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(3).

(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.

(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).

(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.

(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; and

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.

(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 the effective date of these regulations, and unless otherwise required by law, a licensee must maintain a patient's medical records for a minimum period of 10 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 10 years from the date of the last patient encounter or until the patient reaches the age of 18, 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:

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. Physicians who are engaged in a group practice of medicine shall arrange for the retention of the medical records of the individual members in the event of a physician’s death. Physicians must take proactive measures to ensure that their executor or administrator has access to both paper and electronic medical records. Such access must include passwords for medical records maintained in an electronic format. 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 10 years from the date of the last patient encounter.

**(14)   Providing Cancer Patients with Treatment Information.**

**(a)   Unless the licensee's patient waives compliance with 243 CMR 2.07(14), a licensee is required to provide the following information in an understandable manner to a patient whom the licensee accepts for treatment with known or suspected cancer. This information shall include a description of alternative methods of therapy including but not limited to surgical procedures, radiation therapy, chemotherapy and combinations of these methods, hormonal therapy, targeted therapy, and/or gene therapy; a discussion of the currently known risks and benefits of each alternative method; and answers to the patient's questions concerning the medically viable alternative treatments. If the patient asks for a consultation with a surgeon, radiotherapist, chemotherapist, oncologist, psychiatrist or other health care professional, a licensee shall provide the name or names of such qualified consultants.**

**(b)   A licensee may be excused from compliance with this section if the licensee informs the cancer patient of the licensee's willingness to provide information concerning alternative forms of treatment and the patient indicates that he or she does not wish to discuss the matter further.**

**(c)   A licensee shall document compliance with the requirements of this section in the patient's medical record, and shall obtain the patient’s signature indicating compliance, together with the patient's written informed consent.**

**(d) A licensee may have other duties to patients under the “Patient’s Bill of Rights” in M.G.L. c. 111, § 70E. Nothing in this section shall be construed as limiting a patient’s existing rights or remedies.**

(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:

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; or

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; or

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; or

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, and

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; and

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 Part 2, 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; or

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; or

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; or

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).

(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 post‑graduate 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; and

2.   Actively practice medicine at least ten hours per week; and

3.   Have read and interpreted 960 mammograms in the prior 24 months; and

4.   Continues to perform mammograms at this frequency; and

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.

**(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, the terms below 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 should 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 should 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 intelligent 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.**

(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 physician must observe sterile techniques at all times in the practice of medicine, including but not limited to when a physician moves from one surgical procedure to another.**

**(i) A patient is entitled to a copy of the written informed consent and a copy of his or her medical records upon request.**

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.

(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 5.08:  *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 post‑graduate 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; and

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; and

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 5.05(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 243 CMR 2.08(5)(a)2.

(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 5.05(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, the regulations of the Department of Public Health at 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.

(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).

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 5.08:  *Physician Assistant Authorized to Operate Fluoroscopic X-Ray Systems* 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).

(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 5.08:  *Physician Assistant Authorized to Operate Fluoroscopic X-Ray Systems*; 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, 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* (the regulations of the Board of Registration in Nursing).

(2)   Advanced Practice Registered Nurse (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 certified 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.

(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 the regulations of the Board of Registration in Nursing (244 CMR) 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 the BORN regulations.

(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, the regulations of the Department of Public Health at 105 CMR 700.000:   *Implementation of M.G.L. C. 94C*, M.G.L. c. 112, §§ 80B, 80C, 80E, 80G, 80H, 80I and 244 CMR (the regulations of the 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 this section 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

St. 2008, c. 528 (amending M.G.L. c. 94C, §§ 7 and 9 and M.G.L. c. 112, §§ 24B½ and 24B¾) authorized pharmacists and physicians to engage in collaborative drug therapy management (CDTM) in the Commonwealth pursuant to collaborative practice agreements meeting the requirements of regulations adopted by the Boards of Registration in Pharmacy (247 CMR) 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 the Board of Registration in Pharmacy regulations at 247 CMR 2.00:  *Definitions* and 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.

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 purposes of this section, 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 substances 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.

(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 comorbid 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 onsite 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.

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 comanaged, with each disease state identified as either primary or comorbid;

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

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 patients 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 § 203. 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 the Board staff working with the Data Repository.

(2)  Referral to the Enforcement Division.  The Data Repository Unit shall oversee thereferral 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. 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.

(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.

(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*., staff may temporarily remove the profile from public access until the claim of factual inaccuracy is resolved. When there is a 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; or

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

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 by‑laws 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 HCFD‑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 HCFD‑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 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, § 53B, a health care facility shall file an annual disciplinary summary, no later than January 31st 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 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*.

**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 31st 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 at 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.

(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), 243 CMR 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)   Content of a Profile. Pursuant to M.G.L. c. 112, § 5, the Board shall collect and maintain a public profile on each physician who has held a full license. 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:

(a) 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 this section, 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; and

(c) any final board disciplinary actions; and

(d) any final disciplinary actions by licensing boards in other states; and

(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; and

(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; and

(h) graduate medical education; and

(i) specialty board certification; and

(j) number of years in practice; and

(k) names of the hospitals where the licensee has privileges; and

(1) 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; and

(m) information regarding publications in peer-reviewed medical literature within the most recent ten years; and

(n) information regarding professional or community service activities and awards; and

(o) the location of the licensee's primary practice setting; and

(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.

(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; c. 112, §§ 2 through 12DD; c. 112, §§ 61 through 65 and 88.