

## 243 CMR: BOARD OF REGISTRATION IN MEDICINE

### 243 CMR 2.00: LICENSING AND THE PRACTICE OF MEDICINE

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#### 2.01: Scope and Construction

(1) Purpose. 243 CMR 2.00 is the Board of Registration in Medicine's directions concerning licensing and the practice of medicine. The purpose of 243 CMR 2.01 through 2.06 is to ensure that the Board issues certificates of registration only to qualified competent physicians of good moral character and to strengthen the Board's licensing processes. The purpose of 243 CMR 2.07 through 2.04 is to prescribe substantive standards which will promote the public health, safety, and welfare and inform physicians of the Board's expectations and requirements. The Board requires that every physician in the Commonwealth has notice of 243 CMR 1.00 through 3.00 and expects that he or she will practice medicine in accordance with 243 CMR 2.00.

(2) Authority. The Board adopts 243 CMR 2.00 under the authority of M.G.L. c. 13, §§ 9 through 11; M.G.L. c. 112, §§ 2 through 12DD; and M.G.L. c. 112, §§ 61 through 65E and 88.

(3) Structure. 243 CMR 2.00 is organized as follows: 243 CMR 2.01 contains general provisions relating to all of 243 CMR 2.00; Part 1 consists of 243 CMR 2.02 through 2.06, the regulations relating to the licensing of physicians, and Part 2 consists of 243 CMR 2.07 through 2.15, the regulations relating to the practice of medicine.

(4) Definitions. For the purposes of 243 CMR 1.00 through 3.00, the terms listed in 243 CMR 2.01(4) have the following meanings, unless otherwise provided:

ABMS means the American Board of Medical Specialties.

Accredited Canadian Postgraduate Medical Training means training which has been accredited by the Royal College of Physicians and Surgeons of Canada (RCPSC), the College of Family Physicians of Canada (CFPC), or the Federation of Medical Licensing Authorities of Canada (FMRAC).

ACGME means the Accreditation Council for Graduate Medical Education.

Adjudicatory Hearing means a hearing conducted in accordance with M.G.L. c. 30A and with 243 CMR 1.00: *Disciplinary Proceedings for Physicians*.

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AMA means the American Medical Association.

AOA means the American Osteopathic Association.

Board means the Board of Registration in Medicine established by M.G.L. c. 13, § 10.

Canadian Medical Graduate means a person who attained an M.D. or D.O. degree from an accredited Canadian medical school.

Change of License Status refers to a voluntary process whereby a full, active licensee may apply to the Board to change his or her active license status to an Inactive, Volunteer, Administrative, Retired or Restricted license status. Change of license status also refers to the voluntary process whereby a Volunteer, Administrative, Inactive, Retired or Lapsed licensee may apply to the Board for a change of license status.

Child Abuse and Neglect Training means the education and training to recognize and report suspected child abuse or neglect required by M.G.L. c. 119, § 51A(k).

Clinical Quality Measures (CQM) means, in the context of Meaningful Use, the processes, experiences or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable and timely care.

COMLEX means Comprehensive Osteopathic Medical Licensing Examination - USA.

Continuing Medical Education (CME) means educational activities that serve to maintain, develop or increase the knowledge, skills and professional performance and relationships that a physician uses to provide services for patients, the public or profession.

CORI means Criminal Offender Record Information, as defined in M.G.L. c. 6, § 167.

Data means any material upon which written, drawn, spoken, visual, or electromagnetic information or images are recorded or preserved, regardless of physical form or characteristics, as defined in M.G.L. c. 93H, § 1.

Data Subject means the individual to whom personal data refers, as defined in M.G.L. c. 66A, § 1. Data Subject shall not include corporations, corporate trusts, partnerships, limited partnerships, trusts, sole proprietorships, or other business, not-for-profit or charitable entities.

Domestic Violence and Sexual Violence Training means the education and training required by M.G.L. c. 112, § 264.

ECFMG means Educational Commission for Foreign Medical Graduates.

Electronic means relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities. An electronic record is a record created, generated, sent, communicated, received, or stored by electronic means.

Electronic Health Record (EHR) means an electronic record of patient health information generated by one or more encounters in any health care delivery setting.

Electronic Health Record Systems include computerized physician order entry (CPOE), e-prescribing and other health information systems.

End-of-life Care refers to the medical and ethical issues surrounding the end of a patient's life. End-of-life issues include the type and extent of medical care, services, treatments, medications and other options that may be available to the patient. End-of-life care includes palliative care as defined by 105 CMR 130.1900: *Definitions Applicable to 105 CMR 130.1901*.

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Fifth Pathway means a program of medical education which meets all of the following requirements:

- (a) Completion of two years of premedical education in a U.S. college or university acceptable to the Board;
- (b) Completion of all the formal requirements for the degree corresponding to doctor of medicine or doctor of osteopathy at a medical school outside the United States which is recognized by the World Health Organization;
- (c) Completion of one academic year of supervised clinical training sponsored by an approved medical school in the United States, the Commonwealth of Puerto Rico or Canada; and
- (d) Completion of one year of graduate medical education in a program approved by the Liaison Committee on Graduate Medical Education of the American Medical Association.

FLEX means the Federation Licensing Examination.

FSMB means the Federation of State Medical Boards.

Health Care Facility means, for purposes of 243 CMR 2.00, any location where medicine is practiced, a hospital or other institution of the commonwealth, or of a county or of a municipality within it; a hospital or clinic duly licensed or approved by the Department of Public Health; and an out patient clinic operated by the Department of Mental Health.

Health Information Exchange means an electronic platform enabling the transmission of healthcare-related data among providers, payers, personal health records controlled by a patient and government agencies according to national standards, the reliable and secure transfer of data among diverse systems and access to and retrieval of data.

Health Information Technology (Health IT or HIT) means the application of computers and technology in health care settings. HIT may include computerized physician order entry systems, e-prescribing, electronic health records and other health information technology systems.

International Medical School means a medical or osteopathic school in a country other than the United States, the Commonwealth of Puerto Rico or Canada.

International Medical Graduate means a graduate of an international medical school.

Lapsed License means the automatic expiration of a certificate of registration of any full licensee upon the licensee's failure to file a completed renewal application together with the required fee within the time period required.

LCME means Liaison Committee on Medical Education.

License means a certificate of registration which the Board issues to a person pursuant to the requirements of M.G.L. c. 112, §§ 2, 5A, 9 and 9B, and which authorizes the person to engage in the practice of medicine. There are four categories of licenses: full, limited, temporary and restricted. A full license allows a licensee to practice medicine as an independent practitioner free from specific limitations on his or her practice. Any other category of license restricts a licensee's practice.

Licensing Committee means a Committee established by the Board to assist the Board in reviewing license applications filed pursuant to M.G.L. c. 112, §§ 2 through 9B. The Licensing Committee may review the qualifications of applicants and licensees, may conduct an interview, may request additional documentation, may refer an applicant or licensee for an evaluation of health concerns to a Board-approved entity, and may recommend actions to the Board. The Board, with due consideration for patient safety and the public health, safety and welfare, shall determine whether to issue, grant or renew a license, what the license term shall be and whether there shall be any license restrictions.

LMCC means Licentiate of the Medical Council of Canada.

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The Massachusetts Health Information Highway (Mass HIway) means the network, owned and operated by the Massachusetts Executive Office of Health and Human Services (EOHHS) that enables the secure exchange of health information from one hospital or provider to another, regardless of provider affiliation, location or differences in technology. The MassHIway provides a mechanism for the Commonwealth's entire health care community - residents, providers, public health officials and others - to have appropriate access to health information.

MassHealth means the medical assistance program administered by the secretary of health and human services in accordance with M.G.L. c. 118E and Title XIX of the Social Security Act and any federal demonstration project or waiver relating to the medical assistance program.

MCCQE means the Medical Council of Canada Qualifying Examination.

Meaningful Use means the use of certified EHR technology in a meaningful manner, the electronic exchange of health information to improve the quality of health care and the use of certified EHR technology to submit clinical quality and other measures.

Medical School means a legally chartered medical school in any jurisdiction.

Medical Student means a person enrolled in a United States or an international medical school.

NBME means the National Board of Medical Examiners.

NPI means the National Provider Identifier, a unique national identification number issued by the federal government to all providers who bill health insurance plans.

Pain Management Training means the education and training required by M.G.L. c. 94C, § 18(e). Such training shall include, but not be limited to, education in opioids and other pain-relieving medications, training in effective pain management, training in how to identify patients at high risk for substance abuse, and training on how to counsel patients on the side effects and addictive natures of prescription medicines and their proper storage and disposal.

Personal Data has the same meaning in 243 CMR 2.00 as it does in M.G.L. c. 66A, § 1.

Personal Information has the same meaning in 243 CMR 2.00 as it does in M.G.L. c. 93H, § 1.

Physician Assistant (PA) means a person who is duly registered by the Board of Registration of Physician Assistants established by M.G.L. c. 112, § 9F. Supervising physicians and PAs are subject to the requirements of 243 CMR 2.08.

The Physician Profile Program means the program established under M.G.L. c. 112, § 5 listing certain information about each physician holding a full license in Massachusetts and disseminating this to the public, primarily through the Board's website on the Internet.

Physician Reentry means a return to clinical practice in the discipline in which one has been trained or certified following an extended period of clinical inactivity not resulting from discipline or impairment.

The Practice of Medicine means the following conduct, the purpose or reasonably foreseeable effect of which is to encourage the reliance of another person upon an individual's knowledge or skill in the maintenance of human health by the prevention, alleviation, or cure of disease, and involving or reasonably thought to involve an assumption of responsibility for the other person's physical or mental well being: diagnosis, treatment, use of instruments or other devices, or the prescribing, administering, dispensing or distributing of drugs for the relief of diseases or adverse physical or mental conditions.

- (a) A person who holds himself or herself out to the public as a physician or surgeon, or with the initials "M.D." or "D.O." in connection with his or her name, and who also assumes responsibility for another person's physical or mental well being, is engaged in the practice of medicine.

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- (b) The Practice of Medicine includes the following:
  - 1. Telemedicine, as defined in 243 CMR 2.01: Telemedicine; and
  - 2. Providing an independent medical examination or a disability evaluation.
- (c) The practice of medicine does not mean the following:
  - 1. Conduct lawfully engaged in by persons licensed by other boards of registration with authority to regulate such conduct; or
  - 2. Assistance rendered in emergency situations by persons other than licensees.

Reinstatement means the action of the Board restoring a revoked license. The Board may impose reasonable restrictions on a reinstated license.

Renewal Date means the last day on which the license is in effect.

Reviving a License means the restoration of a license that has lapsed or is inactive.

Risk Management Program means a patient care assessment program established by the Board pursuant to M.G.L. c. 111, § 203(d) and recognized as a Risk Management Program within the meaning of M.G.L. c. 112, § 5.

Risk Management Study or Risk Management CME means instruction in medical malpractice prevention, such as risk identification, patient safety, and medical error prevention. Risk management studies may include education in any of the following areas: medical ethics, quality assurance, medical-legal issues, patient relations, electronic health record education, end-of-life care, utilization review that directly relates to quality assurance, and aspects of practice management. Risk management CME may include study of the Board's regulations at 243 CMR 1.00 through 5.00.

Specialty Board means a specialty board recognized by the American Board of Medical Specialties, the American Medical Association or the American Osteopathic Association.

Telemedicine means the provision of services to a patient by a physician from a distance by electronic communication in order to improve patient care, treatment or services.

United States Medical Graduate means a person who attained an M.D. or D.O. degree from a United States medical school.

United States Medical School means an LCME accredited school of medicine, or an AOA accredited school of osteopathy, located in the United States.

USMLE means the United States Medical Licensing Examination.

(5) Computation of Time. Any period of time specified in 243 CMR 2.00 includes every calendar day, whether or not the office of the Board is open on that day, except that, when the last day of the period falls on a day when the Board's office is closed, the period ends instead on the next day on which the office is open.

(6) Public Records and Personal Data. Documentary information obtained by the Board during the licensing process concerning an applicant or licensee may be a Public Record, as defined by M.G.L. c. 4, § 7, clause twenty-sixth, or may be Personal Data, as defined by M.G.L. c. 66A, § 1. The Board may not disclose personal data, unless disclosure is authorized by statute or is otherwise in accordance with M.G.L. c. 66A, § 2

(7) Confidentiality of Personal Information. The security and confidentiality of personal information held by the Board, whether relating to patients, consumers, applicants, licensees or any other persons, shall be protected by the Board in accordance with applicable state and federal laws including, but not limited to, the Confidentiality of Alcohol and Drug Abuse Patient Records, (42 C.F.R. Part 2); the Health Insurance Portability and Accountability Act of 1996, (P.L. 104-191); the Patient Safety and Quality Improvement Act of 2005, (P.L. 109-41); the Massachusetts Security Breach Law, (M.G.L. c. 93H); the Massachusetts Privacy Act, (M.G.L. c. 214, § 1B); the Massachusetts Freedom of Information Act, (M.G.L. c. 66A) and the Massachusetts Public Records Law, (M.G.L. c. 4, § 7, clause twenty-sixth).

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(8) Effective Date. License applications received by the Board on or after August 9, 2019 are governed by 243 CMR 2.00.

2.02: Initial Licensure for Graduates of Medical Schools in the US, Canada, and Puerto Rico

(1) Prerequisites to Initial Licensure. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a full active license to practice medicine. In order to qualify for a full medical license, an applicant shall meet all of the following minimum requirements for licensure:

- (a) Be 18 years of age or older;
- (b) Possess Good Moral Character;
- (c) Have Premedical Education as described in 243 CMR 2.02(2)(a);
- (d) Have a Medical School Education as described in either 243 CMR 2.02 or 2.03;
- (e) Have Postgraduate Medical Training as described in either 243 CMR 2.02 or 2.03;
- (f) Pass a Professional Examination as described in 243 CMR 2.02(3) or (4);
- (g) Complete Pain Management Training, as described in M.G.L. c. 94C, § 18;
- (h) Participate in a Risk Management Program as described in M.G.L. c. 112, § 5;
- (i) Agree to refrain from balance billing Medicare recipients, if the applicant has agreed to treat Medicare recipients, as provided in M.G.L. c. 112, § 2;
- (j) Sign and swear to the contents of his or her Licensing Application;
- (k) Pay a registration fee, as described in 243 CMR 2.05(1) and 801 CMR 4.02 (243);
- (l) Demonstrate Proficiency in Electronic Health Records, as required by M.G.L. c. 112, § 2;
- (m) Obtain professional liability malpractice insurance of at least \$100,000/\$300,000 coverage amounts, as provided in 243 CMR 2.07(16), if providing patient care in the Commonwealth;
- (n) Certify that he or she is in compliance with the laws of the Commonwealth relating to taxes, the reporting of employees and independent contractors, and the withholding and remitting of child support, pursuant to M.G.L. c. 62C, § 49A;
- (o) Complete Domestic Violence and Sexual Violence Training;
- (p) Apply for or participate in MassHealth, either as a provider of services or as a nonbilling provider for the limited purpose of ordering and referring services covered under MassHealth, and provided that regulations governing such limited participation are promulgated under M.G.L. c. 118E; and
- (q) Complete Child Abuse and Neglect Training.

(2) Procedure for Obtaining an Initial Full License for Graduates of Medical Schools in the United States, Canada and the Commonwealth of Puerto Rico. In order to qualify for a full medical license, an applicant shall meet the prerequisites to licensure in 243 CMR 2.02(1) and the following requirements, in addition to other requirements for licensure as set forth in 243 CMR 2.00 and M.G.L. c. 112.

- (a) Premedical Education. An applicant shall have completed a minimum of two or more academic years at a legally chartered college or university. Such premedical training shall include courses in biology, inorganic chemistry, organic chemistry and physics, or their equivalent as determined by the Board.
- (b) Medical Education. An applicant for an initial full license shall have completed and attended for four academic years of instruction, of not less than 32 weeks in each academic year, or courses which in the opinion of the Board are equivalent thereto, in one or more legally chartered medical schools, and have received the degree of doctor of medicine from a medical school accredited by the LCME, or a doctor of osteopathy degree from an osteopathic school accredited by the AOA.
- (c) Postgraduate Medical Training. Each applicant for a full license, whose application is received by the Board on or after February 1, 2012, must have completed two years of postgraduate medical training in an ACGME or AOA approved, or accredited Canadian program. In the case of sub-specialty clinical fellowship programs, however, the Board may accept postgraduate training in a hospital that has an ACGME or AOA approved, or accredited Canadian, postgraduate medical training program in the primary specialty. In its discretion, the Board may consider an applicant who has completed one year of ACGME or AOA approved, or accredited Canadian, postgraduate training and who:

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1. Holds a current, active, unrestricted full medical license in another state;
  2. Demonstrates continuous clinical activity; and
  3. Is board certified by either ABMS or AOA.
- (d) Examination. An applicant for full licensure shall fulfill the examination requirements for licensure as set forth in 243 CMR 2.02(3) or (4), whichever applies; and
- (e) Pain Management Training. Applicants who prescribe controlled substances shall, as a prerequisite to obtaining or renewing a medical license, complete appropriate Pain Management Training and opioid education, according to M.G.L. c. 94C, § 18 and 243 CMR 2.00. Pain Management Training shall consist of at least three credits of Board-approved continuing medical education and may be used toward the required ten credits of risk management training.
- (f) EHR Proficiency Requirement.
1. Demonstrating EHR Proficiency. An applicant for an initial full license must demonstrate proficiency in the use of electronic health records (EHR), as required by M.G.L. c. 112, § 2. An applicant shall demonstrate proficiency in the use of EHR once, and in one of the following ways:
    - a. Participation in a Meaningful Use program as an eligible professional;
    - b. Employment with, credentialed to provide patient care at, or in a contractual agreement with an eligible hospital or critical access hospital with a CMS Meaningful Use program;
    - c. Participation as either a Participant or an Authorized User in the Massachusetts Health Information Highway;
    - d. Completion of three hours of a Category 1 EHR-related CME course that discusses, at a minimum, the core and menu objectives and the CQMs for Meaningful Use. These three EHR credits may be used toward the required ten risk management CME credits.
  2. Exemptions. Exemptions must be claimed each licensing cycle if applicable. The following are exempt from the requirement to demonstrate EHR Proficiency:
    - a. An applicant who will not be engaged in the practice of medicine as defined in 243 CMR 2.01(4);
    - b. An applicant for an Administrative License;
    - c. An applicant for a Volunteer License;
    - d. An applicant on active duty as a member of the National Guard or of a uniformed service called into service during a national emergency or crisis; or
    - e. An applicant for an Emergency Restricted License.
- (g) Participating in a Risk Management Program. The applicant shall agree to participate in a risk management program as a condition of licensure, as required by M.G.L. c. 112, § 5 and 243 CMR 3.00: *The Establishment of and Participation in Qualified Patient Care Assessment Programs, Pursuant to M.G.L. c. 112, § 5, and M.G.L. c. 111, § 203*. The applicant must agree to participate in a risk management program that meets or exceeds the rules, procedures and standards set forth in 243 CMR 3.00.
- (h) Prohibition on Balance Billing of Medicare Beneficiaries. The applicant shall agree, if he or she agrees to treat Medicare beneficiaries, that he or she shall accept as payment in full the Medicare fee schedule amount for the services performed, and shall not balance bill a Medicare beneficiary as provided in M.G.L. c. 112, § 2, and 243 CMR 2.07(15).
- (i) Mandatory Medical Malpractice Insurance. Whenever an applicant renders direct or indirect patient care in Massachusetts, he or she shall maintain professional liability insurance in an amount of at least \$100,000 per claim, \$300,000 minimum annual aggregate, pursuant to 243 CMR 2.07(16).
1. Pursuant to 243 CMR 2.07(16), coverage may be on an individual or shared limit basis. Coverage shall be continued until the expiration of any relevant statutes of limitations relevant to the events or occurrences covered.
  2. The following licensees are not subject to the medical malpractice insurance requirement:
    - a. Licensees with no direct or indirect responsibility for patient care in the Commonwealth; or
    - b. Licensees whose patient care in the Commonwealth is limited to professional services rendered at or on behalf of federal, state, county or municipal health care facilities; or
    - c. Limited licensees pursuant to M.G.L. c. 112, § 9.

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(j) Domestic Violence and Sexual Violence Training. Pursuant to M.G.L. c. 112, § 264, applicants and licensees shall participate in Domestic Violence and Sexual Violence Training once as a condition for licensure, renewal, revival or reinstatement of licensure. The Board, in consultation with the Department of Public Health, will identify programs or courses of study that meet the standards required by this provision and provide its licensees with a list of such programs or courses. This is a one-time training requirement.

(k) MassHealth Requirement. Pursuant to M.G.L. c. 112, §§ 2 and 9, applicants and licensees shall apply to participate in MassHealth, either as a provider of services or as a non billing provider for the limited purpose of ordering and referring services in the MassHealth program, as a condition for licensure, renewal, revival or reinstatement of licensure. A physician who is not engaged in the practice of medicine is exempt from the MassHealth requirement. This is a one-time licensing requirement.

(l) Child Abuse and Neglect Training. Pursuant to M.G.L. c. 119, § 51A(k), applicants and licensees shall complete training in recognizing and reporting suspected child abuse and neglect. Physicians may comply with the training requirement by: receiving training in child abuse and neglect assessment in medical school education or postgraduate training; completing a hospital-sponsored training program in recognizing the signs of child abuse and neglect; completing CME in identifying and reporting child abuse and neglect; completing a Board-approved online training program or completing a specialized certification. This is a one-time training requirement.

(m) Compliance with Tax Laws. Pursuant to M.G.L. c. 62C, § 49A, the applicant for a license to practice medicine shall certify, upon penalties of perjury, that he or she has complied with all the laws of the Commonwealth relating to taxes, the reporting of employees and contractors, and the withholding and remitting of child support. The commissioner of the department of revenue shall notify the board of any returns due or any taxes payable for an applicant.

1. Upon reasonable cause, the commissioner of the department of revenue may issue a waiver of the certification requirement in M.G.L. c. 62C, § 49A.

2. The existence of a non-frivolous appeal of an unfiled tax return or a tax due or an overdue child support assessment, or the existence of a payment agreement with the department of revenue with which the applicant is fully compliant, shall not prevent the issuance of the full license.

3. The commissioner of the department of revenue shall confirm for the Board when the applicant is in good standing with respect to returns due or taxes payable.

(n) Certificate of Registration. If the Board determines that an applicant is qualified, competent and of good moral character, such applicant will be registered as a licensed physician and entitled to a certificate in testimony thereof signed by the chair and secretary.

(3) Examination Requirements.

(a) Conduct Prior to and During an Examination. Applicants who engage in the conduct described in 243 CMR 2.02(3)(a)1. through 3. shall have their test materials confiscated, shall be denied permission to complete the examination and shall be required to leave the examination room:

1. Removing test materials from the examination room; reproducing in any manner or aiding in the reproduction of test materials; selling, distributing, buying or having unauthorized possession of test materials; or

2. Communicating with any other examinee during the exam; copying answers or permitting answers to be copied; having in one's possession, during the examination, any material other than the examination materials; failure to obey instructions to stop working or starting an examination prior to being authorized to do so; or

3. Falsifying or misrepresenting educational credentials or other information required for admission to the exam; having another person take the exam on one's behalf.

(b) Examinations Completed January 1, 2000 or Later. An applicant for an initial full license, except those who satisfy the requirements of 243 CMR 2.02(3)(c), must submit evidence, including certification by the examining body, of having achieved a passing score on each of Steps 1, 2, and 3 of the USMLE, or received a passing score on each of the three levels of NBME's COMLEX exam, within a seven-year time period, beginning with the examination date when the examinee first passes a step of either exam. An applicant for an initial full license must submit evidence of having successfully completed all parts of the MCCQE.



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(c) The Seven-year Rule An applicant who fails to pass Step 3 of the USMLE, or level 3 of the COMLEX, within three attempts, shall be required to take one additional year of ACGME or AOA approved postgraduate training between the third and fourth attempt. If the applicant did not complete an additional year of ACGME or AOA approved postgraduate training between the third and fourth attempt at Step 3 or level 3, the applicant is not eligible for Massachusetts licensure.

If an applicant for licensure fails to pass Step 1 of the USMLE or Level 1 of the COMLEX after four attempts, the applicant is not eligible for Massachusetts licensure. No waiver is available to any candidate that did not pass Step 1 of the USMLE or Level 1 of the COMLEX on the fourth attempt.

If an applicant for licensure fails to pass Step 2 of the USMLE or Level 2 of the COMLEX after four attempts, the applicant is not eligible for Massachusetts licensure. No waiver is available to any applicant that did not pass Step 2 of the USMLE or Level 2 of the COMLEX on the fourth attempt.

If an applicant for licensure fails to pass Step 3 of the USMLE or Level 3 of the COMLEX after four attempts, the applicant is not eligible for Massachusetts licensure. No waiver is available to any candidate that did not pass Step 3 of the USMLE or Level 3 of the COMLEX on the fourth attempt.

1. Joint Degree Waiver of Seven-year Rule. The Board may grant a waiver of the seven-year examination completion requirement in the case of an applicant who is actively pursuing another advanced doctoral study, provided:

- a. The applicant requesting a waiver of the seven-year rule must be enrolled in a LCME accredited program and be a student in good standing.
- b. The Board shall consider the length of time the applicant is beyond the seven years; a candidate requesting a waiver of the seven-year rule will be required to present a verifiable and rational explanation for his or her inability to meet the seven-year requirement. In no case will a waiver be granted beyond a total period of ten years for completion of all three steps of the USMLE.

2. Other Reasons for Requesting a Waiver of the Seven-year Rule. In very limited and extraordinary circumstances, the Board, subject to any policies or guidelines that may be adopted and in effect on the date of the waiver petition, may grant a case-by-case exception to the seven-year period upon petition by an applicant for licensure and demonstration by the applicant of:

- a. A verifiable and rational explanation for the failure to satisfy the regulation;
- b. Strong academic and post-graduate record; and
- c. A compelling totality of circumstances.

(4) Examinations Completed before January 1, 2000. Applicants may submit evidence, including certification by the examining body, of having achieved scores acceptable to the Board on the following combinations of exams, if satisfactorily completed before January 1, 2000, in lieu of passing scores on the USMLE or COMLEX:

- (a) Part I of the examination of the NBME or Step 1 of the USMLE, and Part II of examination of the NBME or Step 2 of the USMLE, and Part III of the examination of the NBME or Step 3 of the USMLE; or
- (b) Both Component 1 and Component 2 of the FLEX; or
- (c) All parts of the MCCQE; or
- (d) Individual state examinations given prior to June 19, 1970, which are satisfactory to the Board; or
- (e) Component 1 of the FLEX and Step 3 of the USMLE; or
- (f) Component 2 of the FLEX and:
  1. Part I and Part II of the examination of the NBME; or
  2. Step 1 and Step 2 of the USMLE; or
  3. Part I of the examination of the NBME and Step 2 of the USMLE; or
  4. Step 1 of the USMLE and Part II of the examination of the NBME.

(5) FLEX Requirements.

(a) Beginning with the June 1985 examination, an applicant who has received the passing score of 75 or higher on Component 1 and 2 has passed the licensing examination. Prior to the June 1985 examination, an applicant who completed the FLEX in one sitting and has received a passing grade of a FLEX weighted average of 75% or higher has passed the licensing examination.

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(b) An applicant who applies on the basis of an examination taken in June 1985 or later must have received a passing score of 75 or higher on each of the two components and be otherwise qualified. An applicant who applies on the basis of an examination taken prior to June 1985 must have taken the FLEX in one sitting, must have received a grade of a FLEX weighted average of 75% or higher and be otherwise qualified.

(6) Restricted Licenses.

(a) Nature of Restrictions. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a restricted license to practice medicine. An applicant for a license issued under M.G.L. c. 112, § 5A shall first satisfy all the applicable prerequisites to licensure outlined in 243 CMR 2.02(1), except the electronic health records requirement in 243 CMR 2.02(1)(l) shall not be required. If the Board determines that an applicant's qualifications and professional training indicate that the Board should restrict his or her practice of medicine, the Board may issue a license restricted to any of the following:

1. A specialty or specified procedures within the specialty in which the applicant is a diplomate; or
2. A specified health care facility in which the applicant will practice under the supervision of a fully licensed specified physician; or
3. Prohibitions on performing certain procedures or operations, or prohibitions on performing procedures or operations under certain circumstances; or
4. In any other manner deemed appropriate by the Board based on the Board's assessment of the applicant's qualifications and professional training.

(b) Emergency Restricted License for a Displaced Physician. The Board may issue an emergency restricted license to practice to a physician licensed in another state, who has been displaced from his or her medical practice by reason of a federally-declared disaster, provided the physician applies for the emergency restricted license under the sponsorship of a licensed Massachusetts physician. An emergency restricted license issued for this purpose shall expire no later than three months after the date of issuance, or upon issuance of a full, unrestricted license, if sooner. If the Board approves a restricted licensee's application for a full, unrestricted license, the issue date of the full unrestricted license shall be the issue date of the emergency restricted license. An emergency restricted license may be restricted by location, specialty or any other manner as described in 243 CMR 2.02(6)(a). For purposes of 243 CMR 2.02(6)(a), a sponsoring physician must have a full, active, unrestricted Massachusetts license, and must be readily available on a continuing basis to provide guidance to the applicant regarding his or her responsibilities under 243 CMR and the statutes of the Commonwealth. Each restricted licensee shall provide the Board with proof of appropriate insurance coverage for malpractice claims.

(7) Limited Licenses.

(a) Purpose. Under M.G.L. c. 112, § 9, the Board issues a limited license to a person who has received an appointment as an intern, resident or fellow at a health care facility or in a training program approved by the Board. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a limited license to practice medicine. A limited license enables a person to complete his or her medical training.

(b) Prerequisites and Exceptions. Applicants for a Limited License shall satisfy the requirements of 243 CMR 2.02(1), except the following:

1. 243 CMR 2.02(1)(e): *Post-graduate Training*;
2. 243 CMR 2.02(1)(f): *Professional Examination*;
3. 243 CMR 2.02(1)(g): *Pain Management Training*;
4. 243 CMR 2.02(1)(h): *Participating in a Risk Management Program*;
5. 243 CMR 2.02(1)(i): *Agreement to not Balance Bill Medicare Patients*;
6. 243 CMR 2.02(1)(l): *Demonstration of Proficiency in Electronic Health Records*;
7. 243 CMR 2.02(1)(q): *Child Abuse and Neglect Training*..

(c) Emergency Restricted Limited License. The Board may issue an emergency restricted limited license to practice to a person who has been displaced from his or her medical training by reason of a federally-declared disaster, provided the person has received an appointment as an intern, resident or fellow at a health care facility or in a training program approved by the Board, and such program sponsors the person for the emergency restricted

## 2.02: continued

limited license. Applicants for an Emergency Restricted Limited License shall satisfy the requirements of 243 CMR 2.02(7)(b). An emergency restricted license issued for this purpose shall expire no later than three months after the date of issuance, or upon issuance of a limited license, if sooner. If the Board approves a restricted licensee's application for a limited license, the issue date of the limited license shall be the issue date of the emergency restricted limited license. An emergency restricted limited license may be restricted by location, specialty or any other manner as described in 243 CMR 2.00. For purposes of 243 CMR 2.02(7), a sponsoring training program or health care facility must designate a physician who is readily available on a continuing basis to provide guidance to the applicant regarding his or her responsibilities under 243 CMR and the laws of the Commonwealth.

(d) Requirements for a Limited Medical License. In order to qualify for a limited medical license, an applicant shall meet the following requirements, in addition to other applicable requirements for licensure as set forth in 243 CMR 2.00 and relevant sections of M.G.L. c. 112:

1. Medical Education. Each applicant for a limited license must satisfy the degree requirements of 243 CMR 2.02(1)(a) through (d) or be a graduate of a Fifth Pathway program.
2. Examination Requirements. Each applicant for a limited license must submit evidence of having achieved a passing score on Steps 1 and 2 of the USMLE, or the first two Levels of the COMLEX exam, or having received a certificate from the MCCQE.
3. ECFMG Certification. International medical graduates, other than graduates of a Fifth Pathway program, shall submit ECFMG certification valid as of the date of issuance.
4. ACGME or AOA Approved Position. Each applicant for a limited license must submit proof of an appointment to an ACGME or AOA approved postgraduate training program in Massachusetts, or a fellowship in a Massachusetts health care facility, which conducts on its premises ACGME or AOA approved programs.

(8) Procedure for Issuing a Limited License. Any applicant who meets all of the requirements of 243 CMR 2.02(8) to the satisfaction of the Board will be granted a limited license and is entitled to a certificate of registration signed by the chair and the secretary of the Board.

(a) Limited License Is Specific to Training Program. A limited license authorizes a limited licensee to practice medicine only in the specified training program. The licensee may only practice at the training program or at the health care facility designated on the limited license or at the facility's approved affiliates. Limited licensees may, however, practice for up to eight weeks in any single year of residency at a non-designated facility, if that facility is a teaching hospital with three or more ACGME or AOA accredited programs. A limited licensee may practice medicine only under the supervision of a full licensee who has been credentialed by the facility where the limited licensee is practicing pursuant to 243 CMR 2.02(8). The Board will not issue more than one limited license to a person at a time.

(b) Report of Disciplinary Actions to the Board. A health care facility that takes a disciplinary action against a limited licensee in a training program must report this action to the Board. In the event that a limited licensee terminates his or her appointment at a health care facility or his or her participation in a training program prior to the limited license's expiration date, or has his or her appointment or participation terminated, the health care facility designated on the license shall submit to the Board, pursuant to M.G.L. c. 111, § 53B, a written notice of termination which sets forth the reasons for the termination and is signed by the director or the administrator of the health care facility or training program.

(9) Duration of a Limited License.

(a) The Duration of a Limited License Shall Be One Academic Year. The Board may, subject to any guidelines that have been adopted by the Licensing Committee and the Board, issue a limited license for the duration of a trainee's enrollment in an ACGME or AOA training program. The issuance of a limited license beyond a total of seven years of practice pursuant to a limited license may be granted only by a majority vote of the Board.

(b) Nothing in 243 CMR 2.02(9) shall limit the Board's authority to revoke a limited license at any time in accordance with M.G.L. c. 112, § 9.

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(10) Restrictions on Billing by Limited Licensees. In a training program, a full licensee may bill for the services of a limited licensee, but only if such services are rendered as part of the training program under the direct supervision of a full licensee. Except as provided in the preceding sentence, no one may bill for the services of a limited licensee, but the salary of a limited licensee may constitute part of a health care facility's service charges.

(11) Volunteer License.

(a) Purpose. In order to encourage physician volunteerism and to serve the public health, the Board establishes a Volunteer License category. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a volunteer license to practice medicine. To qualify for a volunteer license, an applicant shall satisfy the prerequisites for a full initial license as set forth in 243 CMR 2.02(1), except for 243 CMR 2.02(1)(l). In satisfaction of 243 CMR 2.02(1)(k), the candidate shall pay a Volunteer License application fee, if one is established by the secretary of administration and finance pursuant to M.G.L. c. 7, § 3B. The Board may require that the applicant successfully pass a clinical skills assessment or other professional evaluation of clinical competency. The Volunteer License is chosen voluntarily by the applicant, and the Board shall not involuntarily impose this license status on an applicant or licensee.

1. Serving the Public Health. As part of the application for a volunteer license, a candidate shall submit the following information:

- a. A written statement from the applicant outlining the scope and duration of services to be provided by him or her;
- b. A written statement from the director of the applicant's proposed work site outlining the scope and duration of the applicant's responsibilities; and
- c. Evidence satisfactory to the Board that the volunteer physician's proposed work will serve the public interest. An example of work that serves the public interest is treating a medical population in need that may not otherwise have access to medical care.

(b) Issuance of Volunteer License. An applicant who meets all of the requirements of 243 CMR 2.02(11) to the satisfaction of the Board will be granted a volunteer license and is entitled to a certificate of registration signed by the chair and the secretary of the Board.

(c) Scope of Practice for Volunteer Status. A licensee engaged in volunteer practice shall be subject to the same conditions and responsibilities as a full licensee, and may not accept compensation in any form for his or her practice of medicine.

(d) Termination. A volunteer license issued in accordance with 243 CMR 2.02(11) may be renewed biennially. A volunteer license shall terminate automatically when it expires upon its expiration date or upon Board approval of a full license application. A volunteer licensee engaged in patient care is required to have professional malpractice liability insurance as in 243 CMR 2.02(1)(m).

(e) Change in License Status.

1. From Retired to Volunteer License. A licensee holding a Retired inactive license may apply to the Board for a change of license status from Retired inactive status to a Volunteer active license. The licensee shall complete an application for a Volunteer license. If the licensee has been away from the clinical practice of medicine for two or more years, the Board may require the completion of a Board-approved clinical skills assessment program, physician supervision or monitoring, CMEs, medical education or other such requirements to assist the licensee in reentering the clinical practice of medicine.

2. From Full to Volunteer License. If a physician with a full license wishes to change his or her license category to a volunteer license, he or she may file a Request for a Change of License Category with the Board. Such a request may be made at the time of license renewal or anytime during the license term.

3. From Volunteer to Full License. A licensee holding a volunteer license may apply to the Board for a change of license status from a Volunteer license to a full license. The licensee shall complete an application for a full license and pay the difference between the volunteer license application fee and the full license application fee.

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(12) Administrative License. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold an administrative license to practice medicine. In order to qualify for an administrative license, an applicant shall satisfy the educational and postgraduate training requirements for a full license as set forth in at 243 CMR 2.02(1), except for 243 CMR 2.02(1)(g), (l) and (m) and the following requirements:

- (a) General. The Board may issue an administrative license to an applicant whose primary responsibilities are those of an administrative or academic nature; such as professional managerial, administrative, or supervisory activities related to the practice of medicine or the delivery of health care services or medical research, the practice of investigative medicine or the administration of health insurance organizations. The Administrative License status is chosen voluntarily by the applicant, and the Board shall not involuntarily impose this license status on an applicant or licensee. An administrative license does not include the authority to diagnose or treat patients, issue prescriptions for drugs or controlled substances, delegate medical acts or prescriptive authority, or issue opinions regarding medical necessity.
- (b) Malpractice Insurance Requirements. A physician with an administrative license is not required to have professional malpractice liability insurance.
- (c) Issuance of License. An applicant who meets all of the requirements of 243 CMR 2.02(1), except for 243 CMR 2.02(1)(g) and (m), to the satisfaction of the Board will be granted an administrative license and is entitled to a certificate of registration signed by the chair and the secretary of the Board.
- (d) Biennial. An administrative license issued in accordance with 243 CMR 2.02(12) may be renewed biennially. An administrative license shall terminate automatically upon Board approval of a full license application.
- (e) Change in License Status.
  - 1. From Full to Administrative License. If a physician with a Full license wishes to change his or her license category to an Administrative license, he or she may file a request for a Change of License status with the Board.
  - 2. From Administrative to Full License. A licensee with an Administrative license may apply to the Board to change his or her license status to a Full license upon filing a Request for a Change in License status. The licensee shall submit a proposed reentry into clinical practice plan, if applicable, and pay the full license application fee. A reentry into clinical practice plan will describe the applicant's proposal to resume clinical practice, his or her continuing professional development, clinical training and other relevant experience during the time period in which the applicant held an administrative license. The Board may require that a licensee with an Administrative license status, who wishes to return to clinical practice, successfully pass a Board-approved clinical skills assessment or other Board-approved professional determination of clinical competency.

(13) Temporary License. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a temporary license to practice medicine. In order to qualify for an initial temporary license, an applicant must meet the requirements of 243 CMR 2.02(1), except 243 CMR 2.02(1)(l) and except as otherwise provided in 243 CMR 2.00, in addition to the requirements of 243 CMR 2.02(13).

- (a) Academic Faculty Appointment. Pursuant to M.G.L. c. 112, § 9B, the Board may issue an Academic Faculty Appointment license. This is a temporary license that the Board may issue to a visiting physician who is licensed to practice in another jurisdiction, and who has a temporary faculty appointment certified by the dean of a medical school in Massachusetts for purposes of medical education in an accredited hospital associated with the medical school; and a scope of practice plan certified by the Chair of the Department, approved by the Board and subject to audit thereof.
  - 1. A temporary license issued under 243 CMR 2.02(13) shall be valid for a period set by the Board, not exceeding 12 months, may be renewed up to two times, and shall terminate automatically upon termination of the faculty appointment. A temporary license under 243 CMR 2.02(13) and any renewals thereof shall not exceed three years.
  - 2. In order to renew a temporary license under 243 CMR 2.02(13), the licensee shall complete the following requirements:
    - a. The opioid education and pain management training requirement, as described in 243 CMR 2.02(2)(e);

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- b. The end-of-life care education requirement, as described in 243 CMR 2.06(6)(b); and
- c. 50% of the continuing professional development requirement for full licensees, as described in 243 CMR 2.06(6).
- 3. All practice of medicine by a licensee under 243 CMR 2.02(13)(a) must be essential to his or her teaching and shall be restricted to the specified institution or any of that facility's approved affiliates.
- 4. A temporary licensee may not practice outside the scope of practice that is directly related to his or her educational and training responsibilities.
- (b) Substitute Physician.
  - 1. Holds an Out-of-state License. Pursuant to M.G.L. c. 112, § 9B, the Board may issue a temporary license to a physician who is licensed to practice medicine in another U.S. jurisdiction to permit him or her to act as a substitute physician for a physician licensed in Massachusetts. A temporary license issued in accordance with 243 CMR 2.02(13)(b) may be granted only upon written request of the physician licensed in Massachusetts and shall be limited to a period of three months or less. A *locum tenens* physician may be a substitute physician.
  - 2. Diplomate of Specialty Board. The Board may issue a temporary license to a physician eligible for examination or registration in the Commonwealth who is a diplomate of a specialty board approved by the American Medical Association or the American Osteopathic Association to permit him or her to act as a substitute physician for a registered physician in the commonwealth. This temporary license is granted only upon written request of the licensed physician, is limited to the specialty in which the applicant is certified and limited to three months or less.
- (c) Participating in a CME Course. Pursuant to M.G.L. c. 112, § 9B, the Board may issue a temporary license to a physician who is licensed to practice in another jurisdiction, and who is enrolled in a course of continuing medical education in Massachusetts. A temporary license issued in accordance with 243 CMR 2.02(13)(c) is limited to continuing medical education activities conducted under the supervision of a physician licensed in Massachusetts and shall terminate automatically upon termination of the course and, in any event, at the end of three months.
- (d) Issuance of License. An applicant who meets all of the requirements of 243 CMR 2.02(13) to the satisfaction of the Board will be granted a temporary license and is entitled to a certificate of registration signed by the chair and the secretary of the Board.

2.03: Initial License for Graduates of International Medical Schools and Graduates of Fifth Pathway Programs

- (1) Full License. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a full active license to practice medicine. In order to qualify for a full active medical license as that term is defined in M.G.L. c. 112, § 2, and 243 CMR 2.00, a graduate of an international medical school or a graduate of a Fifth Pathway program shall meet the prerequisites for licensure as set forth in 243 CMR 2.02(1), except as otherwise provided, and the standards in 243 CMR 2.03(1)(a) through (e), in addition to the standards imposed by M.G.L. c. 112, § 2, and 243 CMR 2.00:
  - (a) Medical Education. Each applicant for a full license shall have received a degree of doctor of medicine, or its equivalent from a program determined by the Board to be substantially equivalent to the medical school programs accredited by the LCME, or the degree of doctor of osteopathy or its equivalent from a program determined by the Board to be substantially equivalent to the osteopathic school programs accredited by the AOA.
  - (b) Substantial Equivalency of Medical Education. In order to be considered substantially equivalent, such medical education shall include:
    - 1. Two academic years of basic science study, including:
      - a. gross anatomy;
      - b. biochemistry;
      - c. pathology;
      - d. physiology;
      - e. microbiology;

## 2.03: continued

- f. immunology; and
  - g. pharmacology.
- 2. Two academic years of clinical study including:
  - a. internal medicine;
  - b. surgery;
  - c. pediatrics;
  - d. obstetrics and gynecology;
  - e. public health and preventive medicine; and
  - f. psychiatry.
- 3. Clinical Training. The Board must also be satisfied that all clinical training is substantially equivalent to the minimum standards required of United States medical school graduates. The applicant shall submit documentation satisfactory to the Board that all clinical study was done:
  - a. Under the direct control and approval of the medical school and under on-site supervision and evaluation by the faculty of the medical school in which the applicant was enrolled at the time of study, and in hospitals which have, in the Board's opinion, programs equivalent to ACGME or AOA approved programs in the area of clinical study;
  - b. Clinical study done in the United States shall be in hospitals which have ACGME or AOA approved programs in the area of the clinical study. Clinical study done in Canada shall be in hospitals which have accredited Canadian postgraduate medical training programs. Supervising clinical faculty shall be physicians who are fully licensed by the jurisdiction where such study is done.
- 4. Board staff may request additional documentation during the licensure process which may include, but is not limited to:
  - a. A formal evaluation by the faculty of the clinical clerkship;
  - b. A formal written agreement between the medical school and the place of clinical study; or
  - c. A course catalog.
- 5. The Board, in its discretion, may determine that any college of medicine that had its accreditation withdrawn by a national or regional accreditation organization; or had its authorization, certification or licensure revoked or withdrawn by a national governmental supervisory agency; or issued a medical degree based entirely on coursework via the Internet or via online programs, is inconsistent with quality medical education. Such a program of education will not be an approved college of medicine for the purpose of fulfilling the medical education requirement of 243 CMR 2.02(1).
- (c) ECFMG Certificate. A candidate for licensure shall possess an ECFMG certificate which is valid on its face and valid as of the date of licensure. Pursuant to M.G.L. c. 112, § 2, an ECFMG certificate is not required for graduates of Fifth Pathway programs.
- (d) Postgraduate Medical Education. Each applicant for a full license must have satisfactorily completed at least two years of post graduate medical training in an ACGME or AOA approved or accredited Canadian program. Effective January 1, 2014, each applicant for a full license must have satisfactorily completed at least three years of post graduate medical training in an ACGME or AOA approved or accredited Canadian program. However, in the case of subspecialty clinical fellowship programs, the Board may accept post graduate training in a hospital that has an ACGME or AOA or accredited Canadian post graduate medical training program in the parent specialty.
  - 1. The Board may, in its discretion, accept teaching experience as post graduate training, when it consists of a faculty appointment at or above the assistant professor level at a medical school accredited by the LCME, if the majority of the teaching experience documented is clinical teaching with supporting evidence of either special honors or awards which the applicant has achieved or articles the applicant has published in reputable medical journals or medical textbooks. With the same supporting evidence, the Board may accept teaching experience at the instructor level with the following consideration: There is a presumption against accepting instructor level teaching experience when combined with a waiver request for any other section of 243 CMR 2.03. The Board, in its discretion, may overcome this presumption only in extraordinary circumstances.

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2. In its discretion, the Board may consider for licensure an applicant who has completed two years of ACGME or AOA approved or accredited Canadian postgraduate training and who:

- a. Holds a current, active, unrestricted medical license in another state; and
- b. Demonstrates continuous clinical activity; and
- c. Is board certified by either ABMS or AOA.

(e) Waiver of Substantial Equivalency. In situations where an applicant cannot comply with 243 CMR 2.03 requiring substantial equivalency of medical school education, the applicant must submit a waiver request pursuant to 243 CMR 2.03. In order for the Board to grant such a waiver request, the Board must determine that the licensure of this applicant would not impair the public health, safety and welfare, and that the applicant meets the standards of M.G.L. c. 112, §§ 2 through 9B. It is the applicant's responsibility to demonstrate he or she is qualified under these standards. The assessment and determination of the applicant's equivalency of complete medical education will include, but not be limited to, the following factors:

- 1. Applicant must be qualified, competent and of good moral character;
- 2. Applicant must have held an unlimited, unrestricted medical license in a state or states for a period of two years. Any time spent by the applicant in postgraduate training or clinical fellowship shall not be included in the calculation of this two-year requirement;
- 3. Applicant must have satisfactorily completed postgraduate training in an ACGME or AOA approved postgraduate training program;
- 4. Applicant must have American Specialty Board certification by the ABMS or AOA; and
- 5. Applicant must have successfully completed all three Steps of the USMLE or all three Levels of the COMLEX examination within a seven year period. The seven-year period begins on passing the first Step or Level of the examination.

(f) Waiver of Any 243 CMR 2.03 Requirement. An applicant for a full license pursuant to 243 CMR 2.03 may make a written request to the Board for a waiver of any requirement of 243 CMR 2.03. The Board, in its discretion, may grant the waiver as requested, or with modifications thereof, upon finding:

- a. The applicant meets the standards of M.G.L. c. 112, §§ 2 through 9B; and
- b. Such a waiver would promote the public health, safety or welfare.

(2) Limited License for Graduates of an International Medical School or Fifth Pathway Program. The Board shall determine whether an applicant is qualified, competent and of good moral character to hold a limited license to practice medicine. In order to qualify for a limited license as that term is defined in M.G.L. c. 112, § 9, and 243 CMR 2.00, a graduate of an international medical school or a graduate of a Fifth Pathway program shall meet the prerequisites in 243 CMR 2.02(7) and the following standards:

- (a) Postgraduate Training. The applicant shall be enrolled in a post graduate medical education program in hospitals or equivalent institutions within the Commonwealth of Massachusetts. All such training shall be done in ACGME or RRC or AOA approved programs, or in a sub specialty clinical fellowship program in a hospital that has an ACGME or RRC or AOA approved program in the parent specialty.
- (b) Refugee Applicants. In the case of a refugee applicant, the Board, in its discretion, may accept as post graduate training, enrollment in an individualized training program in a hospital or other similar institution for a period of time between one and two years duration under the direct supervision and control of a fully licensed physician on the staff of such institution. An applicant seeking approval for such an alternative program under 243 CMR 2.03(2) shall submit a written proposal to the Board. The Board may adopt guidelines, including a list of criteria for approval of such programs. All training programs must have prior approval of the Board.



## 2.03: continued

(c) Request to Approve Individualized Training Program. The Board may appoint an Advisory Panel on Refugee Physicians. The Board may request such an Advisory Panel or member(s) thereof to review the applications of refugee physicians and make recommendations to the Board regarding said applications, including requests for approval of individualized training programs under 243 CMR 2.03(2). Any such recommendations are advisory and are not binding on the Board of Registration in Medicine. An applicant who wishes to have an individualized training program approved under 243 CMR 2.03(2)(a)2. shall submit documentation that he or she has made a good faith effort to be accepted in an ACGME or AOA or RRC approved program, and has been unsuccessful in that effort. For the purposes of 243 CMR 2.03(2), the term “refugee” shall mean a person who:

1. Has applied and is being considered for, or has received asylum in the United States under the Political Asylum Code, 8 CFR 208;
2. Was admitted to the United States on a humanitarian visa or on the parole authority of the Attorney General of the United States (8 U.S.C. 1142 (D)(5)); or
3. Any person outside his or her country of nationality who is unable or unwilling to return to such country, and is unable or unwilling to avail himself or herself of the protection of that country because of persecution or a well founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.

(d) Standards. The applicant shall meet the standards listed in 243 CMR 2.03(1)(a) through (c).

(e) Waiver of Substantial Equivalency. In situations where a limited license applicant cannot comply with 243 CMR 2.03 requiring substantial equivalency of medical school education, the applicant must submit a waiver request pursuant to 243 CMR 2.03. In order for the Board to grant such a waiver request, the Board must determine that the licensure of this applicant would not impair the public health, safety and welfare, and that the applicant meets the standards of M.G.L. c. 112, §§ 2 through 9B. It is the applicant's responsibility to demonstrate he or she is qualified under these standards. The assessment and determination of the applicant's equivalency of complete medical education and eligibility for training in Massachusetts may include, but not be limited to, the following factors:

1. Applicant must be qualified, competent and of good moral character;
2. Applicant must hold an unlimited, unrestricted medical license in another state or states;
3. Applicant must have held an unlimited, unrestricted medical license in a state or states for a period of two years. Any time spent by the applicant in postgraduate training or clinical fellowship shall not be included in the calculation of this two-year requirement;
4. Applicant must have successfully completed Steps 1 and 2 of the USMLE or Levels 1 and 2 of the COMLEX examination;
5. Quality of basic science education;
6. Quality of clinical clerkship experience (evaluations required);
7. Other distinctions; honors, awards, publications;
8. Nature and quality of anticipated training program, including degree and quality of supervision; and
9. Personal interview with the applicant.

(3) Temporary License for a Graduate of an International Medical School or Fifth Pathway Program. The Board shall determine whether an applicant is qualified, competent and of good moral character, to hold a temporary license to practice medicine. In order to qualify for a temporary license, as that term is defined in M.G.L. c. 112, § 9B, and 243 CMR 2.00, a graduate of an international medical school or a graduate of a Fifth Pathway program shall meet the following standards:

- (a) The applicant shall meet the standards listed in 243 CMR 2.03(1).
- (b) At the discretion of the Board, an applicant may be issued a temporary license in the following circumstance:

2.03: continued

1. If the applicant is a visiting physician, with a license to practice in another state or territory or in the District of Columbia or in another country and has a temporary faculty appointment certified by the Dean of the medical school in the Commonwealth for purposes of medical education in an accredited hospital associated with the medical school; and
  2. Has demonstrated outstanding expertise in a medical specialty. The Board shall take the following factors into consideration when evaluating such an applicant:
    - a. The quality of medical education and clinical training;
    - b. Teaching experience;
    - c. Board certification;
    - d. Special honors or awards;
    - e. Articles published in reputable medical journals and medical textbooks; and
    - f. Perfection of a medical technique which is unique and beneficial for the alleviation or cure of disease.
- (c) A temporary license expires 12 months from the issue date, except as otherwise provided. A subsequent temporary license may be issued at the discretion of the Board.
- (4) Waiver of a 243 CMR 2.03 Requirement. An applicant may make a written request to the Board for a waiver of the provisions of any of the requirements in 243 CMR 2.03. The Board, after determining that the applicant meets the standards of M.G.L. c. 112, §§ 2 through 9B; and that such a waiver would not harm the public health, safety or welfare, may grant the waiver as requested or with modifications thereof.

2.04: Licensing Application Provisions

243 CMR 2.04 applies to all the Board's license applications, unless otherwise specifically noted.

- (1) Application Forms. Each applicant for licensure or renewal shall submit to the Board a completed application form, any additional information requested by the Board, and the applicable fee as determined by the Secretary of Administration and Finance pursuant to M.G.L. c. 7, § 3B. The Board's licensure application forms, with the exception of its renewal application form, shall include, but are not limited to, requests for the following information:
  - (a) The applicant's name, date of birth, and home and principal business addresses; and
  - (b) A verification of the fact that the applicant has completed two years of premedical education, written on the official stationery of the college or university and signed by the dean or other appropriate official. If the school has an official seal, the written verification must be stamped with it. The requirements of this subdivision do not apply to applications for a temporary license; and
  - (c) A written verification of the applicant's attendance by month and year at a medical school, signed by the dean or other appropriate official. If the school has an official seal, the written verification must be stamped with it.
- (2) Submission of Original Licensing Documents. All documents submitted to the Board in support of a license application shall be original documents or certified copies from the primary source, unless otherwise provided by the Board. The Board shall accept electronic records as provided in M.G.L. c. 110G.
- (3) Foreign Language Licensing Documents. An applicant or licensee who wishes to submit an original document or photocopy written in a foreign language must also submit a notarized translation into English of the documents or copy that is prepared by a United States translation service.
- (4) Completed Application. An application for initial licensure or renewal or for reentry into practice status shall be considered complete when:
  - (a) It is legible, signed; and has been sworn to by the applicant;
  - (b) All required information, documentation and signatures have been supplied;
  - (c) The fee has been paid in full; and

2.04: continued

- (d) All supplemental information required by the Board has been supplied.
- (5) Good Moral Character. Pursuant to M.G.L. c. 112, § 2, all applicants for licensure and all licensees shall have good moral character.
- (a) Initial License. An applicant for initial licensure shall submit to the Board a written statement attesting to his or her good moral character. The statement shall be executed by a physician, other than a relative, who has known the applicant for a substantial period of time. The Board especially seeks statements from physicians licensed to practice in the Commonwealth.
- (b) Renewal License. A renewing licensee shall certify that he or she is of good moral character biennially, when signing the renewal application.
- (6) Examination Requirements. Each applicant for licensure shall fulfill the examination and other requirements for a license as set forth in 243 CMR 2.00 or as required by the Board.
- (7) NPI. Each applicant for licensure or renewal shall provide the Board with his or her NPI number or certify that he or she has applied for an NPI number and will provide it to the Board upon receipt.
- (8) CORI. Each applicant for licensure or renewal shall authorize the Board to access information held by the Massachusetts Criminal History Systems Board and other law enforcement agencies.
- (9) Malpractice History. Each applicant for licensure shall provide information and documentation on any malpractice claim in which he or she was a named defendant, as required by the Board.
- (10) Criminal History. Each applicant shall provide information and documentation on any criminal proceeding in which he or she was a defendant, in accordance with M.G.L. c. 6, § 172(a)(3) and other applicable state and federal laws. An applicant should not report minor traffic violations.
- (11) Premedical Education. Each applicant for licensure shall have completed a minimum of two years in a college or university program acceptable to the Board.
- (12) Postgraduate Medical Training. Each applicant for licensure shall satisfy the postgraduate training requirements as set forth in 243 CMR 2.00.
- (13) Applicants for Licensure or Renewal Who Have Changed Their Names. Each applicant for licensure or renewal who has been known by a name other than that used on his or her application shall complete the name change forms used by the Board to verify name changes, and shall submit the completed forms along with the documentation required therein.
- (14) Duty to Update Registration Information.
- (a) During the Application Process. During the initial or renewal application process, an applicant and a licensee have a duty to report to the Board in writing any change in the registration information supplied to the Board in support of his or her application. For an initial application, the process begins on the date the Board receives the first application submission, and ends on the date the license is effective. For a renewal application, the process begins 60 days prior to the anticipated effective date of the license and ends on the date the license is effective. When the applicant or licensee is in the application process, the applicant or licensee shall notify the Licensing Division of the Board as soon as he or she becomes aware of the change in information, but in no event later than 72 hours.
- (b) During the Licensing Term. From the day after the effective date of a license or renewal, until the day the next renewal application process begins, a licensee has a duty to timely report in writing any change in the registration information that was supplied to the Board in support of his or her application for licensure or renewal. However, information required under 243 CMR 2.07(8), must be reported to the Board within 30 days of the date the change occurred, or the date that the licensee became aware of the change, whichever is later. If no time period is specified, a report to the Board should be filed within 30 days from the date of the precipitating event.

2.04: continued

(c) Exception for Certain Health Information. At all times, physicians who are eligible for the exception to the Mandated Reporting law under M.G.L. c. 112, § 5F, and 243 CMR 2.07(23) are exempt from reporting a change in certain health conditions to the Board.

(15) Withdrawal of Application. An applicant may withdraw his or her application prior to review by the Licensing Committee. When a license application is placed on the agenda of a scheduled meeting of the Licensing Committee or the Board, an applicant may not withdraw the application, except in extraordinary circumstances and with the unanimous vote of the full Board. 243 CMR 2.04(15) does not apply to applicants who cannot comply with the Board's medical education requirements for graduates of international medical schools and graduates of Fifth Pathway programs, and who have submitted a waiver request pursuant to 243 CMR 2.03(4).

(16) Preliminary Denial of Licensure.

(a) The Board may preliminarily deny a license application upon a determination that the applicant does not meet the requirements for licensure as set forth in 243 CMR and M.G.L. c. 112 or because of acts which, were they engaged in by a licensee, would violate M.G.L. c. 112, § 5 or 243 CMR 1.03(5), provided however, that no person shall be disqualified from licensure or denied licensure by the Board for providing or assisting in providing reproductive health care services or gender-affirming health care services, as defined at M.G.L. c. 12, § 11I½, so long as the services provided would have been lawful in Massachusetts and are consistent with standards for good professional practice in Massachusetts.

(b) If the Board preliminarily denies a license application pursuant to 243 CMR 2.04(14), the Board will notify the applicant in writing of the following:

1. The facts relied upon as the basis for the preliminary denial;
2. The statutes or regulations which enable the Board to preliminarily deny a license application; and
3. The applicant's right to request a hearing, in writing, within 21 days of such notification from the Board. The hearing referred to in 243 CMR 2.04(14) is a licensing hearing conducted by the Board and is not a disciplinary proceeding.

(c) Upon receipt of an applicant's request for a hearing which meets the requirements of 243 CMR 2.04(14), the Board shall grant such request if:

1. The applicant has specified a factual or legal basis for overturning the preliminary denial; and
2. The Board determines that specific factual or legal issues, if further developed at a hearing, would be sufficient to overturn the preliminary denial.

(d) If, after the expiration of the time in which to request a hearing, or after the Board's decision not to grant a hearing, or after a hearing, the Board decides that the applicant should not be licensed, the Board may vote to deny the license application. If, after a hearing, the applicant has demonstrated to the Board's satisfaction that a license should be issued, the Board shall vote to issue a license. The Board may issue policies or guidelines on the procedures relating to the preliminary denial of a license.

2.05: Miscellaneous Licensing Provisions

(1) License Fees. Fees payable to the Board in the amount of \$5.00 or more may be paid by personal check or money order drawn on a U.S. bank in U.S. funds. Fees payable in the amount of \$5.00 or less may be paid by personal check. However, the Board may require any fee to be paid by certified check, money order, credit card or electronic fund transfer.

The Board's fee schedule for processing various documents is set by the secretary of administration and finance pursuant to M.G.L. c. 7, § 3B. Board licensing fees are located at 801 CMR 4.02(243). The application fee is nonrefundable.

(2) Board Approval of Health Care Facility Affiliations. The Board must approve by a majority vote the affiliations between health care facilities and physician training programs, if one of the affiliations is not an ACGME or AOA accredited program. In order to approve an affiliation, the Board must determine, among other factors, that the supervision available for training purposes is adequate. Limited licensees may rotate between teaching hospitals with three or more ACGME or AOA accredited programs without prior approval of the Board.

(3) Procedure for Approval of Health Care Facility Affiliations. The directors of the health care facilities and the physician training program seeking to affiliate must submit a written joint request to the Board for approval of the affiliation, at least 30 days in advance of when affiliation is sought. If the physician training program is ACGME or AOA accredited, a health care facilities affiliation agreement is not necessary.

2.06: License Renewals

(1) Two-year Licensing Period for Full, Administrative or Volunteer Licenses. Pursuant to M.G.L. c. 112, § 2, a licensee must renew his full, administrative or volunteer license every two years. Time shall be calculated according to the two year licensing period for the licensee, beginning on the date the license was issued or renewed by the Board and ending on the following renewal date.

(2) Requirements for Renewing a Full, Administrative or Volunteer License. In order to renew a full, administrative or volunteer license, a licensee must meet the prerequisite requirements in 243 CMR 2.02(1), except as otherwise provided, and the following renewal requirements:

(a) Timely Submission. A licensee must submit to the Board a completed renewal application form and the proper fee prior to the renewal date. A license that has not been renewed expires at 11:59 P.M. on the renewal date.

(b) Completed Continuing Medical Education Requirements. A licensee must fulfill his or her continuing medical education requirement as defined in 243 CMR 2.06(5) or obtain a waiver from the Board pursuant to 243 CMR 2.06(5)(e).

(c) Effect of Suspension. A licensee may not renew a license during a period of suspension.

(d) Proficiency in EHR. A renewing full licensee shall establish competency in the use of electronic health records (EHR). Electronic health record systems include computerized physician order entry, e-prescribing and other health information systems.

1. Demonstrating EHR Proficiency. A renewing full licensee must demonstrate proficiency in the use of electronic health records (EHR), as required by M.G.L. c. 112, § 2. A renewing full licensee shall demonstrate proficiency in the use of EHR once, and in one of the following ways:

- a. Participation in a Meaningful Use program as an eligible professional;
- b. Employment with, credentialed to provide patient care at, or in a contractual agreement with an eligible hospital or critical access hospital that has implemented an electronic health records program;
- c. Participation, as either a Participant or Authorized User, in the Massachusetts Health Information Highway; or
- d. Completion of three hours of a Category 1 EHR-related CME course that discusses, at a minimum, the core and menu objectives and the CQMs for Meaningful Use. These three EHR credits may be used toward the required ten risk management CME credits.

2. Waiver of the EHR Proficiency Requirement. For purposes of 243 CMR 2.06, a waiver means an extension of time with which to demonstrate EHR Proficiency. A licensee may apply to the Board for a waiver of the EHR Proficiency requirement.

- a. The Board may, in its discretion, grant a 90-day waiver of the EHR Proficiency requirement due to undue hardship in meeting the requirement.
- b. The licensee must submit the waiver request to the Board no later than 30 days prior to the license renewal date. Only in exceptional circumstances shall the Board permit a licensee to file a waiver request less than 30 days prior to the licensee's renewal date.
- c. The Board may extend the validity of the applicant's license through the period of the waiver.

3. Exemptions. Exemptions must be claimed each licensing cycle, if applicable. The following are exempt from the requirement to demonstrate EHR Proficiency:

- a. A licensee who is not engaged in the practice of medicine as defined in 243 CMR 2.01(4);
- b. An Administrative licensee;
- c. A Volunteer licensee;
- d. An Inactive licensee;
- e. An applicant for any license who is on active duty as a member of the National Guard or of a uniformed service called into service during a national emergency or crisis;
- f. An Emergency Restricted licensee; or
- g. An applicant who has already demonstrated proficiency under 243 CMR 2.02(2)(f) or 2.06(2)(d).

## 2.06: continued

(e) Domestic Violence and Sexual Violence Training. Pursuant to M.G.L. c. 112, § 264, applicants and licensees shall participate in Domestic Violence and Sexual Violence Training once as a condition for licensure, renewal, revival or reinstatement of licensure. The Board, in consultation with the Department of Public Health, will identify programs or courses of study that meet the standards required by this provision and provide its licensees with a list of such programs or courses. This is a one-time training requirement.

(f) MassHealth Requirement. Pursuant to M.G.L. c. 112, §§ 2 and 9, applicants and licensees shall apply to participate in MassHealth, either as a provider of services or as a non-billing provider for the limited purpose of ordering and referring services in the MassHealth program, as a condition of licensure, renewal, revival or reinstatement of licensure.

(g) Child Abuse and Neglect Training. Pursuant to M.G.L. c. 119, § 51A(k), applicants and licensees shall complete training in recognizing and reporting suspected child abuse and neglect. Physicians may comply with the training requirement by: completing a hospital-sponsored training program in recognizing the signs of child abuse and neglect; completing CME in identifying and reporting child abuse and neglect; completing a Board-approved online training program or completing a specialized certification. This is a one-time training requirement.

(3) Inactive Status.

(a) Exempt from Certain Requirements. A licensee may request to change his or her license status from a full active license to an inactive status. A request to change license status may be made at any time during the license term or at the time of renewal. A licensee shall certify that he or she will not practice medicine in Massachusetts while in inactive status. A licensee who is inactive is exempt from the continuing medical education requirements set forth in 243 CMR 2.06(2) and (6), the domestic violence and sexual violence training, the MassHealth application requirement, the child abuse and neglect training and professional malpractice liability insurance as set forth in 243 CMR 2.07(16), but is subject to all other provisions of 243 CMR 2.00.

(b) Return to Active Status. An inactive licensee may request at any time a change of license status to return to active status. The Board shall require the licensee to satisfy the domestic violence and sexual violence training, the MassHealth application requirement, the child abuse and neglect training, if these requirements have not been previously satisfied, and such continuing medical education requirements as have accumulated during the period of time the licensee was on inactive status, including the EHR Proficiency requirement, or such CME requirements as the Board requires. The Board shall require that the licensee reinstate appropriate professional malpractice liability insurance requirements.

(4) Retiring from the Practice of Medicine. When resignation, as set forth in 243 CMR 1.05(5): *Resignation*, does not apply, a licensee may retire from the practice of medicine in accordance with the following procedure:

(a) From Active to Retired Status. A licensee who no longer wishes to practice medicine may request, in writing, that the Board change his or her license status from Active to Retired status. A Retired license is an inactive status. The licensee must submit a written statement, signed under the penalties of perjury, detailing the licensee's knowledge of any open or reasonably anticipated complaints before the Board, and agreeing to make patient records accessible in accordance with 243 CMR 2.07(13).

(b) Eligibility for Retired Status. A physician is not eligible to retire if he or she is the subject of an open complaint or reasonably anticipates a complaint will be filed with the Board.

(c) Effective Date of Retirement. If the physician is not the subject of an open complaint, and there are no reasonably anticipated complaints against the licensee, he or she may retire. The physician's retirement status becomes effective on the date set by the Board in its written Notice of a Change in License Status.

## 2.06: continued

(d) Retiree's Duty to Maintain Patient Records. The retired physician shall comply with the requirements of 243 CMR 2.07(13). With respect to patient records existing on or after January 1, 1990, a retiring licensee, a successor physician or the licensee's estate must retain patient records in a manner which permits former patients and their successor physicians to access to them for a minimum period of seven years from the date of the last patient encounter. When the patient is a minor on the date of the last patient encounter, the physician must retain the patient's records for a minimum period of seven years from the date of the last patient encounter or until the date that the minor patient reaches 18 years of age, whichever is the longer retention period.

(e) From Retired Status to Active Status. A physician in Retired status may wish to return to active practice. The physician must complete the Reactivation from Retirement Application and demonstrate EHR Proficiency as set forth in 243 CMR 2.06(2)(d). If the physician has been out of practice for less than two years, he or she may change his or her license status. The Board shall approve such a request provided that the physician has no outstanding complaints or unpaid fines. If the physician in retired status has not engaged in a clinical practice of medicine for two years or more, and the physician intends to return to a practice of medicine that will include direct or indirect patient care, the Board may require that the physician demonstrate current clinical competency prior to reviving the license.

(5) Request for Extension to Complete Certain 243 CMR 2.06 Renewal Requirements. In the circumstances listed in 243 CMR 2.06(5), the Board or its designee may grant a licensee an extension of time in which to file a completed renewal application and may extend the validity of his or her current license through the period of the extension. The Board or its designee may deem that a licensee has requested an extension under 243 CMR 2.06 in the following circumstances:

(a) The Board fails to provide the licensee with a renewal application 60 days prior to the renewal date due to the Board's computer, administrative, or clerical difficulties or other compelling circumstances. Such an extension shall not exceed 60 days.

(b) The licensee fails to receive his or her renewal application in a timely manner because of computer, administrative, or clerical difficulties or other compelling circumstances on the part of the licensee. A licensee's failure to receive his or her renewal application due to his own failure to change his or her address with the Board within 30 days as required by 243 CMR 2.07(8) is not a compelling circumstance.

(6) Continuing Medical Education.

(a) Basic Biennial Requirement. Subject to the exemptions set forth in 243 CMR 2.05(6), each licensee shall obtain no fewer than 100 continuing medical education (CME) credits during each two year period that begins on the date that his or her license is issued or renewed by the Board and ends on the following renewal date. Credits shall be earned as follows:

1. Category 1. Not less than 40 CME credits (example: AMA PRA Category 1 Credit™; AAFP Prescribed credit or AOA Category 1-A) from an organization accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), the American Academy of Family Physicians (AAFP) or a state medical society recognized by the ACCME. The entire 100-credit requirement may be completed by earning Category 1, Prescribed or 1-A credits.

2. Category 2. Not more than 60 credits of Category 2 activities, as defined and adopted by the American Medical Association or AOA.

3. Risk Management Continuing Medical Education Courses. Ten credits studying risk management, as defined in 243 CMR 2.01(3), at least four of which shall be in Category 1.

4. Review of Board Regulations. Two credits in either Category 1 or 2 studying 243 CMR 1.00 through 3.00.

(b) End-of-life Care Studies. Pursuant to M.G.L. c. 13, § 10 and M.G.L. c. 112, § 2, the Board shall require that a licensee participate once in at least two credits of either Category 1 or 2 continuing medical education studying end-of-life care issues as a condition for renewal, revival or reinstatement of licensure. End-of-life care studies may be used to satisfy the risk management requirement in 243 CMR 2.06(6)(a)3. The Board will assist licensees in obtaining end-of-life care education and training by providing an online list of resources.

## 2.06: continued

(c) Clinical Assessment. The Board may require a licensee to participate in a clinical skills or competency assessment, if any such programs exist, as a condition for renewing, reinstating, reviving a license or for changing a license category. An applicant for renewal, revival, reinstatement or change of status may also be required to appear for a personal interview with the Board and its committees. This interview may include, but not be limited to, an inquiry regarding the applicant's reason(s) for renewal, revival, reinstating or change of status and the applicant's plan for practicing medicine in Massachusetts.

1. In determining whether to require a clinical skills assessment or a clinical competency assessment, the Board may consider the length of time that the licensee has been clinically inactive, the licensee's specialty; the cost of the program; the location of the program, and other relevant factors that the Board may by policy develop.

2. The Board may accept the successful completion of an Ongoing Physician Performance Evaluation (OPPE) by a licensee as establishing clinical competency, provided the OPPE is completed within the past year.

3. The Board may accept the successful completion of a Focused Physician Performance Evaluation (FPPE) by a licensee as establishing clinical competency, provided the FPPE is completed within the past year.

(d) Opioid Education and Pain Management Training. Renewing licensees who prescribe controlled substances, as defined in M.G.L. c. 94C, § 1, shall, as a prerequisite to renewing a medical license, complete three credits in pain management training, pursuant to St. 2010, c. 283. Pain management training shall include, but not be limited to, training in how to identify patients at high risk for substance abuse and training in how to counsel patients on the side effects, addictive nature and proper storage and disposal of prescription medicines. Three credits of opioid education and pain management training shall be required of licensees when they biennially renew their licenses. Opioid education and pain management training may be used toward a licensee's required risk management credits of continuing professional education.

(e) CME for Temporary Licensee. A temporary licensee with an academic appointment shall have fulfilled 50% of the CME requirement in order to obtain a renewal of the temporary license.

(f) Exemptions. The following licenses are not required to fulfill the basic biennial CME requirement set forth in 243 CMR 2.06(5)(a):

1. Limited licensees.

2. Licensees on inactive status, except as specified in 243 CMR 2.06(3)(b).

3. Licensees enrolled in any of the following programs:

- a. A post graduate medical education program (*e.g.*, a residency or fellowship) approved by the ACGME or AOA.

- b. The first or second year of a fellowship (including consecutive fellowships) not approved by the ACGME OR AOA (*e.g.*, a pure research fellowship).

4. National Emergency or National Crisis Exemption. The Board shall grant an exemption of the CME requirement to those licensees serving in active military duty as members of the National Guard or of a uniformed service who are called into service during a national emergency or crisis.

- a. An exemption of the CME requirement may be granted on a pro rated basis.

- b. The exemption shall constitute a permanent waiver, and the licensee shall not be required to complete the excused credits at a future time.

- c. A licensee may apply to the Board for a waiver of the CME requirements pursuant to the national emergency or crisis exemption by submitting the waiver request in writing to the Board, together with proof of service, no later than 30 days prior to the license renewal date.

(g) Calculating Credits. Newly licensed or newly active physicians, or licensees initially subject to the exemptions set forth in 243 CMR 2.06(5) shall begin to earn CME credits as follows:

1. A newly licensed physician not otherwise subject to the exemptions set forth in 243 CMR 2.06(5), shall fulfill the basic biennial CME requirement during the two year period that begins on the date his or her license is issued by the Board. If that license will be renewed in less than two years, the licensee shall obtain credits as follows:



2.06: continued

- a. If the license renewal period is one year or shorter, the licensee need not obtain any CME credits during that renewal period.
  - b. If the license renewal period is longer than one year but shorter than two years, the licensee shall fulfill one half of the basic biennial CME requirement during that renewal period.
2. A licensee seeking to return to active status from lapsed license status shall first have fulfilled the basic biennial CME requirement during the two year period ending on the date he or she returns to active status.
3. A licensee completing or leaving a program described in 243 CMR 2.06(5)(b)3.a., shall fulfill the basic biennial CME requirement during the two year period that begins on the first license renewal date after the program or the second fellowship year has ended, or (if earlier) that begins on the first license renewal date after the licensee leaves the program or fellowship.
- (h) Miscellaneous Provisions.
  1. A majority of the total CME credits required for each renewal cycle shall be directly related to the licensee's primary area(s) of practice.
  2. Licensees shall document Category 1 CME credits by maintaining a written record that lists the date and type of activity, the program sponsor (if applicable) and the number of credits earned, and shall retain each certificate of attendance or letter of attestation issued by a program sponsor. Licensees shall document Category 2 CME credits and credits certified pursuant to 243 CMR 2.06(5)(d)4. by maintaining a written record that lists the approximate number of hours spent on each type of CME activity. Such records shall be maintained for no less than one full license renewal cycle after the credits have been earned and must be available for Board inspection upon request.
  3. The Board, by majority vote, may certify that any activity, course or training deemed appropriate shall be eligible for the equivalent of Category 1 or Category 2 credit for purposes of license renewal in Massachusetts.
- (i) Waiver of a CME Requirement.
  1. A licensee may apply to the Board for a waiver of the portion of the CME requirements that he or she cannot meet. The licensee must submit the waiver request to the Board no later than 30 days prior to the license renewal date.
  2. A waiver request must include the following written information:
    - a. An explanation of the licensee's failure to complete the CME requirements;
    - b. A listing of the CME credit hours that the licensee believes that he or she has earned; and
    - c. The licensee's plan for completing the CME requirements.
  3. The Board in its discretion will grant a waiver of the CME requirement. The grounds for waiver include, but are not limited to:
    - a. Prolonged illness of the licensee; and
    - b. Inaccessibility or unavailability of CME programs.
  4. Licensees granted a waiver by the Board will be given additional time to complete the Board's CME requirement. Licensees required (by the terms of a waiver or otherwise) to make up a deficiency in CME credits may apply those credits only to the period in which the deficiency arose.
- (7) Lapsed License Status.
  - (a) Effect of a Lapsed License. A license not renewed shall lapse at 11:59 P.M. on the license renewal date. A licensee whose license has lapsed shall not practice medicine. Continued practice of medicine following the lapse of the license is the unauthorized practice of medicine, and shall be referred to the Enforcement Division of the Board and to law enforcement.
  - (b) Reviving a Lapsed License. A licensee whose license has lapsed may petition the Board, upon submission of a lapsed license application and payment of the required fee, to revive his or her license.
    1. The Board shall require the licensee to satisfy such continuing medical education requirements as have accumulated during the period of the lapse, including the EHR Proficiency requirement, or such CME requirements as determined by the Board. The Board shall require that the licensee reinstate appropriate professional malpractice liability requirements.

## 2.06: continued

2. If the Board has reason to believe the lapsed licensee has committed a violation of law or regulation, or has deviated from good and acceptable standards of medical practice, the matter will be forwarded to the Enforcement Division. The Enforcement Division will review the lapsed license application and if necessary, investigate the matter as an open complaint. The Board may defer action on the lapsed licensee renewal pending completion of the investigation or 180 days after the Board's receipt of a complete lapsed license application, whichever is shorter, or, should the Board issue a Statement of Allegations against the lapsed licensee, pending completion of the adjudicatory process by the Board. The 180-day period allowed for investigation shall be extended by any period of time during which the licensee is unavailable or fails to cooperate with the Board.

3. Where a license has lapsed during the pendency of a temporary suspension or final order of suspension, and the temporary or final order of suspension has been vacated, the lapsed licensee may renew his or her license under the renewal processes set forth in 243 CMR 2.06. The renewal application must be completed and filed with the Board within 60 days of the temporary suspension having been vacated. All information and responses in the application must cover the time period commencing on the date the licensee signed his or her last license application that was granted by the Board. Such license renewal shall not constitute a waiver of the Board's authority to issue a restricted license or otherwise take disciplinary action against the license or physician. Any action taken by the Board on the license renewal application or against the physician shall be subject to and in accordance with 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedure*, and M.G.L. c. 30A. After the 60-day period, the physician must seek to revive his or her license under 243 CMR 2.06(7)(b)1. and 2.

2.07: General Provisions Governing the Practice of Medicine

243 CMR 2.07 addresses some issues relating to the practice of medicine by licensees. The Practice of Medicine is defined in 243 CMR 2.01(4).

(1) Acupuncture. Acupuncture is the practice of medicine and may be performed only by a full licensee or by an acupuncturist duly licensed and registered in the Commonwealth.

(2) Interpretation of Blood Pressure Measurements. The interpretation of blood pressure recordings by any method is the practice of medicine.

(3) Standards Pertaining to the Practice of Medicine by Medical Students. A full licensee may permit a medical student to practice medicine under his or her supervision and subject to the provisions of M.G.L. c. 112, § 9A. The full licensee's supervision of the medical student's activities must meet the following requirements:

(a) The full licensee requires that the medical student is identified as a medical student to each patient and informs patients that they have a right to refuse examination or treatment by the medical student.

(b) The full licensee ensures that the medical student practices medicine in accordance with accepted medical standards.

(4) Delegation of Medical Services. There shall be no delegation of medical services to an individual who is not licensed to perform those services in Massachusetts.

Nothing in 243 CMR 2.07(4) shall be construed as permitting an unauthorized person to perform activities requiring a license to practice medicine. A full licensee who knowingly permits, aids or abets the unlawful practice of medicine by an unauthorized person is subject to discipline pursuant to M.G.L. c. 112, § 5, and 243 CMR 1.05(6).

(5) The Controlled Substances Act. A licensee who violates M.G.L. c. 94C or any regulation promulgated thereunder also violates 243 CMR 2.00.

(6) Hospital Privileges. (Reserved).

(7) Retirement from the Practice of Medicine (Reserved).

2.07: continued

(8) Duty to Report Registration Changes Occurring Outside of the Application or Renewal Process. Pursuant to 243 CMR 2.04, an applicant or licensee shall notify the Board in writing when information provided on his or her licensing or renewal application changes during the application or renewal period. The application or renewal period means the day the initial application or renewal application is filed to the day the license is issued or renewed. In addition, a licensee has a duty to report to the Board when the following information provided to the Board as part of the registration process changes. The licensee shall notify the Board in writing within 30 days of when the change occurred. The applicant or licensee shall keep the following information current:

(a) Home and Business Address. A licensee must report to the Board a change of home or business address within 30 days of the date of the change of address.

(b) Change of Name. An applicant or licensee who changes his or her name shall provide notice to the Board, within 30 days of the date of the name change, on a form prescribed by the Board.

NON-TEXT PAGE

2.07: continued

(c) Change in Sex. An applicant or licensee who changes his or her sex shall provide notice to the Board within 30 days.

(9) Discrimination Against Recipients of Public Assistance Prohibited.

(a) General Rule. A licensee may not discriminate against a person seeking medical services solely because the person is a recipient of public assistance. 243 CMR 2.07(9)(a) prohibits a licensee from acting differently toward a recipient of public assistance in any material manner and requires a licensee to provide medical services of the same quality and in the same manner to a recipient of public assistance as he or she would to any other person in similar circumstances who is not a recipient of public assistance.

(b) Limitations on General Rule. A licensee may act in any of the following ways without violating 243 CMR 2.07(9)(a):

1. The licensee may impose limits upon the availability of his or her services, in other than medical emergencies, which are based upon nondiscriminatory criteria, *e.g.*, professional training and experience;
2. The licensee may impose a limit upon the availability of his or her services, in other than medical emergencies, that requires a person seeking services to present reasonable evidence of the person's ability to pay for services prior to his or her rendition;
3. The licensee may withdraw from or decline to participate in the Commonwealth's medical assistance and medical benefits programs established by M.G.L. c. 118E; or
4. If the licensee is not a Provider within the meaning of M.G.L. c. 118E, § 8, the licensee may require personal payment of his or her usual charge for services by a person who is a beneficiary of the Commonwealth's medical assistance and medical benefits program, after he or she has informed the person, in a manner which the person understands, of the following:
  - a. He or she is not a Provider within the meaning of the laws regulating the Commonwealth's medical care and assistance program;
  - b. If the person nonetheless requests that the licensee provide medical services, the licensee will require the person to pay directly his or her usual charge for the services; and
  - c. Other physicians who are Providers and would not charge the person directly are available; and he or she states that, upon request, he or she will attempt to make a referral to a Provider physician.

(10) Provision of Medical Services in Emergencies.

(a) General Rule. A licensee shall render medical services to a person experiencing a medical emergency. A medical emergency is a set of circumstances that immediately threatens a person's life or is likely to cause serious injury absent the provisions of immediate professional assistance. A licensee shall assume that a person who is referred to him or her by another licensee for the purpose of securing medical services of an emergency nature is experiencing a medical emergency.

(b) Limitations on General Rule.

1. A licensee whose professional training or experience is insufficient to enable him or her to provide medical services of adequate quality to a person experiencing a medical emergency is excused from complying with the requirement of 243 CMR 2.07(10)(a). However, he or she must provide reasonable assistance to the person and make a reasonable attempt to secure competent medical services for the person.
2. A licensee whose professional training or experience, while not insufficient to enable him or her to provide medical services of adequate quality, is not as appropriate as that of another licensee or other competent source of assistance known to him or her, may refer a person experiencing a medical emergency to such an alternative source of services if, in the exercise of reasonable professional judgment, doing so would be in the person's best interests and he or she establishes through verbal communication with the source of services that the person will be seen promptly.

(c) Refusal to Provide Medical Services. A licensee may not refuse to provide medical services in the ordinary course of his or her practice to a person experiencing a medical emergency because the person is unable to pay for the services.

2.07: continued

(11) Advertising and Professional Notices by a Full Licensee.

- (a) A full licensee engaged in the practice of medicine may advertise for patients by means which are in the public interest. Advertising that is not in the public interest includes the following:
  - 1. Advertising that is false, deceptive, or misleading;
  - 2. Advertising that has the effect of intimidating or exerting undue pressure;
  - 3. Advertising that guarantees a cure; or
  - 4. Advertising that makes claims of professional superiority which a licensee cannot substantiate.
- (b) A full licensee may advertise fixed prices, or a stated range of prices, for specified routine professional services, provided such advertisement clearly states whether additional charges may be incurred for related services which may be required in individual cases.
- (c) A full licensee may advertise in any print or electronic media, including television, radio, or Internet, provided that he or she maintains a complete, accurate, and reproducible version of the audio and visual contents of that advertising for a period of three years. The licensee must furnish a complete copy of this advertising to the Board upon request. The cost of maintaining and providing this advertising copy shall be borne by the licensee.
- (d) A full licensee shall include in an advertisement or professional notice his or her name, business address and degree (M.D. or D.O.).
- (e) A full licensee may not represent that he or she holds a degree from a medical school other than that degree that appears on his or her application for registration and has been verified in accordance with the Board's requirements.

(12) Requirement to Respond to Board.

- (a) 30-day Period. A licensee shall respond within 30 days to a written communication from the Board or its designee and shall make available to the Board any relevant and authorized records with respect to an inquiry or complaint about the licensee's professional conduct. The 30-day period commences on the date the Board sends the communication by any method of mailing that provides confirmation of delivery to the licensee's mailing address of record with the Board.
- (b) Ten-day Order to Respond. If the licensee fails to respond to the initial request of the Board or its Committees within the 30-day period set forth 243 CMR 2.07(12)(a), the Board, or its Licensing, Data Repository or Complaint Committees, may issue an order that the licensee respond to its communication within ten days. The Ten-day Order to Respond is an administrative order. A licensee's failure to respond to a written communication from the Board under 243 CMR 2.07(12)(a) and to a Ten-day Order from a Board or its committees under 243 CMR 2.07(12)(b) may be considered grounds for a complaint under 243 CMR 1.03(5): *Grounds for Complaint*.

(13) Medical Records.

- (a) Length of Time to Maintain Patient Records. A licensee shall maintain a medical record for each patient that is complete, timely, legible, and adequate to enable the licensee or any other health care provider to provide proper diagnosis and treatment. Any records received from another health care provider involved in the care and treatment of the patient shall be maintained as part of the patient's medical record. With respect to patient records existing on or after January 1, 1990 and unless otherwise required by law, a licensee must maintain a patient's medical records for a minimum period of seven years from the date of the last patient encounter. However, if the patient is a minor on the date of the last patient encounter, the licensee must maintain the minor patient's records for a minimum period of either seven years from the date of the last patient encounter or until the patient reaches 18 years of age, whichever is the longer retention period. A licensee must maintain a patient's records in a manner which permits the former patient or a successor physician reasonable access to the records within the terms of 243 CMR 2.00. 243 CMR 2.00 applies to all licensees including, but not limited to, those with active, inactive, lapsed, suspended, revoked, resigned or retired status.
- (b) Providing Medical Records. Upon a patient's request, a licensee shall provide the following in a timely manner, to a patient, other licensee or other specifically authorized person:

2.07: continued

1. The opportunity to inspect that patient's medical record, except in the circumstances described at 243 CMR 2.07(13)(e);
  2. A copy of such record, except in the circumstances described at 243 CMR 2.07(13)(e);
  3. A copy of any previously completed report required for third-party reimbursement.
- (c) Fees. A licensee may charge a reasonable fee for the expense of providing the material enumerated in 243 CMR 2.07(13)(b); however, a licensee may not require prior payment of the charges for the medical services to which such material relates as a condition for making the records available. Charges for providing copies of medical records must be in compliance with M.G.L. c. 111, § 70, M.G.L. c. 112, § 12CC and 45 CFR 164.524(c)(4). Charges for providing copies of X-rays and similar documents not reproducible by ordinary photocopying may be at the licensee's actual cost.
- (d) Medical Record Requested in Relation to a Needs-based Benefit Program. A licensee shall not charge a fee of any applicant, beneficiary or individual representing said applicant or beneficiary if the record is requested for the purpose of supporting a claim or appeal under any provision of the Social Security Act or any federal or state financial needs-based benefit program. Any person for whom no fee shall be charged shall present reasonable documentation at the time of such record request that the purpose of such request is to support a claim or appeal under any provision of the Social Security Act or any federal or state financial needs-based benefit program.
- (e) Psychiatric Records. Licensees who devote a substantial portion of their time to the practice of psychiatry shall abide by the provisions of 243 CMR 2.07(13). Pursuant to M.G.L. c. 112, § 12CC, if, in the reasonable exercise of his or her professional judgment, such a licensee determines that providing the entire medical record would adversely affect the patient's well-being, the licensee shall make a summary of the record available to the patient. If a patient continues to request the entire record, notwithstanding the licensee's determination, the licensee shall make the entire record available to the patient's attorney, with the patient's consent, or the patient's legal representative, or to such other psychotherapist as designated by the patient.
- (f) Medical Records of Deceased Physician. The executor or administrator of a deceased physician licensed pursuant to M.G.L. c. 112, § 2, shall retain medical records in existence upon the death of the physician and provide reasonable access to patients' requesting their medical records. The executor or administrator must maintain a patient's medical records for a minimum period of seven years from the date of the last patient encounter.
- (14) Breast Cancer. (Reserved).
- (15) Medicare Payments. When a licensee accepts for treatment a beneficiary of health insurance under Title XVIII of the Social Security Act (Medicare), the licensee shall not charge to or collect from such beneficiary any amount in excess of the Medicare Physician Fee Schedule charge for that service as determined by the United States Secretary of Health and Human Services and as administered by the Centers for Medicare and Medicaid Services.
- (16) Mandatory Professional Malpractice Liability Insurance. As a condition of rendering any direct or indirect patient care in the Commonwealth, a licensee must obtain medical malpractice insurance as follows, except as provided in 243 CMR 2.07(16)(d):
- (a) Professional Malpractice Liability Insurance shall include only insurance or self insurance coverage provided by an entity which provides certification to the Board, upon request, or the Division of Insurance, by a Member of the Casualty Actuarial Society, that funding of the entity is adequate to provide the coverage required under 243 CMR 2.07(16).
  - (b) The coverage amount shall be at least \$100,000 per claim, with a minimum annual aggregate of not less than \$300,000, unless otherwise established by law. Coverage may be provided on an individual or shared limit basis.
  - (c) 243 CMR 2.00 shall not preclude any hospital or other health care facility from requiring greater coverage amounts as a condition of appointment or granting privileges.
  - (d) A Health Care Provider, for purposes of 243 CMR 2.07(16) only, shall mean a health care provider as defined in M.G.L. c. 175, § 193U, and shall not apply to the following categories of licensees:

2.07: continued

1. Licensees who are not engaged in the practice of medicine in the Commonwealth.
  2. Licensees whose patient care in the Commonwealth is limited to professional services rendered at or on behalf of federal, state, county or municipal health care facilities.
  3. Licensees holding only limited registrations pursuant to M.G.L. c. 112, § 9, who are insured through the programs designated on the licensees' certificates of registration.
  4. Administrative licensees.
- (e) In lieu of obtaining such professional malpractice liability insurance, the licensee may petition the Board for permission to obtain a suitable bond or other indemnity against liability for professional malpractice, in the amounts specified in 243 CMR 2.07(16)(b).
- (f) Coverage required by 243 CMR 2.00 shall be continued until the expiration of any statute of limitations relevant to the events or occurrences covered. Compliance may be through occurrence coverage or claims made with appropriate tail coverage.
- (17) Reporting Requirements. (Reserved).
- (18) Excessive Treatment and Billing of People Involved in Automobile Accidents. (Reserved).
- (19) Self-prescribing and Prescribing for Family Members. A licensee is prohibited from prescribing controlled substances in Schedules II, III, and IV for his or her own use. Except in an emergency, a licensee is prohibited from prescribing Schedule II substances to a member of his or her immediate family, including a spouse (or equivalent), parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or other relative residing in the same residence as the licensee. A licensee who prescribes any controlled substance to a member of his or her immediate family, as defined herein, shall maintain a medical record for such person.
- (20) Prescribing Anabolic Steroids. A licensee is prohibited from prescribing anabolic steroids for the purpose of enhancing a patient's athletic ability or performance.
- (21) Prescribing Anorectics. A licensee is prohibited from prescribing any controlled substance in Schedule II for its anorectic effect.
- (22) Business Organizations and the Practice of Medicine.
- (a) A licensee may practice medicine through the following business organizations:
    1. A professional corporation pursuant to M.G.L. c. 156A;
    2. A nonprofit organization, a nonprofit hospital services corporation organized under M.G.L. c. 176A, a nonprofit medical services corporation organized under M.G.L. c. 176B;
    3. A limited liability company organized under M.G.L. c. 156C, provided there are no LLC provisions limiting or eliminating the licensee's liability for intentional tort or negligence;
    4. A partnership (including a registered limited liability partnership) organized under M.G.L. c. 108A, provided the partnership has no provisions limiting or eliminating the licensee's liability for intentional torts or negligence; or
    5. An organization similar to those organizations described in 243 CMR 2.07(22)(a)1. through 4. and organized under a comparable law of any other United States jurisdiction.
  - (b) Nothing in 243 CMR 2.07(22) shall prohibit a licensee from practicing medicine as an employee of a licensed health care facility.
- (23) Exemption for Reports of Drug or Alcohol Misuse to the Board under M.G.L. c. 112, § 5F.
- (a) Requirements for Reporting Exemption to Apply. A health care provider as defined by M.G.L. c. 111, § 1, who is required to report a physician to the Board pursuant to M.G.L. c. 112, § 5F, is exempt from filing such a report if all four of the following conditions are present:
    1. Reasonable Basis to Believe Impairment. The health care provider has a reasonable basis to believe that the physician is or has been impaired by, dependent upon or misusing alcohol or drugs such that a report could be required under M.G.L. c. 112, § 5F;



2.07: continued

2. No Violation of Law or Regulation. The physician has not violated any statute or regulation, including M.G.L. 94C, and including any Board statute or regulation;
  3. No Allegation of Patient Harm or Impairment at the Workplace or While on Call. The physician's involvement with alcohol or drugs has not involved an allegation of patient harm or any impairment occurring at the workplace or while the physician is "on call"; and
  4. Confirmation of Compliance with the Treatment Program. The physician is currently in compliance with a drug or alcohol program, approved under 243 CMR 2.07(23)(b), and the health care provider obtains direct confirmation from such drug or alcohol program, within 30 days of acquiring the "reasonable basis to believe" under 243 CMR 2.07(23)(a), that the physician is in compliance with such program. If the health care provider fails to obtain direct confirmation from such program or if the physician at any time fails to comply with such program, the exemption to the reporting requirement set forth in 243 CMR 2.07(23) ceases and the health care provider must report the impairment to the Board as required by M.G.L. c. 112, § 5F.
- (b) Requirements for Drug or Alcohol Program to Qualify for 243 CMR 2.07(23).
1. The drug or alcohol program must be approved by a majority vote of the Board. Approval may be withdrawn, at any time, for cause, by majority vote of the Board and with reasonable advance notice to the program of the reasons for the proposed withdrawal of approval and an opportunity to dispute such reasons. However, nothing herein shall be construed to provide a right to an adjudicatory hearing pursuant to M.G.L. c. 30A.
  2. The drug or alcohol program shall require as a condition of the physician's participation that the physician consent, pursuant to 42 CFR 1, subpart A, part 2, subsection C, to disclosure of relevant information to the Board, under any of the following conditions:
    - a. If the physician fails to correct, within a reasonable period of time, a failure to provide documentation of his or her continuing freedom from unauthorized substance use;
    - b. If the physician is known by the program to be in a state of unauthorized substance use, or if the physician is in a state of unauthorized substance use after signing his or her contract with the program;
    - c. If the program has a reasonable basis to believe that the physician, for any reason, cannot render professional services without undue risk to the public;
    - d. If the physician revokes consent to disclose information to the Board during the course of his or her contract with the program; or
    - e. If the physician terminates his or her contract with the program for any reason other than his or her successful recovery, in which the program concurs.
  3. The drug or alcohol program requires that the physician consent to confirmation to the reporter, pursuant to federal regulations, that the physician is participating in the program, to the extent that the reporter needs such confirmation pursuant to 243 CMR 2.07(23)(c).
- (24) Standards for Reading and Interpreting Mammography.
- (a) Initial Qualification. Pursuant to M.G.L. c. 112, § 5L, a licensee may read and interpret mammography only if the licensee meets the following criteria:
1. Is licensed to practice under M.G.L. c. 112, § 2; and
  2. Has American Board of Radiology (ABR) or American Osteopathy Board of Radiology (AOBR) certification, or Royal College of Physicians and Surgeons of Canada (RCPSC) certification; or
  3. Has successfully completed and graduated from an accredited radiology residency within the past 24 months; or
  4. Has had at least three months of documented formal training in the interpretation of mammograms and in topics relating to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of 243 CMR 2.07(24)(a).

2.07: continued

(b) Experience for Initial Qualification. The licensee has read and interpreted an average of no less than 480 mammograms in the prior year, and continues to perform mammograms at this frequency.

(c) CME Requirements for Initial Qualification. If initially qualified before April 28, 1999, the licensee has successfully completed or taught a minimum of 40 hours postgraduate Category 1 CME instruction in mammography interpretation; or, if initially qualified after April 28, 1999, has successfully completed or taught a minimum of 60 hours of Category 1 CME instruction in mammography interpretation; and of the Category 1 CME instruction hours required in 243 CMR 2.07(24)(c), 15 hours of the total Category 1 CME hours were acquired within the three years immediately prior to the licensee's qualification date.

(d) Renewal Qualifications. The licensee shall interpret 960 mammographic examinations over a 24-month period, and shall take at least 15 hours of Category 1 CME in mammography in a 36-month period while performing the duties of an Interpreting Physician.

(e) New Mammographic Modalities. Before an Interpreting Physician may independently interpret mammograms produced by a new mammographic modality, *i.e.*, a mammographic modality in which the physician has not previously been trained, the Interpreting Physician shall have at least eight hours of training in the new mammograms.

(f) Interpreting Physician. In addition to the requirements of 243 CMR 2.07, a licensee acting as an Interpreting Physician shall meet the requirements of the Radiation Control Board as set forth in 105 CMR 127.014: *Requirements of the Interpreting Physician.*

(g) Responsible Physician. A licensee acting as a responsible physician, as defined in the regulations of the Radiation Control Program of the department of public health, at 105 CMR 127.005: *Definitions*, must:

1. Meet the requirements of 243 CMR 2.07(24)(a)1. through 3.;
2. Actively practice medicine at least ten hours per week;
3. Have read and interpreted 960 mammograms in the prior 24 months;
4. Continues to perform mammograms at this frequency;
5. Has successfully completed or taught a minimum of 40 hours postgraduate instruction in mammography prior to beginning mammography activities; and
6. Completes or teaches 15 hours of Category 1 CME every 36 months while performing the duties of a Responsible Physician.

(25) Prescribing Hydrocodone-only Extended-release Medication. Prior to prescribing a hydrocodone-only extended release medication that is not in an abuse deterrent form, a licensee must:

- (a) Thoroughly assess the patient, including an evaluation of the patient's risk factors, substance abuse history, presenting condition(s), current medication(s), a determination that other pain management treatments are inadequate, and a check of the patient's data through the online Prescription Monitoring Program;
- (b) Discuss the risks and benefits of the medication with the patient;
- (c) Enter into a Pain Management Treatment Agreement with the patient that shall appropriately address drug screening, pill counts, safe storage and disposal and other requirements based on the patient's diagnoses, treatment plan, and risk assessment, unless a Pain Management Treatment Agreement is not clinically indicated due to the severity of the patient's medical condition;
- (d) Supply a Letter of Medical Necessity as required by the Board of Registration in Pharmacy pursuant to 247 CMR 9.04(8)(c); and
- (e) Document 243 CMR 2.07(25)(a) through (d) in the patient's medical record.

The purpose of 243 CMR 2.07(25) is to enhance the public health and welfare by promoting optimum therapeutic outcomes, avoiding patient injury and eliminating medication errors. Nothing in 243 CMR 2.07(25) shall alter the standard of care a licensee must use when prescribing any Schedule II, III or IV controlled substance.

## 2.07: continued

(26) Informed Consent. A physician has the obligation to obtain and record a patient's written informed consent before diagnostic, therapeutic or invasive procedures, medical interventions or treatments. Informed consent means that the physician has disclosed and explained to the patient's satisfaction the process used to arrive at the medically reasonable and recommended procedure, intervention or treatment, based on reliable evidence of the expected benefit and risk of each alternative, free from any impermissible bias. Written informed consent means that the patient, who has demonstrated capacity, or the patient's representative, has been given ample opportunity to ask questions, with all questions having been answered to the patient's or representative's satisfaction, and with the patient or representative giving consent in writing to the procedure, intervention or treatment.

(a) Definitions. For purposes of 243 CMR 2.07, and 243 CMR 3.10: *Qualified Patient Care Assessment Program - Specified Requirements in the Practice of Medicine*, the terms listed in 243 CMR 2.07(26) have the following meanings:

Attending Physician/Primary Operator means the physician licensed under M.G.L. c. 112, §§ 2 through 9B who has been credentialed by the health care facility to independently perform the patient's procedure, medical intervention or treatment and to supervise physician trainees or physician extenders. The attending physician/primary operator is responsible for discussing the risks and benefits of the procedure, intervention or treatment and obtaining the patient's written informed consent.

Physician means a person licensed to practice medicine under M.G.L. c. 112, §§ 2 through 9B.

Physician Extender means a person who is participating in the patient's procedure, medical intervention or treatment and who is under the direct supervision of the attending physician/primary operator. A physician extender may be a resident, a fellow, a physician assistant, an advanced practice registered nurse or other person authorized by the health care facility to participate in the procedure, intervention or treatment and who is directly supervised by the attending physician/primary operator.

(b) Written Policy on Written Informed Consent. Every physician shall have written policies and procedures designed to address the written informed consent process. At a minimum, the policies should address:

1. The medical procedures, interventions and treatments for which informed consent is required and the content of the information provided.
2. Designation of persons responsible for obtaining informed consent from the patient.
3. How the written informed consent will be documented.
4. Designation of appropriate persons, other than the patient, from whom consent may be obtained, and the circumstances when consent may be obtained from a person other than the patient.

(c) When Informed Consent Is Necessary. Written consent shall be obtained before all diagnostic, therapeutic or invasive procedures, medical interventions or treatments where disclosure of significant medical information, including risks involved, would assist a patient in making an informed decision whether to undergo the proposed procedure, medical intervention or treatment.

(d) Duty of Attending Physician/Primary Operator. It shall be the responsibility of the attending physician/primary operator to obtain the written informed consent of the patient, and to discuss sufficient medical information to enable the patient to decide whether to undergo the proposed procedure, intervention or treatment. Although the attending physician/primary operator is responsible for informing the patient, health care facility personnel may assist in the completion of written informed consent documentation.

(e) Informed Consent Shall Be Clear and Detailed. A patient's written informed consent shall be documented in writing with sufficient clarity and detail so as to satisfy the reader that the patient was given and understood the medical information provided. The written informed consent shall clearly identify the attending physician/primary operator of record. The attending physician/primary operator shall sign the informed consent prior to the procedure, intervention or treatment.

2.07: continued

(f) Patient's Medical Record Must Reflect Who Will Participate in the Procedure. Prior to the procedure, the attending physician/primary operator must inform the patient of who will be participating in the procedure, intervention or treatment, including the names of all physician extenders who are under the direct supervision of the attending physician/primary operator. The attending physician/primary operator shall note the physician extenders on the written informed consent form.

(g) Patient's Medical Record Must Reflect Any Absence of Attending Physician/Primary Operator. The attending physician/primary operator at a medical procedure, intervention or treatment requiring the patient's written informed consent shall be responsible for including in the patient's medical record, or having included, written documentation of the attending physician's presence or absence during the procedure, intervention or treatment. If the attending physician/primary operator was absent for any part of the procedure, the medical record shall reflect the time of the absence(s) and who was the attending physician/primary operator during the absence(s).

(h) A patient is entitled to a copy of the written informed consent.

(27) Infection Prevention and Control.

(a) Whether practicing medicine in a surgical or in an outpatient setting, a physician must implement and maintain infection control policies and procedures. These policies and procedures should be tailored to the healthcare setting and to the patient population and reassessed on a regular basis.

(b) The following are the minimum infection prevention practice areas that apply to all patient care in any setting. They include:

1. Hand hygiene;
2. Use of Personal Protective Equipment (PPE) (*e.g.*, gloves, gowns masks);
3. Safe injection practices;
4. Safe handling of potentially contaminated equipment or surfaces; and
5. Respiratory hygiene/cough etiquette.

2.08: Physician Assistants

(1) Definition of a Supervising Physician. Supervising physician means a full licensee who supervises a physician assistant. A physician assistant's supervising physician may use a physician assistant to assist in the process of gathering data necessary to make decisions and institute patient care plans. A physician assistant may not supplant a licensee as the principal medical decision maker.

(2) Physician Supervision of a Physician Assistant. A full licensee must supervise the activities of a physician assistant. A supervising physician shall afford supervision adequate to assure that:

(a) The physician assistant provides medical services in accordance with accepted medical standards. 243 CMR 2.08 does not require the physical presence of the supervising physician whenever a physician assistant renders medical services.

(b) The physician assistant informs each patient that he or she is a physician assistant. A physician assistant renders medical services only under the supervision of a full licensee, except in life-threatening emergencies when no licensee is available.

(c) The physician assistant wears a name tag which identifies him or her as a physician assistant.

(d) The supervising physician reviews diagnostic and treatment information, as agreed upon by the supervising physician and the physician assistant, in a timely manner consistent with the patient's medical condition.

(e) On follow up care, hospital visits, nursing home visits, attending the chronically ill at home, and in similar circumstances in which the supervising physician has established a therapeutic regimen or other written protocol, the physician assistant checks and records a patient's progress and reports the patient's progress to the supervising physician. Supervision is adequate under 243 CMR 2.08(2) if it permits a physician assistant who encounters a new problem not covered by a written protocol or which exceeds established parameters to initiate a new patient care plan and consult with the supervising physician.

(f) In an emergency, the physician assistant renders emergency medical services necessary to avoid disability or death of an injured person until a licensee arrives.

## 2.08: continued

(g) When a supervising physician is unable or unavailable to be the principal medical decision maker, another licensed physician must be designated to assume temporary supervisory responsibilities of a physician assistant. The name and scope of responsibility for the physician providing the temporary supervision must be readily ascertainable from the records kept in the ordinary course of business which are available to patients. The supervising physician(s) of record is ultimately responsible for insuring that each task performed by a physician assistant is properly supervised.

(3) Delegation of Medical Services to a Physician Assistant.

(a) A supervising physician may permit physician assistants to perform those services which are under the authority of the supervising physician including, but not limited to, prescribing by a physician assistant licensed to prescribe pursuant to M.G.L. c. 94C, and as determined by the supervising physician's assessment of his or her training or experience, and within the scope of services for which the supervising physician can provide adequate supervision to ensure that accepted medical standards are followed.

(b) Physician assistants may approach patients of all ages and with all types of conditions, elicit histories, perform examinations, perform and interpret diagnostic studies, perform therapeutic procedures, instruct and counsel patients regarding physical and mental health issues, respond to life threatening situations, and facilitate the appropriate referral of patients, consistent with his or her supervising physician's scope of expertise and responsibility and delegated to him or her by the supervising physician. Nothing contained in 243 CMR 2.08 shall be construed to allow a physician assistant to:

1. give general anesthesia;
2. perform procedures involving ionizing radiation; except where authorized to operate fluoroscopic X-ray systems pursuant to radiation control program regulations at 105 CMR 120.405(K): *Operator Qualifications*, and in compliance with 243 CMR 2.08(6) and the Board of Registration of Physician Assistants at 263 CMR 5.07: *Physician Assistants Authorized to Operate Fluoroscopic X-ray Systems and to Perform Fluoroscopic Procedures*; or
3. render a formal medical opinion on procedures involving ionizing radiation.

(c) Supervision of Major Invasive Procedures. Where major invasive procedures are allowed, such procedures shall be identified and shall be undertaken under specific written protocols, available to the Board upon request, developed between the supervising physician and the physician assistant, that must specify the level of supervision the service requires, e.g., personal (physician in room), direct (physician in building), or general (physician available by telephone).

(4) Billing for Services of a Physician Assistant. A physician assistant may not bill separately for services rendered.

(5) Prescriptive Practices of a Physician Assistant.

(a) Definition of a Supervising Physician. Supervising physician means a licensee holding an unrestricted full license in the Commonwealth who:

1. has completed ACGME-accredited, AOA accredited or accredited Canadian postgraduate medical training in a specialty area appropriately related to the physician assistant's area of practice, is board-certified in a specialty area appropriately related to the physician assistant's area of practice, or has hospital admitting privileges in a specialty area appropriately related to the physician assistant's area of practice;
2. holds valid registration(s) from the Massachusetts Department of Public Health and the U.S. Drug Enforcement Administration to issue written or oral prescriptions or medication orders for controlled substances;
3. signs mutually developed and agreed upon guidelines with the physician assistant engaged in prescriptive practice; and
4. reviews the physician assistant's prescriptive practice at least every three months and provides ongoing direction to the physician assistant regarding prescriptive practice, or, pursuant to 263 CMR 5.04(3)(g), temporarily delegates such review and direction to another licensee holding an unrestricted full license in the Commonwealth who meets the requirements of 243 CMR 2.08(5)(a)1. and 2..

2.08: continued

- (b) Physician Supervision of a Physician Assistant Engaged in Prescriptive Practice.
1. A supervising physician shall review and provide ongoing direction for the physician assistant's prescriptive practice in accordance with written guidelines mutually developed and agreed upon with the physician assistant pursuant to M.G.L. c. 112, § 9E, 263 CMR 5.00: *Scope of Practice and Employment of Physician Assistants* and 243 CMR 2.08, and signed by both parties. This supervision shall be provided as necessary, taking into account the education, the prescriptive authority under M.G.L. c. 94C, the training and experience of the physician assistant, the nature of the physician assistant's practice, and the availability to the physician assistant of clinical back-up by physicians, to ensure that the physician assistant is providing patient care services in accordance with accepted standards of practice.
  2. A supervising physician shall sign prescriptive practice guidelines only with those physician assistants for whom he is able to provide supervision consistent with 243 CMR 2.08(5)(a) and (b), taking into account factors including, but not limited to, geographical proximity, practice setting, volume and complexity of the patient population, and the experience, training and availability of the supervising physician and the physician assistant(s).
- (c) Development, Approval and Review of Guidelines for a Physician Assistant Engaged in Prescriptive Practice. A physician who supervises a physician assistant engaged in prescriptive practice shall do so in accordance with written guidelines mutually developed and agreed upon with the physician assistant, and signed by both parties. Such guidelines shall be reviewed annually, and dated and initialed by both the supervising physician and the physician assistant at the time of each review. The guidelines may be altered at any time upon agreement by the supervising physician and physician assistant; any such changes shall be initialed and dated by both parties. In all cases, the written guidelines shall:
1. identify the supervising physician;
  2. include a defined mechanism for the delegation of supervision to another physician including, but not limited to, duration and scope of the delegation;
  3. specifically describe the nature and scope of the physician assistant's practice;
  4. identify the types and classes of medication(s) to be prescribed, specify any limitations on medications to be prescribed, indicate the quantity of any medications, including initial dosage limits and refills, and describe the circumstances in which physician consultation or referral is required;
  5. include a defined mechanism to monitor prescribing practices, including documentation of review by the supervising physician at least every three months;
  6. include protocols for the initiation of intravenous therapies and Schedule II drugs;
  7. specify the frequency of review of initial prescriptions or changes in medication of controlled substances; any prescription or medication order issued by a physician assistant for a Schedule II controlled substance, as defined in 105 CMR 700.002: *Schedules of Controlled Substances*, shall be reviewed by his or her supervising physician, or by a temporary supervising physician designated pursuant to 263 CMR 5.04(3)(g), within 96 hours after its issuance;
  8. specify the types and quantities of Schedule VI medications which may be ordered by the physician assistant from a drug wholesaler, manufacturer, laboratory or distributor for use in the practice setting in question;
  9. identify and specify any limitations on the initiation or renewal of prescriptions which are not within the ordinary scope of practice for the specific work setting in question, but which may be needed to provide appropriate medical care; and
  10. conform to M.G.L. c. 94C, 105 CMR 700.000: *Implementation of M.G.L. c. 94C*, M.G.L. c. 112, § 9E, 263 CMR 5.00: *Scope of Practice and Employment of Physician Assistants* and 243 CMR 2.08.
- (d) The use of pre-signed prescription blanks or forms is prohibited.
- (e) The Board may request at any time an opportunity to review the guidelines under which a physician is supervising a physician assistant or physician assistants engaged in prescriptive practice. Failure to provide guidelines to the Board is a basis for and may result in disciplinary action. The Board may require changes in such prescriptive practice guidelines if it determines that they do not comply with 243 CMR 2.08 and accepted standards of medical practice. The Board may also disapprove guidelines in their entirety if it determines that the supervising physician is incapable of providing adequate supervision to the physician assistant(s) engaged in prescriptive practice.

## 2.08: continued

(f) The Board may request at any time documentation of review by the supervising physician of the physician assistant engaged in prescriptive practice. Failure to provide documentation to the Board may be the basis for disciplinary action against the physician.

(6) Physician Assistants Authorized to Operate Fluoroscopic X-ray Systems.

(a) Definitions Applicable to 243 CMR 2.08(6)

1. Fluoroscopic Procedure means the production and display of serial X-ray images for the purpose of observing real-time motion of anatomical structures.
2. Supervising Physician for the purpose of 243 CMR 2.08(6), means a physician holding an unrestricted full license in the Commonwealth who:
  - a. Is board-certified in radiology, or has been trained in the subjects identified in the radiation control program regulations at 105 CMR 120.405(K): *Operator Qualifications*;
  - b. Signs mutually developed and agreed upon guidelines, described in 243 CMR 2.08(6), with each physician assistant authorized to operate fluoroscopic X-ray systems whom such physician supervises; and
  - c. Reviews the physician assistant's performance of fluoroscopic procedures at least once every three months and provides ongoing direction to the physician assistant regarding such procedures or, pursuant to the regulations of the Board of Registration of Physician Assistants (263 CMR), temporarily delegates such review and direction to another physician holding an unrestricted full license in the Commonwealth who meets the requirements of 243 CMR 2.08(6)(a)2.
3. Physician Assistant Authorized to Operate Fluoroscopic X-ray Systems means a physician assistant who has submitted documentation to the facility where he or she works demonstrating that he or she meets the requirements set out in the radiation control program regulations at 105 CMR 120.405(K): *Operator Qualifications*.
4. Fluoroscopy means a technique for generating X-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term radioscopy in the standards of the International Electrotechnical Commission.

(b) Physician Supervision of a Physician Assistant Authorized to Operate Fluoroscopic X-ray Systems. A supervising physician shall review and provide ongoing direction for a physician assistant authorized to operate fluoroscopic X-ray systems in accordance with written guidelines mutually developed and agreed upon with the physician assistant pursuant to M.G.L. c. 112, § 9E, 263 CMR 5.07: *Physician Assistants Authorized to Operate Fluoroscopic X-ray Systems and to Perform Fluoroscopic Procedures* and 243 CMR 2.08(6)(c). Such guidelines shall be developed, signed and dated by both parties prior to any fluoroscopic practice by the physician assistant pursuant to such guidelines. In addition, a physician who is board-certified in radiology or who meets the requirements set out in 105 CMR 120.405(K): *Operator Qualifications*, shall supervise the physician assistant each time the physician assistant operates a fluoroscopic X-ray system. The level of supervision necessary for each procedure shall be identified in the written guidelines.

1. The supervising physician shall provide supervision of the physician assistant authorized to operate fluoroscopic X-ray systems as necessary, taking into account the education, training and experience of the physician assistant, the nature of the physician assistant's practice, and the availability to the physician assistant of clinical backup support by physicians, to ensure that the physician assistant is operating the fluoroscopic X-ray systems in accordance with accepted standards of medical practice.
2. A supervising physician shall sign fluoroscopic X-ray system practice guidelines only with those physician assistants for whom such physician is able to provide the supervision required by 243 CMR 2.08(6)(b), taking into account factors including, but not limited to, geographical proximity, practice setting, volume and complexity of the patient population, and the experience, training and availability of the supervising physician and the physician assistant(s).

## 2.08: continued

(c) Development, Approval and Review of Practice Guidelines for a Physician Assistant Authorized to Operate Fluoroscopic X-ray Systems. A physician who supervises a physician assistant authorized to operate fluoroscopic X-ray systems shall do so in accordance with written practice guidelines mutually developed and agreed upon with the physician assistant, and signed by both parties. The supervising physician and the physician assistant shall review, initial and date such guidelines annually. The guidelines may be revised at any time upon written agreement by the supervising physician and physician assistant; any such changes shall be initialed and dated by both parties at the time of the revision. In all cases, the written guidelines shall:

1. Identify the supervising physician by name;
2. Identify by name each physician who will provide supervision over the physician assistant's operation of a fluoroscopic X-ray system, and describe each physician's qualifications to provide such supervision, as set out in 243 CMR 2.08(6)(a)(2);
3. Provide that supervision shall be required whenever a physician assistant operates a fluoroscopic X-ray system and that a supervising physician shall be readily available, which means a supervising physician must be present in the facility at the time of the operation of the fluoroscopic system;
4. Include a defined mechanism for the delegation of supervision to another physician who is qualified to operate fluoroscopic X-ray systems pursuant to 105 CMR 120.405(K): *Operator Qualifications* including, but not limited to, duration and scope of the delegation;
5. Describe the nature of the supervising physician's practice and practice location;
6. Specifically describe the nature and scope of the physician assistant's practice;
7. Identify the types of procedures in which the physician assistant will operate fluoroscopic X-ray systems, including any limitations on the physician assistant's operation of fluoroscopic X-ray systems;
8. Include a defined mechanism to monitor the physician assistant's operation of fluoroscopic X-ray systems, including documentation of review by the supervising physician at least once every three months;
9. Describe the procedure for providing clinical backup support to the physician assistant in an emergency situation; and
10. Conform to 105 CMR 120.405(K): *Operator Qualifications*; 263 CMR 5.07: *Physician Assistants Authorized to Operate Fluoroscopic X-ray Systems and to Perform Fluoroscopic Procedures*; and 243 CMR 2.08(6).

(d) The Board may request at any time an opportunity to review the fluoroscopic X-ray system practice guidelines under which a physician is supervising a physician assistant authorized to operate fluoroscopic X-ray systems. A supervising physician's failure to have developed fluoroscopic X-ray system practice guidelines consistent with 243 CMR 2.08(6), or failure to provide such guidelines to the Board upon request may be a basis for disciplinary action against the physician. The Board may require changes in such fluoroscopic X-ray system practice guidelines if it determines that the guidelines do not comply with 243 CMR 2.08 and accepted standards of medical practice. The Board may disapprove guidelines in their entirety if it determines that the supervising physician is not able to provide adequate supervision to the physician assistant authorized to operate fluoroscopic X-ray systems.

(e) The Board may request at any time documentation of review by the supervising physician of the physician assistant authorized to operate fluoroscopic X-ray systems. Failure to provide such documentation to the Board upon request may be a basis for disciplinary action against the physician.

## 2.09: Administrative Duties of the Board (Reserved)

## 2.10: Advanced Practice Registered Nurse (APRN) Eligible to Engage in Prescriptive Practice

(1) Purpose. The purpose of 243 CMR 2.10 is to establish, pursuant to M.G.L. c. 112, §§ 80B, 80C, 80E, 80G, 80H and 80I and M.G.L. c. 94C, substantive standards governing the practice of medicine with respect to the supervision of Advanced Practice Registered Nurses (APRN) engaged in prescriptive practice. Such prescriptive practice is defined and regulated in 244 CMR 4.00: *Advanced Practice Registered Nursing*.



2.10: continued

(2) Advanced Practice Registered Nurses (APRN) Eligible to Engage in Prescriptive Practice. The following APRNs are eligible to register with the Department of Public Health pursuant to M.G.L. c. 94C and the U.S. Drug Enforcement Administration to engage in prescriptive practice.

(a) A Certified Nurse Midwife (CNM) means a registered nurse authorized to practice as a certified nurse midwife by the Board of Registration in Nursing pursuant to M.G.L. c. 112, §§ 80B, 80C and 80G, and 244 CMR 4.00: *Advanced Practice Registered Nursing*. Written guidelines governing the practice of a nurse midwife engaged in prescriptive practice shall also comply with the requirements of M.G.L. c. 112, §§ 80C, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

(b) A Certified Nurse Practitioner (CNP) means a registered nurse authorized to practice as a certified nurse practitioner by the Board of Registration in Nursing, pursuant to M.G.L. c. 112, §§ 80B and 80E, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

(c) A Psychiatric Clinical Nurse Specialist (PCNS) means a registered nurse authorized to practice as a psychiatric clinical nurse specialist by the Board of Registration in Nursing, pursuant to M.G.L. c. 112, § 80B and 80E, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

(d) A Certified Registered Nurse Anesthetist (CRNA) means a registered nurse authorized to practice as a nurse anesthetist by the Board of Registration in Nursing, pursuant to M.G.L. c. 112, §§ 80B and 80H, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

(e) A Clinical Nurse Specialist (CNS) means a registered nurse authorized to practice as a clinical nurse specialist by the Board of Registration in Nursing, pursuant to M.G.L. c. 112, § 80B, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

(3) Definitions. The following definitions apply only to 243 CMR 2.10.

Guidelines mean written instructions and procedures describing the methods that an APRN with prescriptive practice is to follow when managing medications or resolving a health care problem and which specifies those instances in which referral to or consultation with a physician is required for appropriate medication management. Guidelines shall also address procedures for the ordering of tests and therapeutics when appropriate.

Immediate Perioperative Care of a Patient means the period commencing on the day prior to surgery and ending upon discharge of the patient from post-anesthesia care.

Prescriptive Practice means issuing written or oral prescriptions or medication orders for controlled substances pursuant to a valid registration from the Massachusetts Department of Public Health under M.G.L. c. 94C and, as appropriate, the U.S. Drug Enforcement Administration.

Supervising Physician means a licensee holding an unrestricted full license in the Commonwealth who:

(a) has completed training in the United States approved by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or in Canada approved by the Royal College of Physicians and Surgeons in Canada (RCPSC) in a specialty area appropriately related to the APRN's area of practice, is board certified in a specialty area appropriately related to the APRN's area of practice, or has hospital admitting privileges in a specialty area appropriately related to the APRN's area of practice. A physician who collaborates with a Certified Psychiatric Clinical Nurse Specialist shall have completed training in psychiatry approved by the ACGME, AOA or the RCPSC, or be Board certified in psychiatry;

(b) holds valid registration(s) to issue written or oral prescriptions or medication orders for controlled substances from the Massachusetts Department of Public Health and the U.S. Drug Enforcement Administration;

(c) provides supervision to a certified nurse practitioner, a certified psychiatric clinical nurse specialist, or certified registered nurse anesthetist, as provided for in the applicable law or regulations of the Boards of Registration in Medicine and in Nursing (BORN) (244 CMR);

(d) APRN signs mutually developed and agreed upon prescriptive practice guidelines with the APRN; and

(e) reviews the prescriptive practice of a CNP, a PCNS or a CRNA as described in the guidelines.

2.10: continued

(4) Physician Supervision of an APRN Engaged in Prescriptive Practice.

- (a) A supervising physician shall review and provide ongoing direction for the APRN's prescriptive practice in accordance with written guidelines mutually developed and agreed upon with the APRN pursuant to 244 CMR: *Board of Registration in Nursing* and 243 CMR 2.10. This supervision shall be provided as is necessary, taking into account the education, training and experience of the APRN, the nature of the APRN's practice, and the physician's availability to provide clinical backup to ensure that the APRN is providing patient care in accordance with accepted standards of practice.
- (b) A supervising physician shall sign prescriptive practice guidelines only with those APRNs for whom he or she is able to provide supervision consistent with 243 CMR 2.10(2) and (3), taking into account factors including, but not limited to geographical proximity, practice setting, volume and complexity of the patient population, and the experience, training and availability of the supervising physician and the APRN(s).
- (c) A supervising physician shall not enter into guidelines, pursuant to 243 CMR 2.10, unless the APRN has professional malpractice liability insurance as required by 244 CMR 4.09: *Malpractice Insurance*.

(5) Development, Approval, and Review of Guidelines for an APRN Engaged in Prescriptive Practice.

- (a) A physician who supervises an APRN engaged in prescriptive practice shall do so in accordance with written guidelines mutually developed and agreed upon with the APRN.
- (b) In all cases, the written guidelines shall:
  - 1. identify the supervising physician and APRN;
  - 2. include a defined mechanism for the delegation of supervision to another physician including, but not limited to, the duration and scope of the delegation;
  - 3. describe the nature and scope of the APRN's prescribing practice;
  - 4. identify the types of medication(s) to be prescribed, specify any limitations on medications to be prescribed; and describe the circumstances in which physician consultation or referral is required;
  - 5. describe the use of established procedures for the treatment of common medical conditions which the nurse may encounter;
  - 6. include provisions for managing emergencies;
  - 7. include a defined mechanism and time frame to monitor prescribing practices;
  - 8. include protocols for the initiation of intravenous therapies and Schedule II drugs;
  - 9. specify that the initial prescription of Schedule II drugs must be reviewed within 96 hours;
  - 10. specify that the guidelines must be kept on file in the workplace and be reviewed and reexecuted every two years; and
  - 11. conform to M.G.L. c. 94C, 105 CMR 700.000: *Implementation of M.G.L. C. 94C*, M.G.L. c. 112, §§ 80B, 80C, 80E, 80G, 80H and 80I, and 244 CMR: *Board of Registration in Nursing*.

(6) The Board may request at any time an opportunity to review the guidelines under which a physician is supervising an APRN engaged in prescriptive practice. Failure to provide guidelines to the Board is a basis for and may result in disciplinary action. The Board may require changes in the guidelines if it determines that they do not comply with 243 CMR 2.10 and accepted standards of medical or nursing practice. The Board may also disapprove guidelines in their entirety if it determines that the supervising physician is incapable of providing adequate supervision to the APRN(s) engaged in prescriptive practice.

(7) The Board may request at any time documentation of any review conducted by the supervising physician of the APRN engaged in prescriptive practice. Failure to provide documentation to the Board is a basis for and may result in disciplinary action.

2.11: Physician Ownership Interests

(1) Physician Ownership in a For-profit Acute Care Hospital or HMO. As required by M.G.L. c. 112, § 5M, a licensee shall report to the Board that he or she has an ownership interest in a for-profit acute care hospital, as defined in M.G.L. c. 111, § 25B, or a for-profit health maintenance organization, as defined in M.G.L. c. 111, § 25B. The licensee shall report to the Board the percentage of ownership interest he or she holds in relation to the total ownership interest in the for-profit entity.

- (a) The licensee shall make an initial report of ownership interest to the Board within 30 days of acquiring such ownership interest.
- (b) After the initial report, the licensee shall report the existence of the ownership interest and the ownership percentage biennially during the license renewal process.
- (c) The licensee shall report a material change in his or her ownership interest to the Board within 30 days of the change.
- (d) A licensee shall report to the Board when he or she ceases to have an ownership interest, within 30 days of ceasing to have an ownership interest.

(2) Physician Ownership Interest in Facilities Providing Physical Therapy Services. A licensee shall report to the Board that he or she has an ownership interest in physical therapy services, pursuant to M.G.L. c. 112, § 12AA.

- (a) The initial report shall be made to the Board within 30 days of acquiring the ownership interest. A sample of the blank written referral form must be submitted to the Board.
- (b) After the initial report, the licensee shall report his or her ownership interest biennially during the licensee's renewal process.
- (c) When there is a change in the information provided in 243 CMR 2.07, including a change to the patient referral form, the licensee shall report the change to the Board within 30 days of the change, and send a copy of the new referral form to the Board.
- (d) Disclosure to Patient. A licensee who refers a patient for physical therapy services to an entity in which he or she has a financial ownership interest, as defined in M.G.L. c. 112, § 12AA, shall do the following:
  - 1. The licensee shall disclose his or her financial ownership interest to the patient.
  - 2. The licensee shall provide the patient with a written referral that informs the patient that physical therapy services may be available from other physical therapists in the community. The referral notice shall conspicuously contain the following language: "The referring registered or licensed person maintains an ownership interest in the facility to which you are being referred for physical therapy. Physical therapy services may be available elsewhere in the community."
  - 3. The licensee shall disclose his or her ownership interest with the Board, along with a copy of a blank written referral notice given to patients.
- (e) Maintaining a Referral List. Any licensee who refers a patient for physical therapy services to any partnership, corporation, firm or other legal entity in which he or she has an ownership interest shall maintain a list of any such referrals. A licensee shall make this list available to the Board for inspection at the Board's request.

(3) Extensions for Good Cause. The Chair of the Board or his or her designee may approve a written request for an extension of the time period required for notification, provided that the basis for such request demonstrates good cause.

(4) Ownership Interest. Ownership Interest shall mean any and all ownership interest, including but not limited to any membership, proprietary interest, stock interest, partnership interest, co-ownership in any form or any profit-sharing arrangement. Ownership interest shall not apply to any financial arrangements between a health maintenance organization licensed under M.G.L. c. 176G or a preferred provider arrangement organized under M.G.L. c. 176I and its participating providers. Ownership interest shall not apply to financial arrangements among participating providers of such health maintenance organization or such preferred provider arrangement.

(5) Statutory Report. Reports under 243 CMR 2.11 are mandated reports under 243 CMR 2.13 and 2.14 and shall be reported to the Data Repository.

2.12: Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacists

M.G.L. c. 94C, §§ 7 and 9 and M.G.L. c. 112, §§ 24B½ and 24B¾ authorize pharmacists and physicians to engage in collaborative drug therapy management (CDTM) in the Commonwealth pursuant to collaborative practice agreements meeting the requirements of 247 CMR: *Board of Registration in Pharmacy* and in Medicine. The Board of Registration in Pharmacy has promulgated 247 CMR 16.00: *Collaborative Drug Therapy Management* in accordance with M.G.L. c. 112, §§ 24B½ and 24B¾. 243 CMR 2.12 includes additional definitions and requirements applicable to pharmacists and physicians entering into collaborative practice agreements to practice CDTM in the Commonwealth.

(1) Definitions. Additional definitions applicable to the practice of CDTM in the Commonwealth appear in 243 CMR 2.12 and in 247 CMR 2.00: *Definitions* and 247 CMR 16.00: *Collaborative Drug Therapy Management*. As used in 243 CMR 2.12, all references to “written” regarding collaborative practice agreement referrals, consents and any other documents related to a collaborative practice agreement shall be:

- (a) if paper based, written in ink, indelible pencil or any other means; or
- (b) transmitted electronically in a format that maintains patient confidentiality and can be read and stored in a retrievable and readable form. Collaborative practice agreements and related referrals, consents and other documentation may be transmitted electronically with the electronic signature(s) without alteration of the information, provided the electronic transmission is in accordance with the requirements of M.G.L. c. 94C, § 23(g); 105 CMR 721.00: *Standards for Prescription Format and Security in Massachusetts*; 247 CMR 9.01(19) and 9.07(1)(a).

As used in 243 CMR 2.12 and defined in M.G.L. c. 112, § 24B½(a), the following words shall have the following meanings:

Authorized Pharmacist means a pharmacist who:

- (a) is currently registered by the Board of Registration in Pharmacy and is in good standing;
- (b) meets the requirements of 247 CMR 16.02: *Pharmacist Qualifications*; and
- (c) is participating in drug therapy management with a supervising physician pursuant to a written CDTM agreement with written protocols.

Board means the Board of Registration in Medicine.

Collaborative Drug Therapy Management or CDTM means the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by an authorized pharmacist under the supervision of a physician in accordance with a collaborative practice agreement. Collaborative drug therapy management may include: collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and, under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation does not include a diagnostic component.

Collaborative Practice Agreement or CDTM Agreement means a written and signed agreement between an authorized pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the authorized pharmacist and supervising physician propose to practice. The collaborative practice must be within the scope of the supervising physician's practice. In the community pharmacy setting, the CDTM agreement shall include a written referral of an identified patient from the supervising physician to an authorized pharmacist, and shall include a written consent to the CDTM agreement by the named patient.

Community Pharmacy means a retail drug business setting, licensed pursuant to M.G.L. c. 112, §§ 38 and 39. When there is a collaborative drug therapy management agreement between an authorized pharmacist in a community pharmacy and a supervising physician, the physician must obtain the informed consent of the patient in writing prior to participating in CDTM.

2.12: continued

License means a certificate of registration which the board issues to a person pursuant to the requirements of M.G.L. c. 112, §§ 2, 9 and 9B, and which authorizes the person to engage in the practice of medicine.

Patient means, for the purposed of 243 CMR 2.12, a person who is referred to an authorized pharmacist by a supervising physician for the purpose of receiving collaborative drug therapy management services from the pharmacist. In the community pharmacy setting, the patient must be notified of, and provide written consent to, the collaborative drug therapy management services, and the supervising physician must provide the patient with a copy of the referral to the authorized pharmacist and the written consent to the referral provided by the patient.

Referral means the individual patient referral by a supervising physician to an authorized pharmacist for the purpose of receiving CDTM services in a community pharmacy setting. In all other practice settings, Referral means the consultation of a supervising physician and an authorized pharmacist about a patient for the purpose of the patient's receiving CDTM services. In the community pharmacy setting, the supervising physician shall execute a written CDTM referral which shall include, but is not limited to, the patient's name and address, the primary diagnosis for which CDTM services are authorized, the diagnosis of any comorbid conditions for which CDTM services are authorized, any known patient drug allergies, a statement that the patient has executed a written consent to CDTM services, and any other specific instructions to the authorized pharmacist.

Supervising Physician means a physician who holds an active license to practice medicine in the Commonwealth of Massachusetts. A supervising physician in a CDTM agreement may only delegate to an authorized pharmacist pursuant to the written agreement and protocols with the pharmacist.

(2) Pharmacist Qualifications. In accordance with M.G.L. c. 112, § 24B½(b), to qualify to enter into a collaborative practice agreement, a pharmacist must:

- (a) hold a current unrestricted license in good standing to practice pharmacy in the Commonwealth and currently be engaged in pharmacy practice in the Commonwealth;
- (b) agree to maintain at least \$1,000,000 (per occurrence) of professional liability insurance during the term of the agreement which specifically covers drug therapy management;
- (c) have earned a doctor of pharmacy degree or have completed five years of experience as a licensed pharmacist;
- (d) agree to devote a portion of the practice to the defined drug therapy area that the pharmacist shall co manage;
- (e) agree to complete, in each year of the term of the agreement, at least five additional contact hours or 0.5 continuing education units (CEUs) of Board of Registration in Pharmacy approved continuing education that address areas of practice generally related to the particular collaborative practice agreement; and
- (f) if prescriptive practices are included in the collaborative practice agreement, agree to maintain a current controlled substance registration issued by the Department during the term of the agreement, pursuant to M.G.L. c. 94C, §§ 7 and 9, and 105 CMR 700.000: *Implementation of M.G.L. c. 94C*;
- (g) Whenever an authorized pharmacist participating in a CDTM agreement is disciplined by the Board of Registration in Pharmacy, whether by consent agreement or by a final decision and order, or otherwise subject to any practice restrictions, the authorized pharmacist must provide written notification of such discipline or practice restriction to each supervising physician.

(3) Physician Qualifications.

- (a) To be eligible to participate in a collaborative drug therapy management agreement, a physician must possess an active license to practice medicine issued by the Board, and must be actively engaged in the clinical practice of medicine and the provision of patient care in the particular field of medicine in which the collaborative drug therapy management is to take place.
- (b) The physician is the supervisor in the CDTM agreement and retains the ultimate responsibility for the care of the patient. In a community pharmacy setting, a physician should enter into only as many CDTM agreements setting as he or she can reasonably and safely supervise at one time.

## 2.12: continued

(c) The supervising physician shall assess the patient and make a written referral of the identified patient to the authorized pharmacist. The supervising physician's written referral shall include a primary diagnosis and any co morbid conditions that are included in the CDTM.

(d) A physician is ineligible to participate in a CDTM if he or she is in a Voluntary Agreement Not to Practice Medicine with the Board, or has had his or her license to practice medicine temporarily suspended or revoked by the Board. A physician shall be deemed ineligible to participate in CDTM if he or she has voluntarily surrendered or has had suspended, revoked or restricted his or her controlled substances license, permit or registration, either state or federal. The Board may revoke a physician's right to participate in a CDTM agreement for any of the grounds for discipline enumerated in 243 CMR 1.03(5): *Grounds for Complaint*.

(e) Whenever the Board enters into a Voluntary Agreement Not to Practice with a licensee, or summarily suspends a physician's license, the Board may require that the physician provide written notification to each authorized pharmacist with whom the physician is in a CDTM agreement. Whenever the Board takes final disciplinary action against a licensee, either by issuing a final decision and order or by approving a consent agreement, the Board may require that the physician provide written notification to each authorized pharmacist with whom he or she is in a CDTM agreement.

(4) Practice Setting Requirements. In accordance with M.G.L. c. 112, § 24B½(c), collaborative drug therapy management may be performed in the following settings by pharmacists meeting the requirements of 247 CMR 16.02(1) and authorized by a supervising physician pursuant to a current collaborative practice agreement:

(a) Hospitals licensed pursuant to M.G.L. c. 111, § 51, subject to approval by the medical staff executive committee at a licensed hospital or designee;

(b) Long term Care Facilities licensed pursuant to M.G.L. c. 111, § 71, subject to approval by the long term care facility medical director or designee;

(c) Inpatient or Outpatient Hospice Settings licensed pursuant to M.G.L. c. 111, § 57D, subject to approval by the hospice medical director or designee;

(d) Ambulatory Care Clinics licensed pursuant to M.G.L. c. 111, § 51, with on-site supervision by the attending physician and an authorized pharmacist, subject to approval by the ambulatory care clinic medical staff executive committee or designee, or medical director or designee;

(e) Community Pharmacies (retail drug business settings) licensed by the Board of Registration in Pharmacy pursuant to M.G.L. c. 112, § 39, subject to restrictions listed below and pursuant to a current collaborative practice agreement that includes the following requirements:

1. Patient Age. Patients must be 18 years of age or older;

2. Vaccine Administration. Pharmacists, as authorized pursuant to a collaborative practice agreement, may administer vaccines;

3. Patient Referral and Consent. The collaborative practice agreement must provide that the supervising physician will:

a. Provide a written referral of the patient to the authorized pharmacist;

b. Specify the primary diagnosis for the patient and any secondary diagnoses in a written referral or a subsequent referral;

c. Provide a copy of the written referral of the patient to the authorized pharmacist for CDTM services to the patient; and

d. Obtain the patient's written and informed consent to the collaboration and provide a copy of the consent to the patient.

4. The patient's written consent form shall include the following: "The pharmacist shall not replace the physician as the principal medical decision maker."

5. Record of Referral and Consent. The authorized pharmacist and supervising physician must maintain a written record of both the individual patient referral and the patient's written informed consent to the collaboration in the patient's record to be maintained by the authorized pharmacist and the supervising physician. The supervising physician shall maintain the original patient consent to the referral in the record in the custody of the supervising physician; transmit a copy of the patient's consent to the authorized pharmacist within 24 hours; and provide copies of the referral and consent to the patient in a timely manner.

## 2.12: continued

6. Limited Prescribing Authority. A pharmacist currently registered by the Department, pursuant to M.G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.00: *Implementation of M.G.L. c. 94C*, to prescribe and possess controlled substances, who practices in a community pharmacy pursuant to a collaborative practice agreement that includes individually developed prescriptive practice guidelines pursuant to which the supervising physician has authorized the pharmacist to prescribe, may:
    - a. extend current drug therapy by 30 days for not more than two 30 day periods or as may otherwise be specifically authorized by the supervising physician in the referral of the patient and as provided in the CDTM agreement;
    - b. initiate, modify or discontinue dosages of medications prescribed by the supervising physician for:
      - i. asthma;
      - ii. chronic obstructive pulmonary disease;
      - iii. diabetes;
      - iv. hypertension;
      - v. hyperlipidemia;
      - vi. congestive heart failure;
      - vii. HIV or AIDS;
      - viii. osteoporosis; and
      - ix. comorbidities, listed in 243 CMR 2.12(4)(e)6.b.i. through viii., and identified by the supervising physician along with the primary diagnosis on the physician's referral of the patient.
    - c. The authorized pharmacist must provide a copy of an initial prescription, a modification or a discontinuation of a prescription to the supervising physician within 24 hours of its issuance, unless more urgent notification is required under the circumstances and must note the action taken in the patient's chart. A copy of all prescriptions must be included in the patient's medical record in the custody of the supervising physician.
  7. No authorized pharmacist in a community pharmacy may prescribe or be authorized to prescribe Schedule II through V controlled substances, as defined in M.G.L. c. 94C, § 3(2) through (5).
  8. An authorized pharmacist in a community pharmacy may be authorized by a supervising physician to issue prescriptions for Schedule VI controlled substances, as defined in M.G.L. c. 94C, § 3(6), for the diagnoses specified in the supervising physician's patient referral.
- (5) Collaborative Practice Agreements.
- (a) Required Agreement Terms for All Practice Settings. In addition to specific practice setting collaborative practice agreement requirements, pursuant to 247 CMR 16.03: *Practice Setting Requirements*, and in accordance with M.G.L. c. 112, § 24B¾, all collaborative practice agreements must also include:
    1. the specific disease state(s) being co managed, with each disease state identified as either primary or co morbid;
    2. the specific pharmacist prescribing authority pursuant to the agreement;
    3. detailed practice protocols;
    4. the description of risk management activities;
    5. documentation of any initiation, modification or discontinuation of a patient's medication in the patient's medical record in the custody of the supervising physician;
    6. the description of outcome measurements;
    7. detailed informed consent procedures that are appropriate to the practice setting;
    8. detailed procedures and periods by which time any test results, copies of initial prescriptions, modifications or discontinuances, copies of the patient consent and the CDTM agreement, and other patient information will be forwarded from the authorized pharmacist to the supervising physician, and a specific procedure for the pharmacist to identify and transmit any urgent communications; and description of the nature and form of the supervision of the authorized pharmacist by the supervising physician, and a description of the procedure to follow when either the authorized pharmacist or the supervising physician is unavailable or absent;
    9. the authorized pharmacist's attestation of satisfaction of the qualifications listed in 247 CMR 16.02(1) for participating in collaborative drug therapy management; and

2.12: continued

10. the supervising physician's attestation of satisfaction of the qualifications listed in 243 CMR 2.12 for participating in collaborative drug therapy management.
- (b) Duties. A collaborative practice agreement shall specify those duties of the authorized pharmacist that may be delegated to other appropriately trained and authorized staff and those duties under the agreement that shall not be delegated. A collaborative practice agreement shall specify when and how a supervising physician may delegate duties under the agreement, and the duration and scope of the delegation.
- (c) Biennial Renewal. A collaborative practice agreement must be reviewed and renewed by the authorized pharmacist and supervising physician at least every two years.
- (d) Termination. Prior to the termination or nonrenewal of a CDTM agreement, the supervising physician and the authorized pharmacist shall arrange for an uninterrupted continuation of the patient's drug therapy, in accordance with the terms of the CDTM agreement. When a CDTM agreement is not renewed or CDTM is otherwise terminated, the authorized pharmacist and the supervising physician shall inform the patient in writing of the termination and of the procedures in place for continuation of the patient's drug therapy, in accordance with the terms of the CDTM agreement. The supervising physician has an ongoing responsibility for patient care unless and until the physician patient relationship is terminated.
- (e) Agreement to Be Filed in Primary Practice Setting. An authorized pharmacist must maintain a copy of the current CDTM agreement, including copies of the current patient referral and patient consent, in the primary practice setting, readily retrievable at the request of the Board of Registration in Medicine and the Board of Registration in Pharmacy. The supervising physician must maintain the original of the current CDTM agreement, including the original patient referral and patient consent, in the patient's medical record in the custody of the supervising physician. The supervising physician must maintain the patient's medical record in his or her custody and make it available upon request during an investigation by the Board of Registration in Medicine.
- (f) Employment Relationships. In accordance with M.G.L. c. 112, § 24B½(e):
  1. A qualified pharmacist may be hired by a physician or group of physicians for the purpose of practicing collaborative drug therapy management under an agreement for the benefit of the patient of that physician or physician group;
  2. A community pharmacy may hire a physician or licensed medical practitioner to conduct quality assurance reviews of pharmacists engaged in collaborative drug therapy management; and
  3. No community pharmacy may employ a physician for the purpose of maintaining, establishing or entering into an agreement.

2.13: The Data Repository

- (1) The Data Repository, Defined. Pursuant to M.G.L. c. 112, § 5, the Board shall maintain a Data Repository to compile all reports filed under M.G.L. c. 112, §§ 5A through 5M, and reports filed under any other state or federal law or regulation requiring that information be reported to the Board, excluding Safety and Quality Reviews filed pursuant to M.G.L. c. 111 § 20. Mandated reports received in the Data Repository are confidential, unless otherwise required by law. The term Data Repository refers to the compilation of all mandated reports received by the Board. Data Repository Unit includes Board staff working with the Data Repository.
- (3) Referral to the Enforcement Division. The Data Repository Unit shall oversee the referral of mandated reports received in the Data Repository. The Licensing Committee or its staff shall oversee the review of licensing materials filed under M.G.L. c. 112, § 2 through 9B and shall oversee the referral to the Enforcement Division when appropriate, except for information that meets the exemption in 243 CMR 2.15(2). Mandated reports shall be reviewed according to the policies and procedures set by the Board. Upon receipt of a mandated report, the Data Repository Unit shall record the date the report was received. Upon receipt of a mandated report, the Data Repository shall refer the report immediately to the Enforcement Division for docketing and review, except for information that meets the exemption in 243 CMR 2.15(2).
  - (a) Physician Profiles. The Data Repository Unit may assist the Board in its duty, pursuant to M.G.L. c. 112, § 5, to collect certain information referred to as the Physician Profile, and to release this information to the public. The contents of a Physician Profile are determined by M.G.L. c. 112, § 5 and are set forth in 243 CMR 2.15.

2.13: continued



(b) Profile Inquiry. A licensee may ask the Board to review a claim of factual inaccuracy in a public profile. During the pendency of a profile inquiry, the Data Repository or Board staff may place the physician's profile on an administrative hold; *i.e.*, the staff may temporarily remove the profile from public access until the claim of factual inaccuracy is resolved. When there is final resolution to the profile inquiry, the administrative hold on the physician's profile will be removed.

## 2.14: Mandated Reporting

(1) Scope of 243 CMR 2.13 and 2.14. 243 CMR 2.13 and 2.14 are mandated reporting sections. A mandated report is also referred to as a “statutory report” throughout 243 CMR 2.00. 243 CMR 2.14 contains a nonexclusive list of mandated reports. Some mandated reports are not listed within 243 CMR 2.13 and 2.14.

(2) Mandated Report, Defined. A mandated report is a written filing, made to the Board of Registration in Medicine, by a reporter required to make the report pursuant to a state or federal law or regulation. The subject of a mandated report shall be a physician, registered with the Board as qualified to practice medicine in the commonwealth, including any person licensed pursuant to M.G.L. c. 112, §§ 2 through 9B. Mandated reports received in the Data Repository are confidential, unless otherwise required by law. A mandated reporter is any entity or individual that is required, by state or federal law or regulation, to make a report to the Board of Registration in Medicine, except for reports filed with the Board pursuant to M.G.L. c. 111, § 205. Reports filed with the Quality and Patient Safety Division are not mandated reports as defined in 243 CMR 2.14(2).

(3) Filing a Mandated Report. Mandated reports shall be filed with the Data Repository Unit, except for licensing materials filed with the Board pursuant to M.G.L. c. 112, § 2 through 9B, which shall be filed with the Licensing Division at the Board's mailing address. Unless otherwise provided by law or regulation, a mandated report shall be filed with the Board no later than 30 days after the date of the incident being reported. A licensee's failure to timely file a mandated report may be a ground for a disciplinary action by the Board.

(4) Mandated Reports Made by a Physician.

(a) Peer Reports. A doctor of medicine or osteopathy, an intern, resident, fellow or medical officer licensed under M.G.L. c. 112, § 9, must report to the Board when he or she has a reasonable basis to believe that a physician may have violated the provisions of M.G.L. c. 112, § 5 or any regulation of the Board. This report is filed under M.G.L. c. 112, § 5F and is referred to as a “peer report”, or a “5F report”. A reporter may be exempt from this reporting requirement when the limited exemption provisions of M.G.L. c. 112, § 5F, and 243 CMR 2.07(23) apply.

(b) Certain Licensing Materials. Licensing materials filed under M.G.L. c. 112, §§ 2 through 9B, and signed and sworn to by the applicant, are mandated reports, portions of which are confidential as provided in M.G.L. c. 112, § 2, and 243 CMR 2.01(5). The mandated reporter is the applicant or licensee. Additional responses or documentation provided by the applicant or licensee and submitted as part of an initial or renewal application may be mandated reports.

(c) Action against Health Care Facility Privileges. A licensee shall notify the Board of any restriction, termination, revocation, suspension or resignation of his or her health care facility privileges in accordance with 243 CMR 1.03(5). A licensee's report of an action against his or her privileges is a mandated report. The licensee shall report the action taken against his or her privileges within 30 days of the health care facility's action, notwithstanding any appeal that may be pending.

(d) Report on Certain Adverse Events Occurring in a Licensee's Office. A licensee must report to the Board the following events, if precipitated by a treatment administered or a procedure performed in a licensee's office setting:

1. an unplanned patient transfer to a hospital;
2. a patient death, when this death was unexpected and not related to the natural course of the patient's illness or underlying condition; or

2.14: continued

3. a serious injury.

The report shall be filed by the licensee as soon as possible, but in no event later than 30 days following the event.

(e) Dissolution or Disassociation from a Professional Practice for Reasons of Competence. A licensee shall report a dissolution of, or disassociation from, a professional corporation, partnership or other professional practice group, however legally organized, when the dissolution is for cause. A licensee shall report to the Board when such dissolution or disassociation is related, directly or indirectly, to:

1. A licensee's competence to practice medicine, or
2. A complaint or allegation regarding any violation of law or regulation, or bylaws of a health care facility, medical staff, group practice, or professional medical association whether or not the complaint or allegation specifically cites violation of a specific law, regulation or bylaw.

(f) Settlement by a Self-insured Physician. A licensee without professional liability insurance at the time when a malpractice action occurs must report to the Board any settlement or arbitration award for damages for death or personal injury. The licensee shall report a settlement or award against him or her caused by the licensee's negligence, error or omission in practice, or for an unauthorized rendering of professional services, as provided in M.G.L. c. 112, § 5E.

(5) Mandated Reports Made by Health Care Facilities or Other Reporters.

(a) Disciplinary Action by Health Care Facility. A health care facility disciplinary action report filed under M.G.L. c. 111, § 53B is a mandated report. The mandated reporter is any person or entity licensed under M.G.L. c. 111, § 51. The reporting entity shall use the definition of Disciplinary Action set forth at 243 CMR 1.01(2).

1. Notice of Termination or Suspension. If the disciplinary action taken is a suspension or termination of privileges, notice must be filed with the Board within two business days of the occurrence of the reportable action. The health care facility giving notice of a suspension or termination to the Board may do so initially by telephone or by facsimile transmission, to be followed by a written report within 30 days of the occurrence of the reportable action.

2. Initial Reports. Whenever a report is required pursuant to M.G.L. c. 111, § 53B, the person or entity reporting shall use Form HCDFD-1, the Board's form prescribed for that purpose. The report shall be filed within 30 days of actual imposition of the disciplinary action, regardless of whether further appellate remedies are available to the licensee. However, at any time after making an initial report, if the reporting entity reverses its disciplinary action, the reporting entity shall notify the Board and file a subsequent report on Form HCDFD-2 within 30 days of the reversal of action.

3. Subsequent Reports. The disciplinary action reporting requirement under M.G.L. c. 111, § 53B does not end until the disciplinary action upon which the report was based is complete. The reporting entity shall submit to the Board a status report at the end of every 60-day period about the ongoing disciplinary action. When the health care facility has completed its disciplinary action, it shall file a Subsequent HCDFD-2 Report within 30 days of the date of the final action.

4. Annual Summary of Disciplinary Actions. Under M.G.L. c. 111, § 53B, a health care facility shall file an annual disciplinary summary, no later than January 31<sup>st</sup> for each previous calendar year, on a Form HCDFD-3. The cumulative, de-identified data compiled by the Data Repository Unit from the total Annual Summary of Disciplinary Actions reports filed in a calendar year shall be a public record, except that information that is deemed confidential pursuant to M.G.L. c. 111, § 53B or M.G.L. c. 112, § 5 shall not be disclosed by the Board.

(b) Nursing Homes. A report of a disciplinary action taken by a convalescent home or nursing home and filed under M.G.L. c. 111, § 203 is a mandated report. The mandated reporter is a nursing home or other entity licensed by the Department of Public Health under M.G.L. c. 111, § 71. A copy of a report sent to the Department of Public Health under M.G.L. c. 111, § 72, that indicates physician incompetency or other physician conduct that seriously affects a nursing home patient's health and safety, is a mandated report under M.G.L. c. 111, § 203. In determining what constitutes a disciplinary action, the nursing home shall rely on the Board's definition of Disciplinary Action set forth in 243 CMR 1.01(2): *Definitions*.

2.14: continued

1. Notice of Termination or Suspension. If the disciplinary action taken is a suspension or termination of privileges, notice must be filed with the Board within two business days of the occurrence of the reportable action. The nursing home giving notice of a suspension or termination to the Board may do so initially by telephone or by facsimile transmission, to be followed by a written report within 30 days of the occurrence of the reportable action.
  2. Initial Reports. Whenever a report is required pursuant to M.G.L. c. 111, § 203, the person or entity reporting shall use the Board's form prescribed for that purpose, Form HCFD-1. The report shall be filed within 30 days of actual imposition of the disciplinary action, regardless of whether further appellate remedies are available to the licensee. However, at any time after making an initial report, if the reporting entity reverses its disciplinary action, the reporting entity shall notify the board and file a subsequent Form HCFD-2 report within 30 days.
  3. Subsequent Reports. The disciplinary action reporting requirement under M.G.L. c. 111, § 203 does not end until the disciplinary action upon which it is based is complete. The reporting entity shall submit to the Board a status report at the end of every 60-day period about the ongoing disciplinary action. When the nursing home has completed its disciplinary action, it shall file a Subsequent HCFD-2 Report within 30 days of the date of the final action.
  4. Annual Summary of Disciplinary Actions. Under M.G.L. c. 111, § 203(e), a nursing home shall file an annual disciplinary summary, no later than January 31<sup>st</sup> for each previous calendar year, on a Form HCFD-3. The cumulative, de-identified data compiled by the Data Repository Unit from the total Annual Summary of Disciplinary Actions filed in a calendar year shall be a public record, except that information that is deemed confidential pursuant to M.G.L. c. 112, § 5 shall not be disclosed by the Board.
- (c) Professional Organizations. A professional medical association disciplinary action report filed under M.G.L. c. 112, § 5B is a mandated report. The reporting entity shall use the definition of Disciplinary Action set forth in 243 CMR 1.01(2): *Definitions*. The mandated reporter is a professional medical association, society, body, professional standards review organization, or similarly constituted professional organization, whether local, regional, state, national, or international in scope. This mandated report shall be filed within 30 days of the disciplinary action.
- (d) Healthcare Agency Employee. When an officer or employee of a state agency, engaged in the provision or oversight of medical or health services, has a reasonable basis to believe that a physician may have violated the provisions of M.G.L. c. 112, § 5 or any Board regulation, he or she shall report this to the Board under M.G.L. c. 112, § 5D as a mandated report. Mandated reporters are officers or employees of an agency, executive office, department, board, commission, bureau, division or authority of the Commonwealth or, of, any political subdivision thereof, that provides medical or health services, or oversees the delivery of healthcare services.
- (e) Peer Reports. A health care provider, as defined in M.G.L. c. 111, § 1, must report to the Board when he or she has a reasonable basis to believe that a physician may have violated the provisions of M.G.L. c. 112, § 5 or any regulation of the Board. This report is filed under M.G.L. c. 112, § 5F and is sometimes referred to as a “peer report”, although the health care provider need not be a peer of the licensee. A health care provider may be exempt from this reporting requirement when the limited exemption provisions of M.G.L. c. 112, § 5F, and 243 CMR 2.07(23) apply.
- (f) Secondary Remedial Action by Insurer. A report of a secondary remedial action, as defined in M.G.L. c. 175A, § 5C(a)(3)(vi) and (vii), and imposed by the experience review committee, as defined in M.G.L. c. 175A, § 5C(a)(6), is a mandated report. The mandated reporter is the medical professional mutual insurance company approved by the commissioner of insurance in M.G.L. c. 175A.
- (g) Insurer's Disposition of a Malpractice Claim. A report of the final judgment, settlement, or disposition of a medical malpractice claim or action, filed under M.G.L. c. 112, § 5C, is a mandated report. The mandated reporters are insurers or risk management organizations providing professional liability insurance to a licensee. The report shall be filed with the Board within 30 days of the date of the final judgment, settlement or disposition.
- (h) Criminal Conviction. A clerk of courts shall report a physician's conviction of a crime, or a physician's plea of *nolo contendere* or admission to sufficient facts to a crime, within one week of the date of conviction or plea. This report, filed under M.G.L. c. 221, § 26, is a mandated report.

2.14: continued

- (i) Medical Malpractice Tribunal Findings. The clerk of the Superior Court shall report the findings of a medical malpractice tribunal, as defined in M.G.L. c. 231, § 60B. This mandated report shall be filed with the Board within 15 days of the date of the finding.
- (j) Final Disposition by Court of Malpractice Claim. A clerk of the superior court shall file with the Board a report of a final judgment, settlement or disposition of a medical malpractice claim or action. This mandated report, filed under M.G.L. c. 231, § 60B, shall be filed within 15 days of the date of the final judgment, settlement or disposition.
- (k) Report from the Health Care Services Board. A report by the Worker's Compensation Health Care Services Board (HCSB) filed under M.G.L. c. 152, § 13(3), and received from an employee, an employer or an insurer, regarding licensees serving as health care providers under the Worker's Compensation Law is a mandated report. The HCSB shall report to the Board when the HCSB finds that a licensee may have engaged in a pattern of abuse such as:
  - 1. Discrimination against compensation claimants;
  - 2. Overutilization of procedures;
  - 3. Unnecessary surgery or other procedures; or
  - 4. Other inappropriate treatment of compensation recipients.
- (l) Additional Reporting Requirements. A report made to the Board of Registration in Medicine about a licensee, filed pursuant to a state or federal statute or regulation or filed under 243 CMR 2.07(8), 2.13 or 2.14, shall be a mandated report, unless otherwise specifically required by law. Statutes or regulations requiring a mandated report to the Board should be read as consistent with 243 CMR 2.07(8), 2.13 and 2.14.

2.15: The Physician Profile Program

- (1) Purpose of the Program. The Physician Profile Program, established by St. 1996, c. 307, provides for public access to information about physicians. This law, codified at M.G.L. c. 112, § 5, is also referred to as the Physician Profile Law. The Profiles Program is intended to give patients and consumers access to information on the education, training and clinical experience of all physicians holding or having held a full license.
- (2) Exemption. Information that arises from a person providing or assisting in providing reproductive health care services or gender-affirming health care services, as defined at M.G.L. c. 12, § 111½, shall not be published on a physician's public profile, so long as the services provided would have been lawful in Massachusetts and are consistent with standards for good professional practice in Massachusetts.
- (3) Content of a Profile. Pursuant to M.G.L. c. 112, § 5, the Board shall collect and maintain a public profile on each physician with a full, active or inactive license under M.G.L. c. 112, § 2. The Board shall create individual physician profiles on licensees and disseminate this information to the public. Pursuant to M.G.L. c. 112, § 5, the following information shall be on a public profile, except for information that meets the exemption in 243 CMR 2.15(2):
  - (a) for any criminal convictions for felonies and serious misdemeanors in all jurisdictions;
    - 1. The Board shall determine what constitutes a "serious misdemeanor";
    - 2. For the purposes of 243 CMR 2.15, a person shall be considered to be convicted of a crime if the person pleaded guilty or was found or adjudged guilty by a court of competent jurisdiction; and
  - (b) any charges for felonies and serious misdemeanors to which a physician pleads *nolo contendere* or where sufficient facts of guilt were found and the matter was continued without a finding by a court of competent jurisdiction;
  - (c) any final Board disciplinary actions;
  - (d) any final disciplinary actions by licensing boards in other states;
  - (e) any revocation or involuntary restriction of privileges by a hospital, clinic or nursing home under chapter 111, or of any employer who employs physicians licensed by the Board for the purpose of engaging in the practice of medicine in the commonwealth, for reasons related to competence or character that have been taken by the governing body or any other official of the hospital, clinic or nursing home or employer who employs physicians licensed by the Board for the purpose of engaging in the practice of medicine in the Commonwealth after procedural due process has been afforded, or the resignation from or nonrenewal of medical staff membership or the restriction of privileges at a hospital, clinic or nursing home or employer who employs physicians licensed by the Board for the purpose of engaging in the practice of medicine in the Commonwealth taken in *lieu* of or in settlement of a pending disciplinary case related to competence or character in that hospital, clinic or nursing home or of any employer who employs physicians licensed by the Board for the purpose of engaging in the practice of medicine or employer who employs physicians licensed by the Board for the purpose of engaging in the practice of medicine in the Commonwealth;

2.15: continued

- (f) all medical malpractice court judgments, all medical malpractice arbitration awards in which a payment is awarded to a complaining party, and all settlements of medical malpractice claims in which a payment is made to a complaining party in all jurisdictions;
  - 1. Information concerning paid medical malpractice claims within the Commonwealth shall be put in context by comparing an individual licensee's medical malpractice judgment awards and settlements to the experience of other physicians within the same specialty.
  - 2. Dispositions of paid claims within the Commonwealth shall be reported in a minimum of 3 graduated categories indicating the level of significance of the award or settlement.
  - 3. Dispositions of paid claims in other jurisdictions shall not be reported in graduated categories unless this information is provided to the Board by the medical board in the other jurisdiction where the claim occurred.
  - 4. Information concerning all settlements shall be accompanied by the following statement: "Settlement of a claim may occur for a variety of reasons which do not necessarily reflect negatively on the professional competence or conduct of the physician. A payment in settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred."
  - 5. Nothing herein shall be construed to limit or prevent the Board from providing further explanatory information regarding the significance of categories in which settlements are reported.
  - 6. Pending malpractice claims shall not be disclosed by the Board to the public.
  - 7. Nothing herein shall be construed to prevent the Board from investigating and disciplining a licensee on the basis of medical malpractice claims that are pending.
  - 8. Payments made as part of a disclosure, apology and early offer program, shall not be construed to be reportable to or by the Board against the physician, absent a determination of substandard care rendered on the part of said physician; and
- (g) names of medical schools and dates of graduation;
- (h) graduate medical education;
- (i) specialty board certification;
- (j) number of years in practice;
- (k) names of the hospitals where the licensee has privileges;
- (l) appointments to medical school faculties and indication as to whether a licensee has a responsibility for graduate medical education within the most recent ten years;
- (m) information regarding publications in peer-reviewed medical literature within the most recent ten years;
- (n) information regarding professional or community service activities and awards; and
- (o) the location of the licensee's primary practice setting;
- (p) the identification of any translating services that may be available at the licensee's primary practice location; and
- (q) an indication of whether the licensee participates in the Medicaid program.

(3) Mandatory Public Profile. Pursuant to M.G.L. c. 112, § 5, all full licensees must have a public Physician Profile.

- (a) The Board shall provide an initial licensee with a copy of his or her profile prior to its release to the public. An initial licensee shall have 14 days from the receipt of the draft profile to report to the Board a claim of factual inaccuracy appearing in the profile. Upon receipt of a physician's claim, Board staff may place a temporary administrative hold on the dissemination of the profile.
- (b) The Board shall provide a licensee with notice of a change in the licensee's public profile when the Board receives notice of a change in information that must be reported to the public pursuant to M.G.L. c. 112, § 5.
- (4) Optional Information. A physician may elect to have his or her profile include certain information, detailed in M.G.L. c. 112, § 5, such as academic appointments and teaching responsibilities, publications in peer-reviewed journals and professional and community service awards.

2.15: continued

(5) Profile Inquiry. A licensee may review his or her public profile on the Internet at any time. A licensee may inquire about the accuracy of a fact published or about to be published on his or her profile. A licensee's inquiry about the contents of his or her Physician Profile is not an adjudicatory proceeding as defined in M.G.L. c. 30A, § 1. The licensee may file with the Data Repository a written request for review of the publication of a fact adverse to the licensee's interest. The licensee's inquiry must clearly identify the factual error claimed and may propose a correction acceptable to the licensee. Upon receipt of a letter of inquiry from a physician, Board staff may place a temporary administrative hold on the dissemination of the profile. Such a temporary hold shall not last longer than the pendency of the profile inquiry. The Board may review the written materials and respond to the licensee's inquiry

REGULATORY AUTHORITY

243 CMR 2.00: M.G.L. c. 13, §§ 9 through 11; M.G.L. c. 112, §§ 2 through 12DD; M.G.L. c. 112, §§ 61 through 65 and 88.