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## Board of Registration in Pharmacy

### Policy 2025-02: Definitions

#### I. Purpose

Unless otherwise specified, these definitions apply throughout 247 CMR 2.00 *et seq.* and are in addition to those found in 247 CMR 2.00, 10.00, and 13.00.

#### II. Definitions

- A. **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).
- B. **Automated Pharmacy System (APS)** means an automated patient-facing device that is designed to perform operations or activities, other than compounding or administration, that may include 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. A "pickup locker" is considered to be an APS.
- C. **Designated Pharmacist-in-Charge (PIC)** means a Board-licensed pharmacist who is responsible for assuring non-resident pharmacy compliance with all Massachusetts laws and regulations pertinent to the practice of pharmacy.
- D. **Manager of Record (MOR)** means a Board-licensed pharmacist who is responsible for the operation of a Massachusetts-located pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy.
- E. **Pharmacy Processing Automation (PPA)** means a mechanical system used within a licensed pharmacy space that, upon receipt of an electronic request, is used to count or measure medication to the quantity required to fill a prescription or medication order, place the medication into a final patient container or

package, and may label or otherwise apply information to the container or package.

**F. Quality Related Event (QRE)** means the incorrect dispensing of a prescribed medication that is received by a patient, including:

- i. a variation from the prescriber's prescription order, including but not limited to:
  - 1. dispensing an incorrect drug;
  - 2. dispensing an incorrect drug strength;
  - 3. dispensing an incorrect dosage form;
  - 4. dispensing a drug to the wrong patient;
  - 5. dispensing an incorrect quantity of medication; or
  - 6. providing inadequate or incorrect packaging, labeling, or directions.
- ii. a failure to identify and manage:
  - 1. over-utilization;
  - 2. therapeutic duplication;
  - 3. drug-disease contraindications;
  - 4. drug-drug interactions;
  - 5. incorrect drug dosage or duration of drug treatment;
  - 6. drug-allergy interactions; or
  - 7. clinical abuse or misuse.

**G. Serious Adverse Drug Event (SADE)** means any untoward, preventable medical occurrence associated with the use of a drug that results in any of the following outcomes:

- i. death;
- ii. a life-threatening outcome;
- iii. inpatient hospitalization or prolongation of existing hospitalization;
- iv. a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- v. a congenital anomaly or birth defect; or
- vi. any other kind of harm as determined by the Department of Public Health in regulation.

Adverse medical occurrences directly associated with the use of a drug that may not immediately result in one of the outcomes listed above may be considered a serious adverse drug event if they develop into or result in any of those outcomes.

**H. Serious Disability** means injuries requiring major intervention and loss or substantial limitation of bodily function lasting greater than seven days (e.g., bodily function related to breathing, dressing/undressing; drinking; eating; eliminating waste; hearing; seeing; sitting; sleeping; walking; getting into and out of bed, chair, etc.).

- I. **Serious Injury** means an injury that is life threatening, results in serious disability or death, or results in additional treatment, testing, or monitoring in a hospital or emergency department.

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