



THE COMMONWEALTH OF MASSACHUSETTS

William Francis Galvin, Secretary of the Commonwealth
State Publications and Regulations

REGULATION FILING AND PUBLICATION

1. Regulation Chapter, Number & Heading **247 CMR**
2. Name of Agency **BOARD OF REGISTRATION OF PHARMACY**
3. This document is reprinted from the Code of Massachusetts Regulations and contains the following:

- 247 CMR**
- 1.00 Reserved**
 - 2.00 Definitions**
 - 3.00 Personal Registration**
 - 4.00 Personal Registration Renewal; Continuing Education Requirement**
 - 5.00 Orally and Electronically Transmitted Prescriptions; Electronic Data Transmission System**
 - 6.00 Registration, Management and Operation of a Pharmacy or Pharmacy Dept.**
 - 7.00 Wholesale Druggists**
 - 8.00 Pharmacy Intern and Technicians**
 - 9.00 Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments**
 - 10.00 Disciplinary Proceedings**
 - 11.00 Registration under Controlled Substances Act (M.G.L.c.94C)**
 - 12.00 Restricted Pharmacy**
 - 13.00 Registration Requirements & Minimal Professional Standards for Nuclear Pharmacies**
 - 14.00 Petition for Waiver**
 - 15.00 Continuous Quality Improvement Program**

Under the Provisions of Massachusetts General Laws, Chapter 30A, and Chapter 233, this document may be used as evidence of the original documents on file with the Secretary of the Commonwealth.
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247 CMR: BOARD OF REGISTRATION IN PHARMACY

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2.00: Definitions

2.00: Definitions

Additional definitions pertaining to:

- (1) nuclear pharmacies are contained in 247 CMR 13.00;
- (2) disciplinary proceedings are contained in 247 CMR 10.00; and
- (3) continuous quality improvement programs are contained in 247 CMR 15.00.

The following definitions apply to 247 CMR.

ACPE means the Accreditation Council for Pharmacy Education.

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.

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 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.

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

Blood Component means that part of blood separated by physical or mechanical means.

Board means the Massachusetts Board of Registration in Pharmacy.

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.

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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.

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.

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 when Board-approved certification is current. If certification lapses, the individual is required to function as a pharmacy technician until certification is current.

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

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

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.

Controlled Substance means a drug, substance, or immediate precursor in any schedule or class referred to in M.G.L. c. 94C.

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.

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.

Department means the Massachusetts Department of Public Health.

Direct Supervision means:

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(a) the type of supervision a Board-approved registered pharmacist preceptor in a pharmacy, pharmacy department, or institutional 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.

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.

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.

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

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 means those virtues of a person which are generally recognized as beneficial to the public health, safety and welfare.

Good Standing means the pharmacist's personal registration is not currently being sanctioned by the Board.

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.

Home-study and Other Mediated Instruction means continuing education activities which do not provide for direct interaction between faculty and participants and may include audio tapes, video tapes, cable television, computer assisted instruction, journal articles and monographs.

Institutional Pharmacy means the physical portion of an organization, including but not limited to hospitals, health maintenance organizations and clinic pharmacies, whose primary purpose is to provide

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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.

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.

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."

Live Program means a continuing education program that provides for direct interaction between faculty and participants and may include, but not be limited to, lectures, symposia, live teleconferences and workshops.

Manager of Record or Pharmacist Manager of Record means a pharmacist, currently registered by the Board pursuant to 247 CMR 6.07, 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.

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

MPJE means the Multistate Pharmacy Jurisprudence Examination.

NABP means the National Association of Boards of Pharmacy.

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

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. 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.").

NCPDP means the National Council for Prescription Drug Programs.

Over-the-counter Drug means any drug whose availability is not restricted to an order of a practitioner.

Patient Identifier means a positive identification of the person who is receiving the prescription for a drug in Schedule II from a pharmacy or pharmacy department, and consists of one of the following:

- (a) a valid driver's license number;
- (b) a valid military identification card number; or
- (c) the number of a valid identification card issued pursuant to M.G.L. c. 90, § 8E or similar statute of another state or the federal government.

In the case of a recipient less than 18 years of age with no such identification, the patient identifier may be that of the recipient's parent or legal guardian. In the case of an animal patient, the patient identifier may be that of the patient's owner.

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

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.

Pharmacy means a facility under the direction or supervision of a registered pharmacist which is authorized to dispense controlled substances. The term "pharmacy" shall not include institutional pharmacies or pharmacy departments except as otherwise provided in 247 CMR.

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.

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.

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.

Pharmacy Technician means an individual who is registered by the Board, pursuant to 247 CMR 8.02, who performs pharmacy duties under the direct supervision of a pharmacist.

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.

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

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.

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.

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.

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

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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.

Program means an educational course, lecture, seminar, conference, session or exercise.

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

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.

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.

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.

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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3.00: PERSONAL REGISTRATION REQUIREMENTS

Section

- 3.01: Examination for Personal Registration as a Pharmacist
- 3.02: Personal Registration by Reciprocity
- 3.03: Duplicate Certificate of Personal Registration

3.01: Examination for Personal Registration as a Pharmacist

In order to be registered as a pharmacist by examination by the Board, an applicant must meet the requirements set forth in 247 CMR 3.01(1) or (2).

(1) Graduates of ACPE-accredited and Board-approved colleges/schools of pharmacy:

(a) An applicant shall be eligible for examination for personal registration as a pharmacist provided the applicant:

1. is 18 years old by the scheduled date of the examination applied for;
2. has earned a qualifying degree in pharmacy from a college/school of pharmacy accredited by the ACPE or approved by the Board;
3. has acquired no less than 1500 hours of practical experience as a pharmacy intern under the supervision of a Board-approved pharmacist preceptor, of which at least 1000 hours must be completed in a pharmacy or pharmacy related setting, as set forth in 247 CMR 8.01; and
4. is of good moral character.

(b) An applicant shall properly apply to take NAPLEX and MPJE. A completed application for examination shall:

1. be fully and correctly completed by the applicant;
2. include a recent passport-size photograph of the applicant showing the applicant's likeness;
3. include a certified birth certificate or other sufficient proof of place and date of birth;
4. in the case of a name change, include a written notification to the Board or the Board's designee of such name change; and
5. be accompanied by a check or money order in the proper amount made payable as directed on the examination application form;

(c) An applicant for personal registration as a pharmacist must pass both NAPLEX and MPJE.

(d) To qualify for personal registration, the applicant must achieve a NAPLEX score of not less than 75% and an MPJE score of not less than 75%.

(e) An applicant who fails to achieve a passing score on either or both NAPLEX or MPJE may be re-examined on either or both examinations provided that the applicant submits a new application for examination to the Board or Board-approved testing service, accompanied by a check or money order made payable, in the proper amount, to the Board's designee as appears on the examination application form.

(f) An applicant who fails either NAPLEX or MPJE must reapply and sit for the examination which the applicant failed within one year of the administration date of the original examination in order for both examination scores to be considered together. If the applicant does not pass both NAPLEX and MPJE within this one-year period, the applicant must apply to retake both NAPLEX and MPJE.

(2) Graduates of non-approved colleges/schools of pharmacy:

(a) In order for a graduate of a non-approved college/school of pharmacy to be eligible to apply for examination for personal registration as a pharmacist, the applicant must have received Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP.

(b) An applicant who has graduated from a non-approved college/school of pharmacy shall be eligible for examination for personal registration as a pharmacist provided the following requirements are met:

1. the applicant is 18 years old by the scheduled date of the examination applied for;
2. the applicant has received official FPGEC Certification from NABP;
3. the applicant has submitted an official copy of the applicant's FPGEC Certificate to the Board;
4. the Board has received official notification from the NABP of the applicant's FPGEC Certification;

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5. the applicant has acquired no less than 1500 hours of practical experience as a pharmacy intern under the supervision of a Board-approved pharmacist preceptor, of which at least 1000 hours must be completed in a pharmacy or pharmacy related setting, as set forth in 247 CMR 8.01; and
6. is of good moral character.

(c) An applicant who has graduated from a non-approved college/school of pharmacy shall properly apply to take NAPLEX and MPJE. A completed application for examination shall:

1. be fully and correctly completed by the applicant;
2. include a recent passport-size photograph of the applicant showing the applicant's likeness;
3. include a certified birth certificate or other sufficient proof of place and date of birth;
4. in the case of a name change, include a written notification to the Board or Board's designee of such name change; and
5. be accompanied by required fee(s).

(d) An applicant for personal registration as a pharmacist who has graduated from a non-approved college/school of pharmacy must pass NAPLEX and MPJE in accordance with the requirements set forth in 247 CMR 3.01(1)(c) through (f).

(3) The Board may refuse to consider any application that has not been properly completed.

(4) All fees submitted to the Board in connection with an application for personal registration as a pharmacist, reviewed and acted upon by the Board, are nonrefundable.

3.02: Personal Registration by Reciprocity

The Board may grant personal registration as a pharmacist to an applicant who furnishes proof satisfactory to the Board that the applicant has been registered by examination in another state or jurisdiction and that the applicant is in good standing in all states where the applicant holds a registration, provided that such other state or jurisdiction requires a degree of competency equal to that required of applicants in Massachusetts, and provided further that the Board recognizes the other state or jurisdiction for purposes of personal registration by reciprocity.

An applicant who seeks personal registration by reciprocity from the Board shall submit a preliminary application to NABP for license transfer. NABP, as agent of the Board, will conduct the preliminary evaluation of an applicant's qualifications for personal registration by reciprocity.

(1) General Requirements:

(a) Whenever an applicant has been notified by NABP that the applicant does not meet the requirements for personal registration by reciprocity, the applicant may in writing request the Board to review the basis of NABP's decision.

(b) The Board shall make the final determination of any applicant's eligibility to be registered as a pharmacist by reciprocity.

(c) A reciprocity application shall be valid for one year after the date of approval by NABP.

(d) All fees submitted to the Board in connection with an application for personal registration by reciprocity, reviewed and acted upon by the Board, are nonrefundable.

(2) Specific Requirements for Graduates of ACPE-accredited or Board-approved Colleges/ Schools of Pharmacy.

(a) The requirements for the issuance by the Board of a personal registration by reciprocity to an applicant who has graduated from an ACPE-accredited or Board-approved college/school of pharmacy shall include the following:

1. NABP approval;
2. documentation of internship experience as required by 247 CMR 8.01;
3. passing score (at least 75%) on MPJE; and
4. if requested, the applicant shall personally appear before the Board to discuss any matter related to the application.

(b) Upon receipt by the Board of evidence of an applicant's NABP approval and the appropriate fee, the applicant may register with NABP to take MPJE.

(3) Specific requirements for graduates of non-approved colleges/schools of pharmacy:

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(a) The requirements for the issuance of a personal registration by reciprocity to an applicant who has graduated from a non-approved college/school of pharmacy shall include:

1. Receipt by the Board of an official copy of the applicant's FPGEC Certificate from NABP;
2. documentation satisfactory to the Board of practical experience as required by 247 CMR 8.01;
3. passing score (at least 75%) on MPJE; and
4. if requested, the applicant shall personally appear before the Board to discuss any matter related to the application.

(b) Upon receipt by the Board of evidence of an applicant's NABP approval and the appropriate fee(s), the applicant must register with NABP to take MPJE.

3.03: Duplicate Certificate of Registration

To request a duplicate certificate of personal registration (wallet card), a registrant shall submit a Board-approved form and required documentation. In the event that an original certificate of registration is recovered after a duplicate certificate has been issued, the duplicate shall be promptly returned to the Board.

REGULATORY AUTHORITY

247 CMR 3.00: M.G.L. c. 112, §§ 24 and 42A.

4.00: Personal Registration Renewal; Continuing Education Requirement

Section

- 4.01: Authority and Purpose
- 4.02: Personal Registration Expiration and Renewal
- 4.03: Continuing Education Requirement
- 4.04: Board Continuing Education Committee
- 4.05: Criteria for Board Approval of Continuing Education Programs
- 4.06: Certificate of Completion of CEU's
- 4.07: Record-Keeping by Authorized Providers
- 4.08: Record-Keeping by Registered Pharmacists
- 4.09: Continuing Education Credit for Pharmacist Instructors
- 4.10: Continuing Education Credit for Postgraduate Pharmacy Curriculum/Program

4.01: Authority and Purpose

Board regulations at 247 CMR 4.00 are promulgated under the authority of M.G.L. c. 112, §§ 24A and 42A, and are designed to maintain pharmacists' professional competencies and to promote the highest standards of professional practice.

4.02: Personal Registration Expiration and Renewal

- (1) All personal registrations shall expire on December 31st of each even-numbered year and shall be timely renewed if the registrant intends to continue his or her practice of pharmacy.
- (2) A registrant who has not renewed his or her personal registration before the date of its expiration may renew such registration upon payment of an annual license fee, applicable back license fees, and a late fee as established by the Commissioner of Administration and Finance under M.G.L. c. 7, § 3B.
- (3) Any practice of pharmacy by a registrant after the expiration of his or her personal registration shall constitute the unlicensed practice of pharmacy and shall be subject to any and all penalties established for such unlicensed practice of pharmacy.
- (4) An applicant who has failed to renew his or her personal registration for a period of more than 60 days, and whose personal registration has not been suspended or revoked by the Board, may apply for a renewal of personal registration upon satisfying conditions imposed by the Board, which may include the completion of additional CEUs.
- (5) An applicant for personal registration renewal who has failed to renew his or her personal registration for more than two years, and whose personal registration has not been suspended or revoked by the Board, shall take and pass the Massachusetts Pharmacy Law Examination and meet all other conditions as determined by the Board as a prerequisite to registration renewal.
- (6) An applicant for personal registration renewal whose personal registration has been revoked or has been suspended for between six months and two years shall take and pass the Massachusetts Pharmacy Law Examination and meet all conditions as determined by the Board as a prerequisite to registration renewal.
- (7) An applicant for personal registration renewal whose personal registration has been revoked or suspended for more than two years shall take and pass the Massachusetts Pharmacy Law Examination and meet all other conditions as determined by the Board, which may include taking and passing the NABPLEX, as a prerequisite to registration renewal.
- (8) Notwithstanding any other provisions of 247 CMR 4.00, whenever the personal registration of an applicant has expired while the applicant was actively serving in the Armed Forces of the United States or the Public Health Service of the United States and the applicant has applied for personal registration renewal during the six months immediately following termination of said service, the Board, in accordance with the provisions of St. 1951 c. 627, § 51 shall renew the applicant's personal registration upon payment of the appropriate fee; provided however, that the applicant is of good moral character and

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renewal of his or her personal registration would be in the best interest of the public. No payment shall be required for the period of time when the applicant was actively serving in the Armed Forces or in the Public Health Service, unless the applicant was practicing pharmacy independent of such Armed Forces or Public Health Service.

4.03: Continuing Education Requirement

- (1) As set forth by M.G.L. c. 112, § 24A, each registered pharmacist seeking personal registration renewal shall complete continuing education as a condition precedent to such renewal.
- (2) No registrant shall be eligible for renewal of a personal registration without completion of the requisite number of CEUs for such renewal.
- (3) A registrant seeking renewal of a personal registration shall submit to the Board with a renewal application a statement, signed under the penalties of perjury, that the applicant has satisfactorily completed a minimum of 3.0 CEUs (30 contact hours) required for such renewal.
- (4) A registrant seeking renewal of a personal registration must complete a minimum of 1.5 CEUs (15 contact hours) each calendar year of the two-year renewal cycle. Of the 15 contact hours, effective for the renewal period beginning January 1, 1991:
 - (a) at least two contact hours shall be in the area of pharmacy law; and
 - (b) not more than ten contact hours shall be acquired through home study and other mediated instruction.
- (5) No CEUs may be carried over from one calendar year to another.
- (6) Notwithstanding any other provisions of 247 CMR 4.03, in the event of extenuating circumstances an applicant for renewal of personal registration who has failed to complete the requisite number of CEUs, or is unable because of a physical disability to conform to the limitation on the number of CEUs acquired through home study and other mediated instruction, shall submit to the Board a detailed statement, signed under the penalties of perjury, setting forth with detail and specificity such extenuating circumstances. In such case, the Board shall determine whether or not a renewal shall be granted. The Board shall notify the applicant of the Board's determination and its reasons therefore.
- (7) Notwithstanding any other provisions of 247 CMR 4.00, CEUs shall not be required of any applicant for personal registration renewal for the period of time when the applicant was actively serving in the Armed Forces of the United States or in the Public Health Service of the United States, unless the applicant was actively practicing pharmacy independent of said Armed Forces or Public Health Service.
- (8) A registrant may not earn more than eight hours of continuing education in a calendar day.
- (9) A registrant shall not be required to complete continuing education in the calendar year in which the registrant has graduated from an approved college/school of pharmacy.

4.04: Board Continuing Education Committee

- (1) The Board shall establish a Continuing Education Committee composed of three Board members whose responsibility it shall be to review all requests from providers for authorization to sponsor continuing education programs and the approval of such programs. The Committee shall have the authority to grant or deny requests for provider authorization and program approval, provided that any denial shall be subject to full Board review as provided by 247 CMR 4.04(4).
- (2) Each request for provider authorization, or program approval from an authorized provider, shall be submitted to the Board Continuing Education Committee no less than 30 days in advance of the date of the proposed program's presentation.
- (3) The Board Continuing Education Committee shall notify providers submitting requests for authorization to sponsor an approved program, or seeking program approval, of the Committee's decision to grant or deny such request for authorization or approval.
- (4) A provider whose request for provider authorization or program approval is denied and who seeks further review of his or her request may appeal the Continuing Education Committee's decision to the full Board.
- (5) Notwithstanding any provision of 247 CMR 4.04, whenever the Board or its Continuing Education Committee has received notice that a person or agency has received current program approval from and is

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in good standing with the ACPE or the American Medical Association CME-1, then the person or agency sponsoring or co-sponsoring the program shall be considered an authorized provider.

4.05: Criteria for Board Approval of Continuing Education Programs

The following guidelines are to assist the registered pharmacist in selecting an appropriate continuing education program and the provider in preparing and implementing continuing education programs for Board approval as an authorized provider.

(1) An applicant for status as a Board-approved provider of a continuing education program shall submit a completed application form, available from the Board, for each continuing education program for which the applicant is seeking approval. The form shall include the following:

(a) The objectives of the program, which shall be:

1. clearly stated;
2. the basis for determining content, learning experience, teaching methodologies, and evaluation;
3. specific;
4. obtainable;
5. measurable; and
6. describe the expected outcomes for the learner.

(b) The appropriate subject matter, which shall include one or more of the following:

1. pharmacy practice management;
2. disease states/therapeutics;
3. research in pharmacy and health care;
4. patient management;
5. clinical topics;
6. drugs and dosage forms;
7. laws and regulations in relation to the practice of pharmacy; and
8. other topics which the Board may find important in educating the pharmacist.

(c) The subject matter shall be described in outline form as follows:

1. learner objectives;
2. content;
3. time allotment;
4. teaching methods; and
5. evaluation format.

(d) Whether the program will be live or a home-study or other mediated instruction.

(e) The date(s) of the intended program.

(f) The location(s) of the intended program, if applicable.

(g) The sponsors(s) of the program.

(h) The tuition required to attend the program.

(i) The amount of continuing education credit, in CEU's, which the program is intended to provide.

(j) The qualifications of the faculty preparing and teaching the intended program.

(k) Other information which the Board may deem important.

(2) When the intended program is an academic course, the course shall be within the framework of curriculum that leads to an academic degree in pharmacy or is relevant to pharmacy, or a course within that curriculum that is necessary to an individual's growth and development within the profession as outlined in 247 CMR 4.11.

(3) When the intended program is intended for home-study or other mediated instruction, it shall:

- (a) Be developed by a professional group;
- (b) follow a logical sequence;
- (c) involve the learner by requiring an active response to materials and provide feedback;
- (d) contain a test to indicate progress and to verify the completion of program; and
- (e) supply a bibliography for continued study.

(4) When the intended program is a live program, it shall:

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- (a) Involve direct interaction between the faculty and participants; and
- (b) the faculty should possess the appropriate credentials related to the discipline being taught.
- (5) Education Methods shall conform to the following:
 - (a) Learning experiences and teaching methods shall be appropriate to achieve the objectives of the program;
 - (b) principles of adult education shall be used in the design of the program;
 - (c) time allotted for each activity shall be sufficient for the learner to meet the objective of the program; and
 - (d) facilities and educational resources shall be adequate to implement the program.
- (6) The faculty shall present documentation satisfactory to the Board indicating his or her competence to teach the content of the intended program and that he or she possesses knowledge of the principles of adult education.
- (7) Attendee and program evaluation:
 - (a) A provision shall be made for evaluating the program participants' attainment of the stated learner objectives; and
 - (b) program participants shall be given the opportunity to evaluate faculty, learning experiences, instructional methods, facilities and educational resources used for the program.

4.06: Certificate of Completion of CEUs

- (1) An authorized provider shall issue to each pharmacist who has satisfactorily completed a program sponsored or co-sponsored by that provider a certificate of completion of CEUs certifying that the pharmacist has completed a specified number of CEUs.
- (2) The following information shall be included on each certificate of completion of CEUs issued by an authorized provider:
 - (a) The name and address of the authorized provider;
 - (b) the participant's name;
 - (c) the title of the continuing education program;
 - (d) the location of the program;
 - (e) the date of completion of the program; and
 - (f) the number of CEUs earned.
- (3) The CEUs noted on the certificate of completion of CEU's may be stated in whole numbers or as decimals or fractions.

4.07: Record-Keeping by Authorized Providers

- (1) Authorized providers shall be responsible for retaining records of the program, including:
 - (a) The name of each participant;
 - (b) the content of the program sponsored;
 - (c) the provider authorization number;
 - (d) the date of the continuing education program;
 - (e) the location of continuing education program;
 - (f) the name of the approved instructor; and
 - (g) an indication of whether the program was completed by home-study or other mediated instruction.
- (2) Authorized providers shall maintain program records for a period of no less than three years from the date of presentation of the program.
- (3) Program records are subject to Board review and shall be made available to the Board and program participants upon request.

4.08: Record-keeping by Registered Pharmacists

- (1) A pharmacist to whom a certificate of completion of CEUs has been issued shall retain that certificate for a period of at least two years from the date of completion.

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(2) Certificates of completion of CEUs are subject to Board review and shall be made available to the Board upon request.

4.09: Continuing Education Credit for Pharmacist Instructors

A registered pharmacist who is a Board-approved continuing education instructor shall receive continuing education credit for the program taught on a one-time basis annually.

4.10: Continuing Education Credit for Postgraduate Pharmacy Curriculum/Program

A registered pharmacist who enrolls in a postgraduate pharmacy curriculum, postgraduate pharmacy program or Board-approved postgraduate medical program, shall be awarded CEUs for satisfactory completion of each course within said curriculum or program, provided that the sponsor or co-sponsor of the postgraduate curriculum or program is a Board-authorized or ACPE accredited provider of continuing professional education, and provided further that the course provides instruction in one or more of the following areas: pharmacy, pharmaceutical sciences, pharmacy practice, or pharmacy law.

REGULATORY AUTHORITY

247 CMR 4.00: M.G.L. c. 112, §§ 24A and 42A.

5.00: Orally and Electronically Transmitted Prescriptions; Electronic Data Transmission System

Section

- 5.01: Foreword
- 5.02: Electronically Transmitted Prescriptions
- 5.03: Emergency Situations in Which Controlled Substances in Schedule II May be Dispensed Upon Orally or Electronically Transmitted Prescription
- 5.04: Utilization of Electronic Data Transmission (EDT) System

5.01: Foreword

Except for the regulations pertaining to electronically transmitted prescriptions, the Department of Public Health and the Board of Registration in Pharmacy, acting jointly under authority of M.G.L. c. 94C, and every other act thereto enabling, and in accordance with the procedures set forth in M.G.L. c. 30A, hereby establish regulations for the implementation of M.G.L. c. 94C.

5.02: Electronically Transmitted Prescriptions

(1) Prescriptions or drug orders may be electronically transmitted from an authorized prescribing practitioner or his or her expressly authorized agent to a pharmacy or pharmacy department of the patient's choice. The prescription or drug order shall be electronically transmitted in a manner that maintains patient confidentiality and in accordance with the requirements of M.G.L. c. 94C, § 23(g) and 105 CMR 721.000 et seq.

(2) A pharmacist or pharmacy shall not enter into any agreement concerning the provision of a computer, facsimile machine, computer modem or any other electronic device which would adversely affect a patient's freedom to select the pharmacy or pharmacy department of his or her choice.

(3) A pharmacist or pharmacy shall not provide a computer, facsimile machine, computer modem or any other electronic device to a prescriber or health care facility for the purpose of providing an incentive to refer patients to a particular pharmacy or pharmacy department.

5.03: Emergency Situations in Which Controlled Substances in Schedule II May be Dispensed Upon Orally or Electronically Transmitted Prescription

(1) "Emergency situations", for the purpose of permitting the dispensing of any controlled substance in Schedule II upon orally or electronically transmitted prescription, means those situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines:

(a) That the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;

(b) that no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II; and

(c) that it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing.

(2) In case of an emergency situation as defined in 247 CMR 5.03(1), a pharmacist may dispense a controlled substance in Schedule II upon receiving the orally or electronically transmitted authorization of a prescribing practitioner, provided that:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) the prescription contains all information required by M.G.L. c. 94C, § 20(a) except for the actual signature of the prescribing practitioner, and in the case of an oral prescription, or prescription transmitted electronically by computer modem or other similar electronic device, the prescription is immediately reduced to writing by the dispensing pharmacist; and

(c) the dispensing pharmacist makes a reasonable good faith effort to determine that the orally or electronically transmitted authorization was issued by an authorized practitioner, which effort may

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include a callback to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity.

(3) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the pharmacy which must have written on its face "Authorization for Emergency Dispensing" and should comply with federal and state law.

(4) Upon receipt of the written prescription, the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration, U.S. Department of Justice, and the Commissioner of Public Health, Massachusetts Department of Public Health, if the prescribing practitioner fails to deliver a written prescription within seven days.

5.04: Utilization of Electronic Data Transmission (EDT) System

247 CMR 5.04, in conjunction with regulations of the Department of Public Health at 105 CMR 700.006, are intended to address the problem of prescription drug abuse and diversion. By requiring the reporting of information relative to prescriptions for controlled substances in Schedule II, a more efficient means of monitoring distribution between the practitioner, dispenser, and patient is provided.

(1) Pharmacy Reporting Responsibilities.

(a) Every pharmacy registered by the Board and hospital pharmacy issued a controlled substances registration by the Board that dispenses controlled substances in Schedule II pursuant to a prescription shall transmit to the Department of Public Health or its agent the following information for each prescription:

1. Pharmacy prescription number;
2. pharmacy NABP Number;
3. patient identifier, where feasible;
4. date the controlled substance is dispensed;
5. metric quantity of controlled substance dispensed;
6. National Drug Code (NDC) Number of controlled substance dispensed;
7. estimated days supply of controlled substance dispensed; and
8. prescriber's U.S. Drug Enforcement Administration (DEA) controlled substance registration number.

(b) The pharmacist shall make a good faith effort to verify the patient identifier of the person to whom the prescription for a controlled substance in Schedule II is delivered in accordance with professional standards and personal judgment.

(c) The information required by 247 CMR 5.04 shall be transmitted to the Department of Public Health or its agent no later than 15 days following the last day of the month in which the prescription was dispensed by use of:

1. An electronic device, computer diskette, or magnetic tape, each of which shall be in a format approved by the Department, or other acceptable electronic method approved by the Department; or
2. a Universal Claim Form (UCF).

(d) Pharmacies reporting data from 25 or more prescriptions in any given month shall provide the required information in accordance with 247 CMR 5.04(1)(c)1..

(2) **Penalties.** Failure to comply with the reporting requirements set forth in 247 CMR 5.04(1) and/or any state law or regulation relating to such reporting requirements may result in formal disciplinary action being initiated against the licensed pharmacist and/or the pharmacy by the Board and/or other state and federal law enforcement agencies.

REGULATORY AUTHORITY

247 CMR 5.00: M.G.L. c. 112, § 42A; c. 94C, § 6.

6.00: Registration, Management and Operation of a Pharmacy or Pharmacy Department

- 6.01: Application for a Registration to Manage and Operate a Pharmacy or Pharmacy Department; Inspection of Proposed Pharmacy or Pharmacy Department
- 6.02: Conditions for Continuing Registration and Operation of a Pharmacy or Pharmacy Department
- 6.03: Requirements for Reporting to the Board a Change in the Management, Operation and/or Ownership of a Pharmacy or Pharmacy Department
- 6.04: Requirements for Reporting to the Board Changes in the Configuration, Square Footage or Location of a Pharmacy or Pharmacy Department
- 6.05: Continuing Responsibilities of All Registered Pharmacists
- 6.06: Renewal of a Pharmacy Permit
- 6.07: Pharmacist Manager of Record
- 6.08: Certificate of Fitness Issued by the Board Permitting Manufacture the and Sale of Alcoholic Beverages
- 6.09: Closing a Pharmacy or Pharmacy Department
- 6.10: Distribution of Controlled Substances Upon Discontinuance or Transfer of Business of a Pharmacy or Pharmacy Department
- 6.11: Inspections of Pharmacies and Pharmacy Departments
- 6.12: Deficiency Statements
- 6.13: Plans of Correction

6.01: Application for Registration to Manage and Operate a Pharmacy or a Pharmacy Department; Inspection of a Proposed Pharmacy or Pharmacy Department

(1) In order to be registered by the Board to manage and operate a pharmacy or pharmacy department and be issued a permit to do so, the registered pharmacist who shall be responsible for the management and operation of the pharmacy or pharmacy department shall obtain and submit to the Board an application for registration to manage and operate a pharmacy or pharmacy department available from the Board. A completed application shall be:

- (a) fully and properly completed and signed, under the penalties of perjury, by the pharmacist who is to manage and operate the pharmacy or pharmacy department;
- (b) accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during regular business hours for each day of the week;
- (c) accompanied by an application, available from the Board, for a Massachusetts controlled substance registration;
- (d) accompanied by an application, available from the Board, for a certificate of fitness, if applicable;
- (e) accompanied by a check or money order made payable, in the proper amount, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and
- (f) accompanied by any additional information as determined by the Board.

(2) A completed application to operate a pharmacy shall include:

- (a) a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth;
- (b) a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation is incorporated in another state;
- (c) a statement of the name and address of each officer and director of the corporation and the position held;
- (d) the d/b/a name of the corporation; and
- (f) if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s).

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(3) The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges.

(4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39.

(5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements:

(a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is maintained on the pharmacy premises:

1. a current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto;
2. a current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record.
3. a current copy or electronic version of Board Regulations 247 CMR 1.00 et seq.;
4. a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually;
5. the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia;
6. prescription labels which bear the name and address of the proposed pharmacy;
7. appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which prescriptions are to be filled;
8. whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription; and
9. whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages.

(b) There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse.

(c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) shall, in addition to the 300 square feet required by 247 CMR 6.01(6)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. This clean room shall meet the following requirements:

1. There shall be a minimum working area of 72 square feet;
2. it shall be closed on all sides except for a door and an opening to allow for the passage of materials;
3. it shall have a laminar flow hood with either vertical or horizontal air flow;
4. the laminar flow hood standards of operation of HEPA (High Energy Particulate Air) filters and prefilters must be determined and certification shall be made annually by a Board-approved hood certification service;
5. the Board shall be notified before beginning operation of the clean room to verify hood certification;
6. the area of the clean room shall be under continual positive pressure unless the hood is self-venting; and
7. applications for construction of a pharmacy with a clean room received after September 30, 1996 shall show the clean room located directly adjacent to the prescription area/department.

(d) Patient Consultation Area.

1. A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.

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2. 247 CMR 6.01(5)(d) shall be effective for all new or relocating pharmacies on April 1, 2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1, 2007.

(6) The Board shall issue a permit indicating the pharmacy or pharmacy department's registration number if the Board finds, in its reasonable discretion that approving the application would be consistent with the best interest of public health, welfare and safety.

(7) All fees submitted to the Board in connection with an application for registration to operate a pharmacy or pharmacy department, which are reviewed and acted upon by the Board, are nonrefundable.

6.02: Conditions for Continuing Registration and Operation of a Pharmacy or Pharmacy Department

Except as provided by exemptions set forth in 247 CMR 12.00 with respect to restricted pharmacies and 247 CMR 13.00 with respect to nuclear pharmacies, the following conditions shall apply to the continuing operation of a pharmacy or pharmacy department:

(1) The premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.

(2) The equipment and publications set forth in 247 CMR 6.01(6)(a) shall be maintained in the pharmacy or pharmacy department at all times.

(3) The following shall be conspicuously displayed within the pharmacy or pharmacy department:

(a) the pharmacy permit;

(b) the pharmacy's Massachusetts controlled substance registration;

(c) the pharmacy's U.S. Drug Enforcement Administration controlled substance registration; and

(d) whenever applicable, the pharmacy's certificate of fitness.

(4) The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.

(5) A pharmacy or pharmacy department shall have a reasonably-sized sign affixed to the main entrance of the business or otherwise installed in an easily observable area outside the premises, identifying the presence of a pharmacy or pharmacy department.

(6) A pharmacy or pharmacy department shall conform to the following security requirements:

(a) All controlled substances in Schedules II through V shall be stored within the prescription area;

(b) controlled substances in Schedule VI shall be stored within the prescription area or in the clean room if the clean room is directly adjacent to the prescription area;

(c) controlled substances in Schedules II, III, IV, and V shall be stored in a securely locked and substantially constructed cabinet, or dispersed in the prescription-drug storage area throughout the stock of Schedule VI controlled substances in such a manner as to obstruct the theft or diversion of these controlled substances;

(d) there shall be a separate working alarm for the pharmacy or pharmacy department which shall be activated when the pharmacy or pharmacy department is closed;

(e) a pharmacy department must be secured by a floor to ceiling barrier, securely locked and separately alarmed at all times when the pharmacy department is closed;

(f) the pharmacist Manager of Record and the pharmacist on duty shall be responsible for pharmacy security and shall control access to the prescription area;

(g) all drug order deliveries containing controlled substances shall be delivered directly to the pharmacy or pharmacy department or to a secured area if the pharmacy is closed, and the security of those controlled substances is the responsibility of the pharmacist Manager of Record; and

(h) each pharmacy or pharmacy department shall comply with all other security requirements which the Board may deem necessary for the protection of the public.

(7) A pharmacy or a pharmacy department shall conspicuously display, in legible letters not less than one inch high, over, on or adjacent to the main entrance of the pharmacy or pharmacy department, the name of the pharmacist Manager of Record who is responsible for the management and operation of the pharmacy or pharmacy department.

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- (8) A pharmacy or pharmacy department shall meet the following requirements concerning the posting of hours of operation:
- (a) The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy department, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy department;
 - (b) if the hours of operation of a pharmacy department, subject to the requirements of 247 CMR 6.02(6)(e) and (10), are different from those of the retail store in which it is located, all advertising referring to the pharmacy department shall clearly specify the pharmacy department's hours of operation; and
 - (c) if the hours of operation of a pharmacy's prescription area, subject to the requirements of 247 CMR 6.02(10), are different from the hours of operation for its non-prescription business, all advertising for the pharmacy shall clearly specify the hours of operation of the pharmacy's prescription area.
- (9) A pharmacy or pharmacy department shall meet the following requirements concerning registered pharmacists on duty and shall be present at all times when non-pharmacist personal have unrestricted access to the pharmacy or pharmacy department:
- (a) A registered pharmacist shall be on duty and on the pharmacy premises at all times the pharmacy or pharmacy department is open for business and shall be present at all times when non-pharmacist personal have unrestricted access to the pharmacy or pharmacy department;
 - (b) each registered pharmacist who is a full-time employee of the pharmacy shall have readily available, or displayed in a conspicuous place, his or her certificate of registration to practice pharmacy and the original or a copy of, his or her current wallet registration card; and
 - (c) a registered pharmacist shall not remain on duty for more than 12 hours per day.
- (10) A pharmacy or pharmacy department shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of " Report of Theft or Loss of Controlled Substance" (DEA BND Form 106), within seven days of such theft or significant loss and, where applicable, shall comply with the reporting requirements of the DEA, the Department and the state and local police.

6.03: Requirements for Reporting to the Board a Change in the Management, Operation and/or Ownership of a Pharmacy or Pharmacy Department

- (1) Whenever there is a change in the pharmacist Manager of Record of a pharmacy or pharmacy department, an application for a change in pharmacist Manager of Record shall be obtained from and promptly submitted to the Board. A completed application shall be fully and properly completed and signed, under the penalties of perjury, by a duly authorized representative of the pharmacy or pharmacy department and include:
- (a) a sworn statement confirming that a complete inventory of controlled substances in Schedules II, III, IV and V signed by the outgoing pharmacist Manager of Record and the incoming pharmacist Manager of Record has been taken and filed with the pharmacy's controlled substance records. In the event the outgoing pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to sign the inventory, provided the Board is notified at the time the application is submitted why the staff pharmacist is signing the inventory;
 - (b) an application for a certificate of fitness, if applicable;
 - (c) the pharmacy permit and, if applicable, the pharmacy or pharmacy department's certificate of fitness;
 - (d) required fee(s); and
 - (e) any additional information as determined by the Board.
- (2) Whenever there is to be a transfer of ownership of a pharmacy or pharmacy department or if the pharmacy or pharmacy department is to be owned by a person or entity other than the person or entity who was listed on the initial application for registration to manage and operate a pharmacy or pharmacy department, an application for transfer of ownership shall be obtained from, and submitted to, the Board. A completed application shall:

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- (a) Meet all the requirements of 247 CMR 6.03(1), if there is a change of pharmacist Manager of Record;
- (b) state the full name of the new owner;
- (c) have attached thereto an official bill of sale; and
- (d) if the new owner is a corporation:
 - 1. have attached thereto a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State, if the corporation is incorporated in the Commonwealth;
 - 2. have attached thereto a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation is incorporated in another state;
 - 3. indicate of the name and address of each officer and director of the corporation and the position held;
 - 4. indicate the d/b/a name of the corporation; and
 - 5. if the corporation is not publicly owned, indicate the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s).
- (3) A registered pharmacist who manages and operates a pharmacy or pharmacy department shall, within ten working days of the commencement or termination of employment, report in writing to the Board such commencement or termination of employment.
- (4) Upon commencement of the employment of a registered pharmacist, the pharmacist's employer or the pharmacist Manager of Record shall verify with the Board that the pharmacist's personal registration issued by the Board is current.
- (5) A corporation or partnership which owns a pharmacy or pharmacy department which is registered by the Board shall notify the Board, within ten working days, in writing, of the following:
 - (a) Any change in its Articles of Organization;
 - (b) any change in its Foreign Corporate Certificate;
 - (c) any change in the d/b/a name of the corporation accompanied by appropriate authorizing documentation;
 - (d) any change in the names and addresses of its officers and/or directors, and/or in their positions; and
 - (e) unless the stock of the corporation is publicly traded, any change in the total amount of stock issued or, names and addresses of the stockholders and the kinds and amounts of stock which they respectively own.
- (6) Pursuant to the provisions of M.G.L. c. 112, § 36, a surviving spouse, executor or administrator of a registered pharmacist who has died or the spouse of one who has become incapacitated who has been authorized to continue operation of a pharmacy or pharmacy department shall, within five days of any change in employment of a registered pharmacist, whether by dismissal, resignation, lay-off or additional hiring, notify the Board thereof in writing.

6.04: Requirements for Reporting to the Board a Change in the Configuration, Square Footage, or Location of a Pharmacy or Pharmacy Department

- (1) Any pharmacy or pharmacy department which is being remodeled in a manner which changes the configuration or square footage of the prescription area shall before commencing any remodeling, submit copies of its structural plans to the Board for approval.
- (2) The following requirements shall apply to any pharmacy or pharmacy department moving to a new address. The pharmacy or pharmacy department shall:
 - (a) submit to the Board a new application and payment of the appropriate fee in accordance with the requirements of 247 CMR 6.01(1) in advance of any relocation;
 - (b) return previously issued permits with the application; and
 - (c) a pharmacy or pharmacy department which has moved to a new address shall not begin to operate in said location until the application has been approved by the Board and until the pharmacy or pharmacy department has received from the Board a permit to manage and operate the pharmacy and a controlled substances registration.

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6.05 Continuing Responsibilities of All Registered Pharmacists

- (1) A registered pharmacist who changes his or her mailing address or name shall notify the Board of such change(s) in writing within ten working days of such change(s). In the case of a change of name, the pharmacist shall submit a sworn statement indicating that the pharmacist has changed his or her name with a photocopy of a valid picture identification card and any other documentation that may be required by the Board.
- (2) A registered pharmacist shall not allow or cause to be displayed, in any pharmacy or pharmacy department where said pharmacist is not employed or associated with the pharmacy business, his or her certificate of personal registration to practice pharmacy.
- (3) A pharmacist shall carry, or have readily available at all times where the pharmacist is employed, a certificate of personal registration or an official statement from the Board which indicates that the pharmacist is currently registered by the Board to practice pharmacy.

6.06: Renewal of a Pharmacy Permit

- (1) Each pharmacy or pharmacy department permit issued by the Board shall expire on December 31st of each uneven numbered year following the date of its issuance.
- (2) Application for renewal of a pharmacy or pharmacy department permit shall be made by a duly authorized representative of the pharmacy on a renewal application form provided by the Board. Such renewal form shall be fully and properly completed and submitted to the Board in a timely manner.
- (3) Each renewal application form submitted to the Board shall be accompanied by a check or money order in the required amount made payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy".

6.07: Pharmacist Manager of Record

- (1) The responsibilities of the pharmacist Manager of Record shall include, but may not be limited, to the following:
 - (a) The maintenance of necessary pharmaceutical equipment and reference texts in accordance with the requirements at 247 CMR 6.01(6)(a);
 - (b) the proper maintenance of records as required by the Massachusetts Controlled Substances Act (M.G.L. c. 94C), Board regulations at 247 CMR 2.00 et seq., and all other applicable state and federal laws and regulations;
 - (c) the maintenance at all times of adequate pharmacy and pharmacy department security consistent Board regulations at 247 CMR 2.00 et seq., and all other applicable state and federal laws and regulations;
 - (d) the establishment, monitoring and enforcement of policies and procedures which encourage acceptable standards of practice consistent with Board regulations at 247 CMR 2.00 et seq., and all other applicable federal and state laws and regulations;
 - (e) the establishment, monitoring and enforcement of policies and procedures which maintain the standards of professional practice as such standards relate to the dispensing of pharmaceuticals, including the proper supervision of technicians, and the delegation of authority to another pharmacist when not on duty;
 - (f) the maintenance of adequate staff in the pharmacy or pharmacy department in order to ensure that the practice of pharmacy shall be carried out in accordance with Board regulations at 247 CMR 2.00 et seq. and all other applicable federal and state laws and regulations;
 - (g) the maintenance of records relating to the responsibilities of pharmacy technicians as outlined in 247 CMR 8.02(6);
 - (h) notification to the Board in writing of his or her termination as pharmacist Manager of Record within ten working days;

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- (i) taking an inventory of controlled substances in Schedules II, III, IV and V, based upon federal biennial inventory requirements, pursuant to the requirements of 247 CMR 6.03(b); and
 - (j) the establishment of procedures for validating questionable purported controlled substance prescriptions and for reviewing existing prescription information, to deter the willful and unlawful dispensing of controlled substances.
- (2) A pharmacist Manager of Record shall not be the Manager of Record of more than one pharmacy or pharmacy department at a time.

6.08: Certificate of Fitness Issued by the Board Permitting the Manufacture and Sale of Alcoholic Beverages

- (1) Pursuant to authority granted to it under M.G.L. c. 138, § 29, the Board may issue to a registered pharmacist who is the Manager of Record of a pharmacy or pharmacy department a certificate of fitness permitting the pharmacy 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.
- (2) A pharmacist Manager of Record, acting on behalf of a pharmacy or pharmacy department, may apply to the Board for the issuance of a certificate of fitness. A completed application shall:
- (a) be fully and properly completed and signed, under penalties of perjury, by the pharmacist Manager of Record who shall manage and operate the pharmacy or pharmacy department; and
 - (b) be accompanied by a check or money order, in the proper amount, made payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy."
- (3) An applicant for a certificate of fitness may be required by the Board to furnish evidence satisfactory to the Board that he or she is a proper person to be entrusted with the authority to manufacture and sell alcoholic beverages and that the issuance of such certificate shall promote the public good.
- (4) The Board may require a personal interview with an applicant for a certificate of fitness to determine the merits of any application for such certificate.
- (5) A certificate of fitness which is issued by the Board to a pharmacy or pharmacy department shall be issued in the name of the pharmacist who manages and operates the pharmacy or pharmacy department and is not transferable.
- (6) A pharmacy or pharmacy department under the supervision of its pharmacist Manager of Record shall comply with the following requirements regarding the sale or transfer of alcohol or alcoholic beverages:
- (a) Prescriptions for alcoholic beverages shall be maintained in a separate file and shall not be refilled;
 - (b) any authorized sale or transfer of alcohol or alcoholic beverages which can be used for human consumption shall be made by a registered pharmacist, or by an adult non-pharmacist employee at the direction, and under the supervision of, a registered pharmacist on the premises;
 - (c) no sale or transfer of any alcohol or alcoholic beverage which can be used for human consumption shall be made to a minor;
 - (d) except upon the written prescription of a practitioner, or except as may be otherwise provided by the local licensing authorities, a pharmacy or pharmacy department which is licensed by the local licensing authority under the provisions of M.G.L. c. 138, § 30A to sell or transfer alcoholic beverages shall neither sell nor transfer such alcoholic beverages on Sundays or legal holidays, or during polling hours, or on any day on which a state or municipal election, caucus, or primary is held in the city or town in which said pharmacy or pharmacy department is located;
 - (e) a pharmacy or pharmacy department which holds a license, issued by local licensing authorities under the provisions of M.G.L. c. 138, or which holds a certificate of fitness under the provisions of M.G.L. c. 138, §§ 29 and 30, shall not in any way advertise the sale of alcohol, wines, malt beverages, or alcoholic beverages;
 - (f) prior to the sale or transfer of any alcoholic beverage, a pharmacy or pharmacy department which is licensed by the local licensing authorities under the provisions of M.G.L. c. 138, § 30A shall record in a bound record book, organized in accordance with M.G.L. c. 138, § 30E, at the time of every sale, the date

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of the sale or transfer, the name and address of the purchaser, and the kind, quantity, price and intended use of said beverage;

(g) in accordance with the provisions of 247 CMR 6.08(7)(f), whenever a pharmacy or pharmacy department which is licensed by local licensing authorities under the provisions of M.G.L. c. 138, § 30A sells or transfers an alcoholic beverage to a purchaser, said purchaser shall sign in the bound record book a dated statement substantially as follows: "I wish to purchase (name of alcoholic beverage). I certify that I am of statutory age to purchase alcoholic beverages and that the alcoholic beverage is to be used for mechanical, chemical, medicinal purpose." (A line shall be drawn through the words which do not indicate the purpose of the purchase.)

(h) in accordance with the provisions of 247 CMR 6.08(7)(f), whenever a pharmacy or pharmacy department which is licensed by local licensing authorities under the provisions of M.G.L. c. 138, § 30A transacts a sale or transfer pursuant to the written prescription of a practitioner, in addition to the information required by 247 CMR 6.08 (7)(f), there shall also be recorded in the bound record book the name of the practitioner; and

(i) a pharmacy or pharmacy department which is licensed by local licensing authorities under the provisions of M.G.L. c. 138, § 30A may display alcoholic beverages only in a small case or on shelving located at the rear of the pharmacy, provided that the total area used for such display shall not exceed 18 square feet.

(7) The Board or local licensing authorities, may, after giving a hearing to the interested parties, revoke or suspend the certificate of fitness for any cause which they may deem proper, and such revocation shall suspend all authority the pharmacist, pharmacy or pharmacy department was granted by 247 CMR 6.08(7).

6.09: Closing of a Pharmacy or Pharmacy Department

(1) Any person who intends to close a pharmacy or pharmacy department registered by the Board shall officially notify the Board in writing, by certified mail, at least 14 days, before the intended closing, unless otherwise authorized by the Board, and shall provide the Board with the following information:

- (a) The name, address and telephone number of the pharmacy or pharmacy department;
- (b) the pharmacy permit number;
- (c) the pharmacy controlled substance registration number issued by the Board;
- (d) the pharmacy certificate of fitness number issued by the Board, if applicable;
- (e) the name of the pharmacist Manager of Record of the pharmacy or pharmacy department;
- (f) the date on which the intended closure shall take place;
- (g) the intended procedures for closing the pharmacy or pharmacy department;
- (h) verification that adequate advance notice of the closure has been given to customers of the pharmacy or pharmacy department; and
- (i) the intended procedures for disposal of controlled substances, or the intended procedures for transfer of controlled substance in accordance with 247 CMR 6.10.

(2) Within ten days of the closure of a pharmacy or pharmacy department, the following shall be completed by the pharmacy or pharmacy department:

- (a) the pharmacy permit shall be returned to the Board;
- (b) the pharmacy controlled substance registration shall be returned to the Board;
- (c) the pharmacy certificate of fitness, if issued, shall be returned to the Board; and
- (d) the Board shall be notified that all controlled substances have been disposed of in accordance with federal regulations at 21 CFR 1307.21.

6.10: Distribution of Controlled Substances Upon Discontinuance or Transfer of Business of a Pharmacy or Pharmacy Department

(1) Any person who intends to transfer controlled substances in Schedules II through VI from one pharmacy or pharmacy department to another pharmacy or pharmacy department within the Commonwealth shall officially notify the Board in writing, by certified mail at least 14 days before the

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intended transfer, unless otherwise authorized by the Board, and shall provide the Board with the following information:

- (a) The name, address and telephone number of the transferor pharmacy or pharmacy department;
 - (b) the name, address and telephone number of the transferee pharmacy or pharmacy department.
 - (c) the pharmacy permit number of the transferor pharmacy or pharmacy department;
 - (d) the pharmacy permit number of the transferee pharmacy or pharmacy department;
 - (e) the pharmacy controlled substance registration number of the transferor pharmacy or pharmacy department;
 - (f) the pharmacy controlled substance registration number of the transferee pharmacy or pharmacy department;
 - (g) the name and pharmacist registration number of the Manager of Record of the transferor pharmacy or pharmacy department;
 - (h) the name and pharmacist registration number of the Manager of Record of the transferee pharmacy or pharmacy department;
 - (i) the date on which the transfer of the controlled substances will take place; and
 - (j) the intended security procedures for transfer of the controlled substances.
- (2) After proper notification, the transfer of controlled substances may occur provided the following procedures are adhered to:
- (a) On the date of the transfer, a complete inventory of all controlled substances in Schedules II through V shall be taken in accordance with federal and state law;
 - (b) said inventory shall be signed by the pharmacist Manager of Record of the transferor pharmacy or pharmacy department and the pharmacist Manager of Record of the transferee pharmacy or pharmacy department. In the event that either pharmacist Manager of Record is unavailable due to death, serious illness, or termination for inappropriate handling of controlled substances, a staff pharmacist may be authorized to sign the inventory, provided the Board is notified at the time the application is submitted as to why the staff pharmacist is signing the inventory;
 - (c) both the transferor and transferee pharmacy or pharmacy department shall maintain a copy of the inventory for two years or as otherwise required by law;
 - (d) a copy of said inventory shall be filed with the Board within ten days of the transfer;
 - (e) the transferee pharmacy or pharmacy department shall receive all required controlled substance and controlled substance inventory records on the date of the transfer and maintain those records for two years; and
 - (f) the transferor pharmacy or pharmacy department shall not possess any controlled substances after the date of transfer.

6.11: Inspections of Pharmacies and Pharmacy Departments

The Board or its designees may visit a pharmacy or pharmacy department at any time without prior notice and inspect it, its staff, activities and records to determine compliance with state law and 247 CMR 2.00 *et seq.* The Board may also inspect pharmacies and pharmacy department premises pursuant to 247 CMR 11.12.

6.12: Deficiency Statements

After every Board inspection in which any violation of 247 CMR 2.00 *et seq.* is observed, the Board or its designees shall prepare a deficiency statement citing every violation observed, a copy of which shall be sent to the pharmacy or pharmacy department.

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6.13: Plans of Correction

A pharmacy or pharmacy department shall submit to the Board a written plan of correction of violations cited in a deficiency statement prepared pursuant to 247 CMR 6.12 within 15 business days after the deficiency statement is sent. Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with the relevant 247 CMR section will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. A plan of correction which does not meet the requirements of the relevant 247 CMR section shall be considered unacceptable by the Board and returned to the pharmacy or pharmacy department.

REGULATORY AUTHORITY

247 CMR 6.00: M.G.L. c. 112, §§ 42A and 30; c. 138, §§ 29 through 30G.

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7.00: Wholesale Druggists

- 7.01: Scope and Purpose
- 7.02: Licensing Requirements
- 7.03: Penalties
- 7.04: Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records

7.01: **Scope and Purpose**

The purpose of 247 CMR 7.00 is to implement the Federal Prescription Drug Marketing Act of 1987 ("PDMA"), U.S. Public Law 100-293, codified at 21 U.S.C. §§ 321 et seq. The PDMA requires that all entities engaged in the interstate and/or intrastate wholesale distribution of prescription drugs be licensed in each state where they are engaged in such activity.

247 CMR 7.00 applies to every wholesale distributor located in the Commonwealth of Massachusetts who engages in the sale, distribution, or delivery at wholesale of prescription drugs.

The purpose of 247 CMR 7.00 is to provide minimum standards, terms and conditions for the licensing by the Board of Registration in Pharmacy of persons located in Massachusetts who engage in the sale, distribution, or delivery at wholesale of prescription drugs.

7.02: **Licensing Requirements**

- (1) Every wholesale distributor located in the Commonwealth of Massachusetts who engages in wholesale distribution of prescription drugs shall be licensed by the Board in accordance with the laws and regulations of the Commonwealth before engaging in such wholesale distribution.
- (2) Applications for a license to conduct a wholesale drug business in the Commonwealth shall be made upon application forms furnished by the Board. Each application shall be completely filled out and signed by each applicant under oath before a notary public. The Board shall not consider any applications within 15 days after the date of its filing with the Board. The Board shall not consider any application which has been improperly completed or which is not accompanied by the appropriate fee(s).
- (3) The Board may require a hearing upon the merits of any application for a license to conduct a wholesale drug business. Where such a hearing is required, the Board shall give the applicant seven days notice by certified mail, of the date, time, and place of the hearing.
- (4) Any person who is engaged in the wholesale drug business at more than one location shall obtain a license for each location.
- (5) Minimum Required Information for Licensure. The Board requires the following information from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:
 - (a) The name, full business address, and telephone number of the applicant or licensee;
 - (b) all trade or business names used by the applicant or licensee;
 - (c) addresses, telephone numbers, and the names of contact persons for each facility used by the applicant or licensee for the storage, handling, and distribution of prescription drugs;
 - (d) the type of ownership or operation (i.e., partnership, corporation, or sole proprietor-ship); and
 1. if a person, the name of the person;
 2. if a partnership, the name of each partner, and the name of the partnership;
 3. if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;
 4. if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
 5. an indication as to whether the applicant or licensee will distribute controlled substances, legend drugs, and/or over-the-counter drugs, as well as a statement concerning the types of drugs to be distributed.
- (6) Changes in any information in 247 CMR 7.02(5) shall be submitted to the Board in writing within 30 days after such change.

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- (7) **Minimum Qualifications.** The Board shall consider the following factors at a minimum in issuing, renewing, or revoking a license to engage in the wholesale distribution of prescription drugs:
- (a) Any convictions of the applicant or licensee under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
 - (b) any felony convictions of the applicant or licensee under federal, state, or local laws;
 - (c) the past experience of the applicant or licensee in the manufacture or distribution of prescription drugs, including controlled substances;
 - (d) the furnishing by the applicant or licensee of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
 - (e) suspension, revocation, or other sanction(s) by federal, state, or local government of any license or registration currently or previously held by the applicant or licensee for the manufacture or distribution of any drugs, including controlled substances;
 - (f) compliance with licensing or registration requirements under previously granted licenses or registrations, if any;
 - (g) compliance with the requirements to maintain and/or make available to state licensing authorities or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors;
 - (h) failure to provide adequate control over the distribution, diversion, theft, and/or loss of drugs;
 - (i) compliance with all requirements set forth in 247 CMR 7.00; and
 - (j) any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.
- (8) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.
- (9) **Personnel.** As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

7.03: **Penalties**

- (1) The agents of the Board may inspect and investigate all wholesale drug distributors of drugs and medicines and shall report all violations of Board regulations and statutes to the Board. Board agents shall provide to the licensee a copy of the inspection report within 15 days of such inspection. At the direction of the Board, Board agents may apply for criminal complaints to be issued against persons guilty of any such violations.
- (2) Every person who is licensed to conduct a wholesale drug business shall not sell or deliver drugs to any unauthorized person, whether upon prescription, at retail, or otherwise.
- (3) Except under the direct supervision of a registered pharmacist, and in compliance with federal Current Good Manufacturing Practices (CGMP's), a person who is licensed to conduct a wholesale drug business shall not package or repackage any drug for resale, nor shall said person label or relabel any drug container.
- (4) The Board may, after hearing or by agreement, suspend or revoke any licenses granted under 247 CMR 7.00 for any violation of federal, state or local drug laws or regulations or for any violation of Board laws or regulations governing the wholesale drug business.

7.04: **Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records**

The following shall constitute minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

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- (1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
 - (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (c) have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;
 - (d) be maintained in a clean and orderly condition; and
 - (e) be free from infestation by insects, rodents, birds, or vermin of any kind.
- (2) Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry in accordance with the requirements of the Board and federal regulations. The following guidelines shall be observed:
 - (a) Access from outside the premises shall be kept to a minimum and be well-controlled.
 - (b) The outside perimeter of the premises shall be well-lighted.
 - (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (d) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (e) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
 - (f) All facilities shall conduct a thorough background check for each employee.
 - (g) All facilities shall report a theft or loss of a significant amount of controlled substances by submitting to the Board a copy of "Report or Loss of Controlled Substances" (DEA BND Form 106) within seven days of such theft or significant loss, and where applicable, shall comply with the reporting requirements of the DEA, the Department, and the state and local police.
- (3) Storage.
 - (a) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium such as the United States Pharmacopoeia/National Formulary (USP/NF).
 - (b) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - (c) appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.
 - (d) The record-keeping requirements in 247 CMR 7.04(6) shall be followed for all stored drugs.
- (4) Examination of Materials.
 - (a) Upon receipt, each outside shipping container shall be visually examined for identity to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
 - (c) The record keeping requirements in 247 CMR 7.04(6) shall be followed for all incoming and outgoing prescription drugs.
- (5) Returned, Damaged, and Outdated Prescription Drugs.
 - (a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed in accordance with all applicable state and federal regulations or returned to the supplier.

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(b) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed in accordance with all applicable state and federal regulations or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed in accordance with all applicable state and federal regulations, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The record-keeping requirements in 247 CMR 7.04(6) shall be followed for all out-dated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) Record Keeping.

(a) Wholesale drug distributors shall establish and maintain, in a manner consistent with good business practices, complete and accurate inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped, or in the case of distribution, the name and address of the purchaser;
2. the identity and quantity of the drugs received and distributed or disposed of; and
3. the dates of receipt and distribution or other disposition of the drugs. In the case of registered wholesale drug distributors who are also licensed by the Board as pharmacies, no records shall be required to be maintained for the receipt or disposition of over-the-counter drugs.

(b) Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental entity charged with enforcement of 247 CMR 7.00 for a period of two years following disposition of the drugs.

(c) Records described in 247 CMR 7.04(6) that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the two-year retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of 247 CMR 7.00.

(7) Written Policies and Procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board;
2. any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
3. any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

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- (c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
- (d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.
- (e) In the case of wholesale drug distributors who are also licensed by the Board as pharmacies, the requirements of 247 CMR 7.05 shall apply to legend drugs only.
- (8) Responsible Persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
- (9) Compliance with Federal, State, and Local Laws.
 - (a) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
 - (b) Wholesale drug distributors shall permit the agents of the Board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.
 - (c) Wholesale drug distributors that deal in controlled substances as defined in M.G.L. c. 94C shall register with the Board, the Massachusetts Department of Public Health and with the United States Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and federal regulations.
 - (d) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, and local laws that relate to prescription drug product salvaging or reprocessing.

REGULATORY AUTHORITY

247 CMR 7.00: M.G.L. c. 112, §. 36A, 36B, 36C and 42A; c. 94C, § 6.

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8:00 PHARMACY INTERNS AND TECHNICIANS

Section

- 8.01: Pharmacy Interns
- 8.02: Pharmacy Technicians
- 8.03: Pharmacy Technician Trainees
- 8.04: Certified Pharmacy Technicians
- 8.05: Requirements for the Handling of Schedule II Controlled Substances by Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees
- 8.06: Duties of Pharmacist Utilizing Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees
- 8.07: Registration and Renewal Procedures; General Requirements

For the purposes of 247 CMR 8.00 "pharmacy" shall include retail, institutional, restricted and nuclear pharmacies and pharmacy departments.

8.01: Pharmacy Interns

- (1) To be eligible for personal registration as a pharmacist a candidate shall have completed a pharmacy internship. A pharmacy intern shall have:
- (a) completed two years of education, or achieved standing as a student beyond the second year, in an approved college/school of pharmacy in which the candidate is currently enrolled; and
 - (b) completed 1500 hours of Board-approved pharmacy internship experience, of which:
 1. at least 1000 hours has been acquired in a pharmacy or pharmacy-related setting approved by the Board; and
 2. no more than 500 hours has been acquired in any one, or any combination of Board-approved internships(s) in the following areas:
 - a. clinical pharmacy;
 - b. demonstration project;
 - c. manufacturing; or
 - d. analytical and/or industrial pharmacy.
- (2) The pharmacy internship shall be performed under the direct supervision of a registered pharmacist preceptor.
- (3) A pharmacy intern may receive credit for up to 12 hours of pharmacy internship credit per day.
- (4) Pharmacy internship hours may be acquired throughout a calendar year.
- (5)(a) Before the commencement of a pharmacy internship in Massachusetts, persons who are enrolled, either full or part-time, in an approved college/school of pharmacy shall record, on a form provided by the Board, certain information regarding the internship as the Board shall require. This form shall be fully completed and returned to the Board before commencement of any internship. This information shall include:
1. the applicant's name;
 2. the applicant's address;
 3. the applicant's date of birth;
 4. have attached thereto a recent passport-size photo revealing the applicant's likeness; and
 5. a certified statement by the approved college/school of pharmacy which indicates that the applicant has completed two years of education or has achieved standing as a student beyond the second year.
- (b) Graduates of Non-approved Colleges/Schools of Pharmacy. Before the commencement of a pharmacy internship in Massachusetts, a graduate of a non-approved college/school of pharmacy must have authorization from NABP to sit for the FPGEE (issued within the preceding year) and must provide a copy of the NABP FPGEE authorization to the Board and any other documentation required by the Board.

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- (6) During the course of the pharmacy internship, preceptors and pharmacy interns shall, in a timely manner submit, on a form provided by the Board, such information as the Board may require regarding the internship.
- (7) **A pharmacy intern who has graduated from an approved college/school** of pharmacy may continue to act in the capacity of pharmacy intern until he or she becomes registered as a pharmacist.
- (8) The Board may grant credit for out-of-state pharmacy internship experience where an affidavit or certificate of approval issued by the jurisdiction wherein the experience was acquired, is presented to the Board indicating that such internship experience has been duly approved in the jurisdiction.
- (9) Massachusetts approved colleges/schools of pharmacy shall submit to the Board a written description of each demonstration project or clinical pharmacy program for which pharmacy internship credit is desired. The Board shall review this information and determine whether or not student participation in such project(s) or program(s) may be credited to the internship requirement.
- (10) The Board shall issue a Summary of Objectives and Procedures for Pharmacy Internship and guidelines for registered pharmacist preceptors and pharmacy interns.
- (11) A pharmacy intern shall wear a name tag which indicates the intern's name and the words "pharmacy intern."
- (12) A pharmacy intern acting under the direct supervision of an approved registered pharmacy preceptor may supervise pharmacy technicians.
- (13) A registered pharmacist preceptor shall not directly supervise more than two pharmacy interns at one time.
- (14) A pharmacy intern found to have engaged in conduct in violation of federal and/or state laws and/or regulations may be prohibited from taking the examination for personal registration, in addition to other sanctions imposed by the Board.

8.02: Pharmacy Technicians

(1) Requirements for Registration as a Pharmacy Technician.

- (a) An applicant for registration as a pharmacy technician must meet the following requirements:
1. be at least 18 years of age;
 2. be a high school graduate or the equivalent or currently enrolled in a program which awards such degree or certificate;
 3. be of good moral character;
 4. not been convicted of a drug related felony or admitted to sufficient facts to warrant such findings;
 5. **Training/Experience Requirement.** An applicant for registration as a pharmacy technician must meet the following training program or experience requirements:
 - a. have successfully completed a Board-approved pharmacy technician training program, which training program shall include coverage of the topics of job descriptions, pharmacy security, commonly used medical abbreviations, routes of administration, product selection, final check by pharmacists, guidelines for the use of pharmacy technicians, and any other requirements of the Board. Training programs which may be approved by the Board include:
 - i. a pharmacy technician training program accredited by the American Society of Health System Pharmacists;
 - ii. a pharmacy technician training program provided by a branch of the United States Armed Services or Public Health Service;
 - iii. a Board-approved pharmacy technician training program which includes a minimum of 240 hours of theoretical and practical instruction; provided a minimum of 120 training hours are in theoretical instruction in a curriculum; or
 - iv. any other pharmacy technician training course approved by the Board; or
 - b. have successfully completed a minimum of 500 hours of employment as a pharmacy technician trainee. Documentation of completion of the required 500 hours of experience shall be attested to by the applicant under the pains and penalties of perjury and witnessed by the employer; and

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6. Examination Requirement. An applicant for registration as a pharmacy technician must achieve a Board-approved passing score on either:

- a. a Board-approved pharmacy technician assessment examination administered by the employer or the employer's agent. The examination must cover the following knowledge based areas:
 - i. practice settings;
 - ii. duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel;
 - iii. laws and regulations regarding the practice of pharmacy and patient confidentiality;
 - iv. medical abbreviations and symbols;
 - v. common dosage calculations; and
 - vi. identification of drugs, dosages, routes of administration, and storage requirements; or
- b. a Board-approved national technician certification examination.

(b) GRANDPARENT PROVISION FOR EXPERIENCE PRIOR TO JULY 1, 2002 ONLY- Application Expiration Date of July 1, 2003 for Experience Prior to July 1, 2002. An applicant for registration as a pharmacy technician based on at least 500 hours of employment as a pharmacy technician prior to July 1, 2002 shall be required to:

- a. apply to the Board for registration prior to July 1, 2003. Documentation of completion of the required 500 hours of experience must be attested to by the applicant under the pains and penalties of perjury and witnessed by the employer; and
- b. 2. meet the examination requirements of 247 CMR 8.02(1)(a)6. prior to July 1, 2003. Documentation of satisfaction of the examination requirements of 247 CMR 8.02(1)(a)6. must be provided with the application for technician registration.

(2) Reciprocity Registration. A pharmacy technician currently registered and in good standing in another state may be registered by the Board; provided the requirements for registration in the state of original and current registration are equivalent to the requirements of the Board.

(3) Pharmacy Technician Duties and Responsibilities.

(a) A pharmacy technician shall wear a name tag which indicates the individual's name and the title "Pharmacy Technician".

(b) A pharmacy technician may relay to the patient or responsible person the pharmacist's "offer to counsel", as referenced in M.G.L. c. 94C, § 21A and 247 CMR 9.07(3).

(c) With the approval of the pharmacist on duty, a pharmacy technician may request and accept authorizations for refills from the prescriber or prescriber's agent provided that no information has changed from the previous prescription.

(d) A pharmacy technician may not administer controlled substances; perform drug utilization review; conduct clinical conflict resolution; contact prescribers concerning drug order clarification or therapy modification; provide patient counseling; perform dispensing process validation; receive new prescription drug orders; or conduct prescription transfers.

8.03: Pharmacy Technician Trainees

(1) A pharmacy technician trainee must meet the following requirements:

- (a) be at least 16 years of age;
- (b) be a high school graduate or the equivalent or currently enrolled in a program which awards such degree;
- (c) be of good moral character; and
- (d) not been convicted of a drug related felony or admitted to sufficient facts to warrant such findings.

(2) Pharmacy Technician Trainee Duties and Responsibilities.

(a) A pharmacy technician trainee shall wear a name tag with the individual's name and the title "Pharmacy Technician Trainee".

(b) Except as set forth below, a pharmacy technician trainee may be authorized to perform the duties of a pharmacy technician while receiving the training and supervision required by 247 CMR 8.02(1)(a)5. and acting under the direct supervision of a pharmacist.

(c) A pharmacy technician trainee is not authorized to take prescriptions over the telephone.

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(3) Limitation on Period of Employment as a Pharmacy Technician Trainee. An individual may act and be designated as a pharmacy technician trainee for not more than 1000 hours, unless an extension is granted by the Board. Pharmacy technician trainees under the age of 18 are not subject to the 1000 hour limitation.

8.04: Certified Pharmacy Technicians

(1) Qualifications.

(a) A pharmacy technician currently:

1 registered by the Board; and
2 certified by a Board-approved certifying body may perform the duties as authorized to be performed by a certified pharmacy technician in 247 CMR 8.04(2).

(b) At any time that certification lapses, the certified pharmacy technician:

1 is limited to performing the functions of a pharmacy technician;
2 must use the title "pharmacy technician" and be limited to performing the duties authorized to be performed by pharmacy technicians, as set forth in 247 CMR 8.02; and
3 must be counted as a "pharmacy technician" in calculating supervisory ratios, as set forth in 247 CMR 8.06(3).

(2) Certified Pharmacy Technician Duties and Responsibilities.

(a) A pharmacy technician eligible to function as a certified pharmacy technician shall wear a name tag with the individual's name and the title "Certified Pharmacy Technician".

(b) A certified pharmacy technician may relay to the patient or responsible person the pharmacist's "offer to counsel", as referenced in M.G.L. c. 94C, § 21A and 247 CMR 9.07(3).

(c) A certified pharmacy technician, after identifying him/herself as such, may request refill authorizations from the prescriber or prescriber's agent and, with the approval of the pharmacist on duty, receive new or omitted prescription information from the prescriber or agent, except where otherwise prohibited by federal or state law and regulations.

(d) A certified pharmacy technician may, with the approval of the pharmacist on duty, perform prescription transfers between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedule VI only, any such transfer to be in accordance with the requirements of 247 CMR 9.02.

(e) A certified pharmacy technician may not administer controlled substances; perform drug utilization review; conduct clinical conflict resolution; contact prescribers concerning prescription drug order clarification or therapy modification; provide patient counseling; or perform dispensing process validation.

8.05: Requirements for the Handling of Schedule II Controlled Substances by Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians, and Pharmacy Technician Trainees

(1) Accountability for and security of Schedule II controlled substances shall be the direct responsibilities of the pharmacist.

(2) Under the supervision of a pharmacist:

(a) a pharmacy technician may assist in the transporting of Schedule II controlled substances; and

(b) a certified pharmacy technician may assist in the transporting and handling of Schedule II controlled substances; provided, the pharmacist has approved the certified pharmacy technician or pharmacy technician to assist the pharmacist in the handling or transporting of Schedule II controlled substances, in accordance with 247 CMR 8.05(2) and as evidenced by written policies and procedures to be followed in the pharmacy in the transporting and handling Schedule II controlled substances, such policies and procedures to be made available to the Board on request.

8.06: Duties of a Pharmacist Utilizing Pharmacy Interns, Certified Pharmacy Technicians, Pharmacy Technicians and Pharmacy Technician Trainees

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In addition to the requirements of 247 CMR 8.02 to 8.05, the following shall apply to a pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians and pharmacy technician trainees:

(1) A pharmacist Manager of Record of a pharmacy or pharmacy department or the Director of Pharmacy in an institutional pharmacy which utilizes certified pharmacy technicians, pharmacy technicians, or pharmacy technician trainees shall make the following available to the Board upon request:

- (a) a list of currently employed certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees;
- (b) a written description of the duties delegated to certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees; and
- (c) a written description of the scopes of responsibility for certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees.

(2) A pharmacist may train a pharmacy technician or pharmacy technician trainee through an on-the-job training program, in accordance with the requirements of 247 CMR 8.02(1)(a)5.a. and b. All such training programs shall comply with written guidelines formulated by the pharmacy or pharmacy department in a manner consistent with professional, ethical, and legal standards of proper pharmacy practice. Copies of training program guidelines shall be provided to the Board on request.

(3) Supervisory Ratios.

(a) A pharmacist utilizing pharmacy interns, certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees to assist in filling prescriptions may utilize such support personnel in accordance with the following ratio requirements:

1. 1:4 One pharmacist for a maximum of four support personnel; provided:
 - a. at least one of the four support personnel is a certified pharmacy technician and one is a pharmacy intern; or
 - b. at least two of the support personnel are certified pharmacy technicians.
2. 1:3 One pharmacist for a maximum of three support personnel; provided at least one of the three support personnel is a pharmacy intern or a certified pharmacy technician.

(b) Sales clerks, messengers, delivery personnel, secretaries and any other persons who do not fall within the definitions of a pharmacy intern, certified pharmacy technician, pharmacy technician or pharmacy technician trainee shall not be included for purposes of determining the ratios set forth in 247 CMR 8.06(3) as long as such persons are not supporting the pharmacist in any professional capacity.

8.07: Registration and Renewal Procedures; General Requirements

(1) Application for Registration. Upon meeting the requirements for registration as a pharmacy technician, an applicant may apply for registration on forms provided by the Board.

(2) Renewal of Registration.

- (a) Pharmacy technician registrations expire every two years on the birthdate of the registrant.
- (b) A pharmacy technician registration must be timely renewed to continue practice as a pharmacy technician. Any practice as a pharmacy technician after the expiration date of a pharmacy technician registration shall constitute unlicensed practice as a pharmacy technician subjecting the individual to any and all penalties established for unlicensed practice.
- (c) A pharmacy technician whose registration has lapsed may renew such registration upon filing of a renewal application and payment of an annual license, applicable back fees, and a late fee, as established by the Commissioner of Administration and Finance, pursuant to M.G.L. c. 7, § 3B.
- (d) A pharmacy technician whose registration has lapsed for more than two years may be required to meet other conditions as determined by the Board as a prerequisite to registration renewal.

(3) General Requirements.

(a) A pharmacy technician who changes his or her mailing address or name shall notify the Board of such change(s) in writing within ten working days of such changes(s) (M.G.L. c. 112, § 24F). In the case

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of a change of name, the pharmacy technician shall submit a sworn statement indicating that the pharmacy technician has changed his or her name with a photocopy of a valid picture identification card.

(b) A pharmacy technician shall carry, or have readily available, at all times where the pharmacy technician is employed, evidence of current registration with the Board.

REGULATORY AUTHORITY

247 CMR 8.00: M.G.L. c. 112, §§ 30 and 42A.

9.00: Code Of Professional Conduct;

Professional Standards For Registered Pharmacists, Pharmacies and Pharmacy Departments

- 9.01: Code of Professional Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments
- 9.02: Transfer of Prescriptions
- 9.03: Advertising
- 9.04: Requirements for Dispensing and Refilling Prescriptions
- 9.05: Maintenance of Prescription Files
- 9.06: Procedures for Verifying a Practitioner's Prescriptive Authority
- 9.07: Maintaining Patient Records, Conducting a Prospective Drug Utilization Review and Patient Counseling

For the purposes of 247 CMR 9.00, "pharmacy" shall include retail, restricted and nuclear pharmacies, and pharmacy departments.

9.01: Code of Professional Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments

- (1) A registered pharmacist shall at all times, conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board.
- (2) A pharmacist shall not dispense drugs, devices, or other substances in a manner which is intended, either directly or indirectly, to circumvent the law.
- (3) A pharmacist shall observe the standards of the current United States Pharmacopoeia.
- (4) Unless otherwise permitted by law, a pharmacist shall not redispense any medication which has been previously dispensed.
- (5) While on duty, a pharmacist shall be responsible for the proper preservation and security of all drugs in the pharmacy or pharmacy department, including the proper refrigeration and storage of said drugs.
- (6) A pharmacist shall not engage in any fraudulent or deceptive act.
- (7) A pharmacist shall not enter into an agreement or arrangement with any person for the purpose of dispensing drugs which have been ordered by coded prescriptions.
- (8) A pharmacist, pharmacy or pharmacy department shall not promise to any person who owns, operates, manages or is an employee of a hospital, nursing home or other health care facility, or to any authorized practitioner, any rebate, refund, discount, commission or other valuable consideration for, or on account of, or based upon income received or resulting from, the sale, or furnishing of any such pharmacist, pharmacy, or pharmacy department, of drugs devices or services to patients of such persons, organizations or facilities.
- (9) A pharmacist shall not in any way aid or abet the unlawful practice of pharmacy.
- (10) A pharmacist shall not dispense or distribute expired, outdated or otherwise substandard drugs or devices or counterfeit drugs or devices to any person or entity that is not licensed or legally authorized to receive such drugs or devices.
- (11) A pharmacist may dispense prescription drugs by mail or common carrier in a manner consistent with federal and state laws and regulations, including the regulations of the Board. All pharmacists shall have available sufficient information to contact the patient and the prescribing practitioner.
- (12) Unless otherwise permitted by law, a pharmacist connected with, or employed by, a hospital or clinic shall not dispense drugs to any person other than inpatients or outpatients, or to employees of said hospital or clinic, or to said employees' spouses and children who live in the same household with said employees.
- (13) A pharmacist, pharmacy, pharmacy department, pharmaceutical organization or pharmacy corporation shall not provide any practitioner with prescription blanks which refer to any pharmacist, pharmacy or pharmacy department.

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- (14) A pharmacist shall keep a perpetual inventory of each controlled substance in Schedules II which the pharmacist has received, dispensed or disposed of in accordance with the law. This inventory must be reconciled at least once every ten days.
- (15) Unless otherwise provided for by law, a pharmacist shall not limit his or her services to a particular segment or segments of the general public.
- (16) A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.
- (17) A pharmacist shall not purchase drug samples for the purpose of compounding, dispensing, or in any way reselling these samples.
- (18) A pharmacist shall comply with the mandatory counseling provisions contained in M.G.L. c. 94C, § 21A.
- (19) A pharmacist shall maintain patient confidentiality at all times. Confidential information shall include information maintained by the pharmacist in the patient's records or information which is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

9.02: **Transfer of Prescriptions**

- (1) A prescription may be transferred between pharmacies or pharmacy departments, at the patient's request, for the purpose of dispensing authorized refills on the prescription provided that:
- refills remain on the prescription; and
 - the prescription authorizing the refill has not expired.
- (2) The procedure for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedules III, IV and V shall be as follows:
- The transferring pharmacist must record the following information:
 - Write the word "VOID" on the face of the invalidated prescription;
 - record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; and
 - record, on a written transfer log or by entry into a computerized system, the prescription number, date of the transfer, the name or identification of the pharmacist transferring the information and the name of the pharmacy or pharmacy department to which the prescription is transferred.
 - The transferring pharmacist shall cancel all refills remaining on the transferred prescription.
 - The pharmacist receiving the transferred prescription information shall complete the following:
 - Write the word "transfer" on the face of the transferred prescription; and
 - write all information required by state and federal law to be on the prescription and include:
 - the date of issuance of the original prescription;
 - the original number of refills authorized on the original prescription;
 - the date of original dispensing;
 - the number of valid refills remaining and date of last refill; and
 - the pharmacist's name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.
 - The pharmacist receiving the transferred information shall inform the patient that the original prescription's refills have been canceled at the pharmacy or pharmacy department from which it has been transferred.
- (3) The procedure for transferring a prescription between pharmacies or pharmacy departments for prescriptions issued for controlled substances in Schedule VI shall be as follows:
- The transferring pharmacist or certified pharmacy technician must record, on a written transfer log or by entry into a computerized system the following: the prescription number; date of the transfer; the name

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or identification of the pharmacist transferring the information; and the name of the pharmacy or pharmacy department to which the prescription is being transferred.

(b) The transferring pharmacist or certified pharmacy technician shall cancel all refills remaining on the transferred prescription.

(c) The pharmacist or certified pharmacy technician receiving the transferred prescription information shall:

1. write the word "transfer" on the face of the transferred prescription;
2. write all information required by state and federal law to be on the prescription including:
 - a. the date of issuance of the original prescription;
 - b. the original number of refills authorized on the original prescription;
 - c. the date of original dispensing;
 - d. the number of valid refills remaining and date of last refill; and
 - e. the pharmacy's name, address, DEA number and original prescription number from which the prescription information was transferred; and the name of the transferor pharmacist.

(d) The pharmacist or certified pharmacy technician receiving the transferred prescription shall inform the patient that the original prescription's refills have been canceled at the pharmacy or pharmacy department from which it has been transferred.

(4) Prescriptions authorizing refills for Schedule III through V controlled substances may be transferred between pharmacies or pharmacy departments on a one-time only basis except as otherwise permitted by law.

(5) Prescriptions authorizing refills for Schedule VI controlled substances may be transferred between pharmacies or pharmacy departments within one year of the date of issuance.

(6) Both the original and transferred prescriptions must be maintained for a period of two years from the date of last refill.

9.03: Advertising

(1) A pharmacist shall not utilize false, deceptive or misleading advertising.

(2) Whenever a pharmacist advertises the consumer price for a particular prescription drug, said advertisement shall not contain any representation, either expressed or implied, concerning that drug's safety, effectiveness, or indications for use.

(3) Any pharmacist who advertises a prescription drug in a manner which provides price information to consumers shall include the following information regarding each advertised prescription drug:

- (a) The proprietary name, if any;
- (b) the established or generic name, if any;
- (c) the quantity of active ingredient per dosage unit of the prescription drug product when-ever the prescription contains a single active ingredient;
- (d) the strength of the prescription whenever said product contains more than one active ingredient by a relevant strength that can be associated with the product without indicating each active ingredient; the established name and quantity of each active ingredient shall not be required whenever said product contains more than one active ingredient;
- (e) the dosage form; and
- (f) the price charged for filling a prescription.

(4) A pharmacist who advertises prescription drugs in a manner which provides price information to consumers may identify professional or convenience services provided by the pharmacy or pharmacy department, or may include other written, printed or graphic matter, provided that no information included in such advertising shall be false, deceptive or misleading.

(5) Whenever a pharmacist advertises prescription drugs in a manner that provides price information to consumers, any stated price with respect to a particular prescription drug shall include all charges to the consumer. These charges shall include, but not be limited to, any professional or handling fees and any mailing and delivery fees. This advertising may indicate each separate fee which is to be added to the price of the prescription drug.

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(6) The requirements of 247 CMR 9.03 apply to all prescription drug advertisements, including price lists, catalogs, and other promotional material, whether mailed, posted in a pharmacy, placed in a newspaper, or aired on radio or television, which serve to provide consumers with information regarding the price charged for prescriptions.

9.04: Requirements for Dispensing and Refilling Prescriptions

(1) Whenever a prescription drug has been distributed solely under a generic name, the dispensing pharmacist shall record on the prescription the name of the manufacturer or, if the manufacturer's name is not available, the name of the distributor, packer, or repacker.

(2) The information on the label which the pharmacist, pharmacy intern, pharmacy technician or pharmacy technician trainee affixes to a prescription drug container shall be clearly printed or typed.

(3) Only a pharmacist, pharmacy intern, and certified pharmacy technician who has the approval of the pharmacist on duty may receive new prescriptions over the telephone from a prescriber or authorized agent.

(4) A pharmacist who refills a prescription for a controlled substance in Schedules III through VI shall record on the prescription:

- (a) the date of dispensing;
- (b) the amount of the drug dispensed; and
- (c) his or her initials.

(5) A dispensing pharmacist who does not indicate the quantity of a drug dispensed on the back of a prescription which the pharmacist has refilled shall be deemed to have dispensed a refill for the full face amount of the prescription.

(6) Subject to the provisions of federal regulations at 21 CFR 1306, an automated data-processing system may be used as an alternative to the provisions of 247 CMR 9.04 (4) and (5). This data-processing system may be used for the storage and retrieval of information pertaining to the refilling of prescriptions for controlled substances in Schedules III through VI.

(7) A pharmacist or anyone acting on behalf of a pharmacy or pharmacy department shall not collect prescriptions at industrial plants, places of business, or other sites where specific groups of people are regularly employed or affiliated, unless the prescriptions meet the following requirements:

- (a) the prescriptions are for persons regularly employed at, or affiliated with, such plant, place of business or other such site;
- (b) the prescriptions are collected in person by a pharmacist, pharmacy employee, or authorized agent of the pharmacy;
- (c) the prescriptions are distributed in person to the patients or an authorized agent of the patient by a pharmacist, pharmacy employee, or authorized agent of the pharmacy; and
- (d) the pharmacist shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf, and for verifying the authority of any person purporting to act on a patient's behalf; nothing in 247 CMR 9.04(7) shall be deemed to permit conduct of a prescription business in violation of any other regulation of the Board.

9.05: Maintenance of Prescription Files

A pharmacist shall maintain prescription files as follows:

(1) Prescriptions for controlled substances in Schedule II shall be segregated from all other records and shall be maintained in a separate file identified as such.

(2) Prescriptions for controlled substances in Schedules III, IV, and V shall be maintained in a separate file identified as such.

(3) Prescriptions for controlled substances in Schedule VI, prescriptions for non-controlled substances, and prescriptions for syringes and instruments adaptable to hypodermic administration, shall be segregated from all other records and shall be maintained together in a separate file identified as such.

9.06: Procedures for Verifying a Practitioner's Prescriptive Authority

A prescription written by a practitioner may be filled only if the pharmacist called upon to fill such prescription, in the exercise of that pharmacist's professional judgment, determines that:

- (1) The prescription is issued pursuant to a valid patient/practitioner relationship and for a legitimate medical purpose by an authorized practitioner acting in the course of his or her professional practice;
- (2) the prescription is authentic; and
- (3) the dispensing is in accordance with M.G.L. c. 94C, § 19(a).

9.07: Maintaining Patient Records, Conducting a Prospective Drug Utilization Review and Patient Counseling

The purpose of 247 CMR 9.07 is to enhance the public health and welfare by requiring that pharmacists offer consultation to patients regarding their prescriptions in order to promote optimum therapeutic outcomes, avoid patient injury and reduce medication errors.

(1) Patient Records.

(a) A pharmacist or pharmacist's designee shall maintain a confidential record for all patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed drugs at the time the prescription is presented for dispensing. The pharmacist or pharmacist's designee shall make a reasonable effort to obtain, record, and maintain the following information:

1. name, address, telephone number, date of birth or age, and gender of the patient for whom the prescription is intended;
2. individual history, including known drug allergies and drug reactions;
3. a comprehensive list of medications and relevant devices dispensed by the pharmacy; and
4. the pharmacist's comments relevant to the patient's drug therapy.

(b) A pharmacist shall maintain the patient's record for a period of not less than 12 months from the date of the last entry in the profile record, except as otherwise required by state and federal law. This record may be computerized.

(2) Prospective Drug Utilization Review.

(a) A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. This DUR may include a review of the patient record and each new prescription presented for dispensing, for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify the following:

1. over-utilization or under-utilization
2. therapeutic duplication;
3. drug-disease contraindication;
4. drug-drug interaction;
5. incorrect drug dosage or duration of drug treatment;
6. drug-allergy interactions;
7. clinical abuse or misuse; and
8. any significant change in drug, dose or directions.

(b) Upon identifying any of the above, the pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner and/or direct consultation with the patient.

(c) The review shall be based upon current standards which may include the following:

1. The American Hospital Formulary Service Drug Information;
2. the United States Pharmacopoeia Drug Information;
3. the American Medication Association Drug Evaluations; and
4. other peer-reviewed medical literature.

(3) Patient Counseling.

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- (a) The pharmacist or pharmacist's designee shall offer the services of the pharmacist to discuss, with all persons presenting new prescriptions, issues that in the pharmacist's professional judgment are deemed to be significant for the health and safety of the patient.
- (b) The pharmacist's designee shall be an individual appropriately trained to make the offer to counsel and under the direct supervision of the pharmacist.
- (c) A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.00 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. Said sign shall read, in letters not less than ½" in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."
- (d) When the offer to counsel is accepted, the pharmacist shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the following:
1. Name and description of the medication;
 2. dosage form, dosage, route of administration and duration of therapy;
 3. special directions and instructions for preparation, administration and use by the patient;
 4. common severe side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications which the pharmacist deems relevant;
 5. techniques for self-monitoring drug therapy;
 6. proper storage;
 7. prescription refill information; and
 8. action to be taken in the event of a missed dose or adverse reaction.
- (e) The offer to counsel shall be made to the patient, or the person acting on behalf of the patient when confidentiality can be maintained, either by face to face communication or telephone. If the patient does not pick up the prescription at a pharmacy or the offer is not made by telephone then the offer must be made in writing. This offer must provide a toll-free telephone service to facilitate communication between such person and the pharmacist and must state the following: "Dear patient, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist". Printed material containing information on the drug may accompany this written offer to counsel provided the patient is informed that said information is not comprehensive and that the patient should call for further information if needed.
- (f) Counseling must be made by a pharmacist, or a pharmacy intern under the direct supervision of the pharmacist if deemed appropriate by the pharmacist.
- (g) Counseling must be available at all times when a pharmacy is open for business.
- (h) The provisions of 247 CMR 9.07 shall apply to pharmacists who directly dispense medications to outpatients and patients being discharged from hospitals, institutions and clinics.
- (i) The provisions of 247 CMR 9.00 shall not apply to any drug dispensed to an inpatient at a hospital, nursing home or any other setting where medication is administered by an authorized individual, except to the extent required by the Federal Health Care Financing Administration pursuant to the provisions of 42 USC 139r-8.

REGULATORY AUTHORITY

247 CMR 9.00: M.G.L. c. 112, §§ 30 and 42A.

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10.00: Disciplinary Proceedings

- 10.01: Purpose
- 10.02: Definitions
- 10.03: Grounds for Complaints
- 10.04: Informal Conference
- 10.05: Disposition by the Board
- 10.06: Disciplinary Action
- 10.07: Suspension Prior to Hearing

10.01: Purpose

The purpose of 247 CMR 10.00 is to outline the procedures used by the Board in order to handle complaints received against Board registrants or licensees. The Board may take disciplinary action against a registered pharmacist, pharmacy technician, pharmacy, pharmacy department, wholesale license, and/or controlled substance registration issued by the Board.

10.02: Definitions

Adjudicatory Hearing means a formal administrative hearing held by the Board conducted to determine the truth and validity of complaints filed against a registrant or licensee. Such hearing is held pursuant to M.G.L. c. 30A and 801 CMR 1.01.

Complaint means a communication filed with the Board or the Division of Health Professions Licensure which the Board determines, after investigation, merits further consideration or action.

Investigative Conference means an informal discussion relating to a complaint held with the Board.

Order to Show Cause means a document served by the Board upon a registrant ordering the registrant or licensee to appear before the Board for a formal adjudicatory hearing.

10.03: Grounds for Complaints

Grounds for complaints are acts which indicate that the registrant or licensee is in violation of relevant provisions of federal and state laws and/or regulations including the regulations of the Board. The Board may take disciplinary action for any violation of the Code of Professional Conduct, 247 CMR 9.00, regardless of whether the act complained of occurred in Massachusetts or in another state or jurisdiction.

10.04: Investigative Conference

To facilitate disposition of any complaint, the Board may schedule an investigative conference at any time prior to the commencement of a formal adjudicatory proceeding. The Board shall give timely notice of the conference, and this notice shall include a general statement of the nature of the issues to be discussed.

10.05: Disposition by the Board

After receipt of a complaint and all related investigative materials, the Board may schedule an investigative conference or may schedule a formal adjudicatory hearing pursuant to M.G.L. c. 30A and 801 CMR 1.01 if it determines that one is required.

10.06: Disciplinary Action

Actions which may be taken by the Board after investigation of a complaint are:

- (1) **Dismissal of the complaint.**
- (2) **Advisory Letter.** An official written document retained in the Board's files delineating the Board's concerns with the registrant's or licensee's professional practice. An advisory letter does not constitute formal disciplinary action.
- (3) **Reprimand or Censure of the Registrant or Licensee.** A reprimand constitutes formal disciplinary action. A censure is a severe reprimand.

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(4) **Probation.** Probation constitutes disciplinary action against the registrant or licensee and consists of a period of time during which the registrant or licensee may practice under conditions imposed by the Board pursuant to a formal adjudicatory hearing or consent agreement.

(5) **Suspension/Revocation of Personal Registration, Pharmacy Permit, License or Controlled Substances Registration.** Suspension or revocation of a personal registration, pharmacy permit, license or controlled substance registration may be imposed pursuant to a decision and order of the Board following a formal adjudicatory hearing or following the execution of a consent agreement.

(6) **Consent Agreement.** A resolution of a complaint agreed upon by the Board and the registrant or licensee which may contain conditions placed by the Board on the registrant's or licensee's professional conduct and practice and which may include the voluntary suspension or surrender of a personal registration, pharmacy permit, license or controlled substance registration. The voluntary surrender of a personal registration, pharmacy permit, license, or controlled substance registration, may be permanent or for a fixed period of time. The voluntary surrender agreement shall:

(a) be in writing and be signed by the registrant or the licensee and the Board;

(b) recite the facts upon which the agreement is based and shall include, but not be limited to provisions addressing reinstatement and any conditions the Board may elect to impose;

(c) state that the registrant or licensee realizes that the voluntary surrender of his or her personal registration, pharmacy permit, license or controlled substance registration, is an act which deprives him or her of all privileges of registration and is not subject to judicial review; and

(d) be placed in the registrant's or licensee's Board file as part of the registrant's or licensee's permanent Board records.

(7) **Disciplinary Action Against a Massachusetts Registrant or Licensee Taken in Another State.** Disciplinary action taken against a Massachusetts registrant or licensee by another state or jurisdiction in which that person is also registered or licensed may be the basis for initiation by the Board of disciplinary action against the Massachusetts registrant or licensee provided that the conduct disciplined in another state or jurisdiction constitutes a violation of Massachusetts law.

10.07: Suspension Prior to Hearing

If, based upon affidavits or other documentary evidence, the Board determines that a licensee is an immediate or serious threat to the public health, safety, or welfare, the Board may suspend or refuse to renew a license pending a final hearing on the merits of the allegations regarding the licensee. A hearing limited to the determination of the necessity of the summary action shall be afforded the licensee within seven days of the Board's action.

REGULATORY AUTHORITY

247 CMR 10.00: 801 CMR 1.01; M.G.L. c. 112, §§ 24 and 42A; c. 30A.

11.00: Registration Under the Controlled Substances Act (M.G.L. c. 94C)

- 11.01: Controlled Substance Registration
- 11.02: Requirement of a Controlled Substance Registration
- 11.03: Standard for Issuance of a Controlled Substance Registration
- 11.04: Requirement of a Pharmacy Permit or Wholesale Druggist License
- 11.05: Application for a Controlled Substance Registration
- 11.06: Separate Registration Required
- 11.07: Expiration of a Controlled Substance Registration
- 11.08: Renewal of a Controlled Substance Registration
- 11.09: Changes in the Name, Address and/or Status of Registrant
- 11.10: Transfer or Assignment of a Controlled Substance Registration Prohibited
- 11.11: Wholesale Druggist Activities Limited
- 11.12: Inspection of Registered Premises
- 11.13: Records and Inventories
- 11.14: Revocation and Suspension of a Controlled Substance Registration; Grounds; Effect
- 11.15: Summary Suspension of a Controlled Substance Registration

11.01: Controlled Substance Registration

For the purposes of 247 CMR 11.00, the term "registrant" shall mean the individual to whom a controlled substance registration is issued by the Board.

For the purposes of 247 CMR 11.00, the term "pharmacy" shall mean a retail, restricted, and nuclear pharmacy and a pharmacy department.

11.02: Requirement of a Controlled Substance Registration

(1) In accordance with the Massachusetts Controlled Substances Act, M.G.L. c. 94C, the Board may issue a controlled substance registration to a qualified owner or operator of pharmacy or of a wholesale drug business who intends to engage in any activity for which a controlled substance registration is required by law.

(2) No pharmacy or wholesale drug business shall engage in any activity for which registration is required until a controlled substance registration has been issued by the Board.

11.03: Standard for Issuance of a Controlled Substance Registration

The Board shall issue a controlled substance registration to an applicant unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider, but shall not be limited to considering, the following factors:

- (1) The maintenance of effective controls against diversion of controlled substances;
- (2) compliance with applicable federal, state and local laws and regulations;
- (3) any conviction of the applicant under any federal and/or state law relating to any controlled substance;
- (4) past experience in the manufacture or distribution of controlled substances;
- (5) furnishing by the applicant of false or fraudulent material in any application filed under the provisions of M.G.L. c. 94C or other applicable state or federal law or regulation;
- (6) suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense controlled substances as authorized by federal law; and
- (7) any other factors relevant to, and consistent with, the public health and safety.

11.04: Requirement of a Pharmacy Permit or Wholesale Druggist License

All applicants for a controlled substance registration shall be determined by the Board to be qualified to receive a Board pharmacy permit or a Board wholesale druggist license before being issued a controlled substance registration.

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11.05: **Application for a Controlled Substance Registration**

Application for a controlled substance registration shall be made on a form provided by the Board. All applications submitted to the Board shall:

- (1) be fully and properly completed, and
- (2) be accompanied by a check or money order payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy" in the appropriate amount, which shall be non-refundable.

11.06: **Separate Registration Required**

A separate controlled substance registration shall be required at each principal place of business where the registrant manufactures, distributes or dispenses controlled substances.

11.07: **Expiration of a Controlled Substance Registration**

A controlled substance registration issued by the Board shall be valid as follows:

- (1) Pharmacy: The controlled substance registration issued to a pharmacy shall be valid for two years beginning January 1st of each even-numbered year.
- (2) Wholesale druggist: The controlled substance registration issued to a wholesale druggist shall be valid for one year beginning on December 1st of each year.

11.08: **Renewal of a Controlled Substance Registration**

(1) A registrant may renew a controlled substance registration on a renewal form provided by the Board. All renewal applications submitted to the Board shall:

- (a) be submitted in a timely manner;
 - (b) be fully and properly completed; and
 - (c) be accompanied by a check or money order payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy" in the appropriate amount, which shall be non-refundable.
- (2) Renewal of a controlled substance registration shall be made prior to the following dates:
- (a) December 31st of each odd-numbered year for a pharmacy; and
 - (b) November 30th of each year for a wholesale druggist.
- (3) Failure by a registrant to renew a controlled substance registration in a timely manner may result in the imposition of a late renewal fee.

11.09: **Changes in the Name, Address and/or Status of Registrant**

(1) The controlled substance registration of any registrant shall automatically terminate and become invalid if:

- (a) the person named on the controlled substance registration dies;
- (b) the pharmacy or wholesale business named on the controlled substance registration ceases to exist;
- (c) the name and/or address of the pharmacy or wholesale business to which the controlled substance registration was issued changes; or
- (d) the pharmacy or wholesale business to which the controlled substance registration was originally issued is sold.

(2) A registrant affected by 247 CMR 11.09(1) shall notify the Board in writing within ten days of such change(s).

(3) A registrant affected by 247 CMR 11.09(1) shall make application to the Board for the issuance of a new controlled substance registration. Such application may be submitted to the Board before the effective date of such change. The Board shall review such application as a first-time application for a controlled substance registration.

(4) A registrant affected by 247 CMR 11.09(1) shall promptly provide written notice thereof to the regional office of the U.S. Drug Enforcement Administration.

11.10: Transfer or Assignment of a Controlled Substance Registration Prohibited

A controlled substances registration issued by the Board, or any authority conferred thereby, shall not be assigned or transferred.

11.11: Wholesale Druggist Activities Limited

A wholesale druggist which is registered to distribute a controlled substance or class of controlled substances shall be authorized to distribute only that controlled substance or class of controlled substances.

11.12: Inspection of Registered Premises

The Board or its authorized agents may inspect, in accordance with Board regulations, the establishment of a registrant or of an applicant for a controlled substance registration.

11.13: Records and Inventories

Registrants shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of the federal "Comprehensive Drug Prevention and Control Act of 1970", or any amendment thereof, and 21 U.S.C. § 301 et seq. (Federal Food, Drug and Cosmetic Act), and with all other applicable state laws and regulations.

11.14: Revocation and Suspension of Registration; Grounds; Effect

- (1) The Board may suspend or revoke a controlled substance registration issued by it after a hearing pursuant to the provisions of M.G.L. c. 30A upon a finding that the registrant:
 - (a) has furnished false or fraudulent material information in any application filed under the provisions of M.G.L. c. 94C;
 - (b) has been convicted under any state or federal law of any criminal violation relating to his or her fitness to be registered under M.G.L. c. 94C;
 - (c) has had his or her state or federal controlled substance registration to manufacture, distribute, dispense, administer or possess controlled substances suspended or revoked, or has voluntarily surrendered said controlled substance registration;
 - (d) is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dispense, or possess any controlled substance; or
 - (e) has violated any provision of M.G.L. c. 94C and/or any other applicable federal or state laws and regulations.
- (2) The suspension or revocation by the Board of a controlled substance registration shall be grounds for the suspension or revocation of the retail pharmacy's permit or wholesale druggist's license issued by the Board.
- (3) The Board may limit revocation or suspension of a controlled substance registration issued by it to the particular controlled substance with respect to which grounds for revocation or suspension exist.
- (4) Whenever the Board has substantial reason to believe that a registrant to whom it has issued a controlled substance registration has committed a criminal violation of any provision of M.G.L. c. 94C, the Board shall promptly report all pertinent facts to the district attorney in the county where the violation is believed to have occurred or to the attorney general.
- (5) If the Board suspends or revokes a controlled substances registration issued by it, all controlled substances which are affected by such suspension or revocation order at the time of suspension or the effective date of the revocation order shall be placed under embargo pursuant to the procedures prescribed in M.G.L. c. 94, §§ 189 and 189A. No disposition may be made of substances under such embargo until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the Commonwealth.

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(6) The Board shall promptly notify the U.S. Drug Enforcement Administration and, where appropriate the Department of Public Health of all orders suspending or revoking a controlled substances registration and all forfeitures of controlled substances.

11.15: Summary Suspension of a Controlled Substance Registration

(1) The Board may, without hearing, suspend or refuse to renew any controlled substance registration issued by it if it finds that there is an imminent danger to the public health or safety which warrants this action; provided, however, that the Board promptly affords the registrant an opportunity for a hearing in accordance with M.G.L. c. 30A, 801 CMR 1.01 and 247 CMR 10.00.

(2) Any suspension summarily imposed by the Board shall continue in effect until the conclusion of the final hearing on the merits of any Order to Show Cause issued by the Board in connection with its investigation of the pharmacy or wholesale druggist, including judicial review thereof, unless sooner dissolved by a court of competent jurisdiction, or withdrawn by the Board.

(3) The procedure for summary suspension is as follows:

(a) Closure of Pharmacy: Upon receipt by the Board of reliable information that a registrant is an imminent and serious threat to the public health or safety, the Board shall vote to take summary action on the registrant's controlled substances registration. Upon the Board's vote to summarily suspend such registration, Board Agents are authorized to:

1. immediately close the registrant's establishment or business;
2. at the registrant's expense, replace the locks on all doors to the registrant's establishment or business and retain the key(s);
3. conspicuously display at the entrance(s) to the registrant's establishment or business a sign, in letters no less than one inch in height and one inch wide, stating: "THE REGISTRATION OF THIS PHARMACY/ ESTABLISHMENT HAS BEEN SUS-PENDED BY ORDER OF THE MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY."; and
4. conduct an inventory and audit of all drugs and record of drugs within the registrant's establishment or business.

(b) Order of Suspension: The Board shall promptly issue an Order of Suspension of Controlled Substance Registration and shall send such Order, with a Notice of Hearing as set forth in 247 CMR 11.15(3)(c), to the establishment's owner or pharmacy's Manager of Record by certified mail, or shall deliver such Order and Notice of Hearing by hand.

(c) Hearing on Necessity for the Summary Action: The Board shall convene a hearing on the necessity for the summary suspension of a controlled substance registration within seven days after the order of suspension. The establishment's owner and/or pharmacy's Manager of Record shall be notified of the date, time and place of the hearing.

At the hearing, the Board shall receive testimony and documentary evidence limited to determining whether the summary suspension of the controlled substance registration shall continue in effect pending a final hearing on the merits of any Order to Show Cause issued by the Board against the pharmacy or establishment in connection with its investigation.

Following the hearing, the Board shall vote on whether to continue the summary suspension in effect and shall promptly notify the registrant in writing of its decision.

(4) The Board's summary suspension of a controlled substance registration shall be grounds for the summary suspension of the pharmacy's permit or wholesale druggist's license issued by the Board. The summary suspension of a pharmacy's permit or wholesale druggist's license permit shall continue in effect pending a final hearing on the merits of any Order to Show Cause issued by the Board against the pharmacy or wholesale druggist in connection with its investigation, including judicial review thereof, unless sooner dissolved by a court of competent jurisdiction or withdrawn by the Board.

REGULATORY AUTHORITY

247 CMR 11.00: M.G.L. c. 112, §§ 30 and 42A; c. 94C, §§ 6, 7 and 10 through 15.

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12.00: Restricted Pharmacy

- 12.01: Authority
- 12.02: Limitation on the Functions and Operations of a Restricted Pharmacy
- 12.03: Application for an Initial Permit
- 12.04: Renewal of a Permit
- 12.05: General Requirements for the Operation of a Restricted Pharmacy

12.01: Authority

The Board may, under authority granted to it by M.G.L. c. 112, § 39A, register a restricted pharmacy for the limited transaction of a drug business as defined in M.G.L. c. 112, § 37. A restricted pharmacy may furnish pharmacy services only to beneficiaries, as defined in M.G.L. c. 151D, § 1, of a trust, fund, pension plan, combination plan, or profit-sharing plan which is subject to the provisions of M.G.L. c. 151D.

12.02: Limitation on the Functions and Operations of a Restricted Pharmacy

Registration as a restricted pharmacy shall not authorize such a restricted pharmacy to function or operate as a retail pharmacy as defined in M.G.L. c. 112, § 39.

12.03: Application for an Initial Registration

- (1) Application for an initial permit to operate as a restricted pharmacy shall be made by the plan administrator or trustee of the trust, fund, pension plan, combination plan, or profit-sharing plan on a form provided by the Board.
- (2) A restricted pharmacy shall comply with the requirements for the issuance of a pharmacy permit as provided by 247 CMR 6.00.

12.04: Renewal of a Permit

A restricted pharmacy shall comply with the requirements for permit renewal as provided by 247 CMR 6.00.

12.05: General Requirements for the Operation of a Restricted Pharmacy

- (1) A restricted pharmacy may, after written notice to the Board, limit its operation to a specific schedule of drugs.
- (2) A restricted pharmacy shall be exempt from the application of 247 CMR 9.01(15).
- (3) A restricted pharmacy shall be subject to all applicable provisions of 247 CMR except as specifically exempted by the Board.

REGULATORY AUTHORITY

247 CMR 12.00: M.G.L. c. 112, §§ 39A and 42A.

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13.00: Registration Requirements And Minimal Professional Standards For Nuclear Pharmacies

- 13.01: Authority and Purpose
- 13.02: Definitions
- 13.03: Requirements for the Issuance of a Nuclear Pharmacy Permit
- 13.04: Renewal of Nuclear Pharmacy Permit
- 13.05: General Requirements for Nuclear Pharmacies
- 13.06: Educational and Experience Requirements of a Qualified Nuclear Pharmacist

13.01: Authority and Purpose

247 CMR 13.00 is promulgated under the authority granted the Board by M.G.L. c. 112, § 39B to register an establishment for transacting business as a nuclear pharmacy as defined in M.G.L. c. 94C. The purpose of 247 CMR 13.00 is to establish minimum professional standards for the operation of a nuclear pharmacy in order to safeguard the public health and welfare.

13.02: Definitions

Authentication of product history means the identification of the purchasing source, or of any intermediate handler, or of the ultimate fate of any radiopharmaceutical or component thereof.

Authorized practitioner means a practitioner who is legally authorized to receive and administer radiopharmaceutical drugs.

Compounding of radiopharmaceuticals means the addition of a radioactive substance, or the use of a radioactive substance in preparation of a single-dose or multiple-dose medication, pursuant to the prescription of an authorized practitioner for a patient who is being treated by the that practitioner. Such compounding of radiopharmaceuticals includes, but is not limited to, loading and eluting of radionuclide generators, using manufactured reagent kits to prepare radio-pharmaceuticals, preparing reagent kits, aliquoting reagents, and formulating and conducting quality assurance tests of radiochemicals which are to be used as radiopharmaceuticals.

Internal test assessment means such testing or quality assurance which is necessary to insure the integrity of a particular test.

Nuclear pharmacy means a facility under the direction or supervision of a registered pharmacist which is registered by the Board to dispense radiopharmaceutical drugs pursuant to M.G.L. c. 112, § 39 and 247 CMR 13.00.

NRC means the Nuclear Regulatory Commission.

Qualified nuclear pharmacist means, for the purposes of 247 CMR 13.00, a pharmacist who is registered as a pharmacist by the Board pursuant to the provisions of M.G.L. c. 112, § 24, who is employed in a nuclear pharmacy, and who has submitted evidence satisfactory to the Board that he or she meets the requirements of 247 CMR 13.00 in regard to education, training and experience, and who has received from the Board an official letter stating that, on the basis of the evidence submitted, he or she has been found qualified to deal with radiopharmaceutical drugs and to handle radiopharmaceutical services.

Radioactive biological product means a biological product which is labeled with a radionuclide or intended to be labeled solely with a radionuclide.

Radiolabeling means the process of adding a radioisotope to a suitable nonradioactive substance.

Radiopharmaceutical means a radioactive drug or other radioactive pharmaceutical products.

Radiopharmaceutical drug means any substance defined as a drug in section 201(g)(1) of 21 USCA § 321 et seq. (Federal Food, Drug and Cosmetic Act) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons, and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

Radiopharmaceutical quality assurance means the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals, and the interpretation of the resulting data to determine

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the suitability of the radiopharmaceutical for use in humans or animals. The term includes internal test assessment, authentication of product history, and the maintenance of proper records.

Radiopharmaceutical service means the counting, dispensing, labeling, and delivery of radiopharmaceuticals; participating in radiopharmaceutical selection and radiopharmaceutical utilization reviews; properly and safely storing and distributing radiopharmaceuticals; maintaining radiopharmaceutical quality assurance; advising on therapeutic values, hazards, and use of radiopharmaceuticals; and offering or performing those acts, services, operations or transactions necessary in the conduct, operation, management and control of radio-pharmaceutical services within a nuclear pharmacy.

13.03: Requirements for the Issuance of Nuclear Pharmacy Permit

- (1) An applicant for an initial permit to establish a nuclear pharmacy shall be made by submitting to the Board a fully and properly completed application form provided by the Board.
- (2) An application for a nuclear pharmacy permit shall be accompanied by a check or money order in the required amount payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy".
- (3) No permit shall be issued to a proposed nuclear pharmacy unless there are maintained on the pharmacy premises the following publications:
 - (a) The most recent edition of the United States Pharmacopoeia, including the latest supplement thereto;
 - (b) the most recent edition of Remington's Pharmaceutical Sciences; and
 - (c) current texts on the practice of nuclear pharmacy and radiation safety.
- (4) No permit shall be issued to a proposed nuclear pharmacy by the Board unless said proposed nuclear pharmacy maintains on the premises the following equipment:
 - (a) A dose preparation station;
 - (b) a dose calibrator;
 - (c) an exhaust hood and filter system for handling radioactive gases or volatile radioactive materials;
 - (d) a refrigerator for exclusive storage of radioactive materials or reagent kits which require refrigeration;
 - (e) chromatographic apparatus as required for radiopharmaceutical quality assurance;
 - (f) a portable radiation survey meter capable of detecting 0.005 microcuries of radio-nuclides;
 - (g) area radiation detection room monitors;
 - (h) personnel dosimeters;
 - (i) a single-channel or multichannel scintillation analyzer; and
 - (j) supplies necessary for dispensing including, but not limited to, sterile multi-dose vials, syringes, disposable alcohol swabs, and adequate shielding for each dosage dispensed.
- (5) No permit shall be issued to a proposed nuclear pharmacy by the Board unless said proposed pharmacy conforms to the following conditions:
 - (a) The premises are clean and sanitary; and
 - (b) no entrances or exits shall connect directly with other places of business.
- (6) Prior to acting upon any application for the issuance of a permit for a nuclear pharmacy, the Board may require the applicant to appear before the Board to discuss the merits of the application.
- (7) The Board shall issue a nuclear pharmacy permit to such person as it deems qualified to conduct such a pharmacy; provided, however, that the Board may deny the issuance of a permit if, in its discretion, it determines that such pharmacy would be inconsistent with, or opposed to, the best interest of the public health, welfare, and safety.
- (8) The Board shall, within 150 days after the filing of an application for an initial nuclear pharmacy permit, render a final decision denying or allowing the issuance of such permit. Failure to render such decision; except when failure to act is caused by the delay of the applicant, shall constitute the approval of the application and the permit shall be issued.
- (9) The Board shall not issue a nuclear pharmacy permit to a corporation unless it appears to the satisfaction of the Board that such nuclear pharmacy is managed and operated by a registered pharmacist in good standing with the Board.

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(10) When the Board is satisfied that a proposed nuclear pharmacy has complied with the requirements of 247 CMR 13.00 and shall be operated in compliance with applicable federal, state and local statutes, ordinances, and/or regulations, it shall issue a permit to the applicant nuclear pharmacy.

13.04: **Renewal of a Nuclear Pharmacy Permit**

- (1) Each nuclear pharmacy permit issued by the Board shall expire on December 31st of each uneven numbered year following the date of its issuance.
- (2) Application for renewal of a nuclear pharmacy permit shall be made on a renewal application form provided by the Board. Such renewal form shall be fully and properly completed and submitted to the Board in a timely manner.
- (3) Each renewal application form submitted to the Board shall be accompanied by a check or money order in the required amount made payable to the "Commonwealth of Massachusetts Board of Registration in Pharmacy."

13.05: **General Requirements for Nuclear Pharmacies**

- (1) A nuclear pharmacy registered pursuant to 247 CMR 13.00 shall comply with all applicable laws, regulations, and guidelines of the United States Nuclear Regulatory Commission, the United States Food and Drug Administration, and other appropriate federal and state agencies.
- (2) No person other than a qualified nuclear pharmacist shall be employed by a nuclear pharmacy to direct and manage the pharmacy.
- (3) Only designated qualified nuclear pharmacists shall conduct the radiopharmaceutical activities of a nuclear pharmacy and at least one qualified nuclear pharmacist shall be in personal attendance at the pharmacy at all times.
- (4) A nuclear pharmacy shall not dispense those radiopharmaceuticals which do not comply with acceptable professional standards of radiopharmaceutical quality assurance.
- (5) A nuclear pharmacy shall maintain in readily retrievable form for at least three years detailed records of the acquisition and disposition of all radiopharmaceuticals. These records shall be available to the Board or its agents for inspection upon request.
- (6) A nuclear pharmacy shall not prepare, compound, or dispense radiopharmaceutical drugs except upon a valid prescription from an authorized practitioner. In order to be valid, a prescription for radiopharmaceutical drugs shall contain the following information:
 - (a) the name, address, registration number and, in the case of a written prescription, the signature of the practitioner;
 - (b) the date of the prescription;
 - (c) the name, dosage unit, and strength per dosage unit of the radiopharmaceutical drug;
 - (d) the name and address of the patient; if the name of the patient is unknown at the time the prescription is received, the nuclear pharmacy shall obtain the name and address of the patient within 72 hours after dispensing the radiopharmaceutical drug; the address of the facility where the patient is being treated will be sufficient if his or her residential address is unavailable; and
 - (e) any specific instructions required.
- (7) A nuclear pharmacy shall assign a serial number to each radiopharmaceutical drug it dispenses.
- (8) A nuclear pharmacist shall, upon receiving an oral prescription for a radiopharmaceutical drug from a practitioner or his or her expressly authorized representative, immediately reduce such prescription to writing on a prescription form, record on it the same information required under 247 CMR 13.05(6), and assign a serial number to such prescription.
- (9) In the event a prescribed radiopharmaceutical drug is not administered, it shall be returned to the nuclear pharmacy to be disposed of in accordance with the requirements established by the Nuclear Regulatory Commission and the nuclear pharmacy shall note on the prescription form, or shall record on a readily retrievable record form, that the radiopharmaceutical drug has been returned and shall state the amount of the radiopharmaceutical drug that has been returned. The nuclear pharmacy shall comply with all NRC regulations regarding the return and disposal of radioactive materials.

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- (10) A nuclear pharmacy may, with proper record-keeping, transfer to authorized persons radioactive materials or side-products which are not intended for medicinal use.
- (11)(a) Radiopharmaceuticals may be dispensed in bulk amounts necessary to activate the single unit doses. The bulk radioactivity shall be supplied no more than once in a 12-hour period. If an emergency radiopharmaceutical is used, the nuclear pharmacy shall, within 72 hours, obtain a written or oral prescription for the radiopharmaceutical which shall contain all the information included in 247 CMR 13.04(5). If the bulk radioactivity is not used, the nuclear pharmacy shall obtain and record a written or oral verification to that effect from the authorized practitioner to whom it was dispensed.
- (b) A nuclear pharmacy shall maintain records on all emergency supplies it dispenses as set out in 247 CMR 13.04(11) (a). The records shall include the names of the authorized practitioner and the institution within which he is or she is practicing, the amounts of non-radioactive material and radioactive material supplied, the dates supplied, the dates the radiopharmaceutical was administered, and the prescription serial number for each dose that was administered. The nuclear pharmacist's records shall also contain the authorized practitioner's written or oral verification when the bulk radioactivity is not used. These records shall be made available for inspection by the Board or its agents upon request.
- (12) In addition to any other labeling required by federal, state, or local laws or regulations, a registered nuclear pharmacy which dispenses radiopharmaceuticals shall place each such pharmaceutical in an outer container and affix to said container a label bearing the following information:
- (a) the standard radiation symbol;
 - (b) the words "Caution - Radioactive Material";
 - (c) the name of the radionuclide;
 - (d) the chemical form or common name;
 - (e) the amount of radioactive material, stated in millicuries or microcuries, or in SI units (becquerels) at the time of calibration;
 - (f) if a liquid, the volume in cubic centimeters or milliliters;
 - (g) auxiliary warning labels, if any, as needed; and
 - (h) the expiration date or time.
- (13) In the case of investigational radioactive drugs, the nuclear pharmacy's records shall include an investigator's protocol for the preparation of radioactive drugs, a copy of the Human Use Committee Approval, a copy of the approved patient consent form, and a letter from the manufacturer - "sponsor" indicating that the physician requesting the radioactive drug is a qualified investigator.
- (14) The premises of a nuclear pharmacy shall at all times be kept in a clean and sanitary manner.
- (15) A nuclear pharmacy shall, in legible letters not less than one inch high, conspicuously display the name of the director of pharmacy services on the premises.
- (16) A nuclear pharmacy shall have a qualified nuclear pharmacist on the premises during the entire time when said pharmacy is open for business.
- (17) A nuclear pharmacy shall keep posted and displayed in a conspicuous place its permit and the certificate of personal registration to practice pharmacy of each registered pharmacist who is employed on a full-time basis by the pharmacy.
- (18) A nuclear pharmacy shall in advance of any move to a new location submit to the Board an application for a new permit and payment of the appropriate fees.
- (19) Any nuclear pharmacy which is being established, remodeled, or relocated must first submit to the Board for review and approval copies of its structural plans.
- (20) A nuclear pharmacy which has moved to a new location shall not operate in said location until said nuclear pharmacy has been approved by the Board and until it has received from the Board a new permit to manage and operate a nuclear pharmacy and a new controlled substances registration.
- (21) Each nuclear pharmacy shall, within ten days of the commencement of employment of any pharmacist, or within ten days of the termination of employment of any pharmacist, report to the Board such employment or termination of employment. Such reports may be made upon forms available from the Board.

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- (22) A nuclear pharmacy shall maintain adequate security measures which are consistent with federal regulations and with the requirements of the Board.
- (23) A nuclear pharmacy shall not perform any pharmacy functions other than the dispensing of radiopharmaceutical drug products; it shall not perform the functions of, or operate as, a retail pharmacy or institutional pharmacy.
- (24) Only a nuclear pharmacy shall keep in stock or handle radiopharmaceuticals.
- (25) No nuclear pharmacy shall require or permit the same nuclear pharmacist to remain on duty for more than 12 hours per day.
- (26) A nuclear pharmacy shall be exempt from the following regulations of the Board:
- (a) 247 CMR 6.01;
 - (b) 247 CMR 6.02;
 - (c) 247 CMR 6.08;
 - (d) 247 CMR 9.01(12), (15) and (16); and
 - (e) 247 CMR 9.04(4) and (6).
 - (g) auxiliary warning labels, if any, as needed; and
 - (h) the expiration date or time.
- (13) In the case of investigational radioactive drugs, the nuclear pharmacy's records shall include an investigator's protocol for the preparation of radioactive drugs, a copy of the Human Use Committee Approval, a copy of the approved patient consent form, and a letter from the manufacturer - "sponsor" indicating that the physician requesting the radioactive drug is a qualified investigator.
- (14) The premises of a nuclear pharmacy shall at all times be kept in a clean and sanitary manner.
- (15) A nuclear pharmacy shall, in legible letters not less than one inch high, conspicuously display the name of the director of pharmacy services on the premises.
- (16) A nuclear pharmacy shall have a qualified nuclear pharmacist on the premises during the entire time when said pharmacy is open for business.
- (17) A nuclear pharmacy shall keep posted and displayed in a conspicuous place its permit and the certificate of personal registration to practice pharmacy of each registered pharmacist who is employed on a full-time basis by the pharmacy.
- (18) A nuclear pharmacy shall in advance of any move to a new location submit to the Board an application for a new permit and payment of the appropriate fees.
- (19) Any nuclear pharmacy which is being established, remodeled, or relocated must first submit to the Board for review and approval copies of its structural plans.
- (20) A nuclear pharmacy which has moved to a new location shall not operate in said location until said nuclear pharmacy has been approved by the Board and until it has received from the Board a new permit to manage and operate a nuclear pharmacy and a new controlled substances registration.
- (21) Each nuclear pharmacy shall, within ten days of the commencement of employment of any pharmacist, or within ten days of the termination of employment of any pharmacist, report to the Board such employment or termination of employment. Such reports may be made upon forms available from the Board.
- (22) A nuclear pharmacy shall maintain adequate security measures which are consistent with federal regulations and with the requirements of the Board.
- (23) A nuclear pharmacy shall be separate from, and independent of, any other business or store.
- (24) A nuclear pharmacy shall not perform any pharmacy functions other than the dispensing of radiopharmaceutical drug products; it shall not perform the functions of, or operate as, a retail pharmacy or institutional pharmacy.
- (25) Only a nuclear pharmacy shall keep in stock or handle radiopharmaceuticals.
- (26) No nuclear pharmacy shall require or permit the same nuclear pharmacist to remain on duty for more than 12 hours per day.
- (27) A nuclear pharmacy shall be exempt from the following regulations of the Board:
- (a) 247 CMR 6.01;
 - (b) 247 CMR 6.02;

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- (c) 247 CMR 6.08;
- (d) 247 CMR 9.01(12), (15) and (16); and
- (e) 247 CMR 9.04(4) and (6).

13.06: Education and Experience Requirements of a Qualified Nuclear Pharmacist

A qualified nuclear pharmacist shall:

- (1) Be currently registered under M.G.L. c. 112, § 24;
- (2) have received 200 contact hours of formal academic training in the area of radio-pharmaceutical preparation and handling, with no more than 60 of said hours being acquired through laboratory training;
- (3) have received, in addition to formal academic training, a minimum of three months of full-time, or 500 hours of actual on the job practical experience in the field of radioactive drugs and radiopharmaceutical services under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured nuclear pharmacy training program of a Board-approved college/school of pharmacy; and
- (4) submit a detailed affidavit of experience and training to the Board.

REGULATORY AUTHORITY

247 CMR 13.00: M.G.L. 112, §§ 24, 39B and 42A.

14.00: Petition For Waiver

- 14.01: Petition to the Board to Grant a Waiver to the Provisions of 247 CMR for Licensure of a Pharmacy/Pharmacy Department

14.01: Petition to the Board to Grant a Waiver to the Provisions of 247 CMR for Licensure of a Pharmacy/Pharmacy Department

- (1) The Board may grant a waiver to the provisions of 247 CMR, pertaining to the licensure of a pharmacy or pharmacy department, if the Board finds:
- (a) that there is a compelling public interest which would be served by the granting of such a waiver;
 - (b) that adherence to a particular provision of 247 CMR would be impractical and unduly burdensome; and
 - (c) that sufficient safeguards are in place to protect the public health, welfare and safety.
- (2) Unless otherwise prohibited by law, when the Board finds that a provision of 247 CMR, may be waived, it may issue a special or limited-use pharmacy or pharmacy department permit. Such permit shall be issued when the scope, degree or type of pharmacy practice is of a special, limited or unusual nature as compared to a regular pharmacy service. In order to request a waiver of a Board regulation, the registered pharmacist who shall be responsible for the management and operation of a pharmacy or pharmacy department shall submit to the Board a Petition for Waiver of Board Regulations, upon a form supplied by the Board. A completed petition shall:
- (a) List the regulatory requirement(s) for which a waiver is requested and a brief explanation as to why each regulation should not apply to that pharmacy or pharmacy department;
 - (b) explain why there is a compelling public interest which would be served by granting the waiver;
 - (c) explain why adherence to the regulation(s) would be impractical and unduly burdensome to the petitioner;
 - (d) include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety; and
 - (e) be accompanied by any additional information as determined by the Board.
- (3) Before acting upon any petition, the Board may require the applicant to personally appear before the Board to answer questions that would enable the Board to determine that the issuance of a permit would be in the best interest of the public health, welfare and safety and adherence to 247 CMR would be unreasonable.
- (4) Upon the granting of a waiver and issuance of a special or limited-use permit, the Board shall issue a written finding that recites the specific Board regulation(s) which are being waived, the reasons the Board is waiving the regulation(s) at issue, and lists any contingent restrictions under which the pharmacy or pharmacy department may operate.

REGULATORY AUTHORITY

247 CMR 14.00: M.G.L. c. 112, §§ 36A through 42A.

15.00: Continuous Quality Improvement Program

- 15.01: Definitions
- 15.02: Continuous Quality Improvement Program
- 15.03: Quality Related Event Discovery, Notification and Documentation
- 15.04: Records

15.01: Definitions

Continuous Quality Improvement Program or **CQI Program** means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

Quality-Related Event or **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 the drug to the wrong patient; or
5. providing inadequate or incorrect packaging, labeling, or directions; or

(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/misuse.

Pharmacy, as referenced in 247 CMR 15.00, means a pharmacy, or a group of pharmacies under common ownership and control of one entity, licensed by the Board pursuant to M.G.L. c. 112.

Pharmacy Personnel means pharmacist, pharmacy intern, pharmacy technician and pharmacy support personnel.

15.02: Continuous Quality Improvement Program

(1) **Continuous Quality Improvement Program Requirements.** Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality-Related Events (QREs). At a minimum, a CQI program shall include provisions to:

- (a) designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;
- (b) identify and document QREs;
- (c) minimize impact of QREs on patients;
- (d) analyze data collected in response to QREs to assess causes and any contributing factors;
- (e) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
- (f) provide ongoing education at least annually in the area of CQI to pharmacy personnel.

(2) **Implementation Date.** The CQI Program requirements of 247 CMR 15.00 shall be implemented by each pharmacy by December 31, 2005.

15.03: Quality Related Event Discovery, Notification and Documentation

(1) **QRE Discovery and Notification.** All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:

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- (a) notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team;
 - (b) directions for correcting the error; and
 - (c) instructions for minimizing the negative impact on the patient.
- (2) **QRE Documentation.**
- (a) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.
 - (b) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:
 - 1. the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy;
 - 2. the names and titles of the persons recording the QRE information and performing the QRE analysis;
 - 3. a description of the QRE reviewed; and
 - 4. documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team.
- (3) **QRE Analysis and Response.**
- (a) **QRE Analysis.** The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:
 - 1. a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels;
 - 2. any recommended remedial changes to pharmacy policies, procedures, systems, or processes; and
 - 3. the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time.
 - (b) **Response.** Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program.

15.04: **Records**

- (1) Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel.
- (2) Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report.
- (3) QRE records shall be maintained in an orderly manner and filed by date.
- (5) QRE records may be stored at a site other than the pharmacy where the QRE occurred.

REGULATORY AUTHORITY

247 CMR 15.00: M.G.L. c. 112, §§ 37 through 39 and 42A.