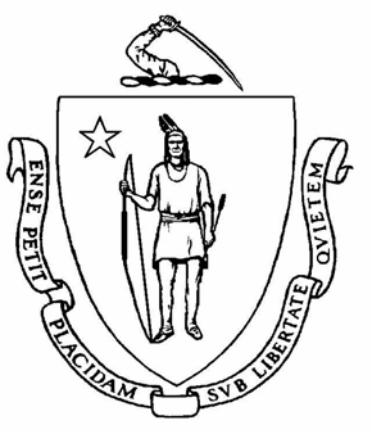

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(Revised 06/29/07)

DEFINITIONS

247 CMR 2.00:
Section

2.00: Definitions

Additional definitions pertaining to nuclear pharmacies are contained in 247 CMR 13.00. Additional definitions pertaining to disciplinary proceedings are contained in 247 CMR 10.00.
The following definitions apply to 247 CMR 2.00 through 13.00:

ACPE means the American Council on Pharmaceutical 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.

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 it's 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.

Direct Supervision means:
(a) the type of supervision a Board-approved registered pharmacist preceptor in a pharma-cy, 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.

Department means the Massachusetts Department of Public Health.

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 to a pharmacy by facsimile machine, computer modem or other similar electronic device.

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

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

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

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.

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.

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 a provide a physical environment for patients to obtain health care services under the supervision and direction of a registered pharmacist and is authorized to dispense controlled substances.

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 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.

NABP means the National Association of Boards of Pharmacy.

NABPLEX means the National Association of Boards of Pharmacy Licensing Examination.

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

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.

Non-fading Legibility means a facsimile transmission which will not fade and deteriorate before the record-keeping time limit is reached.

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 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.

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 2.00 through 13.00.

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 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.

Technician means an individual employed at a pharmacy and working under the direct supervision of a registered pharmacist or pharmacy intern.

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) Intra company 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.

PHARMACY INTERNS AND TECHNICIANS

247 CMR 8.00:
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 competed 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 1100 hours has been acquired in a pharmacy or pharmacy-related setting approved by the Board; and
2. no more than 400 hours has been acquired in any one, or any combination of the following:
    a. a Board-approved internship in clinical pharmacy;
    b. a Board-approved internship in a demonstration project;
    c. a Board-approved internship in manufacturing; and/or
    d. a Board-approved internship in 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) 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:

(a) The applicant's name;
(b) the applicant's address;
(c) the applicant's date of birth;
(d) have attached thereto a recent passport-size photo revealing the applicant's likeness; and
e) 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.

(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

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:

1. 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
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 presecriber 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; 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.

(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 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, 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 **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 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

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 place of employment, residence 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 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.

CODE OF PROFESSIONAL CONDUCT; PROFESSIONAL STANDARDS FOR REGISTERED PHARMACISTS, PHARMACIES AND PHARMACY DEPART-MENTS

247 CMR 9.00:
Section

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, institutional, 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 who 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.

(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, dispens-ing, 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:

(a) refills remain on the prescription; and
(b) 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:

(a) The transferring pharmacist must record the following information:
    1. Write the word "VOID" on the face of the invalidated prescription;
    2. 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
    3. 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.
(b) The transferring pharmacist shall cancel all refills remaining on the transferred prescription.
(c) The pharmacist receiving the transferred prescription information shall complete the following:
    1. Write the word "transfer" on the face of the transferred prescription; and
    2. write all information required by state and federal law to be on the prescription and include:
        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 pharmacist'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 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:

(a) The transferring pharmacist 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 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 shall cancel all refills remaining on the transferred prescription.

(c) The pharmacist receiving the transferred prescription information shall complete the following:

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 and include:
    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;
    e. 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.

(d) The pharmacist 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 informa-tion 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 .

(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 dispens-ing 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
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.

(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. The procedure for making the offer to counsel shall be a part of the technician training manual as set forth in 247 CMR 8.02(5) and the policies and procedures of the pharmacy.

(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.

DISCIPLINARY PROCEEDINGS

247 CMR 10.00:
Section

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

10.01: 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, the Investigative Unit, or the Division of Registration which the Board determines, after investigation, merits further consideration or action.

Informal 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: Informal Conference

To facilitate disposition of any complaint, the Board may request the complaining party and the registrant or licensee who is the subject of the complaint to attend an informal 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 forwarded to it by the Investigative Unit, the Board may schedule an informal conference with the registrant or licensee 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) Letter of Warning - An official written document retained in the registrant's Board file delineating the deficiencies found in the registrant's or licensee's professional practice. A letter of warning does not constitute formal disciplinary action.

(3) Formal reprimand of the registrant or licensee - A reprimand constitutes formal disciplinary action.

(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.

REGULATORY AUTHORITY

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