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2010-02 Joint Guidelines for the Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies

The Department of Public Health/Board of Registration in Pharmacy, Drug Control Program and Division of Health Care Quality, jointly issue these Guidelines to facilitate patient access to Schedule VI controlled substance REFILL prescriptions in pharmacies. These Guidelines are distinct from the Joint Guidelines for Use of Automated Devices for the Dispensing of Controlled Substances in Health Care Facilities relating to medication dispensing devices utilized for authorized personnel access to inpatient medications.

(1) Definitions.
(a) Automated Pharmacy System means a mechanical system, located either in wall of a pharmacy or within 20 feet of a pharmacy, which performs operations and activities, other than compounding or administration, and maintains transaction information, related to the storage and dispensing of Schedule VI controlled substance refill prescription medication directly to pharmacy customers during or after pharmacy hours of operation; or such other system as may be approved by the Board of Registration in Pharmacy (Board), the Department of Public Health (Department), Drug Control Program (DCP) and the Division of Health Care Quality (DHCQ).
(b) Pharmacist-in-Charge means the Director of Pharmacy or Pharmacist Manager of Record or a pharmacist so designated by one of the above. The Pharmacist-in-Charge is responsible for the establishment and enforcement of policies and procedures regarding the use of automated pharmacy systems.
(c) Pharmacy means a pharmacy, pharmacy department, and institutional pharmacy, all as defined in 247 CMR 2.00.

(2) General Requirements. Prior to using an automated pharmacy system, a pharmacy is required to:
(a) notify the Board and the Department in writing of the intent to use an automated pharmacy system, including the name and address of the pharmacy location, the hours of operation of the system, the type or name of the system, and a description of how the system is used by pharmacy; and
(b) develop and maintain on-site a policy and procedure manual that includes detailed information regarding the following:
1. Name and address of the pharmacy where the automated pharmacy system is being used;
2. Manufacturer's name, model, and serial number or other identifying nomenclature of the system;

3. Description of how the system is used by the pharmacy;
4. Quality assurance procedures to determine continued appropriate use of the system;
5. Policies and procedures for system operation, safety, security, accountability, accuracy, patient confidentiality, access (multilingual capabilities recommended) and malfunction, with requirement that any malfunction of the system shall be reported immediately to the Pharmacist-in-Charge for corrective action; and
6. Procedures related to identification and analysis of any system dispensing error, in accordance with 247 CMR 15.00.

(3) Patient Consultation and Patient Choice. A pharmacy or Pharmacist-in-Charge shall establish policies and procedures that ensure that the automated pharmacy system used by the pharmacy:
(a) only contains Schedule VI controlled substance medication for REFILL prescriptions that:
1. do not require oral consultation by law; and
2. are properly labeled and verified by a pharmacist before placement into the automated pharmacy system and subsequent release to pharmacy customers;
(b) allows a patient to choose whether or not to use the system; and
(c) provides opportunity for a patient to consult with a pharmacist during any hours that prescriptions are available for pickup from the automated dispensing system.

(4) Security. An automated pharmacy system must be secured against or within the wall or floor in a manner that prevents unauthorized removal of the system. A pharmacy must have written policies and procedures that provide for adequate security systems and procedures that:
(a) provide a method to identify the patient and only release that patient's prescription; and
(b) ensure system methods to prevent unauthorized access; including such methods as use of electronic passwords, biometric scanning (optic scanning or fingerprinting) or other coded identification.

(5) Records. An automated pharmacy system must maintained records and electronic data that include the following information:
(a) name of providing pharmacy;
(b) prescription number;
(c) name, strength, dosage form, and quantity of the drug accessed;
(d) name of the patient for whom the drug was ordered;
(e) date and time of dispensing;
(f) name of prescribing practitioner;
(g) identity of the pharmacist who approved the prescription order; and
(h) identity of the person to whom the drug was released.

(6) Access.
(a) Access to and limits on access (e.g., security levels) to the automated pharmacy system must be established by policy and procedures that comply with state and federal regulations and provide adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices.
(b) The Pharmacist-in-Charge shall have sole responsibility to:
1. assign, discontinue, or change access to the system;

2. ensure that access to system drugs or devices is restricted to authorized licensed personnel for the purposes of administration based on a valid prescription order; and
3. ensure that the automated pharmacy system is stocked accurately and in accordance with written policies and procedures.

(7) Stocking and Returning Medication. The stocking and return of all prescription medications in the automated pharmacy system shall:
(a) only be completed by a pharmacist or certified pharmacy technician;
(b) be recorded and maintained in the system and include identification of the person(s) authorized to stock medication and perform accuracy checks of the system stock;
(c) be limited to medications not requiring refrigeration or reconstitution, which are packaged and labeled in accordance with federal and state laws and regulations;
(d) include procedures for securing and accounting for prescription medications removed from and subsequently returned to pharmacy stock;
(e) include procedures for securing and accounting for wasted prescription medications or discarded medications and well as product recalls generated by manufacturer, distributor, or pharmacy, in accordance with existing regulations; and
(f) utilize two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process, to ensure that the proper medication is dispensed from the system.

Adopted by the Board of Registration in Pharmacy: May 11, 2010