700.001: Definitions

Delegate means an authorized support staff member, or colleague of the participant who is not a primary account holder, who may access the prescription monitoring program on behalf of a participant.

Emergency Medical Technician (EMT) means a person certified by the Department, pursuant to M.G.L. c. 111C, § 9 and 105 CMR 170.000: *Emergency Medical Services System*, in accordance with his or her level of training, to administer controlled substances pursuant to his or her training and the Statewide Treatment Protocols. The term EMT shall include EMT-Basic and the ALS levels of advanced EMT EMT-Intermediate and EMT-Paramedic as defined in 105 CMR 170.000.

Participant means a registered individual practitioner or other person who is duly authorized to prescribe or dispense a controlled substance by the appropriate Massachusetts Board of Registration or is authorized by the Department to utilize the prescription monitoring program.

Physician Assistant means a physician assistant authorized to practice by the Board of Registration of Physician Assistants, as provided for in accordance with M.G.L. c. 112, § 9I, and authorized to prescribe in accordance with M.G.L. c. 112, § 9E, and 263 CMR 5.00: *Scope of Practice and Employment of Physician Assistants*.

Primary account holder means a participant who has sub-accounts, or a facility-hospital licensed by the Division of Health Facilities Licensure and Certification and approved by the Department, for purposes of permitting interns and residents to be delegates of the hospital.

Utilize means to access (directly or through a delegate) and assess a patient’s prescription history from the prescription monitoring program.

700.003: Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)

(A)(1) An EMT-Paramedic, or an EMT-Paramedic student as part of his or her participation in a Department-approved Paramedic training program, may administer only those controlled substances, in quantity and kind, that are necessary for the performance of his or her duties in accordance with 105 CMR 170.000: *Emergency Medical Services System and the Statewide Treatment Protocols*;

(2) An Advanced EMT, Advanced EMT EMT-Intermediate, EMT-Intermediate student as part of his or her participation in a Department-approved Intermediate training program, EMT-Basic or EFR may administer only those controlled substances in Schedule VI for which he or she has been approved by the Department and that are necessary for the performance of his or her duties in
accordance with 105 CMR 170.000: Emergency Medical Services System and the provisions of the Statewide Treatment Protocols;

(3) Administration of controlled substances by an EMTs at all levels, and EMT students at all levels, EMT-Paramedic student, EMT-Intermediate Advanced EMT student or EFR is also subject to the following conditions:

(a) The ambulance service or EFR service for which the individual serves, shall be registered in accordance with 105 CMR 700.004 for the appropriate controlled substances;
(b) The ambulance service or EFR service shall maintain a current listing of names of its employees and volunteers who are authorized to administer controlled substances;
(c) The EMT, EMT-Paramedic student, EMT-Intermediate Advanced EMT student or EFR shall perform only those functions for which he or she is authorized by, and trained in accordance with 105 CMR 170.000: Emergency Medical Services System;
(d) Administration of controlled substances shall be conducted:
   1. pursuant to the order of a practitioner and the Statewide Treatment Protocols; and
   2. in accordance with 105 CMR 170.000: Emergency Medical Services System and the provisions of the Statewide Treatment Protocols.

…

(C) (1) A certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant may issue written prescriptions and medication orders for Schedule II through VI controlled substances, provided that the following requirements are met:
(a) The certified nurse practitioner, psychiatric clinical nurse specialist, and certified registered nurse anesthetist meets all requirements set forth in 244 CMR 4.00: The Practice of Nursing in the Expanded Role Advanced Practice Registered Nursing and M.G.L. c. 112, §§ 80B, 80E, and 80H.
(b) The physician assistant meets all requirements set forth in regulations established by the Board of Registration of Physician Assistants in 263 CMR 2.00, 3.00, and 5.00, and M.G.L. c. 112, §§ 9C through 9K.
(c) The certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant registers with the Department's Division of Food and Drugs Prescription Monitoring and Drug Control Program, in accordance with 105 CMR 700.004 and with the Drug Enforcement Administration, in accordance with 21 CFR 1300.
(d) The certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant practices in accordance with written guidelines governing the prescription of medication mutually developed and agreed upon by the certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant and a supervising physician pursuant to regulations promulgated under M.G.L. c. 112, §§ 80B, 80E, and 80H and M.G.L. c. 112, § 9E that describes the methods to be followed in managing a health care situation or in resolving a health care problem. All prescriptions issued by the certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant are consistent with the scope of practice as defined by 244 CMR 4.26 4.00 for nurses practicing in the expanded role and 263 CMR 5.00: Scope of Practice and Employment of Physician Assistants for physician assistants.
(e) The certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant may order controlled substances in Schedule VI from a drug wholesaler, manufacturer, laboratory or distributor. For the purpose of dispensing medication in Schedules II-V for immediate treatment, the certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant may obtain such medication only as supplied by the supervising physician, obtained through a written prescription for the patient, or in the case of certified
registered nurse anesthetist, as supplied by a practitioner for immediate treatment of a patient, in accordance with guidelines of the Board of Registration in Medicine.

(f) A certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant may issue oral prescriptions in accordance with M.G.L. c. 94C, § 20, provided that the person issuing the prescription clearly identifies his or her name and professional designation to the pharmacist and provides his or her registration number, work address, phone number, and the name of the supervising physician. An oral prescription shall be followed up with a written prescription by the certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant to be provided to the pharmacist or postmarked within a period of not more than seven days or such shorter period as required by federal law, in accordance with M.G.L. c. 94C, § 20.

(g) A certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant may prescribe controlled substances for a patient in a health facility or other setting through use of written medication orders entered on the patient's medical record maintained at the facility, provided that such written orders meet all applicable provisions of 105 CMR 700.000.

(2) A certified nurse midwife may issue written prescriptions and medication orders, in accordance with the provisions of M.G.L. c. 112, §§ 80C and 80G, for those controlled substances in Schedules II through VI.

700.004: Registration Requirements

(L) Suspension or Revocation of Registration. The Commissioner may suspend or revoke a registration issued by him or her to manufacture, distribute, dispense, or possess a controlled substance in accordance with procedures outlined in 105 CMR 700.100 through 700.120:

1. After a hearing pursuant to the provisions of M.G.L. c. 30A upon a finding that the registrant:
   a. Has furnished false or fraudulent material information in any application filed under the provisions of 105 CMR 700.000, or
   b. Has been convicted under any state or federal law of any criminal violation relating to his or her fitness to be registered under 105 CMR 700.000, or
   c. Has had his or her federal registration suspended or revoked to manufacture, distribute, dispense, administer or possess controlled substances, or
   d. Is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dispense or possess any controlled substance, or
   e. Has violated the requirements of 105 CMR 700.012(E)(3).

2. Pursuant to the provisions of M.G.L. c. 94C, § 13 for violation of any provision 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)(5)(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 Substances 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)-(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(K)(E)(3) or other state law.

(G) Automatic Authorization to Utilize the Prescription Monitoring Program

(1) Effective January 1, 2013, every registered individual practitioner except a veterinarian who holds a valid Massachusetts Controlled Substance Registration will automatically, in a manner and form determined by the Department, be granted authority to utilize the prescription monitoring program, as established pursuant to 105 CMR 700.012(F).

(H) Requirement to Utilize the Prescription Monitoring Program

(1) A registered individual practitioner must utilize the prescription monitoring program prior to prescribing, to a patient for the first time:
   (a) a narcotic drug in Schedule II or III; or
   (b) a benzodiazepine; or
   (c) a Schedule IV or V controlled substance, as designated in guidance to be issued by the Department.

(2) A registered individual practitioner must utilize the prescription monitoring program each time the prescriber issues a prescription to a patient for any drug in Schedule II or III which has been determined by the Department to be commonly misused or abused and which has been designated as a drug that needs additional safeguards in guidance to be issued by the Department.
   (a) The Department shall convene an advisory group to develop this guidance.
   (b) The advisory group shall consist of nine members, chaired by the Commissioner or the Commissioner’s designee, and must include experts in the fields of medicine, nursing, pharmacy, pain management treatment, addiction treatment, academia, and law enforcement.
   (c) The advisory group will hold a public hearing before each revision to the guidance and shall invite comment prior to adding any drug to the guidance.
   (d) The advisory group shall meet no less than one time a year and as many times as needed. Each member shall serve a three year term.

(3) 105 CMR 700.012(H)(1) and (2) shall not apply to:
   (a) A registered individual practitioner authorized to prescribe, administer, possess, order, or dispense samples of controlled substances only in Schedule VI;
(b) A registered individual practitioner providing medical, dental, podiatric, pharmaceutical, or nursing care to hospice patients;

(c) A registered individual practitioner treating a patient in an Emergency Department who does not anticipate writing a prescription for a controlled substance in Schedules II-V during that encounter with the patient or does not prescribe more than a five-day supply of a controlled substance in Schedules II-V;

(d) An instance in which emergency care is required and, in the professional opinion of the prescriber, utilization of the prescription monitoring program is likely to result in patient harm.

(e) A registered individual practitioner providing medical, dental, podiatric, pharmaceutical or nursing care to hospital inpatients;

(f) A registered individual practitioner providing medications for immediate treatment in accordance with M.G.L. c. 94C, § 9(b);

(g) An instance in which it is not reasonably possible to utilize the prescription monitoring program, including when the system is not operational due to temporary technological or electrical failure;

(h) A registered individual practitioner examining or treating a patient under 96 months of age;

(i) A registered individual practitioner granted a waiver pursuant to 105 CMR 700.012(I); and

(j) Other exceptions as defined in guidance issued by the Department.

(I) Waiver of Requirement to Utilize the Prescription Monitoring Program

(1) The Department may waive the requirements established in 105 CMR 700.012(H)(1) and (2) for a participant who submits a request, in a manner and form determined by the Department, if the Department determines that a waiver is appropriate based on the criteria listed in 105 CMR 700.012(I)(2).

(2) A request for a waiver of the requirements in 105 CMR 700.012(H)(1) and (2) shall include a description of the following:

(a) The participant’s history of compliance with laws and regulations related to controlled substances;

(b) A substantial hardship created by a natural disaster or other emergency beyond the control of the participant;

(c) Technological limitations not reasonably within control of the participant; or

(d) Temporary technological limitations within the control of the participant that will be rectified within six months.

(J) Delegate Sub-Accounts

(1) A primary account holder may authorize support staff as delegates to use the prescription monitoring program on behalf of the participant when the participant submits a written request to create delegate sub-accounts in a manner and form
determined by the Department. An individual eligible to be a primary account holder may not be a delegate.

(2) A primary account holder submitting a request to establish delegate sub-accounts must provide, upon request by the Department, the hospital’s, clinic’s, medical office’s or pharmacy’s written policies and procedures regarding the management and security of prescription monitoring data and reports.

(3) A request for delegate sub-accounts must include an attestation that the primary account holder will:
   (a) Ensure that delegates comply with the prescription monitoring program Sub-Account User Terms and Conditions;
   (b) Monitor delegate use of the prescription monitoring program and inform the Department when a delegate has violated the Sub-Account User Terms and Conditions or is no longer authorized by the participant to be a delegate within one business day; and
   (c) Take reasonable steps to ensure that the delegate is sufficiently competent in the use of the prescription monitoring program.

(4) The primary account holder is responsible for all delegate use of the prescription monitoring program and may be referred to the appropriate licensing authority if delegate use is inconsistent with the Sub-Account User Terms and Conditions.

(K) Suspension of Authorization to Utilize the Prescription Monitoring Program

(1) If the Department learns, by means of system audit, complaint, or other mechanism, that a participant has, or may have, utilized the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, the Department:
   (a) May immediately restrict the participant’s electronic access to the prescription monitoring program system; and
   (b) Shall contact the participant to investigate the potential violation.

(2) If the Department determines after investigation that the participant did not utilize the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, the Department shall immediately reinstate the participant’s electronic access to the prescription monitoring program system, if such access has been restricted.

(3) If the Department determines after investigation that the participant did utilize the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, the Department may, depending on the severity of the violation, take the following action:
   (a) Issue a warning letter to the participant;
   (b) Require the participant to undergo training on the appropriate use of the prescription monitoring program;
   (c) Temporarily suspend the participant’s access to the prescription monitoring program; and
   (d) Take action pursuant to 105 CMR 700.115.

(4) If the Department takes action under 105 CMR 700.012(K)(3), the participant may contest the Department’s findings, in writing, and request further review.

700.100: Complaints
(A) The Department shall investigate every complaint about drug diversion or tampering received related to a registrant’s registration pursuant to M.G.L. c. 94C and 105 CMR 700.000.

(B) If the Department finds that an investigation is not required because the alleged act or practice is not in violation of M.G.L. c. 94C or 105 CMR 700.000, or any policies of the Department pursuant thereto, the Department shall make a note in the complaint file of this finding and the reasons on which it is based.

(C) If the Department finds that an investigation is required, because the alleged act or practice may be in violation of M.G.L. c. 94C or 105 CMR 700.000, or any policies of the Department pursuant thereto, the Department shall investigate. If a finding is made that the act or practice does constitute such a violation, the Department shall apply whichever enforcement procedure(s), as provided in 105 CMR 700.000, is appropriate to remedy the situation and the Department shall notify other interested parties, including law enforcement or a licensing board, as appropriate, of its action in this matter.

(D) Investigation of complaints may lead to enforcement actions, including a warning letter or a letter of reprimand; or a revocation, suspension, or refusal to renew a registration by the Department. The Department may specify in any such enforcement action taken against a registrant a requirement to undergo and successfully complete remedial training, in accordance with terms set out in the enforcement action.

700.105: Grounds for Revocation, Suspension, or Refusal to Renew a Registration

(A) Grounds for revocation, suspension, or refusal to renew a registration include, but are not limited to, whether the registrant:

1. has furnished false or fraudulent material information in any application filed under the provisions of this chapter;
2. has been convicted under any state or federal law of any criminal violation relating to his fitness to be registered under this chapter;
3. has had his federal registration suspended or revoked to manufacture, distribute, dispense, administer or possess controlled substances;
4. is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dispense, or possess any controlled substance;
5. has violated any provision of M.G.L. c. 94C; or
6. has used the online prescription monitoring program system, or prescription data derived therefrom, in a manner inconsistent with the terms and conditions for such use.

(B) Revocation, suspension, or refusal to renew a registration may be appealed in accordance with 105 CMR 700.115.

700.110: Summary Suspension of Registration

(A) Pursuant to M.G.L. c. 94C, § 14, the Commissioner may, without a hearing, if the Commissioner finds that public health or safety is endangered, immediately suspend a registration. Written notice of the reasons for the suspension shall promptly be issued by the Department. The affected person shall also be notified in writing of the right to an adjudicatory hearing and shall be promptly afforded an opportunity for a hearing provided that written request for a hearing is submitted within 14 days after notification of suspension.

(B) After hearing or waiver thereof, the Department may modify a registration or suspend, revoke, or refuse to renew a registration pursuant to 105 CMR 700.115.

(C) Upon receipt of notice of the Department's final decision, the affected person must immediately return to the Department a registration previously issued.
700.115: Suspension, Revocation, or Refusal to Renew a Registration
(A) If the Department initiates action to suspend, revoke, or refuse to renew a registration, the affected person shall be notified in writing of the reasons for the Department's action and of his/her right to an adjudicatory proceeding.
(B) Written request for a hearing must be submitted within 14 days of receipt of notification of Department action.
(C) After hearing or waiver thereof, the Department may modify, suspend, revoke, or refuse to renew a registration.
(D) If the Department requires a suspension of a registration, the Department shall indicate the term of the suspension.
(E) If the Department requires a revocation or refusal to renew a registration, the Department shall indicate whether or not the registrant may, at a future date, reapply for a registration.
(F) Upon receipt of notice of the Department's final decision, the affected person must immediately return to the Department a registration previously issued.

700.120: Void Registrations
A registration is void if the registrant’s underlying professional licensure on which the registration is based is suspended or revoked.

700.125: Adjudicatory Proceedings
(A) All adjudicatory proceedings will be conducted in accordance with M.G.L. c. 30A and the Standard Rules of Practice and Procedure, 801 CMR 1.01 et seq.
(B) The Commissioner shall designate a Presiding Officer to conduct a hearing and render a tentative decision containing findings of fact and rulings of law. If the Presiding Officer finds any single ground for revocation, suspension, or refusal to renew any registration, the Presiding Officer shall render a decision affirming the action initiated by the Department.

700.130: Nonexclusivity of Enforcement Procedures
The enforcement procedures contained in 105 CMR 700.000 are not mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

700.020 700.200: Severability
The provisions of 105 CMR 700.000 are severable, and if any provision shall be in violation of any Federal rule or regulation or any Federal or Massachusetts law, such provision shall be null and void and such violation shall not affect or impair any of the remaining provisions.
721.020: Prescription Formats

Every prescription written in the Commonwealth must be in a prescription format that conforms to the following requirements:

(A) a prescription must permit the practitioner to instruct the pharmacist to dispense a brand name drug product by indicating “no substitution”, provided that:

(1) the indication of “no substitution” is not the default indication;
(2) the prescription indicates that “Interchange is mandated unless the practitioner indicates ‘no substitution’ in accordance with the law”; and
(3) the indication of “no substitution” is a unique element in the prescription and shall not be satisfied by use of any other element, including the signature;

(B) if the prescription is paper-based, including but not limited to a prescription that is transmitted via facsimile or similar technology, or reduced to writing by a pharmacist, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his/her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his or her name, there shall be a space in which the practitioner may indicate "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law”;

(C) if the prescription is transmitted electronically, the practitioner shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form;
(D) the name and address of the practitioner shall be clearly indicated on the prescription. A hospital or clinic prescription shall have the name and address of the hospital or clinic clearly indicated on the prescription;
(E) the prescription shall contain the following information:
(1) the registration number of the practitioner or nurse midwife;
(2) date of issuance of the prescription;
(3) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;
(4) name and address of the patient, except in a veterinary prescription or a prescription for expedited partner therapy issued in accordance with 105 CMR 700.003(J), in which case the words “Expedited Partner Therapy”, “E.P.T.” or “EPT” may be used in place of the name of the patient, and the address may be left blank; or in the case of a prescription for naloxone the person taking delivery of the naloxone may be used in place of the name of the patient, and the address may be left blank.
(5) directions for use, including any cautionary statements required;
(6) a statement indicating the number of times to be refilled;
(F) beginning July 1, 2013, a prescription must be written on a tamper-resistant form consistent with federal requirements for Medicaid; and
(G) a prescription issued by a nurse practitioner, psychiatric nurse, physician assistant, nurse anesthetist or pharmacist shall also contain the name of the supervising physician.