247 CMR 2.00: DEFINITIONS AND SEVERABILITY

Section

2.01: General

2.02: Definitions

2.03: Severability

2.01: General

1. Additional definitions specific to nuclear pharmacy practice are contained in 247 CMR 13.00.
2. The definitions in this chapter apply throughout 247 CMR 2.00 *et seq*., unless otherwise specified.

2.02: Definitions

Applicant means any person or entity that applies to the Board for a license or registration. In the case of an applicant that is not an individual, each of the following parties shall be deemed an applicant: any individual owning 5% or more of any entity; any officer and any director of any corporate applicant; any limited partner owning 5% or more and any general partner of any partnership applicant; any trustees of any trust applicant; any sole proprietor of any applicant which is a sole proprietorship; any mortgagee in possession; and any executor, personal representative, or administrator of any applicant which is an estate.

Authorized Personnel means a pharmacist, pharmacy intern, certified pharmacy technician, pharmacy technician, pharmacy technician trainee, and any unlicensed persons such as cashiers and delivery personnel.

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).

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.

Automatic Refill Program means a program that may be offered by pharmacies where a pharmacy automatically refills a prescription based on a calculation of the expected refill date of a prescription without the need for patient request.

Board means the Massachusetts Board of Registration in Pharmacy.

Collaborative Drug Therapy Management (CDTM) means the initiating, monitoring, modifying, and discontinuing of a patient’s drug therapy by an authorized pharmacist under the supervision of a physician in accordance with a collaborative practice agreement and M.G.L. c. 112, § 24B½.

Complex Non-Sterile Compounding means compounding of non-sterile drug preparations which require special training, special environment, special facilities or equipment, or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient.

Controlled Substance means any medication that is approved by the U.S. Food and Drug Administration (FDA) that may only be dispensed pursuant to a valid prescription as required by state or federal law. This definition includes Schedule VI controlled substances, as specified in M.G.L. c. 94C, § 3.

Controlled Substance Registration means the registration issued by the Board pursuant to M.G.L. c. 94C, § 7 that allows the holder to possess and dispense controlled substances.

Defective Drug Preparation means any sterile or non-sterile compounded preparation with a known or suspected defect such as improper composition, incorrect potency, contamination, instability, mislabeling, or other quality issue.

Department means the Massachusetts Department of Public Health.

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.

Good Moral Character (GMC) means those virtues of a person which are generally recognized as law-abiding and in the best interest of public health, safety, and welfare.

Good Standing means a license or registration that is active or retired, does not have a current status of probation, or has been suspended, surrendered, or revoked.

Improper Dispensing is also known as a Quality Related Event (QRE).

Interest Holder means an:

1. individual who is the immediate family member of the applicant or licensee;
2. individual who is not an applicant or licensee but who has a financial interest in the pharmacy; or
3. individual who operates a substantial amount of control over the operation of the pharmacy.

Interim Manager means a Board-licensed pharmacist who is expected to fulfill the duties of a Manager of Record in the event of a Manager of Record’s extended absence or departure.

Licensee means any person or entity holding a license or registration issued by the Board. In the case of an entity, each of the following individuals shall be deemed a licensee: any individual owning 5% or more, any officer, and any director of any corporate licensee; any limited partner owning 5% or more and any general partner of a partnership licensee; any trustee of any trust licensee; any sole proprietor of any licensee which is a sole proprietorship; any mortgagee in possession, and any executor, personal representative, or administrator of any licensee which is an estate.

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.

Pharmacy means a Board-licensed pharmacy under the direction or supervision of a Board-licensed pharmacist that is authorized to dispense controlled substances. The term "pharmacy" includes drug store pharmacies, sterile compounding pharmacies, complex non-sterile compounding pharmacies, nuclear pharmacies, institutional sterile compounding pharmacies, non-resident drug store pharmacies, non-resident sterile compounding pharmacies, non-resident complex non-sterile compounding pharmacies, and non-resident nuclear pharmacies.

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.

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

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

Registered Pharmacist (R.Ph.) also known as a licensed pharmacist, means a pharmacist who, pursuant to the provisions of M.G.L. c. 112, § 24, is licensed by the Board to practice pharmacy.

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:

1. death;
2. a life-threatening outcome;
3. inpatient hospitalization or prolongation of existing hospitalization;
4. a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. a congenital anomaly or birth defect; or
6. any other kind of harm as determined by the Department 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.

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.).

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.

Supervising Physician means a physician who:

1. holds an active license in good standing to practice medicine in Massachusetts; and
2. may delegate specific CDTM services to an authorized pharmacist pursuant to the terms of the CDTM agreement with the authorized pharmacist.

2.03: Severability

The provisions of 247 CMR *et seq.* are severable. If any provision therein is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining portions shall not be affected.

REGULATORY AUTHORITY

247 CMR 2.00: M.G.L. c. 112, §§ 24 and 42A