS is secured against or within a wall or floor in a manner that prevents unauthorized access and removal.
- C. The location and APS are monitored by continuous, recordable video surveillance.
- D. A pharmacy may not stock medications in an APS that require refrigeration or reconstitution.
- E. The APS utilizes industry standard technological verification, such as bar code verification, electronic verification, weight verification, radio frequency identification, or another similar process, to ensure the correct medication is dispensed to the correct patient.
- F. The APS or the pharmacy that operates the APS maintains electronic data that creates an audit trail of activity and includes the identity of each person to whom a drug was released.

- G. The pharmacy allows the patient to choose whether or not to use an APS.
- H. In the case of new or changed therapy for the patient, the pharmacy must provide the offer to counsel before placing the filled prescription in the APS.
- I. The pharmacy provides the means and opportunity for a pharmacist consultation during the pharmacy's usual hours of operation.
- J. Board-licensed pharmacies must submit a written request to the Board with details including but not limited to:
 - 1. type of APS (e.g., brand, model, etc.);
 - 2. specific location within the building;
 - 3. security measures;
 - 4. schedules of controlled substances (limited to Schedule IV through VI);
and
 - 5. hours the APS will be available for use.

II. A pharmacy utilizing an APS shall maintain policies and procedures pertaining to the APS that include:

- A. APS location(s);
- B. operation and maintenance;
- C. security;
- D. controlled substances accountability;
- E. quality assurance;
- F. stocking and return activities; and
- G. patient confidentiality.

Supersedes Policy 2010-02

Please direct any questions to: Pharmacy.Admin@mass.gov