Prescription Monitoring Program State Profiles - Massachusetts

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MASSACHUSETTS

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- Status of Program – operational
- Housing Entity – Department of Public Health
- Advisory Commission – yes
- Funding – not specified in PMP statutes or regulations
- Drugs Monitored – Schedules II – V and non-controlled/non-scheduled substances
- Who's Required to Report Dispensing Information – all pharmacies
- Exemptions from Reporting – dispensing to a hospital inpatient
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – no
- Data Collection Interval – weekly/7 days
- Notice to Consumers – no
- Interstate Sharing – with other PMPs
- Persons Authorized to Receive Information – law enforcement and judicial/prosecutorial officials; licensing/regulatory boards; office of health and human services regarding Medicaid participants; patient or parent of minor child; health care agent; prescribers; dispensers
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to prescribers, pharmacists, law enforcement, and licensing boards
- Training Required – yes
- Mandatory Enrollment – yes; practitioners who prescribe controlled substances are automatically registered with the PMP upon obtaining or renewing a controlled substances registration
- Mandatory Access – yes; requires the department to promulgate rules that require participants to access the PMP prior to the initial issuance of a narcotic drug in Schedule II or III; prior to issuing a written certification of a debilitating condition, the physician must check the PMP; various practitioners required to check the PMP prior to prescribing a hydrocodone only extended release medication that is not in an abuse deterrent form; pharmacists may not fill or dispense any prescription for a hydrocodone only extended release medication that is not in an abuse deterrent form without first checking the PMP

Massachusetts General Laws Annotated (2014)
Part I. Administration of the Government (Ch. 1-182)
Title XV. Regulation of Trade (Ch. 93-110H)
Chapter 94C. Controlled Substances Act

§ 7A. Registration as participant in prescription monitoring program

Upon obtaining or renewing a registration under section 7, a practitioner who prescribes controlled substances shall automatically and without further action be registered as a participant in the prescription monitoring program established in section 24A. The department shall provide each participant with a unique user name and access code for the program. For the purposes of this section, a practitioner shall not include a veterinarian; provided, however, that a practitioner shall include a physician assistant, nurse anesthetist or a registered nurse authorized by the board of registration in nursing to practice in an advanced practice nursing role.

Massachusetts General Laws Annotated (2014)
Part I. Administration of the Government (Ch. 1-182)
Title XV. Regulation of Trade (Ch. 93-110H)
Chapter 94C. Controlled Substances Act

§ 18. Issuance of prescription by practitioner or physician

(a) A prescription for a controlled substance may be issued only by a practitioner who is:

(1) authorized to prescribe controlled substances; and

(2) registered pursuant to the provisions of this chapter.

(b) An oral prescription issued by a practitioner may be communicated to a pharmacist by an expressly authorized employee or agent of the practitioner.

(c) A prescription for a controlled substance contained in schedules III to VI, inclusive, as defined in section three may also be issued by an authorized practitioner who is duly licensed to practice medicine and duly registered in the state wherein he resides, if required, and duly registered under federal law to write prescriptions. It is the duty of the registered pharmacist who is filling a prescription under this paragraph to determine, in accordance with professional standards and personal judgment, that such prescription is authentic and valid; provided, however, that if the substance is in schedules III to V, inclusive, the registered pharmacist shall verify the prescription by telephone or other means. A pharmacist shall not fill a prescription for which said verification cannot be obtained. The pharmacist shall not be held liable for refusing to fill a prescription for which said verification cannot be obtained, provided that documented good faith efforts were made to determine the authenticity and validity of the prescription. This paragraph shall be valid only for the purpose of authorizing the filling of prescriptions, issued within the preceding thirty days, and shall not authorize said physician to process, administer or dispense controlled substances as provided in section nine or to practice medicine within the commonwealth. In the case of any oral prescription for a schedule III through V substance, the pharmacist shall record that he has requested that the practitioner deliver or mail to the dispensing pharmacy a written prescription for the controlled substance within seven days or such shorter period required by Federal law. Any prescription issued under this paragraph shall be issued in the manner prescribed in section twenty-two and all relevant provisions of this chapter shall apply to such physician and prescription. Nothing contained in this section shall be deemed to authorize any mail order pharmacies.

(d) A prescription for a nonnarcotic substance contained in Schedule II of section three may also be issued by a physician who is licensed to practice medicine and registered in another state where he resides or practices, if required, and registered under federal law to write prescriptions. A registered pharmacist filling a prescription under the provisions of this paragraph shall determine, in accordance with professional standards and personal judgment, that such prescription is authentic and valid; and shall verify such prescription by telephone or other means. A pharmacist shall not fill a prescription for which said verification cannot be obtained.

A pharmacist shall not be held liable for refusing to fill such prescription for which said verification cannot be obtained; provided, however, that documented good faith efforts were made to determine the authenticity and validity of such prescription. This paragraph is only for the purpose of authorizing the filling of prescriptions within the commonwealth, issued within the preceding five days, and shall not authorize such practitioner to possess, administer or dispense controlled substances as provided in section nine, or to practice medicine within the commonwealth. Any prescription issued under the provisions of this paragraph shall be issued in the manner prescribed in section twenty-two and all relevant provisions of this chapter shall apply to such practitioner and prescription. In the case of any prescription for a Schedule II substance filled under the provisions of this paragraph, a pharmacist filling such prescription shall within thirty days after the filling of such prescription deliver to the department a copy of each such Schedule II prescription; provided, however, that such copy shall not include the name and address of the patient for whom the prescription is issued and that such copy and the information contained thereon shall not be deemed to be public record within the meaning of section seven of chapter four and shall be subject to the restrictions set forth in section two of chapter sixty-six A. Nothing contained in this section shall be deemed to authorize any mail order pharmacies.

(d 1/2) A prescription for a narcotic substance contained in Schedule II of section 3 may also be issued by a physician who is licensed to practice medicine and registered in Maine or in a state contiguous with the commonwealth wherein such physician resides or practices, if required, and registered under federal law to write prescriptions. A registered pharmacist filling a prescription under this subsection shall determine, in accordance with professional standards and personal judgment, that such prescription is authentic and valid and shall verify the prescription by telephonic or other means. A pharmacist shall not fill a prescription for which a verification cannot be obtained. A pharmacist shall not be liable for refusing to fill a prescription for which a verification cannot be obtained provided that documented good faith efforts were made to determine the authenticity and validity of such prescription. This subsection shall only apply to authorizations for the filling of prescriptions within the commonwealth, issued within the preceding 5 days, and shall not authorize such practitioner to possess, administer or dispense controlled substances under section 9 or to practice medicine within the commonwealth. A prescription issued under this subsection shall be issued in the manner provided in section 22 and all relevant provisions of this chapter shall apply to any such practitioner and any such prescription. In the case of a prescription for a Schedule II substance filled pursuant to this subsection, a pharmacist shall, within 30 days after filling such prescription, deliver to the department a copy of each such Schedule II prescription; provided, however, that such copy shall not include the name and address of the patient for whom the prescription was issued; and provided further, that such copy and the information contained therein shall not be a public record within the meaning of section 7 of chapter 4 and shall be subject to the restrictions set forth in section 2 of chapter 66A. Nothing in this section shall authorize a mail-order pharmacy.

Nothing in this subsection shall be interpreted to prohibit a retail pharmacy operating within the commonwealth from filling prescriptions or shall be written by a nurse practitioner or physician assistant who is authorized by the state of the prescription's origin to write the prescription and is licensed and registered in the same state or a contiguous state to where the prescription is to be

delivered and is registered under federal law to write prescriptionsfor a narcotic substance contained in schedule II of section 3 to residents of states other than Maine and the states contiguous with the commonwealth, provided, however, that:

(1) the pharmacy shall be licensed for retail by the commonwealth and, if applicable, registered with the appropriate regulatory authorities in the state from which the prescription is received and the United States Drug Enforcement Administration, as applicable, for the dispensing of controlled substances;

<[Clause (2) of second paragraph of subsection (d 1/2 effective until October 31, 2014. For text effective October 31, 2014, see below.]>

(2) the prescription shall be filled by a pharmacist licensed and registered in the state from which the prescription originates, if the state of the prescription's origin requires such registration and licensing, and shall be written by a physician licensed to practice medicine and registered in the same state or a contiguous state to where the prescription is to be delivered and registered under federal law to write prescriptions;

<[Clause (2) of second paragraph of subsection (d 1/2 as amended by 2014, 359, Sec. 21 effective October 31, 2014. For text effective until October 31, 2014, see above.]>

(2) the prescription shall be filled by a pharmacist licensed and registered in the state from which the prescription originates, if the state of the prescription's origin requires such registration and licensing, and shall be written by a physician licensed to practice medicine and registered in the same state or a contiguous state to where the prescription is to be delivered and registered under federal law to write prescriptions or shall be written by a nurse practitioner or physician assistant who is authorized by the state of the prescription’s origin to write the prescription and is licensed and registered in the same state or a contiguous state to where the prescription is to be delivered and is registered under federal law to write prescriptions;

(3) the prescription shall be received by the retail pharmacy via mail or commercial carrier or through an equivalent electronic means as may be authorized by federal law;

(4) a registered pharmacist filling a prescription under this subsection shall determine, in accordance with professional standards and personal judgment, that such prescription is authentic, valid, legitimate and legal in the state from which it is received and shall verify the prescription by telephonic or other means; provided, however, that a pharmacist shall not fill a prescription for which verification cannot be obtained; and provided further, that any delivery of controlled substances to residents of another state shall be in full compliance with all laws and regulations of that state relative to the issuance and filling of prescriptions;

(5) the pharmacy shall comply with all reporting requirements of the state to which the prescription is delivered including, but not limited to, enrollment in and adherence to the rules, regulations and requirements of the state's prescription monitoring program or any program equivalent thereto, where applicable; and

(6) any substances delivered under this subsection shall be delivered via mail or by a commercial carrier to a verified address in the state of residence of the person for whom the prescription was written and shall not enter into the hands of any person in the commonwealth not directly associated by employment or subcontract with the United States Postal Service or commercial carrier selected for such purpose.

(e) Practitioners who prescribe controlled substances, except veterinarians, shall be required, as a prerequisite to obtaining or renewing their professional license, to complete appropriate training relative to: (i) effective pain management; (ii) identification of patients at high risk for substance abuse; and (iii) counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications. The boards of registration for each professional license that requires such training shall develop the standards for appropriate training programs.

Massachusetts General Laws Annotated (2014)
Part I. Administration of the Government (Ch. 1-182)
Title XV. Regulation of Trade (Ch. 93-110H)
Chapter 94C. Controlled Substances Act

§ 24A. Electronic monitoring of the prescribing and dispensing of controlled substances and certain additional drugs

(a)(1) The department shall establish and maintain an electronic system to monitor the prescribing and dispensing of all schedule II to V, inclusive, controlled substances and certain additional drugs by all professionals licensed to prescribe or dispense such substances. For the purposes of this section, "additional drugs" shall mean substances determined by the department to carry a bona fide potential for abuse.

(2) The department shall enter into reciprocal agreements with other states that have compatible prescription drug monitoring programs to share prescription drug monitoring information among the states.

(b) The requirements of this section shall not apply to the dispensing of controlled substances to inpatients in a hospital.

(c) For the purposes of monitoring the prescribing and dispensing of all schedule II to V, inclusive, controlled substances and additional drugs, as authorized in subsection (a), the department shall promulgate regulations including, but not limited to, (1) a requirement that each pharmacy that delivers a schedule II to V, inclusive, controlled substance or a substance classified as an additional drug by the department to the ultimate user shall submit to the department, by electronic means, information regarding each prescription dispensed for a drug included under subsection (a); and (2) a requirement that each pharmacy collects and reports, for each prescription dispensed for a drug under subsection (a), a customer identification number and other information associated with the customer identification number, as specified by the department. Each pharmacy shall submit the information in accordance with transmission methods and frequency requirements promulgated by the department; provided, however, that the information shall be submitted at least once every 7 days. The department may issue a waiver to a pharmacy that is unable to submit prescription information by electronic means. The waiver shall permit the pharmacy to submit prescription information by other means promulgated by the department; provided, however, that all information required in this section is submitted in this alternative format.

The department shall promulgate rules and regulations relative to the use of the prescription monitoring program by registered participants, which shall include requiring participants to utilize the prescription monitoring program prior to the issuance, to a patient for the first time, of a prescription for a narcotic drug that is contained in schedule II or III. The department may require participants to utilize the prescription monitoring program prior to the issuance, to a patient for the first time, of benzodiazepines or any other schedule IV or V prescription drug, which is commonly abused and may lead to physical or psychological dependence or which

causes patients with a history of substance dependence to experience significant addictive symptoms. The regulations shall specify the circumstances under which such narcotics may be prescribed without first utilizing the prescription monitoring program. The regulations may also specify the circumstances under which support staff may use the prescription monitoring program on behalf of a registered participant. When promulgating the rules and regulations, the department shall also require that pharmacists be trained in the use of the prescription monitoring program as part of the continuing education requirements mandated for licensure by the board of registration in pharmacy, under section 24A of chapter 112. The department shall also study the feasibility and value of expanding the prescription monitoring program to include schedule VI prescription drugs.

(d) Prescription information submitted to the department under this section shall be confidential and exempt from disclosure under clause Twenty-sixth of section 7 of chapter 4 and chapter 66. The department shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except as provided for in this chapter.

(e) The department shall review the prescription and dispensing monitoring information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the department shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity and provide prescription information required for an investigation.

(f) The department shall, upon request, provide data from the prescription monitoring program to the following:--

(1) persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients;

(2) individuals who request their own prescription monitoring information in accordance with procedures established under chapter 66A;

(3) persons authorized to act on behalf of state boards and regulatory agencies that supervise or regulate a profession that may prescribe controlled substances; provided, however, that the data request is in connection with a bona fide specific controlled substance or additional drug-related investigation;

(4) local, state and federal law enforcement or prosecutorial officials working with the executive office of public safety engaged in the administration, investigation or enforcement of the laws governing prescription drugs; provided, however, that the data request is in connection with a bona fide specific controlled substance or additional drug-related investigation;

(5) personnel of the executive office of health and human services regarding Medicaid program recipients; provided, however that the data request is in connection with a bona fide specific controlled substance or additional drug-related investigation; or

(6) personnel of the United States attorney, office of the attorney general or a district attorney; provided, however, that the data request is in connection with a bona fide specific controlled substance or additional drug related investigation.

(g) The department may, at its initiative, provide data from the prescription monitoring program to practitioners in accordance with section 24.

(h) The department may provide de-identified, aggregate information to a public or private entity for statistical research or educational purposes.

(i) The department may contract with another agency or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. A contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in this section.

(j) The department shall promulgate rules and regulations setting forth the procedures and methods for implementing this section.

(k) The department shall submit an annual report on the effectiveness of the prescription monitoring program with the clerks of the house and senate, the chairs of the joint committee on public health, the chairs of the joint committee on health care financing and the chairs of the joint committee on public safety and homeland security.

(l) Upon receiving a report of an overdose-related death from the chief medical examiner, under section 16 of chapter 38, or a report of examination or treatment of a person with injuries resulting from an opiate, illegal or illicit drug overdose, under section 12A of chapter 112, the department shall review the prescription monitoring program to determine if a notification should be made under subsection (e).

Code of Massachusetts Regulations (2014)
Title 105: Department of Public Health
Chapter 700.000: Implementation of M.g.l. C. 94C

700.012: Prescription Monitoring Program

(A) Pharmacy Reporting Requirements.

(1) The reporting requirement of 105 CMR 700.012 shall apply to every pharmacy in a health facility registered with the Commissioner that dispenses a controlled substance pursuant to a prescription in Schedules II through V, or a controlled substance classified by the Department as an additional drug, and to any pharmacy in another state, commonwealth, district or territory that delivers such a controlled substance to a person in Massachusetts. Such a pharmacy shall, in accordance with standards established by the Commissioner or designee, transmit to the Department or its agent the following information for each such prescription:

(a) pharmacy identifier;

(b) prescription number;

(c) customer identifier, as defined in 105 CMR 700.001;

(d) relationship of customer to patient;

(e) patient name;

(f) patient address;

(g) patient date of birth;

(h) patient gender;

(i) source of payment for prescription;

(j) date prescription written by prescriber;

(k) date the controlled substance is dispensed;

(l) identifier of controlled substance dispensed;

(m) metric quantity of controlled substance dispensed;

(n) estimated days supply of controlled substance dispensed;

(o) refill information; and

(p) prescriber identifier.

(2) 105 CMR 700.012 shall not apply to the dispensing pursuant to a medication order of a controlled substance to an inpatient in a hospital.

(3) A pharmacy that dispenses a controlled substance subject to the requirements in 105 CMR 700.012 must report the customer identifier required by 105 CMR 701.004. A pharmacy may dispense a controlled substance without a customer identifier, provided it meets the requirements of 105 CMR 701.004(B) and provides to the Department those informational fields required by the Department.

(4) The Commissioner or designee may waive or modify the requirement in 105 CMR 700.012(A)(1)(c) and/or (d), for a pharmacy to report a customer identifier and/or the relationship of the customer to the patient for prescription refills, prescription deliveries and/or other activities/situations specified by the Commissioner or designee.

(5) The information required by 105 CMR 700.012 shall be transmitted to the Department or its agent in accordance with any procedures established by the Commissioner or designee at least once every seven days and no later than ten days after dispensing, or as otherwise specified in guidelines of the Department, by use of encrypted electronic device or electronic transmission method in a format approved by the Commissioner or designee.

(6) If a pharmacy is not able to submit dispensing information by electronic means, the Commissioner or designee may issue a waiver to authorize another means of transmission, provided that all information required in accordance with 105 CMR 700.012(A) is submitted in this alternate format.

(B) Prescription Monitoring Program Advisory Council.

(1) The Commissioner of the Department of Public Health may establish a Prescription Monitoring Program Advisory Council to advise the Department on the implementation of 105 CMR 700.012. The membership of the Advisory Council may include, but need not be limited to, representatives of the Department of Public Health; Executive Office of Health and Human Services; Executive Office of Public Safety; Boards of Registration responsible for licensing professionals authorized to prescribe or dispense controlled substances, including the Boards of Registration in Medicine, Pharmacy, Dentistry, Podiatry, Veterinary Medicine, Optometry, Nursing and Physician Assistants; representatives of associations or societies representing professions authorized to prescribe or dispense controlled substances, patient interests, privacy interests; and a person with expertise in the design or operation of a secure automated data system.

(2) The Prescription Monitoring Program Advisory Council may assist the Department and Boards of Registration, as appropriate, in designing education programs for the appropriate use of prescription monitoring program information.

(C) Prescription Monitoring Program Medical Review Group.

(1) The Commissioner may establish the Prescription Monitoring Program Medical Review Group to advise the Department on accepted medical practice standards related to the disclosure of information pursuant to subsection 105 CMR 700.012(D)(4)(b). The Medical Review Group shall advise the Department in the evaluation of prescription information and clinical aspects of the implementation of 105 CMR 700.012.

(2) Members of the Medical Review Group shall be licensed health care practitioners and pharmacists and, to the extent feasible, at least one member shall be licensed in the same discipline as the practitioner whose records are under review. Practitioners serving on the Medical Review Group must have a valid Controlled Substances Registration for Schedules II through VI pursuant to M.G.L. c. 94C, § 7.

(D) Privacy, Confidentiality and Disclosure.

(1) Except where otherwise provided by judicial order, statute or regulation, including but not limited to 105 CMR 700.012(D)(2), the information collected pursuant to 105 CMR 700.012 shall be kept confidential by the Department.

(2) The Department shall, upon request and to the extent made feasible by 105 CMR 700.012(F), provide data collected pursuant to 105 CMR 700.012 to:

(a) an individual authorized and registered to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care to a patient;

(b) a person authorized to act on behalf of an entity designated by M.G.L. c. 94C, § 24A, provided the request is in connection with a bona fide specific controlled substance or additional drug-related investigation, and further provided that such entity is:

1. a state board or regulatory agency that supervises or regulates a profession that may prescribe or dispense controlled substances;

2. a local, state or federal law enforcement agency or prosecutorial office working with the Executive Office of Public Safety engaged in the administration, investigation or enforcement of criminal law governing controlled substances;

3. the Executive Office of Health and Human Services, acting with regard to a MassHealth program recipient;

4. the United States Attorney;

5. the Office of the Attorney General; or

6. the office of a District Attorney.

(c) a duly authorized representative of a health department or other agency in another state, commonwealth, district, territory or country that maintains prescription information in a data system with privacy, security and other disclosure requirements consistent with those established in the Commonwealth, in accordance with a valid, written reciprocal data sharing agreement establishing the terms and conditions for exchange of data; and

(d) an individual or the individual's parent or legal guardian, who requests the individual's own prescription monitoring information in accordance with procedures established under M.G.L. c. 66A and other applicable statute or regulation of the Commonwealth.

(3) A request for information collected pursuant to 105 CMR 700.012 shall be in writing or, if applicable, transmitted electronically pursuant to 105 CMR 700.012(F) and shall be made in accordance with procedures established by the Commissioner or designee to ensure compliance with the requirements of 105 CMR 700.012(D) and (E).

(4) The Commissioner or designee may initiate disclosure of data on a patient or research subject collected pursuant to 105 CMR 700.012 to an individual authorized and registered to prescribe or dispense controlled substances in any or all of the Schedules II through V, and Schedule VI if applicable, pursuant to 105 CMR 700.000, provided that:

(a) The authorized individual has prescribed or dispensed such a controlled substance to the patient or research subject;

(b) The Commissioner or designee has determined that the patient or research subject is receiving a controlled substance or additional drug from more than one source and in quantities that he determines to be harmful to the health of the patient or research subject or that disclosure is otherwise necessary to prevent the unlawful diversion of a controlled substance; and

(c) Such disclosure shall not require or direct the authorized individual to take action that he or she believes to be contrary to the patient's or research subject's best interests.

(5) (a) The Department shall review the prescription monitoring information collected pursuant to 105 CMR 700.012. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Department shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity and provide prescription monitoring information required for an investigation.

(b) Disclosure at the initiation of the Commissioner or designee pursuant to 105 CMR 700.012(D)(4) and (5) shall be in conformance with any protocols established by the Commissioner or designee, who may consult with the Medical Review Group. When such consultation is provided on Commissioner initiated disclosure, the Medical Review Group shall review the content and application of the protocols, make recommendations to the Commissioner for effective use of such protocols and as needed review specific instances of Commissioner initiated disclosure. If undertaking such review, the Medical Review Group may be provided upon request with such pertinent information as needed.

(6) The Commissioner or designee may provide de-identified, aggregate data to a public or private entity for statistical research or educational purposes.

(7) Data collected pursuant to 105 CMR 700.012(A) shall not be a public record and shall not be disclosed to anyone other than those persons specifically authorized under 105 CMR 700.012(D).

(E) Security Protections.

(1) Any disclosure or transmission of personally identifying information collected pursuant to 105 CMR 700.012 shall be in accordance with Department security requirements for such disclosure and transmission, including requirements for technical non-repudiation, confidentiality, and authentication, as those terms are defined in 105 CMR 721.000. Such protections shall include the establishment of a record of each request and transmission.

(2) A person authorized to receive information pursuant to 105 CMR 700.012(D) shall promptly notify the Department of any potential violation of confidentiality or use of the data in a manner contrary to 105 CMR 700.012 or applicable professional standards.

(3) A person's Controlled Substance Registration may be suspended or terminated in accordance with 105 CMR 700.004(L)(1) for the following:

(a) a request for data pursuant to 105 CMR 700.012(D), or use or disclosure of data that involves a willful failure to comply with the standards in 105 CMR 700.012 for request, transmission or disclosure of data;

(b) a failure to reasonably protect data in accordance with the requirements of 105 CMR 700.012 or other applicable state or federal law; or

(c) an attempt to obtain data through fraud or deceit.

(F) Electronic Transmission of Prescription Monitoring Program Information.

(1) The Department may establish means for secure electronic transmission of prescription monitoring program information to facilitate disclosure of such information authorized pursuant to 105 CMR 700.012.

(2) The Department may allow an authorized individual listed in 105 CMR 700.012(D)(2)(a) through (c), or a designee of such individual as approved by the Commissioner or designee, to use the secure electronic transmission system established pursuant to 105 CMR 700.012(F)(1) in accordance with security protocols established by the Commissioner or designee.

(3) Use of the secure electronic transmission system shall be limited to the uses authorized by 105 CMR 700.012.

(4) An authorized end user of the secure electronic transmission system must agree and attest to terms and conditions of use established by the Commissioner or designee.

(5) Failure of an end user to comply with 105 CMR 700.012 may result in revocation of the end user's authorization to use the secure electronic transmission system and may subject the end user to further sanction pursuant to 105 CMR 700.012(E)(3) or other state law.

Code of Massachusetts Regulations (2014)
Title 105: Department of Public Health
Chapter 725.000: Implementation of an Act for the Humanitarian Medical Use of Marijuana

725.010: Certifying Physician's Written Certification of a Debilitating Medical Condition for a Qualifying Patient

(A) A certifying physician issuing a written certification on or after July 1, 2014, must have completed a minimum of 2.0 Category 1 continuing professional development credits as defined in 243 CMR 2.06(6)(a)1. Such program must explain the proper use of marijuana, including side effects, dosage, and contraindications, including with psychotropic drugs, as well as on substance abuse recognition, diagnosis, and treatment related to marijuana.

(B) A certifying physician issuing a written certification shall comply with generally accepted standards of medical practice, including regulations of the Board of Registration in Medicine at 243 CMR 1.00 through 3.00.

(C) A certifying physician may not delegate to any other health care professional or any other person, authority to diagnose a patient as having a debilitating medical condition.

(D) A certifying physician may issue a written certification only for a qualifying patient with whom the physician has a bona fide physician-patient relationship.

(E) Before issuing a written certification, a certifying physician must utilize the Massachusetts Prescription Monitoring Program, unless otherwise specified by the Department, to review the qualifying patient's prescription history.

(F) A patient who has had a diagnosis of a debilitating medical condition in the past but does not have an active condition, unless the symptoms related to such condition are mitigated by marijuana for medical use, and is not undergoing treatment for such condition is not suffering from a debilitating medical condition for which the medical use of marijuana is authorized.

(G) An initial written certification submitted before a clinical visit is prohibited. A renewal written certification may be submitted after a clinical visit or a telephonic consultation, however a clinical visit must occur no less than once per year.

(H) A certification must indicate the time period for which the certification is valid, and shall not be less than 15 calendar days or longer than one year.

(I) A certifying physician may determine and certify that a qualifying patient requires an amount of marijuana exceeding ten ounces as a 60-day supply and shall document the amount and the rationale in the medical record and in the written certification. For that qualifying patient, that amount of marijuana constitutes a 60-day supply.

(J) A qualifying patient who is younger than 18 years old and has been diagnosed by two Massachusetts licensed certifying physicians, at least one of whom is a board-certified pediatrician or a board-certified pediatric subspecialist, with a debilitating life-limiting illness, may receive a written certification, provided however that the physicians may certify a qualifying patient who is younger than 18 years old who has a debilitating medical condition that is not a life-limiting illness if those physicians determine that the benefits of the medical use of marijuana outweigh the risks. This must include a discussion of the potential negative impacts on neurological development with the parent or legal guardian of the qualifying patient, written consent of the parent or legal guardian, and documentation of the rationale in the medical record and the written certification.

(K) A certifying physician, and such physician's co-worker, employee, or immediate family member, shall not:

(1) Have ever directly or indirectly accepted or solicited from, or offered to an RMD, a board member or executive of an RMD, any RMD personnel, or any other person associated with an RMD, or a personal caregiver, anything of value;

(2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular personal caregiver or RMD;

(3) Examine or counsel a patient, or issue a written certification, at an RMD;

(4) Have a direct or indirect financial interest in an RMD; or

(5) Directly or indirectly benefit from a patient obtaining a written certification, which shall not prohibit the physician from charging an appropriate fee for the clinical visit.

(L) A certifying physician shall not issue a written certification for himself or herself or for his or her immediate family members.

(M) A certifying physician issuing a written certification for his or her employees or co-workers shall do so in accordance with 105 CMR 725.010, including conducting a clinical visit, completing and documenting a full assessment of the patient's medical history and current medical condition, explaining the potential benefits and risks of marijuana use, and maintaining a role in the ongoing care and treatment of the patient.

(N) A written certification shall be issued in a form and manner determined by the Department.

Code of Massachusetts Regulations (2014)
Title 234: Board of Registration in Dentistry
Chapter 5.00: Requirements for the Practice of Dentistry and Dental Hygiene

5.06: Controlled Substances

(1) Dentists registered to dispense, administer and prescribe any controlled substances shall do so in accordance with M.G.L. c. 94C and 105 CMR 700.00 and all applicable state and federal statutes and regulations pertaining to controlled substances.

(2) Dentists are limited to writing prescriptions for controlled substances for legitimate dental purposes in the usual course of practice and are prohibited from prescribing controlled substances in Schedules II-IV for personal use.

(3) Except in an emergency, a dentist is prohibited from prescribing Schedule II controlled substances to a member of his/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 permanently residing in the same residence as the licensee.

(4) Prior to prescribing 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) and a check of 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;

(d) Supply a Letter of Medical Necessity as required by the Board of Registration in Pharmacy that includes the patient's diagnoses and treatment plan, verifies that other pain management treatments have failed, indicates that a risk assessment was performed and that the licensee and the patient have entered into a Pain Management Treatment Agreement; and

(e) Document 234 CMR 5.06(4)(a) through (d) in the patient's medical record.

Code of Massachusetts Regulations (2014)
Title 243: Board of Registration in Medicine
Chapter 2.00: The Practice of Medicine

2.07: General Provisions Governing the Practice of Medicine

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

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

(2) Interpretation of Blood Pressure Measurements. (Reserved).

(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 assures that the medical student practices medicine in accordance with accepted medical standards.

(4) Delegation of Medical Services. A full licensee may permit a skilled professional or non-professional assistant to perform services in a manner consistent with accepted medical standards and appropriate to the assistant's skill. The full licensee is responsible for the medical services delegated to a skilled professional or nonprofessional assistant. Nothing in 243 CMR 2.07(4) shall be construed as permitting an unauthorized person to perform activities requiring a license to practice medicine. A full licensee shall not knowingly permit, aid or abet the unlawful practice of medicine by an unauthorized person, pursuant to M.G.L. c. 112, § 9A, M.G.L. c. 112, § 61, and 243 CMR 1.05(6).

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

(6) Hospital Privileges. (Reserved').

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

(8) Changes in Registration Information Occurring Outside of the Licensing 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 certain information provided to the Board as part of the registration process changes. A written report shall be sent to the Board 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, pursuant to the procedures set forth in 243 CMR 2.02(14).

(c) Change in Sex. An applicant or licensee who changes his or her sex pursuant to M.G.L. c. 46, § 13(e) shall provide notice to the Board within 30 days of the date of the amendment of his or her birth certificate.

(d) Physician Ownership in a For-profit Acute Care Hospital or HMO.

1. Report to the Board. 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. Ill, § 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. Ownership Interest For purposes of 243 CMR 2.07(8)(d), 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 financial arrangements between a health maintenance organization organized under M.G.L. c. 176G, or a preferred provider arrangement organized under M.G.L. c. 1761 and their participating providers, and shall not apply to financial arrangements among participating providers of such health maintenance organization or such preferred provider arrangement.

(e) Physician Ownership Interest in Facilities Providing Physical Therapy Services

1. Report to the Board. 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.

2. 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. 1761 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

3. 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:

a. The licensee shall disclose his or her financial ownership interest to the patient.

b. 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.“

c. 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.

4. 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.

(f) 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.

(g) Other Reporting Obligations. In addition to his or her duties under 243 CMR 2.07(8), a licensee may have a reporting obligation under 243 CMR 2.04 or 243 CMR 2.14.

(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 non discriminatory 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.

4. Advertising that makes claims of professional superiority which a licensee cannot substantiate.

(b) A full licensee may advertise fixed prices, or a stated range of prices, for specified routine professional services, provided such advertisement clearly states whether additional charges may be incurred for related services which may be required in individual cases.

(c) A full licensee may advertise in any print or electronic media, including television, radio, or Internet, provided that he or she maintains a complete, accurate, and reproducible version of the audio and visual contents of that advertising for a period of three years. The licensee must furnish a complete copy of this advertising to the Board upon request. The cost of maintaining and providing this advertising copy shall be borne by the licensee.

(d) A full licensee shall include in an advertisement or professional notice his or her name, business address and degree (M.D. or D.O.).

(e) A full licensee may not represent that he or she holds a degree from a medical school other than that degree that appears on his or her application for registration and has been verified in accordance with the Board's requirements.

(12) Requirement to Respond to Board.

(a) 30 Day Period. A licensee shall respond within 30 days to a written communication from the Board or its designee and shall make available to the Board any relevant and authorized records with respect to an inquiry or complaint about the licensee's professional conduct. The 30 day period commences on the date the Board sends the communication by any method of mailing that provides confirmation of delivery to the licensee's mailing address of record with the Board.

(b) Ten Day Order to Respond. If the licensee fails to respond to the initial request of the Board or its Committees within the 30 day period set forth 243 CMR 2.07(12)(a), the Board, or its Licensing, Data Repository or Complaint Committees, may issue an order that the licensee respond to its communication within ten days. The Ten Day Order to Respond is an administrative order. A licensee's failure to respond to a written communication from the Board under 243 CMR 2.07(12)(a) and to a Ten Day Order from a Board or its committees under 243 CMR 2.07(12)(b) may be considered grounds for a complaint under 243 CMR 1.03(5): Grounds for Complaint.

(13) Medical Records.

(a) Length of Time to Maintain Patient Records. A licensee shall maintain a medical record for each patient that is complete, timely, legible, and adequate to enable the licensee or any other health care provider to provide proper diagnosis and treatment. Any records received from another health care provider involved in the care and treatment of the patient shall be maintained as part of the patient's medical record. With respect to patient records existing on or after January 1,1990, and unless otherwise required by law, a licensee must maintain a patient's medical records for a minimum period of seven years from the date of the last patient encounter. However, if the patient is a minor on the date of the last patient encounter, the licensee must maintain the pediatric patient's records for a minimum period of either seven 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

(14) Breast Cancer. (Reserved).

(15) Medicare Payments. When a licensee accepts for treatment a beneficiary of health insurance under Title XVIII of the Social Security Act (Medicare), the licensee shall not charge to or collect from such beneficiary any amount in excess of the Medicare Physician Fee Schedule charge for that service as determined by the United States Secretary of Health and Human Services and as administered by the Centers for Medicare and Medicaid Services.

(16) Mandatory Professional Malpractice Liability Insurance. As a condition of rendering any direct or indirect patient care in the Commonwealth, a licensee must obtain medical malpractice insurance as follows, except as provided in 243 CMR 2.07(16)(d):

(a) Professional Malpractice Liability Insurance shall include only insurance or self insurance coverage provided by an entity which provides certification to the Board, upon request, or the Division of Insurance, by a Member of the Casualty Actuarial Society, that funding of the entity is adequate to provide the coverage required under 243 CMR 2.07(16).

(b) The coverage amount shall be at least $100,000 per claim, with a minimum annual aggregate of not less than $300,000, unless otherwise established by law. Coverage may be provided on an individual or shared limit basis.

(c) 243 CMR 2.00 shall not preclude any hospital or other health care facility from requiring greater coverage amounts as a condition of appointment or granting privileges.

(d) A Health Care Provider, for purposes of 243 CMR 2.07(16) only, shall mean a health care provider as defined in M.G.L. c. 175, § 193U, and shall not apply to the following categories of licensees:

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. lese

(19) Self-prescribing and Prescribing for Family Members. A licensee is prohibited from prescribing controlled substances in Schedules II, III, and IV for his own use. Except in an emergency, a licensee is prohibited from prescribing Schedule II substances to a member of his 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) l. 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) Exception for Reports to the Board tinder M.G.L. c. 112. S 5F.

(a) Requirements for Reporting Exception to Apply. A health care provider (reporter), 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 three of the following conditions are present:

1. Reasonable Basis to Believe Impairment. The reporter 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 that the physician has not violated any other Board statute or regulation as set forth in M.G.L. c. 112, § 5 or 243 CMR 1.00 through 3.00; and

2. No Allegation of Patient Harm. The physician's involvement with alcohol or drugs has not involved an allegation of patient harm; and

3. Confirmation of Compliance with the Treatment Program. The physician is currently in compliance with a drug or alcohol program, and the reporter 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 reporter fails to obtain direct confirmation from such program or if the physician at any time fails to comply with such program, the exception to the reporting requirement set forth in 243 CMR 2.07(23) ceases and the health care provider must report the impairment 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 requires as a condition of the physician's participation that the physician consent, pursuant to 42 CFR 1, subpart A, part 2, sub C, to disclosure of relevant information to the Board, under any of the following conditions:

a. If the physician fails to correct, within a reasonable period of time, a failure to provide documentation of his or her continuing freedom from unauthorized substance use;

b. If the physician is known by the program to be in a state of unauthorized substance use, or if the physician is in a state of unauthorized substance use after signing his or her contract with the program;

c. If the program has a reasonable basis to believe that the physician, for any reason, cannot render professional services without undue risk to the public;

d. If the physician revokes consent to disclose information to the Board during the course of his or her contract with the program; or

e. If the physician terminates his or her contract with the program for any reason other than his or her successful recovery, in which the program concurs.

3. The drug or alcohol program requires that the physician consent to confirmation to the reporter, pursuant to federal regulations, that the physician is participating in the program, to the extent that the reporter needs such confirmation pursuant to 243 CMR 2.07(23)(c).

(24) Standards for Reading and Interpreting Mammography.

(a) Initial Qualification. Pursuant to M.G.L. c. 112, § 5L, a licensee may read and interpret mammography only if the licensee meets the following criteria:

1. Is licensed to practice under M.G.L. c. 112, § 2; and

2. Has American Board of Radiology (ABR) or American Osteopathy Board of Radiology (AOBR) certification, or Royal College of Physicians and Surgeons of Canada 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) CPD 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 CPD 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 CPD 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)l. 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 post graduate instruction in mammography prior to beginning mammography activities; and

6. Completes or teaches 15 hours of Category 1 CPD every 36 months while performing the duties of a Responsible Physician.

(25) Prescribing Hydrocodone-only Extended-release Medication. Prior to prescribing 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) and a check of 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;

(d) Supply a Letter of Medical Necessity as required by the Board of Registration in Pharmacy that includes the patient's diagnoses and treatment plan, verifies that other pain management treatments have failed, indicates that a risk assessment was performed and that the licensee and the patient have entered into a Pain Management Treatment Agreement; 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.

Code of Massachusetts Regulations (2014)
Title 244: Board of Registration in Nursing
Chapter 4.00: Advanced Practice Registered Nursing

4.07: APRN Eligible to Engage in Prescriptive Practice

(1) Purpose.The purpose of 244 CMR 4.07 is to establish, pursuant to M.G.L. c. 112, §§ 80B, 80C, 80E, 80G and 80H, regulations governing the practice of those APRNs who are registered prescribers.

The following APRN 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 means an RN authorized to practice within a healthcare system as a nurse midwife by the Board pursuant to M.G.L. c. 112, §§ 80B, 80C and 80G, and 244 CMR 4.00.

(b) A Certified Nurse Practitioner means an RN authorized to practice as a nurse practitioner by the Board pursuant to M.G.L. c. 112, §§ 80B, and 80E and 244 CMR 4.00.

(c) A Psychiatric Clinical Nurse Specialist means an RN authorized to practice as a psychiatric nurse mental health clinical specialist by the Board pursuant to M.G.L. c. 112, §§ 80B, and 80E and 244 CMR 4.00.

(d) A Certified Registered Nurse Anesthetist means an RN authorized to practice as a nurse anesthetist by the Board pursuant to M.G.L. c. 112, §§ 80B, and 80H and the regulations of the Board at 244 CMR 4.00. The prescriptive practice of a CRNA is limited to the immediate perioperative care of a patient

(2) Development Approval, and Review of Prescriptive Practice Guidelines.

(a) Except for the CNM who does not require guidelines for prescriptive practice, an APRN engaged in prescriptive practice will do so in accordance with written guidelines mutually developed and agreed upon with the APRN and the physician supervising the APRN's prescriptive practice.

(b) In all cases, the written guidelines will:

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, duration and scope of the delegation;

3. describe the nature and scope of the APRN's prescribing practice;

4. identify any limitations on medications or intravenous therapy to be prescribed;

5. describe circumstances in which physician consultation or referral is required for the pharmacologic treatment of medical conditions or for managing emergencies;

6. include a defined mechanism and time frame to monitor prescribing practices;

7. specify that the initial prescription of Schedule II drugs must be reviewed within 96 hours;

8. be kept on file in the workplace and be reviewed and re-executed every two years; and

9. 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,105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts,M.G.L. c. 112, §§ 80B, 80E, 80H, 801, the regulations of the Board of Registration in Nursing at 244 CMR 4.00 and the regulations of the Board of Registration in Medicine at 243 CMR 2.10: Advanced Practice Nurse (APN) Eligible to Engage in Prescriptive Practice.

The Board may request at any time an opportunity to review the APRN prescriptive practice guidelines. 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 244 CMR 4.00 and accepted standards of nursing practice.

(3) Prescribing Hydrocodone-only Extended Release Medication.

Prior to prescribing a hydrocodone-only extended release medication that is not in an abuse deterrent form, an APRN engaged in prescriptive practice 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 in 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 244 CMR 4.28(a) through (d) in the patient's medical record.

The purpose of 244 CMR 428 is to enhance the public health and welfare by promoting optimum therapeutic outcomes, avoiding patient injury and eliminating medication errors. Nothing in 244 CMR 4.28 shall alter the standard of care a licensee must use when prescribing any Schedule II, III or IV controlled substance.

(4) Self Prescribing and Prescribing for Family Members.An APRN authorized to prescribe medication is prohibited from prescribing drugs in Schedules II, III, and IV for personal use. Except in an emergency, such APRN is prohibited from prescribing Schedule II drugs to a member of her immediate family, including spouse or equivalent, a parent, a child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step sibling and any other relative residing in the same household.

(5) At the time of initial application for Massachusetts Controlled Substance Registration and subsequently during each APRN authorization renewal period the APRN must comply with all state and federal requirements for continuing education.

All continuing education offerings must be consistent with Board requirements at 244 CMR 5.00: Continuing Education.

Code of Massachusetts Regulations (2014)
Title 247: Board of Registration in Pharmacy
Chapter 5.00: Orally and Electronically Transmitted Prescriptions; Prescription Monitoring Program (Pmp) Reporting Requirements

5.04: Reporting Requirements to the Prescription Monitoring Program (PMP)

(1) Pharmacy Reporting Requirements (105 CMR 700.012). Every pharmacy registered by the Board and every pharmacy located in a health facility registered with the Commissioner of the Department that dispenses controlled substances in Schedule II pursuant to a prescription shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012). Effective January 1, 2011, every pharmacy registered by the Board that dispenses controlled substances in Schedules II-V shall, in accordance with standards established by the Department, transmit to the Department or its agent, required information for each prescription, in accordance with Prescription Monitoring Program reporting requirements (105 CMR 700.012). (M.G.L. c. 94C, § 24A)

(2) Penalties. Failure to comply with the Prescription Monitoring Program reporting requirements set forth in 105 CMR 700.012 and/or any state law or regulation relating to such reporting requirements may result in formal disciplinary action being initiated against the licensed pharmacist and/or the pharmacy by the Board and/or other state and federal law enforcement agencies.

Code of Massachusetts Regulations (2014)
Title 247: Board of Registration in Pharmacy
Chapter 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments

9.04: Requirements for Dispensing and Refilling Prescriptions

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

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

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

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

(a) the date of dispensing;

(b) the amount of the drug dispensed; and

(c) his or her initials.

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

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

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

(a) the prescriptions are for persons regularly employed at, or affiliated with, such plant, place of business or other such site;

(b) the prescriptions are collected in person by a pharmacist, pharmacy employee, or authorized agent of the pharmacy;

(c) the prescriptions are distributed in person to the patients or an authorized agent of the patient by a pharmacist, pharmacy employee, or authorized agent of the pharmacy; and

(d) the pharmacist shall be responsible for the conduct of any pharmacy employee or authorized agent acting on the pharmacist's behalf, and for verifying the authority of any person purporting to act on a patient's behalf; nothing in 247 CMR 9.04(7) shall be deemed to permit conduct of a prescription business in violation of any other regulation of the Board.

(8) A pharmacist may not fill or dispense any prescription for a hydrocodone-only extended release medication that is not in an abuse deterrent form unless:

(a) the medication is stored in a securely locked and substantially constructed cabinet at all times while on pharmacy premises;

(b) the medication is dispensed in a container with a child proof safety cap or within a locked box;

(c) the prescriber has supplied a Letter of Medical Necessity for each prescription that is compliant with 243 CMR 2.07(25): Prescribing Hydrocodone-only Extended-release Medication and that includes the patient's diagnoses and treatment plan, verifies other pain management treatments have failed, and indicates a risk assessment was performed and the prescriber and patient entered into a Pain Management Treatment Agreement and the pharmacist keeps the Letter of Medical Necessity in a readily retrievable manner;

(d) each prescription is accompanied by a written warning approved by the Board regarding the specific dangers of hydrocodone-only extended release medication that is not in abuse deterrent form;

(e) the pharmacist provides counseling that includes a review of the written warning supplied in accordance with 247 CMR 9.04(8)(c) and may include, but is not limited to:

1. the name and description of the medication;

2. the dosage form, dosage, route of administration and duration of drug therapy;

3. special instructions and precautions for preparation, administration and use by the patient;

4. common adverse or severe side effects or interactions and therapeutic contraindications;

5. techniques for self-monitoring drug therapy;

6. proper storage;

7. prescription refill information;

8. action to be taken in the event of a missed dose; and

(f) the pharmacist checks the patient's history on the online Prescription Monitoring Program.

Code of Massachusetts Regulations (2014)
Title 249: Board of Registration in Podiatry
Chapter 4.00: Practice of Podiatric Medicine

4.02: Drug Dispensing and Prescribing

(1) In accordance with M.G.L. c. 94C, a podiatrist has the same rights in possessing, administering, dispensing and prescribing drugs as other practitioners and may prescribe, dispense and administer all reasonable substances which shall include but not be limited to all prescription drugs and controlled substances; or he or she may cause the same to be administered under his or her direction by a nurse.

(2) 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 249 CMR 4.02(2)(a) through (d) in the patient's medical record.

The purpose of 249 CMR 4.02(2) is to enhance the public health and welfare by promoting optimum therapeutic outcomes, avoiding patient injury and eliminating medication errors. Nothing in 249 CMR 4.02(2) shall alter the standard of care a licensee must use when prescribing any Schedule II, III or IV controlled substance.

Code of Massachusetts Regulations (2014)
Title 263: Board of Registration of Physician Assistants
Chapter 5.00: Scope of Practice and Employment of Physician Assistants

5.07: Prescription Practices of a Physician Assistant

(1) Any physician assistant who holds a full certificate of registration, issued by the Board pursuant to 263 CMR 3.02: Requirements for Registration, may issue written or oral prescriptions or medication orders for a patient, provided that he or she does so in accordance with all applicable state and federal laws and regulations including, but not limited to, M.G.L. c. 112, § 9E; M.G.L. c. 94C, §§ 7, 9 and 20; 105 CMR 700.000: Implementation of M.G.L. c. 94C; and 263 CMR 5.07(1).

(2) A physician assistant who holds a temporary certificate of registration, issued by the Board pursuant to 263 CMR 3.04: Temporary Practice Certificates, may prepare a written or oral prescription or medication order for a patient, provided that:

(a) Any such written prescription or medication order is signed by his or her supervising physician, or by another licensed physician who has been designated to assume temporary supervisory responsibilities with respect to that physician assistant pursuant to 263 CMR 5.05(4)(g), prior to the issuance of said prescription or medication order to the patient;

(b) Any such oral prescription or medication order is approved, in writing, by his or her supervising physician, or by another licensed physician who has been designated to assume temporary supervisory responsibilities with respect to that physician assistant pursuant to 263 CMR 5.05(4)(g), prior to the issuance of that oral prescription or medication order; and

(c) All such oral or written prescriptions or medication orders are issued in the name of the supervising physician, and are otherwise issued in accordance with all applicable state and federal laws and regulations, including but not limited to, M.G.L. c. 112, § 9E; M.G.L. c. 94C, §§ 7, 9 and 20; 105 CMR 700.000: Implementation of M.G.L. c. 94C; and 263 CMR 5.07(2).

(3) 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(4)(g), within 96 hours after its issuance.

(4) All physician assistants shall issue prescriptions or medication orders in accordance with written guidelines governing the prescription of medication which are mutually developed and agreed upon by the physician assistant and his or her supervising physician(s).

(a) Such guidelines shall address, but need not be limited to, the following issues:

1. Identification of the supervising physician(s) for that work setting;

2. Frequency of medication reviews by the physician assistant and his or her supervising physician;

3. Types and classes of medications to be prescribed by the physician assistant;

4. The initiation and/or renewal of prescriptions for medications 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;

5. The quantity of any medication to be prescribed by a physician assistant, including initial dosage limits and refills;

6. 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;

7. Review of initial prescriptions or changes in medication; and

8. Procedures for initiating intravenous solutions.

(b) Such guidelines shall be available for review by any duly authorized representative of the Board, the Massachusetts Board of Registration in Medicine, the Massachusetts Department of Public Health, and such other state or federal government agencies as may be reasonably necessary and appropriate to ensure compliance with all applicable state or federal laws and regulations. Copies of such guidelines, however, need not be filed with those agencies.

(c) All such guidelines must be in writing and must be signed by both the supervising physician and the physician assistant. Such guidelines shall be reviewed annually and dated and initialed by both the supervising physician and the physician assistant at the time of each such review. The physician assistant and his or her supervising physician may alter such guidelines at any time and any such changes shall be initialed by both parties and dated.

(5) All prescriptions or medication orders issued by a physician assistant shall be issued in a manner which is consistent with the scope of practice of the physician assistant, the guidelines developed pursuant to 263 CMR 5.07(4), and accepted standards of good medical practice for licensed physicians with respect to prescription practices.

(6) At least four hours of the continuing medical education which a physician assistant is required to obtain pursuant to 263 CMR 3.05(3): Renewal of Registration as a condition for license renewal shall be in the field of pharmacology and/or pharmacokinetics.

(7) All prescriptions written by a physician assistant shall be written in accordance with 105 CMR 721.000: Standards for Prescription Format and Security in Massachusetts.

(8) A physician assistant may order only Schedule VI controlled substances from a drug wholesaler, manufacturer, distributor or laboratory, and only in accordance with the written guidelines developed with his/her supervising physician pursuant to 263 CMR 5.07(4). A physician assistant may sign only for sample Schedule VI controlled substances received by or sent to the practice setting by a pharmaceutical representative.

(9) The use of pre-signed prescription blanks or forms is prohibited.

(10) A physician assistant shall not prescribe controlled substances in Schedules II, III and IV for his or her own use. Except in an emergency, a physician assistant shall not prescribe Schedule II controlled substances for a member of his or her immediate family, including a parent, spouse or equivalent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or other relative permanently residing in the same residence as the physician assistant.

(11) The physician assistant and the supervising physician for that work setting shall be jointly responsible for all prescriptions or medication orders issued by the physician assistant in that work setting.

(12) 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 263 CMR 5.07(12)(a) through (d) in the patient's medical record.

The purpose of 263 CMR 5.07(12) is to enhance the public health and welfare by promoting optimum therapeutic outcomes, avoiding patient injury and eliminating medication errors. Nothing in 263 CMR 5.07(12) shall alter the standard of care a licensee must use when prescribing any Schedule II, III or IV controlled substance.