The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
100 Cambridge Street, 19th floor, Boston, MA 02114-2509
https://www.mass.gov/orgs/board-of-registration-in-pharmacy

Board of Registration in Pharmacy
Drug Control Program

Policy 2019-02: Automated Dispensing Device Use

Unless otherwise authorized jointly by the Board of Registration in Pharmacy (Board) and the Drug Control Program (DCP), pharmacies under the jurisdiction of the Board or DCP may use an Automated Dispensing Device in accordance with this policy to secure and dispense medications in a Massachusetts licensed health care facility. All licensees must maintain full compliance with all federal and state laws, regulations, and policies, including, but not limited to 105 CMR 700.00, 247 CMR 2.00, *et seq.*, and M.G.L. c. 94C while implementing and utilizing ADDs.

Automated Dispensing Device (ADD) means a mechanical system designed for use in health care facilities allowing for computer-controlled storage and dispensing of drugs and devices to licensed health care professionals near the point of care. These systems are also known as Automated Dispensing Machines (ADM) and Automated Dispensing Cabinets (ADC).

Requirements:

1. Massachusetts-licensed health care facilities may use ADDs to store and dispense controlled substances as authorized by their health care licensure.

2. If a healthcare facility does not have an on-site pharmacy, the facility must determine if approval from the facility's licensing body is required for the use and placement of an ADD.

3. The ADD and its contents, until dispensed for administration, remain the property of the pharmacy.

4. The facility must implement and maintain adequate and appropriate policies, procedures, and quality assurance programs in order to ensure safety, accuracy, security, accountability, patient confidentiality, and proper functioning.

5. Access to the ADD must be restricted to authorized licensed personnel and the list of users periodically reviewed and updated.

6. Dispensing from an ADD must be pursuant to a valid patient-specific prescription.

7. Records must be maintained onsite at the pharmacy for not less than 2 years and be readily available upon request. Such records must include:
   a. Documentation of the approval for use and placement of the ADD has been received from the facility's licensing body, if applicable;
   b. Locations of all ADDs;
   c. Delivery manifests or similar electronic documentation that monitors the transport of controlled substances between the pharmacy and the ADD;
   d. ADD cleaning and maintenance logs, or similar documentation;
   e. Records and / or electronic data of all events involving the ADD including, but not limited to:
      1. identity of all personnel who access the contents;
      2. location of system accessed;
      3. type of transaction with date / time stamp;
      4. name, strength, dosage form, and quantity of the accessed product;
      5. name or other identifier of the patient; and
      6. reconciliation of all inventory activities.

8. Medications to be administered to the patient must be in the manufacturer's sealed, original packaging or repackaged in accordance with professional practice standards for a single dose or person.

9. Medication losses must be reported in accordance with the requirements of the pharmacy's licensing body.

10. Retail pharmacies utilizing ADDs for emergency medication kits or other similar approved use (e.g. Hospice Inpatient Facilities), must be loaded by either a Massachusetts-licensed:
    a. pharmacy technician (only Schedules III through VI), certified pharmacy technician, pharmacy intern, or pharmacist; or
    b. nurse.

    ***Non-resident retail pharmacies must obtain a machine-specific Controlled Substance Registration (CSR) from the Board and the pharmacy must determine whether a machine-specific DEA number is also required.*

11. Retail pharmacies must utilize an ADD for acute use medications in Hospice Inpatient Facilities. A machine-specific CSR must be obtained from the Board and the pharmacy must determine whether a machine-specific DEA number is also required.

12. Retail pharmacies utilizing an ADD for daily medication dispensing must obtain a machine-specific DEA number (if applicable) and CSR.

13. Retail pharmacies utilizing ADDs for daily medication dispensing must ensure that the ADD is:
    a. continuously monitored by video; and
    b. loaded by one of the following Massachusetts-licensed individuals:
        1. a pharmacist; or
        2. either a certified pharmacy technician or a pharmacy intern while being supervised by a Massachusetts licensed pharmacist.

Please direct any questions to:
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