

247 CMR 2.00: DEFINITIONS

2.01: General

2.02: Definitions

2.01: General

The following definitions pertain to 247 CMR 2.00 et seq.

2.02: Definitions

~~(4)~~ (1) Above Action Level Environmental Monitoring Result means results of viable and nonviable testing that exceed levels described in 247 CMR 17.XX.

~~(2)~~ 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.

~~(3)~~ ACPE means the Accreditation Council for Pharmacy Education.

(4) ACPE-approved Provider means an institution, organization, or agency that is recognized by the ACPE, ~~in accordance with its policies and procedures,~~ as qualified to provide continuing education for pharmacists.

~~(5)~~ Applicant means any person or entity that applies to the Board for a license ~~to operate a pharmacy~~. In the case of an applicant which is not ~~a natural person an individual~~, each of the following individuals shall be deemed an applicant: any individual owning 5% or more; 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 or administrator of any applicant which is an estate.

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

~~(7)~~ Authorized Pharmacist means a pharmacist who:

~~(a)~~ is currently registered by the Board and in good standing;

~~(b)~~ meeting the requirements of 247 CMR 16.XX; and

~~(c)~~ is participating in drug therapy management with a supervising physician pursuant to a written CDTM agreement with written protocols.

~~(87)~~ Authorized Provider means a person who or agency which, sponsors or co-sponsors one or more contact hours of continuing education for pharmacists and which has received the approval of the ACPE, CME/Category 1, or the Board.

~~(98)~~ Blood means whole blood collected from a single donor and processed, whether for transfusion or further manufacturing.

~~(109)~~ Blood Component means that part of blood separated by physical or mechanical means.

~~(110)~~ Board means the Massachusetts Board of Registration in Pharmacy.

~~(124)~~ Board-approved Program means a program which has been approved by the Board for

continuing education credits. Such program may be sponsored by the ACPE, and/or sponsored or co-sponsored by any person who has been granted prior written approval by the Board for the particular program. The Board may, within its discretion, accept comparable continuing education hours approved by other Boards of Pharmacy.

(13) CDTM referral means the individual patient referral by a supervising physician to an authorized pharmacist for the purpose of receiving CDTM services in a community pharmacy setting. In other practice settings, "referral" means the consultation of a supervising physician and an authorized pharmacist about a patient for the purpose of receiving CDTM services. In accordance with 243 CMR 2.12, the supervising physician shall execute a written CDTM referral which shall include, but not be limited to, the patient's name and address, the primary diagnosis for which CDTM services are authorized, the diagnosis of any co-morbid conditions for which CDTM services are authorized, any known patient drug allergies, a statement that the patient has executed a written consent to CDTM services and any other specific instructions to the authorized pharmacist.

(14) Certificate of Approved CEUs means a document, issued to a named pharmacist by an authorized provider, certifying that the pharmacist has satisfactorily completed a specified number of CEUs.

(15) Collaborative Drug Therapy Management or 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. Collaborative drug therapy management may include: collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure, and respiration; and, under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component.

(16) Community pharmacy means a pharmacy that holds a drug store pharmacy license.

~~(9) — Certificate of Fitness means a document issued by the Board to a pharmacy or pharmacy department which permits a pharmacy or pharmacy department to use alcohol for the manufacture of U.S. Pharmacopoeia or National Formulary preparations and all medicinal preparations unfit for beverage purposes, and to sell alcohol as authorized under M.G.L. c. 138.~~

~~(10) — Certified Pharmacy Technician means a pharmacy technician who is currently:~~

- ~~(a) — registered by the Board; and~~
- ~~(b) — certified by a Board approved certifying body.~~

~~A pharmacy technician may perform the duties authorized to be performed by a certified pharmacy technician in 247 CMR 8.04: Certified Pharmacy Technicians when Board approved certification is current. If certification lapses, the individual is required to function as a pharmacy technician until certification is current.~~

(17) Contact Hour means a unit of measure of educational credit which is a minimum of ~~50~~ 60 minutes, or the equivalent as determined by the Board, of satisfactory participation in a Board-approved program of continuing education.

(18) Continuing Education (CE) means participation by registered pharmacists in Board-approved educational programs and is a prerequisite for the renewal of a personal registration.

(19) Continuous Quality Improvement Program (CQI Program) means a system of standards and procedures to identify and evaluate quality related events and improve patient care.

~~(13) — Continuing Education Unit (CEU) means a unit of measure of educational credit which is equal to ten contact hours, or its equivalent as determined by the Board, of satisfactory participation in a Board approved program of continuing education.~~

~~(14) — Controlled Substance means a drug, substance, or immediate precursor in any schedule or~~

~~class referred to in M.G.L. c. 94C.~~

(2016) Controlled Substance Registration means a document issued by the Board which allows the holder to receive and dispense, pursuant to a valid prescription, controlled substances.

(2117) CME/Category 1 means continuing medical education (CME) credits sponsored by an organization accredited for CME by the Accreditation Council for Continuing Medical Education, the Postgraduate Medical Institute or the state medical society.

(2248) Customer Identifier means the identification number on a valid government issued identification, as specified by the Department, which a pharmacy obtains by inspecting the identification of the ultimate user or agent of the ultimate user to whom a prescription is dispensed. (105 CMR 700.001: *Purpose*)

(2349) Department means the Massachusetts Department of Public Health.

(240) Direct Supervision means:

(a) ~~contemporaneous observation and direction of the activities of a pharmacy intern, pharmacy technician, or technician in training; and~~

(b) ~~a preceptor or supervisor is responsible for the actions of a pharmacy intern, pharmacy technician, or technician in training while that intern or technician is acting within his/her scope of practice, Board regulations, and the policies and procedures of the facility.~~

~~(a) the type of supervision a Board approved registered pharmacist preceptor in a pharmacy is required to provide to a pharmacy intern when said preceptor oversees and directs the professional activities of the pharmacy intern, and includes directly reviewing the work of the intern; and~~

~~(b) the type of supervision a registered pharmacist in a pharmacy, pharmacy department, hospital pharmacy, or institutional pharmacy is required to provide a pharmacy technician when said pharmacist oversees and directs the activities of the pharmacy technician.~~

~~(20) Dispensing means the physical act of delivering a drug, chemical, device or combination thereof to an ultimate user pursuant to the lawful order of a practitioner, as defined in M.G.L. c. 94C, § 1, including the utilization of the professional judgment of the pharmacist and the packaging, labeling, or compounding necessary to prepare the drug, chemical, or device for delivery.~~

(254) Disciplinary action means an action including, suspension, probation, censure, reprimand, or restriction of the license 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.

(262) Drug Sample means a unit of a prescription drug that is not intended to be sold. Electronically Transmitted Prescription means an order of a practitioner which has been transmitted electronically to a pharmacy in accordance with 105 CMR 721.020: *Prescription Formats*.

(273) Federal agency means any U.S. Government agency that has regulatory purview over the clinical practice of pharmacy or of pharmacy operations, including, but not limited to, all agencies in the U.S. Department of Health and Human Services, the U.S. Occupational Safety and Health Administration, and the U.S. Department of Justice.

~~(22) Facsimile Machine (fax) means a machine that electronically transmits exact images through connection with an electronic network.~~

(284) FPGEC means the NABP's Foreign Pharmacy Graduate Examination Committee.

(295) 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.

(3026) 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.

(3127) FPGEE means the NABP's Foreign Pharmacy Graduate Equivalency Examination.

(3228) Good Moral Character means those virtues of a person which are generally recognized as beneficial to the public health, safety and welfare.

(3329) Good Standing means ~~a the pharmacist's personal registration license or registration is active or retired and not currently being sanctioned is not under Board sanction by the Board.~~

~~(30) Graduate of Non-approved College/School of Pharmacy means a pharmacist whose undergraduate pharmacy degree was not conferred by an ACPE-accredited or Board-approved college/school of pharmacy yet was conferred by a recognized college/school of pharmacy outside of the United States, the District of Columbia and Puerto Rico. Recognized colleges/schools of pharmacy are those colleges and universities listed in the World Health Organization's World Directory of Schools of Pharmacy, or otherwise approved by the FPGEC.~~

(344) Home-study and Other Mediated Instruction means continuing education activities which do not provide for direct interaction in real time between faculty and participants and may include paper or digital format, audio tapes, video tapes, cable television, computer assisted instruction, journal articles, and monographs.

(352) Improper dispensing of a prescription drug means the incorrect dispensing of a prescribed medication that is received by a patient, as more particularly described in 247 CMR 15.01: Quality-related Event or QRE.

~~(363) Institutional Pharmacy means a pharmacy located in a hospital or clinic that does not hold a drug store pharmacy license or an institutional sterile compounding pharmacy license. the physical portion of an organization, including but not limited to hospitals, health maintenance organizations, and clinic pharmacies, whose primary purpose is to provide a physical environment for patients to obtain health care services under the supervision and direction of a registered pharmacist and is authorized to dispense controlled substances.~~

(374) Interest holder means (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.

~~(35) Internship means the period of training under the supervision of a Board-approved registered pharmacist preceptor, which training is a prerequisite to examination for personal registration as a pharmacist in the Commonwealth of Massachusetts.~~

(386) Legend Drug, Device or Gas means a drug, device or gas which by federal law must bear the legend: "Caution: Federal law prohibits dispensing without prescription."

(397) Licensee means any person or entity holding a license to operate a pharmacy. In the case of a licensee which is not a natural person, each of the following individuals shall be deemed a licensee: any individual owning five percent 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 or administrator of any licensee which is an estate.

~~(3408) Live Program means a continuing education program that provides for direct interaction in real time between faculty and participants ~~and may include, but not be limited to, lectures, symposia, live teleconferences and workshops.~~ (36) ~~Manager of Record or Pharmacist Manager of Record means a pharmacist, currently registered by the Board pursuant to 247 CMR 6.07: Pharmacist Manager of Record, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs.~~~~

~~(37) Manufacturer means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug.~~

(4139) MPJE means the Multistate Pharmacy Jurisprudence Examination.

(4240) NABP means the National Association of Boards of Pharmacy.

~~(41) NABP Number means a unique seven digit number issued by the National Council for Prescription Drug Programs.~~

(4342) NAPLEX means the North American Pharmacist Licensure Examination.

(443) 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. The NDC number has three components: the first component identifies the drug manufacturer ("Labeler No."); the second component identifies the product ("Product No."); and the third component identifies the package size ("Pkg.").

~~(454) NCPDP means the National Council for Prescription Drug Programs, a unique seven digit number issued by the National Council for Prescription Drug Programs.~~

~~(465) Over-the-counter Drug means any drug whose availability is not restricted to an order of a practitioner, a drug that is available for purchase without a prescription.~~

~~(44) Person means an individual, corporation, government, governmental subdivision or agency, business trust, estate trust, partnership or association, or any other legal entity.~~

~~(45) Personal Registration means a document issued by the Board to a qualified pharmacist, under the provisions of M.G.L. c. 112, § 24, permitting the pharmacist to engage in the practice of pharmacy.~~

(476) Pharmacy means a facility licensed by the Board and under the direction or supervision of a registered pharmacist which is authorized to dispense controlled substances. The term "pharmacy" includes drug store pharmacies, sterile compounding pharmacies, complex non-sterile compounding pharmacies, institutional sterile compounding pharmacies, non-resident pharmacies, non-resident sterile compounding pharmacies, and non-resident complex non-sterile compounding pharmacies. ~~shall not include institutional pharmacies or pharmacy departments except as otherwise provided in 247 CMR.~~

~~(47) Pharmacy Department means that part of a retail store registered by the Board in which a drug business, as defined in M.G.L. c. 112, § 37, is transacted.~~

~~(48) Pharmacy Intern means an individual who has completed two years of academic curriculum or who has standing as a student beyond the second year class in the undergraduate academic sequence of an approved college/school of pharmacy, and who is registered by the Board to acquire, under the direction of a Board approved registered pharmacist preceptor to whom he or she has been assigned, that practical experience which is a prerequisite to examination for personal registration as a pharmacist. A pharmacy intern may~~

~~engage in the full range of activities conducted by a registered pharmacist provided that at all time he or she is under the direct supervision of a registered pharmacist preceptor.~~

~~(49) — Pharmacy Permit means a document issued by the Board to a registered pharmacist in the name of a pharmacy or pharmacy department to manage and operate a pharmacy or a pharmacy department.~~

~~(50) — Pharmacy Technician means an individual who is registered by the Board, pursuant to 247 CMR 8.02: *Pharmacy Technicians*, who performs pharmacy duties under the direct supervision of a pharmacist.~~

~~(51) — Pharmacy Technician Trainee means an individual preparing to be registered as a pharmacy technician who performs pharmacy duties under the direct supervision of a pharmacist.~~

~~(47) — Postgraduate means graduation and award of an entry-level degree in pharmacy from a Board approved or ACPE-accredited college/school of pharmacy.~~

~~(53) — Practitioner means any person with prescriptive privileges as defined in M.G.L. c. 94C, § 1. Preceptor means a registered pharmacist in good standing who has completed at least one year of the actual practice of pharmacy and who the Board has approved to supervise and direct the training of pharmacy interns and to assist in the training of other pharmacy interns.~~

~~(54) — Prescription means an order for a drug, chemical, device or combination thereof, either written, given orally or otherwise transmitted to a registered pharmacy by a practitioner or his or her expressly authorized agent, to be dispensed or compounded in a registered pharmacy and dispensed by a registered pharmacist to a patient or his or her agent with necessary and appropriate counseling.~~

~~(55) — Prescription Drug means any and all drugs which, under Federal Law, are required, prior to being dispensed or delivered, to be labeled with the statement "Caution, Federal law prohibits dispensing without prescription" or a drug which is required by any applicable Federal or State law or regulation to be dispensed pursuant only to a prescription drug order.~~

~~(56) — Prescription Device means an instrument, apparatus, implement, machine, contrivance, implant, or other similar related article, including any component part or accessory, which is required by federal law and regulations to bear the label, "Caution, Federal law prohibits dispensing without prescription" or a device which is required by any applicable Federal or State law or regulation to be dispensed pursuant only to a prescription order.~~

~~(48) — Program means an educational course, lecture, seminar, conference, session or exercise.~~

(489) 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:

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. providing inadequate or incorrect packaging, labeling, or directions; or
6. dispensing an incorrect quantity of medication.

(b) 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.

~~(4950)~~ Registered Pharmacist (R.Ph.) means a pharmacist who, pursuant to the provisions of M.G.L. c. 112, § 24, is ~~licensed~~registered by the Board to practice pharmacy.

~~(5054)~~ Serious adverse drug event 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 in 247 CMR 20.01(1)(b) may be considered a serious adverse drug event if they develop into or result in any of the outcomes listed in 247 CMR 20.01(1)(b).

~~(5152)~~ 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; getting into and out of bed, chair, etc.; hearing; seeing; sitting; sleeping or walking).

~~(5253)~~ 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 ~~room~~department.

~~(5354)~~ State agency means any U.S. State or Territory that licenses, oversees, or otherwise regulates pharmacies or pharmacist practice.

~~(54)~~ 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.

~~(8)~~ 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; getting into and out of bed, chair, etc.; hearing; seeing; sitting; sleeping or walking).

~~(555)~~ 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 5% or more in control of the pharmacy

~~(59) Restricted Pharmacy means a pharmacy licensed by the Board for the limited transaction of a drug business as defined in M.G.L. c. 112, § 37.~~

~~(56) Universal Claim Form (UCF) means a nationally recognized standard form developed by the NCPDP used for billing prescription drug claims to insurance plans. Universal Claim Forms are available through a pharmacy's local wholesaler.~~

(567) 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.

(578) Wholesale Distributor means a person engaged in wholesale distribution of prescription drugs or devices including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

REGULATORY AUTHORITY

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

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