247 CMR 2.00: DEFINITIONS AND SEVERABILITY

Section

2.01: General

(1) Additional ~~D~~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

~~Above Action Level Environmental Monitoring Result means results of viable and nonviable testing that exceed levels as referenced in Board policy.~~

~~Accreditation means a process by which a professional association or non-governmental agency grants recognition or certification to a pharmacy for demonstrated ability to meet certain pre-defined criteria.~~

~~ACPE Accredited Provider means an institution, organization, or agency that is recognized by the Accreditation Council for Pharmacy Education (ACPE) as qualified to provide continuing education for pharmacists and pharmacy technicians.~~

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 ~~individuals~~ 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.

~~Approved College/School of Pharmacy means a college or school of pharmacy which has been accredited by the ACPE or approved by the Board.~~

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.

~~Authorized Pharmacist means a pharmacist who:~~

~~(a) is currently licensed by the Board and in good standing; and~~
~~(b) meets the requirements of 247 CMR 16.02; and~~
~~(c) is participating in drug therapy management with a supervising physician pursuant to a written CDTM agreement with written protocols.~~

~~Authorized Provider means a person who or agency which, sponsors or co-sponsors one or more contact hours of continuing education for pharmacists and has received the approval of the ACPE, American Medical Association (AMA PRA Category 1 Credit), or a Board of Pharmacy located in the United States.~~

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~~s~~ operations or activities, other than compounding or administration, ~~relative to~~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.

~~Batch means more than one unit of a compounded preparation prepared in a single process, typically for multiple patients in anticipation of patient orders, and is intended to have uniform characteristics and quality, within specified limits.~~

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, ~~a~~ special environment, ~~or~~ special facilities or equipment, or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient. -

~~Contact Hour means a unit of measure of educational credit which is a minimum of 60 minutes, or the equivalent as determined by the Board, of satisfactory participation in a Board-approved program of continuing education.~~

~~Containment Hood means engineering safety control designed to protect the facility environment and the operator while compounding, measuring, weighing, and transferring non-sterile powders by capturing particulate through filtration. Also known as a containment ventilated enclosure (CVE).~~

Controlled Substance~~s~~ mean~~s~~ any~~all~~ medication~~s~~ that is~~are~~ approved by the U.S. Food and Drug Administration (FDA) ~~and~~ that may only be dispensed pursuant to a valid prescription as ~~are~~ required by state or federal ~~or state~~ law. ~~to be dispensed only upon a prescription of a licensed prescriber.~~ This definition includes Schedule VI controlled substances, as specified in M.G.L. c. 94C, § 3.~~This includes prescription medications that are not federally scheduled.~~

Controlled Substance Registration means the registration issued by the Board pursuant to M.G.L. c. 94C, § 7 ~~which~~ 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.

~~Disciplinary Action means an action including, suspension, probation, censure, reprimand, or restriction of the licensee to operate a pharmacy or practice pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency.~~

~~Drug Sample means a prescription drug designated as "drug samples not for resale" by the manufacturer.~~

~~FPGEC means the NABP's Foreign Pharmacy Graduate Examination Committee.~~

~~FPGEC Certificate means a document issued by the NABP evidencing the assessment of the educational equivalency of a graduate of a non-approved college/school of pharmacy.~~

~~FPGEC Certification means the NABP's Foreign Pharmacy Graduate Examination Committee's process of documenting and assessing the educational equivalency of a graduate of a non-approved college/school of pharmacy.~~

~~FPGEE means the NABP's Foreign Pharmacy Graduate Equivalency Examination.~~

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

and welfare.

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

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

Interest Holder means an:

(a) individual who is the immediate family member of the applicant or licensee;
(b) individual who is not an applicant or licensee but who has a financial interest in the pharmacy; or
(c) 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 ~~a licensee that is~~ 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 ~~, currently licensed by the Board,~~ who is ~~designated as~~ responsible for the operation of a Massachusetts-located ~~Board licensed~~ pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy.

~~Massachusetts Licensed Designated Pharmacist in Charge means a pharmacist, currently licensed by the Massachusetts Board, who is responsible for assuring non-resident pharmacy compliance with all Massachusetts laws and regulations pertinent to the practice of pharmacy.~~

~~MPJE means the Multistate Pharmacy Jurisprudence Examination.~~

~~NABP means the National Association of Boards of Pharmacy.~~

~~NAPLEX means the North American Pharmacist Licensure Examination.~~

~~National Drug Code (NDC) Number means a nationally recognized standard which identifies drug products using a unique number issued by the United States Food and Drug Administration.~~

~~Outsourcing Facility means an entity at one geographic location or address that:~~
~~(a) is engaged in the compounding of sterile drug preparations; and~~
~~(b) has registered with the federal Food and Drug Administration (FDA) as an outsourcing facility pursuant to 21 U.S.C. section 353b.~~

Pharmacy means a Board-licensed pharmacy ~~licensed by the Board and~~ 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 Personnel means a pharmacist, pharmacy intern, certified pharmacy technician, pharmacy technician, pharmacy technician trainee, and any unlicensed persons such as sales clerks and delivery personnel.~~

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 ~~consumer~~ final patient ceontainer or package, and may label or otherwise apply information ~~affix a pharmacy label~~ to the ~~consumer~~ container or package.

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

(a) a variation from the prescriber's prescription order, including but not limited to:
  i. dispensing an incorrect drug;
  ii. dispensing an incorrect drug strength;
  iii. dispensing an incorrect dosage form;
  iv. dispensing a drug to the wrong patient;
  v. dispensing an incorrect quantity of medication; or
  vi. providing inadequate or incorrect packaging, labeling, or directions.

(b) a failure to identify and manage:
  i. over-utilization;
  ii. therapeutic duplication;
  iii. drug-disease contraindications;
  iv. drug-drug interactions;
  v. incorrect drug dosage or duration of drug treatment;
  vi. drug-allergy interactions; or
  vii. 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 ~~in humans~~ that results in any of the following outcomes:

(a) death;
(b) a life-threatening outcome;
(c) inpatient hospitalization or prolongation of existing hospitalization;
(d) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
(e) a congenital anomaly or birth defect; or
(f) 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 ~~in humans~~ 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 ~~products~~; 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:

(a) holds an active license in good standing to practice medicine in ~~the Commonwealth of~~ Massachusetts; and
(b) may delegate specific CDTM services to an authorized pharmacist pursuant to the terms of the CDTM agreement with the authorized pharmacist.

~~Transfer of Ownership means a transfer of a majority interest in the ownership of the pharmacy. In the case of a corporation, transfer of ownership includes the transfer of a majority of the stock thereof. In the case of a partnership, transfer of ownership includes the transfer of a majority of the partnership interest. In the case of a trust, transfer of ownership includes change of the trustee, or majority of trustees. In the case of a non-profit corporation, such changes in the corporate membership or directors as the Board determines to constitute a shift of 50% or more in control of the pharmacy.~~

~~Wholesale Distribution means distribution of prescription drugs and prescription devices to persons other than a consumer or patient, but does not include:~~

~~(a) Intracompany sales;~~
~~(b) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug or device for its own use from the group purchasing organization or from other hospitals or healthcare entities that are members of such organizations;~~
~~(c) the sale, purchase or trade of a drug or device or an offer to sell, purchase or trade a~~

~~drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;~~

~~(d) the sale, purchase or trade of a drug or device or an offer to sell, purchase or trade a drug or device among hospitals or other health care entities that are under common control; for purposes of 247 CMR 7.00, "common control" means that power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;~~

~~(e) the sale, purchase or trade of a drug or device or an offer to sell, purchase, or trade a drug or device for emergency medical reasons; for purposes of 247 CMR 7.00, "emergency medical reasons" includes transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;~~

~~(f) the sale, purchase or trade of a drug or device, an offer to sell, purchase or trade a drug or device, or the dispensing of a drug or device pursuant to a prescription;~~

~~(g) the lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or~~

~~(h) the sale, purchase or trade of blood and blood components intended for transfusion.~~

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