

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 700.000: IMPLEMENTATION OF M.G.L. c. 94C

Section

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700.001: Definitions

For the purpose of 105 CMR 700.000, the following definitions apply, in addition to those definitions appearing in M.G.L. c. 94C, § 1, unless the context or subject matter requires a different meaning.

Additional Drug means a controlled substance in Schedule VI determined by the Department to carry a *bona fide* potential for abuse.

Administer means the direct application of a controlled substance whether by injection, inhalation, ingestion or any other means to the body of a patient or research subject by:

- (1) A practitioner; or
- (2) A registered nurse or licensed practical nurse at the direction of a practitioner in the course of his or her professional practice; or
- (3) A registered pharmacist or pharmacy intern administering medications for treatment of mental health or substance use disorders and at the direction of a prescribing practitioner in the course of the practitioner's professional practice; or
- (4) An ultimate user or research subject at the direction of a practitioner in the course of his or her professional practice.

Agent means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser; except that such term does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

Ambulance Service means an entity licensed as an ambulance service by the Department in accordance with M.G.L. c. 111C, § 6 and 105 CMR 170.000: *Emergency Medical Services System*.

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

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Certified Registered Nurse Anesthetist means a registered nurse authorized to practice as a certified registered nurse anesthetist by the Board of Registration in Nursing as provided for in M.G.L. c. 112, § 80B and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

Chemical Analyst means a person engaged in the qualitative or quantitative analysis of controlled substances within a scientific laboratory.

Commissioner means the Commissioner of Public Health or his or her duly authorized designee.

Community EMS Program means a program developed by the primary ambulance service with the approval of the local jurisdiction and the affiliate hospital medical director utilizing emergency medical services providers acting within their scope of practice to provide community outreach and assistance to residents to advance injury and illness prevention within the community.

Community Program means any community residential or day program that is funded, operated or licensed by the Massachusetts Department of Mental Health, Department of Developmental Services, or Department of Children and Families, with the exception of programs funded under Title XIX of the Social Security Act.

Compounding shall have the same meaning as used in 247 CMR and M.G.L. c. 112, § 39D.

Controlled Substance means a drug, substance, or immediate precursor in any schedule or class referred to in M.G.L. c. 94C or 105 CMR 700.000.

Customer Identifier means the identification number on a valid government issued identification, including, but not limited to, state issued identification; military identification card, permanent resident card, passport, driver's license, or other identification as specified by the Department, which a pharmacy obtains by inspecting the identification of the ultimate user or agent of the ultimate user to whom a prescription is dispensed.

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.

Deliver means to transfer, whether by actual or constructive transfer, a controlled substance from one person to another, regardless of whether there is an agency relationship.

Dental Hygienist means a dental hygienist registered by the Board of Registration in Dentistry pursuant to M.G.L. c. 112, § 51.

Department means the Massachusetts Department of Public Health.

Department of Children and Families means the Massachusetts Department of Children and Families.

Department of Developmental Services means the Massachusetts Department of Developmental Services.

Department of Mental Health means the Massachusetts Department of Mental Health.

Device means an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part or accessory for use as outlined in 21 U.S.C. § 321.

Dispense means to deliver a controlled substance to an ultimate user or research subject or to the agent of an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery.

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Distribute means to deliver, other than by administering or dispensing, a controlled substance.

Drug means:

- (1) Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary or any supplement to any of them;
- (2) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in people or animals;
- (3) Substances, other than food, intended to affect the structure or any function of the body of people and animals; or
- (4) Substances intended for use as a component of any article specified in 105 CMR 700.001: Drug(1) through (3), exclusive of devices or their components, parts or accessories.

Drug Enforcement Administration means the United States Drug Enforcement Administration in the United States Department of Justice, or its successor agency.

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, who is authorized to administer controlled substances pursuant to his or her training and the Statewide Treatment Protocols. EMT shall include EMT-basic and the ALS levels of Advanced EMT and Paramedic as defined in 105 CMR 170.000. EMT shall also include an EMT who is authorized to administer controlled substances by the clinical protocols of a Department-approved MIH or community EMS program with which he or she is working in accordance with M.G.L. c. 111O.

EMS First Responder (EFR) means a person certified as an EFR by the Department, in accordance with M.G.L. c. 111C, § 9 and 105 CMR 170.000: *Emergency Medical Services System*, who is authorized to administer controlled substances pursuant to his or her certification and the Statewide Treatment Protocols. EMS First Responder (EFR) shall include an EFR who is authorized to administer controlled substances by the clinical protocols of a Department-approved MIH or community EMS program with which he or she is working in accordance with M.G.L. c. 111O.

EMS First Response Service (EFR Service) means an entity licensed as an EFR service by the Department in accordance with M.G.L. c. 111C, § 6 and 105 CMR 170.000: *Emergency Medical Services System*.

Extended-release Long-acting Opioid in a Non-abuse Deterrent Form means a drug that is:

- (1) subject to the United States Food and Drug Administration's extended release and long acting opioid analgesics risk evaluation and mitigation strategy;
- (2) an opioid approved for medical use that does not meet the requirements for listing as a drug with abuse deterrent properties pursuant to M.G.L. c. 17, § 13; and
- (3) identified by the drug formulary commission as posing a heightened level of public health risk.

First Responder means a First Responder as defined in M.G.L. c. 111, § 201 and 105 CMR 171.000: *Massachusetts First Responder Training*, and who is authorized to administer controlled substances in accordance with 105 CMR 171.000, his or her training thereunder and the Statewide Treatment Protocols.

Fluoride Program Monitor means a dental assistant, school teacher, school nurse, school aide or school volunteer.

Health Care Entity means a provider or provider organization including, but not limited to, an ambulance service licensed under M.G.L. c. 111C, a visiting nurse association, accountable care organization and a home health agency.

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Health Facility means:

- (1) A hospital, hospital pharmacy, long-term care facility or clinic, licensed or maintained by the Department or clinic, established solely to provide service to employees or students of such corporation or institution as authorized by M.G.L. c. 111, § 52; or
- (2) A public medical institution as defined in M.G.L. c. 118E, § 8; or
- (3) Any institution licensed or maintained by the Department of Mental Health;
- (4) Any hospital, long-term care facility or clinic maintained by the Commonwealth; or
- (5) Any ambulance service licensed by the Department to provide Advanced Life Support services.

Home Care Setting means any place where a person resides which is not licensed or funded by the Commonwealth to provide institutional care or custody. Home care settings include, but are not limited to the following:

- (1) an individual's private home;
- (2) community residences or group homes licensed or funded by an agency of the Commonwealth;
- (3) shelters and day centers for the homeless; and
- (4) hospice settings which are approved by the Department and which are not licensed to provide acute care or operated by a hospital so licensed.

Hospital means any institution, however named, whether conducted for charity or for profit, which is advertised, announced, established or maintained for the purpose of caring for persons admitted thereto for diagnosis, medical, surgical or restorative treatment which is rendered within said institution.

Immediate Precursor means a substance which the Commissioner has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture.

Implantable Infusion Pump means a device that is intended to be implanted in the human body for the purpose of delivering a controlled flow of drug(s).

Investigation means, for the purpose of 105 CMR 700.012(C)(2)(b), an inquiry, appropriate to agency authority, that has been opened previously, is ongoing, has been undertaken with a stated purpose and is based on a complaint, allegation, evidence or other useful information concerning a potential violation of law or regulation by a specific prescriber, pharmacy, or patient or other individual to whom a controlled substance has reportedly been dispensed.

Isomer means the optical isomer, except that wherever appropriate it shall mean the optical, position or geometric isomer.

Labeling means in the definition of "manufacture", labeling or relabeling other than by a practitioner, or by a pharmacist.

Long-term Care Facility means any institution whether conducted for charity or profit, that is advertised, announced or maintained for the express or implied purpose of providing three or more individuals admitted thereto with long-term resident, nursing, convalescent or rehabilitative care; supervision and care incident to old age for ambulatory persons; or retirement home care for elderly persons. Long-term care facility shall include convalescent or nursing homes, rest homes, infirmaries maintained in towns and charitable homes for the aged.

Manufacture means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, including any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for his or her own use, or the preparation, compounding, packaging or labeling of a controlled substance:

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- (1) By a practitioner as an incident to his or her administering a controlled substance in the course of his or her professional practice; or
- (2) By a practitioner, or by his or her authorized agent under his or her supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

Massachusetts Prescription Awareness Tool (MassPAT) means the online prescription monitoring program database created pursuant to M.G.L. c. 94C, § 24A.

Medical Assistant means a medical assistant authorized by M.G.L. c. 112, § 265 to administer immunizations under the supervision of a practitioner and in accordance with Departmental guidance.

Medication Order means a written order for a medication entered on a patient's medical record maintained at a hospital, other health facility, or ambulatory health care setting and is dispensed for immediate administration to the ultimate user by an individual authorized by M.G.L. c. 94C to administer such medication.

Mobile Integrated Health Care or MIH means a health care program approved by the department that utilizes mobile resources to deliver care and services to patients in an out-of-hospital environment in coordination with health care facilities or other health care providers, for services including, but not limited to, community paramedic provider services, chronic disease management, behavioral health, preventive care, post-discharge follow-up visits, or transport or referral to facilities other than hospital emergency departments.

Narcotic Drug means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

- (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;
- (2) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in 105 CMR 700.001: Narcotic Drug, but not including the isoquinoline alkaloids of opium;
- (3) Opium poppy and poppy straw; or
- (4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

National Drug Code Number (NDC) means a nationally recognized standard which identifies drug products using a unique number, issued by the United States Food and Drug Administration, involving three components. The first component identifies the drug manufacturer ("LABELER NO."), the second identifies the product ("PRODUCT NO."), and the third identifies the package size ("PKG").

Non-self-administering means personally taking or applying a controlled substance in the manner directed by the prescribing practitioner, with more than minimal assistance or direction by the program staff, as determined in accordance with procedures and criteria established by the Department of Mental Health, Department of Developmental Services, or Department of Children and Families and approved by the Department of Public Health.

Nurse Midwife means a registered nurse authorized to practice as a certified nurse midwife by the Board of Registration in Nursing as provided for in M.G.L. c. 112, § 80B, and 244 CMR 4.00: *Advanced Practice Registered Nursing*.

Opiate means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under M.G.L. c. 94C, § 2, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts, dextromethorphan. It does include its racemic and levorotatory forms.

Opium Poppy means the plant of the species *Papaver somniferum L.*, except its seeds.

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Oral Prescription means an oral order for medication which is dispensed to or for an ultimate user, but not including an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse, or practical nurse.

Packaging means in the definition of "manufacture", packaging or repackaging a controlled substance other than:

- (1) By a practitioner or;
- (2) By a pharmacist.

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

Perfusionist means a perfusionist licensed by the Board of Registration of Perfusionists pursuant to M.G.L. c. 112, § 212.

Person means individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

Pharmacist means a pharmacist duly licensed by the Board of Registration in Pharmacy in accordance with M.G.L. c. 112, § 24 and 247 CMR 3.00: *Personal Registration Requirements*.

Pharmacy Intern or Pharmacist Intern means a pharmacy intern licensed by the Board of Registration in Pharmacy pursuant to M.G.L. c. 112, § 24G.

Physician Assistant means a physician assistant authorized to practice by the Board of Registration of Physician Assistants, 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*.

Practical Nurse means a practical nurse licensed by the Board of Registration in Nursing pursuant to the provisions of M.G.L. c. 112, § 74A.

Practitioner means:

- (1) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, prescribe, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the Commonwealth;
- (2) A pharmacy, hospital or other institution registered to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in the Commonwealth.
- (3) An optometrist authorized by M.G.L. c. 112, §§ 66 and 66B and registered pursuant to M.G.L. c. 94C, § 7(h) to utilize and prescribe topical therapeutic pharmaceutical agents, as defined in M.G.L. c. 112, § 66B, in the course of professional practice in the Commonwealth.

Prescription means an order for medication which is dispensed to or for an ultimate user. A prescription does not mean an order for medication which is dispensed for immediate administration to the ultimate user.

Prescription Drug means a drug upon which the manufacturer or distributor has, in compliance with federal laws and regulations, placed the following: "Caution, Federal law prohibits dispensing without prescription".

Primary Account Holder means a participant who has sub-accounts or a 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.

Private School means the board of trustees, board of directors or comparable board responsible for operating a private elementary or secondary school program.

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Provider ID means the unique six-digit number issued by the National Counsel for Prescription Drug Programs.

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

Registered Individual Practitioner means a physician, dentist, veterinarian, podiatrist, nurse midwife, certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant who is registered pursuant to 105 CMR 700.004.

Registered Nurse means a nurse who is registered by the Department pursuant to the provisions of M.G.L. c. 112, § 74.

Registrant means a person who is registered by the Department pursuant to any provision of M.G.L. c. 94C.

Registration means, unless the context specifically indicates otherwise, such registration as is required and permitted only pursuant to the provisions of M.G.L. c. 94C.

Registration Number means the unique registration number required with respect to a practitioner by, and assigned to a practitioner by, the Drug Enforcement Administration or by the Department of Public Health or both.

Research Drug means an investigational new drug as defined in 21 CFR 312.3, or the investigational use of any scheduled drug in a research study or project where it will be administered or dispensed.

Researcher means a person who engages in or conducts research involving substances, whether controlled or not, or the direct supervisor, department chair or chief academic officer of such person.

Respiratory Therapist means a respiratory therapist licensed by the Board of Registration of Respiratory Care pursuant to M.G.L. c. 112, §§ 23R through 23BB.

Sample Medication for the purpose of 105 CMR 700.000 shall mean a unit of prescription drug distributed by the manufacturer or distributor to practitioners in the original package from the manufacturer, not repackaged and given free of charge to patients. Such medications shall include, but not be limited to, those medications dispensed as part of an indigent patient drug program.

Schedule means the list of controlled substances established by the Commissioner pursuant to the provisions of M.G.L. c. 94C, § 2 for purposes of administration and regulation.

School means a public or private elementary or secondary school, or day care center or group care facility licensed by the Office for Children in accordance with M.G.L. c. 28A, § 10.

School District means the local educational agency, which includes the school committee, board of trustees, educational collaborative board, or other public entity responsible for operating a public elementary or secondary school program.

Scientific Laboratory means a facility maintained primarily for the analysis or examination of controlled substances or their precursors, and which is not a facility or part of a facility otherwise registered to manufacture, distribute, dispense or possess controlled substances.

Self-administering means personally taking or applying a controlled substance in the manner directed by the prescribing practitioner, with no more than minimal assistance or direction from program staff, in accordance with procedures and criteria established by the Department of Mental Health, Department of Developmental Services, or Department of Children and Families and approved by the Department of Public Health.

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Statewide Treatment Protocols means the Emergency Medical Service Pre-hospital Treatment Protocols approved by the Department for application statewide in accordance with M.G.L. c. 111C and 105 CMR 170.000: *Emergency Medical Services System*.

Supervising Physician means a physician who provides supervision to a physician assistant, certified nurse practitioner, psychiatric clinical nurse specialist, pharmacist or certified registered nurse anesthetist in accordance with M.G.L. c. 112, §§ 2 through 12CC and 243 CMR 2.00: *Licensing and the Practice of Medicine*.

Teacher means a person who conducts teaching activities using controlled substances in a teaching institution accredited by the Commission on Institutions of Higher Education.

Ultimate User means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household or for administering to an animal owned by him or her or by a member of his or her household.

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

Virtual Manufacturer means a person in the business of manufacturing or distributing a controlled substance and who has a principal place of business located in the Commonwealth, but at no time takes physical possession of any controlled substance in the Commonwealth.

Written Prescription means a lawful order from a practitioner for a drug or device for a specific patient that is communicated directly to a pharmacist in a licensed pharmacy, including an electronic prescription; provided, however, that "written prescription" shall not include an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse or practical nurse.

700.002: Schedules of Controlled Substances

The following schedules of controlled substances are established:

(A) Schedule I. Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.11.

(B) Schedule II. Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.12.

(C) Schedule III. Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.13.

(D) Schedule IV. Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.14.

(E) Schedule V. Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in 21 CFR 1308.15.

(F) Schedule VI. Schedule VI shall consist of all prescription drugs, which are not included in any other schedule established by the Commissioner.

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

- (A) (1) A Paramedic or a 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, or in accordance with his or her duties as authorized by clinical protocols in a Department-approved MIH program or community EMS program pursuant to M.G.L. c. 111O;
- (2) An Advanced EMT, Advanced EMT student as part of his or her participation in a Department-approved training program, EMT or EFR may administer only those controlled substances 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, or in accordance with his or her duties as authorized by clinical protocols in a Department-approved MIH program or community EMS program pursuant to M.G.L. c. 111O;
- (3) Administration of controlled substances by EMTs at all levels, and EMT students at all levels, is also subject to the following conditions:
- (a) The ambulance service, EFR service, or Department-approved MIH or community EMS program for which the individual serves, shall be registered in accordance with 105 CMR 700.004 for the appropriate controlled substances;
 - (b) The ambulance service, EFR service, or Department-approved MIH or community EMS program shall maintain a current listing of names of its employees and volunteers who are authorized to administer controlled substances;
 - (c) The EMT, Paramedic student, 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.
- (4) A Paramedic may dispense by administration influenza vaccine and other immunizations designated by the Department to persons 18 years of age or older, as authorized by clinical protocols in a Department-approved MIH program or community EMS program.
- (B) Dental hygienists and fluoride program monitors employed by or affiliated with a registered school may administer fluoride tablets or fluoride mouth rinse to school children three through 18 years old provided that:
- (1) The school has registered with the Department by sending a letter of intent to administer fluoride treatments to the Division of Dental Health and by providing whatever further information the Commissioner may require; and
 - (2) The child's parent or guardian has been informed in writing of the nature, dose and effects of fluoride tablets and mouth rinse, and has consented in writing to the administration of fluoride tablets or mouth rinse on behalf of the child; and
 - (3) The tablets or mouth rinse is administered in accordance with the order of a physician or dentist employed by or associated with a local Board of Health or school; and
 - (4) The fluoride program monitor has been trained to administer and store fluoride tablets and mouth rinse in accordance with a training program designed by the Commissioner; and
 - (5) All fluoride mouth rinse and tablets possessed by the registered school are stored securely under lock and key; and
 - (6) The registered school maintains such records and files such reports concerning the fluoride program as the Commissioner may require.
- (C) (1) A certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant may issue prescriptions and medication orders for Schedule II through VI controlled substances, which comply with the prescribing requirements of M.G.L. c. 94C, § 20 and c. 112, § 66B, provided that the following requirements are met:

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- (a) The certified nurse practitioner, psychiatric clinical nurse specialist, and certified registered nurse anesthetist meet all requirements set forth in 244 CMR 4.00: *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: *Purpose, Authority and Definitions*, 3.00: *Registration of Individual Physician Assistants*, and 5.00: *Scope of Practice and Employment of Physician Assistants* 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 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 4.00: *Advanced Practice Registered Nursing* 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 through 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 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.
- (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 prescriptions and medication orders, in accordance with the provisions of M.G.L. c. 94C, § 20, c. 112 and §§ 80C and 80G, for those controlled substances in Schedules II through VI.
- (D) Persons specified in 105 CMR 700.003(D) may administer epinephrine or opioid antagonist approved by the Department, or atropine, pralidoxime chloride or other designated nerve agent antidotes ("nerve agent antidotes") in a life threatening emergency, where medical professionals are not readily available, in accordance with any applicable Department protocols and the following:
- (1) To the extent authorized by 105 CMR 700.003(D), the following persons may administer epinephrine or opioid antagonist approved by the Department, or nerve agent antidotes:

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- (a) a first responder may administer epinephrine or opioid antagonist approved by the Department in accordance with 105 CMR 171.000: *Massachusetts First Responder Training*, and the Statewide Treatment Protocols;
 - (b) a public employee of or volunteer to a municipality or an agency, department or authority of the Commonwealth (agency), whose function includes emergency preparedness and response and who is designated by a municipality's or agency's medical director pursuant to 105 CMR 700.003(6)(b) (authorized public employee), may administer epinephrine or opioid antagonist approved by the Department as well as nerve agent antidotes approved by the Department to another authorized public employee; and
 - (c) an authorized employee of or volunteer to a facility or program funded, operated or licensed by a municipality or agency may administer an opioid antagonist approved by the Department to individuals served by such a program or facility ("program");
- (2) A municipality or agency may approve administration of epinephrine or opioid antagonist approved by the Department, or nerve agent antidotes by authorized public employees, and a municipality or agency may approve administration of epinephrine by employees or volunteers of a program, provided that the municipality or agency registers with the Department in accordance with 105 CMR 700.004. This registration requirement shall not apply to:
- (a) a municipality or agency registered under 105 CMR 700.004(A)(2)(a) through (t);
 - (b) a school district or non-public school subject to the provisions of 105 CMR 210.000: *The Administration of Prescription Medications in Public and Private Schools*;
- (3) Any administration is pursuant to the order of a practitioner and, in the case of first responders, the Statewide Treatment Protocols;
- (4) The epinephrine or opioid antagonist approved by the Department or nerve agent antidote is:
- (a) dispensed by a pharmacy pursuant to the order or prescription of a practitioner or other authorized prescriber; or
 - (b) obtained by a municipality or agency in accordance with said entity's registration.
- (5) The epinephrine or nerve agent antidote is packaged in a prefilled, automatic injection device intended for self-administration, and the opioid antagonists approved by the Department is in the manufacturer's original packaging;
- (6) A qualified, licensed practitioner shall be designated by the registered municipality or agency as medical director for purposes of 105 CMR 700.003(D).
- Such person shall:
- (a) be the responsible person named on the registration of the municipality or agency;
 - (b) authorize administration of epinephrine or opioid antagonists approved by the Department and nerve agent antidotes, as appropriate, and oversee compliance with 105 CMR 700.003(D);
 - (c) establish and enforce written protocols and procedures to ensure that individuals administering epinephrine or opioid antagonists approved by the Department or nerve agent antidotes are properly trained, evaluated for competence, and up to date in their skills and knowledge.
- Training shall include, but not be limited to:
1. procedures for risk reduction;
 2. recognition of the symptoms of an opioid overdose or a severe allergic or nerve agent reaction;
 3. proper use of an auto-injector for epinephrine or nerve agent antidote, and other acceptable method of administration for opioid antagonists approved by the Department;
 4. procedures for notification of emergency medical services and other appropriate persons following administration;
- (d) establish and enforce written protocols and procedures to ensure:
1. proper storage, handling and return or disposal of opioid antagonists approved by the Department, epinephrine or nerve agent antidote;
 2. review and evaluation of an emergency response;
 3. reporting of adverse events to the medical director;
 4. monitoring of program compliance with 105 CMR 700.003(D); and

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- (e) establish and enforce written protocols and procedures to ensure that a registered municipality or agency, or a program if authorized to administer epinephrine or opioid antagonists approved by the Department by a municipality or agency, maintains current and readily retrievable records of:
 - 1. the authorized public employees or volunteers who may administer epinephrine and nerve agent antidotes or authorized program employees or volunteers who may administer epinephrine;
 - 2. individual trainings and evaluations;
 - 3. receipt and any return or disposal of epinephrine opioid antagonists approved by the Department or nerve agent antidotes; and
 - 4. administration of epinephrine, or opioid antagonists approved by the Department or nerve agent antidote;
- (7) Each program authorized by a registered municipality or agency to administer epinephrine or opioid antagonists approved by the Department pursuant to 105 CMR 700.003(D) shall:
 - (a) comply with the policies and procedures established pursuant to 105 CMR 700.003(D) by the registered municipality or agency;
 - (b) designate a licensed health care practitioner, whenever possible, or the program director or designee, to oversee the program's implementation of said policies and procedures;
 - (c) in the case of minors served by the program, obtain prior informed consent whenever possible from the minor's parent or legal guardian for the administration of epinephrine;
 - (d) develop individualized medication administration plans that address indications for administration of epinephrine or opioid antagonists approved by the Department, any unique issues around storage or handling of the epinephrine or opioid antagonist approved by the Department and persons to be notified in the event that epinephrine or opioid antagonists approved by the Department is administered.
 - (e) immediately notify emergency medical services and designated contact persons, including those identified in the medication plan, in the event that epinephrine or opioid antagonists approved by the Department is administered; and
- (8) The registered municipality or agency, and the Department shall have full access to all pertinent records for monitoring purposes.

(E) A school district or private school may register solely for the purpose of permitting trained school personnel to administer controlled substances in accordance with 105 CMR 210.000: *The Administration of Prescription Medications in Public and Private Schools*.

(F) An employee of a community program may administer or assist in the administration of a controlled substance or other prescription medication to a stable non-self-administering person as those terms are defined in applicable Department guidance, provided that:

- (1) Registration. The community program is registered with the department in accordance with 105 CMR 700.004, and meets the following requirements:
 - (a) Administration or assistance in the administration of prescription medication to a non-self-administering individual shall be carried out only by a duly licensed professional staff or by an unlicensed program staff of a registered community program who has successfully completed the training specified in 105 CMR 700.003(F)(2);
 - (b) The program shall establish, maintain, and operate in accordance with policies that ensure that only properly trained and certified personnel administer medication;
 - (c) The program shall maintain a current written list of those staff members who have successfully completed a training program meeting the requirements of 105 CMR 700.003(F)(2);
 - (d) The program shall permit the Department to inspect program and individuals' records pertaining to the use and administration of prescription medications. The Department may make announced or unannounced on-site visits or inspections of common areas and such other inspections as the Department is authorized to make in order to monitor the program's compliance with 105 CMR 700.000.
 - (e) The Drug Control Program within the Department shall promptly be notified by the program of any suspected shortages, tampering, or diversion of prescription medication;

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- (f) The program shall document in the individual's record any administration of prescription medication in a manner inconsistent with the practitioner's prescription or order or in violation of 105 CMR 700.000. The program shall also promptly report to the Department of Mental Health, Department of Developmental Services, or Department of Children and Families, in accordance with procedures and on a form approved jointly by the Department and said Departments, any administration of prescription medication in a manner inconsistent with the practitioner's prescription or in violation of 105 CMR 700.000. Such form shall be provided, upon request, to the Department;
- (g) The program shall provide or arrange for technical assistance and advice to be provided as needed by a registered nurse, registered pharmacist, or other licensed practitioner when questions arise regarding appropriate administration practices or the effects of medications. The program shall establish policies and procedures that ensure reasonable access to such assistance and advice;
- (h) The program, professional staff and program staff shall comply with all applicable requirements of M.G.L. c. 94C, the Controlled Substances Act, as well as 105 CMR 700.000 and all pertinent regulations of the Department of Mental Health, Department of Developmental Services, or Department of Children and Families, as appropriate, including those pertaining to storage, labeling, administration and documentation of prescription medication, medical back-up, review of medication, and emergency procedures.
- (i) Program and professional staff may not engage in other duties or obligations while performing documentation and medication administration tasks under this section and must comply with applicable Department guidance.
- (2) Training. No unlicensed staff person may administer or assist in the administration of a prescription medication without successfully completing a training program that meets the specifications for a training curriculum and examination process established jointly by the Department and the Department of Mental Health, Department of Developmental Services, or Department of Children and Families, as well as the following requirements:
- (a) The training program shall be taught by a registered nurse, certified nurse practitioner, physician assistant, pharmacist, or physician who meets applicable requirements for a trainer established jointly by the Department and the Department of Mental Health, Department of Developmental Services, or Department of Children and Families;
- (b) The Department and, as appropriate, the Department of Mental Health, Department of Developmental Services, and Department of Children and Families shall have the authority to monitor the training program for compliance with established standards;
- (c) The training program shall keep records of all persons who have successfully completed the training program which shall be made available to the Department and, as appropriate, to the Department of Mental Health, Department of Developmental Services, or Department of Children and Families upon request;
- (d) Each person who successfully completes the training program shall be certified by the Department of Mental Health, Department of Developmental Services, and Department of Children and Families, and shall be provided with such documentation of completion of the training program as approved by the Department of Mental Health, Department of Developmental Services, and Department of Children and Families. Documentation of certification shall be provided to and maintained by the program;
- (e) No person shall continue to administer or assist in the administration of prescription medication beyond two years from the completion of the initial certification unless such person has met standards for retraining and/or retesting established by the Department of Mental Health, Department of Developmental Services, and Department of Children and Families and approved by the Department.
- (3) Storage. The program meets all applicable regulations of the Department of Mental Health, Department of Developmental Services, or Department of Children and Families, as appropriate, and Department regarding storage and handling of prescription medications as well as the following requirements:

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- (a) All prescription medications that are consumed by individuals who are non-self-administering shall be appropriately secured in a locked container or area. The program shall have a written policy on which persons may have access to such container or area, how access to the key or combination and container or area is to be restricted, and under what conditions authorized persons may have access to the container or area;
 - (b) Prescription medications for individuals who are self-administering shall be stored in a locked container or area unless the program director makes a determination that unlocked storage of the prescription medication poses no threat to the health or safety of the individual or other individuals; provided, however, that all controlled substances in Schedules II through V shall be appropriately secured in a locked container or area;
 - (c) Outdated prescription medications and prescription medications that have not been administered shall be disposed of and the disposal documented in accordance with policies established by the program, provided that disposal occurs in the presence of at least two witnesses and in accordance with any policies of the Department:
- (4) Labeling. All medications shall be properly labeled in accordance with M.G.L. c. 94C, § 21 and the following requirements:
- (a) Program staff shall not repack or relabel prescription medications. If an individual needs to bring prescription medication for administration at a location or program regularly or frequently attended, such prescription medications shall be packed and labeled by a pharmacist or, in the case of prescription medication dispensed for immediate treatment, by the dispensing practitioner;
 - (b) Where prescription medication is consumed by an individual at two or more locations on a regular or frequent basis, the prescription medication shall be stored in a separate, properly packaged, labeled, and appropriately secured medication container at each location. In circumstances in which this is not practical or feasible, the Department of Mental Health, Department of Developmental Services, or Department of Children and Families shall establish an alternative procedure approved by the Department.
 - (c) The program shall have policies for obtaining a properly labeled container where there is a change in prescription or where the individual frequently or regularly receives prescription medication in two or more locations.
- (5) Administration. All prescription medications shall be administered in accordance with M.G.L. c. 94C, the appropriate regulations for the Department of Mental Health in 104 CMR 28.06: *Medication*, Department of Developmental Services in 115 CMR 5.15: *Medication*, or Department of Children and Families in 110 CMR 11.00: *Medical Authorizations*, and the following requirements:
- (a) All prescription medications shall be administered in accordance with the prescription of a practitioner;
 - (b) Prescribed medications shall only be administered to or taken by the individual for whom the prescription has been written;
 - (c) The program shall have a policy that specifies the administrative procedures to be followed when there is a medical emergency relating to medication. Such policy shall include a list of staff persons and medical personnel to be contacted which is up to date, readily available to staff and clearly indicates who is to be contacted on a 24-hour a day, seven days a week basis. The medical personnel to be contacted shall include the prescribing practitioner or, if unavailable, another licensed practitioner or appropriate emergency room personnel;
 - (d) Certified staff employed by programs registered with the Department may only administer prescription medications that are oral, topical, ophthalmic, otic, intranasal, suppository, or products that are administered by inhalation;
 - (e) Parenteral drugs generally intended for self administration, or drugs administered via a gastrostomy/jejunostomy tube may be administered by certified staff members who have successfully completed a specialized training program in such technique taught by a physician, physician assistant, pharmacist, registered nurse, or certified nurse practitioner, approved by the Department and the Department of Mental Health, Department of Developmental Services, or Department of Children and Families. Such technique shall be used only with the written authorization and in accordance with the written instructions of the prescribing physician;
 - (f) Whenever possible, a prescription for medication shall be limited to a 37-day supply and one refill. The prescribing practitioner shall be notified by program staff of this requirement;

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- (g) Where an individual who is non-self-administering receives prescription medication at a location other than a program site covered by 105 CMR 700.000 (off-site), the program whenever possible shall identify program staff responsible for administering the medication and make available to that person instructions as to how the medication is to be administered;
- (h) An over-the-counter drug may be consumed or applied by a non-self administering individual who is already receiving prescription medication only:
1. with the prior approval of a practitioner; or
 2. after consultation with a pharmacist or registered nurse; or
 3. in accordance with applicable guidelines established by the Department of Mental Health, Department of Developmental Services, or Department of Children and Families, with the approval of the Department.
- (6) Documentation. All prescriptions and administration of prescription medications shall be documented in accordance with applicable regulations of the Department of Mental Health, Department of Developmental Services, or Department of Children and Families and the following requirements:
- (a) All prescriptions for medication shall be documented in the individual's record. Such documentation shall specify for each individual the name and dosage of medication, the indication for which the medication is prescribed, and contraindications or possible allergic reactions, possible side effects and appropriate staff response, and special instructions, including steps to be taken if a dose is missed. The program shall establish appropriate policy and procedures to address how program staff shall obtain relevant prescription information in accordance with the requirements of 105 CMR 700.003(F)(6). In addition, such policy and procedures shall ensure that telephone medication orders and medication changes are received from licensed practitioners and properly documented in the individual's record;
- (b) The program shall ensure that staff have ready access to such information as listed in 105 CMR 700.003(F)(6)(a), by maintaining on site either an appropriate reference approved by the Department or, for each drug administered, a copy of the pertinent section of such reference or a medication-specific drug information sheet that states in plain language generally why the drug is used, when it is to be administered, how it should be administered, any special instructions or precautions, proper storage conditions, possible side effects and what is to be done if a dose is missed;
- (c) The taking or applying of medications for non-self-administering individuals, including over-the-counter drugs, shall be documented in the individual's record;
1. the time that the medication is taken or applied shall be noted in the record;
 2. the record shall indicate any off-site taking or applying of medication by a non-self-administering individual that would normally occur at the program site;
 3. individuals who are self-administering shall not be required to document their own self-administration of medication;
- (d) Any change in medications or dosage levels of a medication shall be treated as a new medication order for the purposes of documentation;
- (e) A non-self-administering individual's residential program shall notify the individual's day program of any prescription medications that the individual is taking and shall provide the program with a copy of the medication order for each prescription medication that the individual receives. Where a non-self-administering individual receives prescription medication solely at the day program, the day program shall have responsibility for notifying the residential program and providing it with a copy of the medication order;
- (f) The program shall establish procedures to document the date that any individual's prescription is filled and the quantity of medication dispensed by the pharmacy;
- (g) Except for persons who are self-administering, the program shall maintain a documented accounting of the quantities of all controlled substances in Schedules II through V, stored by the program, which shall be reconciled at the end of each shift or as otherwise approved by the Department.

(G) Optometrists may utilize and issue prescriptions and medication orders, in accordance with the provisions of M.G.L. c. 112, §§ 66 and 66B, for those topical pharmaceutical agents in Schedule VI required for the diagnosis, prevention, management or treatment of abnormal ocular conditions or diseases as defined in M.G.L. c. 112, § 66, except glaucoma.

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(H) Notwithstanding any other Department regulation, a health care professional duly licensed or certified by the Department, or a student duly enrolled in an approved or accredited program for licensure as a health care professional and acting in accordance with the policies of that program, may possess and administer any vaccine designated by the Commissioner for the prevention of a pandemic, novel, or other vaccine-preventable disease, provided the Commissioner determines that there are or will be insufficient health care professionals available for timely vaccine administration and issues an order authorizing such administration.

(1) To the extent authorized by 105 CMR 700.003(H), a health care professional duly licensed or certified by the Department, or a student duly enrolled in an approved or accredited program for licensure as a health care professional and acting in accordance with the policies of that program, may administer vaccine if:

(a) authorized to administer vaccine by order of the Commissioner;

(b) administration is in accordance with the Commissioner's order and the order or prescription of a duly registered practitioner authorized to issue an order or prescription for a vaccine pursuant to 105 CMR 700.000; and

(c) with respect to a student administering vaccine pursuant to 105 CMR 700.003(H), authorized and supervised by a licensed and qualified health care professional.

(2) In accordance with the Commissioner's order, a person administering vaccine shall:

(a) receive proper training and supervision in the administration of the vaccine;

(b) comply with written protocols to ensure proper storage, handling and return of vaccine, recordkeeping regarding administration, response to adverse events, and safe and appropriate administration of vaccine.

(I) A pharmacist may issue, modify or discontinue a written prescription, oral prescription or medication order as authorized in a collaborative practice agreement meeting the requirements of 247 CMR 16.00: *Collaborative Drug Therapy Management*, 243 CMR 2.12: *Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacies*, and M.G.L. c. 112, § 24B½, provided the following requirements are met:

(1) the pharmacist meets all applicable requirements of the Board of Registration in Pharmacy established in accordance with M.G.L. c. 112, § 24, and 247 CMR 1.00 through 16.00;

(2) the pharmacist registers with the Department, in accordance with 105 CMR 700.004, and the Drug Enforcement Administration, if applicable, in accordance with 21 CFR 1300, for the purpose of prescribing under 105 CMR 700.000;

(3) the pharmacist issues, modifies or discontinues a prescription or medication order in accordance with M.G.L. c. 112, § 24B½, 105 CMR 700.000, 247 CMR 16.00: *Collaborative Drug Therapy Management*, 243 CMR 2.12: *Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacists*, and the collaborative practice agreement between the pharmacist and supervising physician established in accordance with 247 CMR 16.00 and 243 CMR 2.12;

(4) the pharmacist, if practicing in a retail setting, may issue a written prescription for a controlled substance in Schedule VI only, in accordance with 105 CMR 700.003(I)(3);

(5) the pharmacist may dispense a controlled substance for immediate treatment in accordance with M.G.L. c. 94C, § 9, provided the pharmacist is authorized by 105 CMR 700.003(I) to prescribe such controlled substance;

(6) the pharmacist may order from a drug wholesaler, manufacturer, laboratory or distributor, for purposes of dispensing for immediate treatment, those controlled substances in Schedule VI which the pharmacist is authorized by 105 CMR 700.003(I) and the collaborative practice agreement to prescribe. For the purposes of dispensing controlled substances in Schedules II through V for immediate treatment in accordance with 105 CMR 700.003(I)(5), the pharmacist may obtain such controlled substances only as supplied by the supervising physician or obtained through a written prescription or medication order for the patient;

(7) the pharmacist may issue a prescription in accordance with M.G.L. c. 94C, § 20, provided that the prescribing pharmacist clearly identifies his or her name and professional designation to the dispensing pharmacist and provides his or her registration number, work address, phone number, and the name of the supervising physician.

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(8) the pharmacist may prescribe a controlled substance for a patient in a licensed health facility, including a hospital, long term care facility, ambulatory care clinic or hospice, through the use of a written medication order entered on the patient's medical record maintained at the facility, provided that such a written order meets all applicable provisions of 105 CMR 700.000;

(9) the pharmacist maintains a record of any controlled substance maintained for the purpose of dispensing for immediate treatment or administering pursuant to 105 CMR 700.000 and any related Department guidelines;

(10) the pharmacist provides a copy of an initial prescription or a modification or discontinuation of a prescription to the supervising physician within 24 hours of its issuance, unless more urgent notification is required under the circumstances.

(J) Notwithstanding any other provision of 105 CMR 700.000, a registered physician, physician assistant, certified nurse practitioner, or nurse midwife may provide expedited partner therapy (EPT) for the treatment of chlamydia infection, which is the prescribing or dispensing for immediate treatment of an appropriate therapeutic agent in Schedule VI for the treatment of a sex partner or partners of a patient diagnosed with chlamydia infection, provided that:

(1) The prescribing or dispensing is in accordance with 105 CMR 700.003(J), 243 CMR 2.00: *Licensing and the Practice of Medicine*, 263 CMR 5.00: *Scope of Practice and Employment of Physician Assistants*, 244 CMR 4.00: *Advanced Practice Registered Nursing*, as well as any applicable guidelines of the Department, Board of Registration in Medicine, Board of Registration of Physician Assistants, Board of Registration in Nursing, and U.S. Centers for Disease Control and Prevention;

(2) In a case in which the patient is provided with a therapeutic agent for immediate treatment of the patient's sex partner, the therapeutic agent shall be provided to the patient in a separate, properly labeled container for the sex partner to be given the therapeutic agent;

(3) In a case in which the patient is provided with a written prescription for the patient's sex partner, there shall be a separate prescription for the sex partner, which includes on the prescription form, where the name and address of the patient is to be noted, either the name of the sex partner or the words "Expedited Partner Therapy," "E.P.T." or "EPT"; and

(4) The physician, physician assistant, certified nurse practitioner, or nurse midwife counsels the patient about EPT and whenever possible provides the patient with an information sheet provided by the Department, or comparable to that provided by the Department, for the sex partner. Such information sheet shall include pertinent information about procedures for taking the medication, avoiding sexual activity as required during treatment, possible allergic reactions, and avoiding future infection. As appropriate, patient counseling may also include suggested ways of notifying and providing the medication or prescription to the sex partner.

(K) A non-licensed individual authorized by a registered individual practitioner registered pursuant to 105 CMR 700.000 may administer topical fluoride varnish or comparable fluoride agent approved by the Department for topical administration to prevent dental caries, provided that:

(1) the non-licensed individual administering the fluoride varnish or other approved fluoride agent has successfully completed a Department approved training and any Department mandated refresher courses in proper administration, storage, handling, record keeping, and reporting of adverse reactions;

(2) the fluoride varnish or other approved fluoride agent is administered in accordance with the order of a registered individual practitioner; and

(3) the non-licensed individual administering the fluoride varnish or other approved fluoride agent is supervised by a registered individual practitioner.

The requirements of 105 CMR 700.003(K)(1) do not apply to any individual subject to 234 CMR: *Board of Registration in Dentistry*.

(L) A medical device manufacturer may register solely for the purpose of purchasing and storing specific controlled substances which are to be used solely as part of the manufacturing and quality control processes.

700.004: Registration Requirements

(A) Persons Required to Register. Every person who is required to be registered with the Commissioner under M.G.L. c. 94C shall register with said Commissioner as hereafter provided:

(1) Every person other than a registered retail drug business or wholesale druggist shall register if he or she:

- (a) Manufactures, distributes, or dispenses any controlled substance; or
- (b) Uses any controlled substance in research, teaching, or chemical analysis; or
- (c) Possesses controlled substances with the intent to manufacture, distribute; or dispense any such substance; or
- (d) Possesses controlled substances with the intent to conduct research, teaching or chemical analysis using any such substance.
- (e) Is required to register pursuant to M.G.L. c. 94C.

(2) Persons required to be registered under 105 CMR 700.004(A)(1) shall register separately for each one of the following business or professional activities applicable to him or her.

- (a) Chemical Analyst;
- (b) Community Program;
- (c) Dentist;
- (d) Health Facility;
- (e) Manufacturer;
- (f) Physician;
- (g) Podiatrist;
- (h) Researcher;
- (i) Scientific Laboratory;
- (j) Teacher;
- (k) Veterinarian;
- (l) Ambulance Service/EFR Service;
- (m) School;
- (n) Physician Assistant;
- (o) Certified Nurse Practitioner;
- (p) Nurse Midwife;
- (q) Psychiatric Clinical Nurse Specialist;
- (r) School District;
- (s) Private School;
- (t) Optometrist;
- (u) Municipality/Non-municipal Public Agency;
- (v) Pharmacist;
- (w) Certified Registered Nurse Anesthetist;
- (x) Health Care Entity, including an ambulance service which is a Department-approved MIH program; and
- (y) Virtual Manufacturer.

(3) A person involved in the qualitative or quantitative analysis of controlled substances within a scientific laboratory is required to register as an individual chemical analyst; in addition to the requirement that the scientific laboratory also register.

(4) A hospital or other health facility is required to register if:

- (a) It is not registered with the Board of Registration in Pharmacy and
- (b) It possesses controlled substances which are safeguarded for or intended to be dispensed to any patient.

(5) A teacher in a teaching institution using controlled substances for instructional purposes is required to register, but the teaching institution is not required to register for teaching purposes.

(B) Exemptions from Requirement to Register. Persons primarily responsible for activities involving controlled substances in Massachusetts are required to register.

(1) Owners, partners and stockholders and parent corporations of registered businesses shall be exempt with regard to such ownership activities from the requirement to register.

(2) The following persons are exempt from the requirement to register pursuant to M.G.L. c. 94C:

- (a) An agent or employee of a registered manufacturer, distributor or dispenser acting in the usual course of his or her business or employment;

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- (b) A common or contract carrier or warehouseman or his or her employee, acting in his or her usual course of business or employment;
 - (c) A public official or law enforcement officer acting in the regular performance of his or her official duties.
 - (d) An ultimate user or research subject, at the direction of a practitioner in the course of his or her professional practice;
 - (e) A registered nurse, licensed practical nurse, respiratory therapist, dental hygienist, or perfusionist, acting under the direction or authorization of a practitioner in the course of their professional practices.
- (3) Any student enrolled in a school for nurses, practical nurses, respiratory therapists, dental hygienists, or perfusionists, duly approved in accordance with M.G.L. c. 112, shall be exempt from the requirement to register when:
- (a) Performing nursing, respiratory therapy, dental hygiene, or perfusion services incidental to any prescribed course in such school, and
 - (b) Authorized or directed by a physician, dentist, podiatrist, veterinarian, nurse midwife, certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant duly registered under 105 CMR 700.000.
- (4) Certain persons engaged in interstate or foreign commerce shall be exempt from the requirement to register with respect to the exempted business activities only as follows:
- (a) Vessels engaged in international trade or in trade between ocean ports of the United States.
 - (b) Aircraft operated by air carriers under a certificate or permit issued pursuant to the Federal Aviation Act of 1958.
 - (c) Persons who import controlled substances into the jurisdiction of the United States, and are in compliance with applicable Federal law.
 - (d) Persons who export controlled substances from the jurisdiction of the United States, and are in compliance with applicable Federal law.
- (5) An intern, fellow, medical officer, alien physician, registered nurse, licensed practical nurse, or other authorized person may dispense controlled substances under the registration of the hospital or other registered health facility by which he is employed and a "responsible person", as defined by the Department, may dispense controlled substances by ingestion only at the direction of a practitioner in the course of his professional practice, under the registration of the registered health facility by which such person is employed, in *lieu* of being registered himself or herself provided that:
- (a) He or she is authorized to dispense controlled substances in accordance with M.G.L. c. 112 if applicable, and
 - (b) Such dispensing is done in the usual course of his business or professional practice, and
 - (c) The hospital or other registered health facility by whom he is employed has verified with the appropriate Board of Registration, if applicable, that the person is permitted to dispense controlled substances within Massachusetts, and
 - (d) Such person is acting only within the scope of his employment in the hospital or other registered health facility, and
 - (e) The hospital or other registered health facility authorizes the person to dispense controlled substances under the registration number of the hospital or other registered health facility and designates a specific internal code to consist of a numeric suffix to the health facility registration number preceded by a hyphen for each such person so authorized, and
 - (f) The hospital or other registered health facility maintains a current list of internal codes and makes such codes available at all times to other registrants, the Commissioner, and authorized law enforcement agencies.
- (6) A registered pharmacist and pharmacist intern may dispense by administration influenza vaccine and other immunizations designated by the Department to persons nine years of age or older provided that:
- (a) Such registered pharmacist or pharmacist intern is authorized to dispense controlled substances in accordance with M.G.L. c. 112;
 - (b) Such administration is conducted pursuant to the order of a practitioner;

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(c) Each pharmacy that provides immunizations shall follow Department guidelines to disclose whether it receives vaccines free of charge through the Massachusetts Immunization Program and shall notify patients that there may be a difference in cost between immunization services provided at a pharmacy and at a primary care provider's office; and

(d) Such activity is conducted in accordance with guidelines adopted by the Department which shall include, but not be limited to, requirements for:

1. training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body;
2. pre-administration education and screening;
3. vaccine storage and handling;
4. administration of medication, including administration of controlled substances as necessary for the management of medical emergencies;
5. where immunization is being administered to a person younger than 18 years old, providing information on primary care providers in the pharmacy's geographic area;
6. if the purpose of the visit is for a childhood immunization other than the influenza vaccine, providing counseling on the importance of establishing and maintaining a relationship with a pediatric or family practice for ongoing medical and well-child care;
7. record keeping; and
8. reporting of adverse events.

(7) A health care professional duly licensed or certified by the Department or a student duly enrolled in an approved or accredited program for such licensure or certification and authorized by 105 CMR 700.003(H) to possess and administer vaccine is exempt from registration for purposes of administering vaccine pursuant to 105 CMR 700.003(H).

(8) Any pharmacist employed as an instructor by a school or educational program for pharmacists shall be exempt when purchasing supplies from Schedule VI for use in instruction at the school or educational program.

(9) A pharmacist or a pharmacy intern is authorized to dispense by administration FDA approved mental health or substance use disorder treatment drugs to persons 18 years of age or older provided that:

- (a) The pharmacist or pharmacy intern is authorized to dispense controlled substances in accordance with M.G.L. c. 112.
- (b) Such administration is conducted pursuant to a valid prescription;
- (c) Such dose is not the first dose of such agent the person has received;
- (d) Such prescription is subject to reassessment at appropriate intervals as determined by the prescriber; and
- (e) Such activity is conducted in accordance with guidelines adopted by the Department, which shall include, but not be limited to, requirements for:
 1. Specific drugs permitted to be administered pursuant to 105 CMR 700.004(B)(9);
 2. Training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body appropriate for the medications being administered and their respective patient populations;
 3. Current CPR certification;
 4. Maintaining continued competency regarding the populations served, medications administered and current guidelines;
 5. Pre-administration patient counseling;
 6. Dosing and administration of the medications only in accordance with manufacturer approved labeling;
 7. Administration of medication, including administration of controlled substances as necessary for the management of medical emergencies;
 8. Record keeping; and
 9. Reporting of adverse events.

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(10) Recreational Camps for Children licensed pursuant to 105 CMR 430.000: *Minimum Standards for Recreational Camps for Children (State Sanitary Code, Chapter IV)* and camp staff are exempt from registration for the purposes of administering epinephrine through use of an auto-injector to other camp staff and camp participants in compliance with that regulation.

NON-TEXT PAGE

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(11) No person shall be required to register with the Department for the purposes of purchasing, storing, possessing, or administering naloxone, or other opioid antagonist approved by the Department.

(12) A medical assistant shall be exempt when administering immunizations under the supervision of a practitioner, as authorized by M.G.L. c. 112, § 265 and in accordance with Departmental guidance.

(13) A municipality or non-municipal public agency that is duly registered pursuant to M.G.L. c. 94C, § 7(g) shall not be required to register with the Department as a distributor in order to convey or exchange naloxone or another opioid antagonist approved by the department to or with another duly registered entity to ensure the availability and use of unexpired naloxone or other approved opioid antagonist; provided however, that such an exchange shall be recorded in a memorandum between the registered entities as authorized by Department guidance.

(C) Separate Registrations Required for Separate Activities. Each person shall obtain a separate registration for each group of activities in which he or she engages.

(1) A person engaged in one of the following business or professions shall be deemed to be registered only for the activities appropriate to that business or profession as follows:

(a) A person registered as a manufacturer is deemed to be:

1. registered to manufacture controlled substances; and
2. registered to distribute controlled substances to registered persons.

(b) A person registered as a chemical analyst or scientific laboratory is deemed to be:

1. registered to manufacture controlled substances;
2. registered to conduct chemical analysis including quality control with respect to controlled substances; and
3. registered to distribute controlled substances to other registrants.

(c) A person registered as a teacher is deemed to be:

1. registered to manufacture controlled substances; and
2. registered to conduct instructional activities with controlled substances.

(d) A registered physician, dentist, veterinarian, or podiatrist, registered by the appropriate Board of Registration is deemed to be registered to dispense controlled substances.

(e) A registered hospital, or other registered health facility is deemed to be registered to dispense controlled substances.

(f) A person registered as a researcher is deemed to be, within the scope of the protocol submitted to the Commissioner, if applicable:

1. registered to manufacture controlled substances;
2. registered to distribute controlled substances to registered persons; and
3. registered to conduct research with respect to controlled substances.

(g) A registered ambulance service or EFR service shall only be registered to possess those controlled substances and instruments used to administer controlled substances, in quantity and in kind, that are necessary for pre-hospital emergency medical care in accordance with 105 CMR 170.000: *Emergency Medical Services System* and the Statewide Treatment Protocols and that are obtained from the hospital pharmacy, provided that auto-injectors containing epinephrine, nerve agent antidotes and medications approved by the Department may be obtained directly from the manufacturer or another source registered by the Department.

(h) A registered school is deemed to be registered solely in order to possess fluoride tablets and mouth rinse and to authorize fluoride program monitors and dental hygienists to administer fluoride tablets and mouth rinse in accordance with 105 CMR 700.000.

(i) A community program is registered for the sole purpose of authorizing its employees to administer or assist in the administration of controlled substances which are obtained from a pharmacy upon the prescription or order of a practitioner.

(j) A municipality or agency of the Commonwealth is registered for the purpose of authorizing possession and administration, in accordance with 105 CMR 700.003(D) of:

1. auto-injectors containing epinephrine for use by first responders and authorized employees and volunteers of a program operated, funded or licensed by the agency;
2. auto-injectors containing epinephrine, atropine, pralidoxime chloride and other nerve agent antidotes approved by the Department for use by public employees and volunteers whose functions include emergency preparedness and response, including first responders;

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3. An opioid antagonist approved by the Department for use by first responders and authorized employees and volunteers of a program operated, funded or licensed by the agency; and

4. An opioid antagonist approved by the Department for use by public employees and volunteers whose functions include emergency preparedness and response, including first responders.

(k) A pharmacist is registered for the purpose of issuing, modifying or discontinuing a written prescription, oral prescription or medication order in accordance with requirements for collaborative drug therapy management specified in 247 CMR 16.00: *Collaborative Drug Therapy Management*, 243 CMR 2.12: *Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacies* and M.G.L. c. 112, § 24B½.

(l) A certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist or physician assistant, authorized and registered by the appropriate board of registration is deemed to be registered to dispense controlled substances in accordance with written guidelines mutually developed and agreed upon with a supervising physician.

(m) A nurse midwife, authorized and registered by the Board of Registration in Nursing (244 CMR), is deemed to be registered to dispense controlled substances.

(n) A registered optometrist registered by the Board of Registration in Optometry may utilize and issue written prescriptions and medication orders, in accordance with the provisions of M.G.L. c. 112, §§ 66 and 66B, for those topical pharmaceutical agents in Schedule VI required for the diagnosis, prevention, management or treatment of abnormal ocular conditions or diseases as defined in M.G.L. c. 112, § 66, except glaucoma.

(2) No person shall engage in any activities involving any controlled substance in any schedule for which he is not registered.

(D) Automatic Registrations. The Commissioner shall automatically issue a registration to dispense controlled substances other than for research projects and studies pursuant to M.G.L. c. 94C, § 8, to any physician, dentist, podiatrist, or veterinarian who is duly authorized to practice his or her profession in the Commonwealth, provided that, any such physician, dentist, podiatrist, or veterinarian shall only be registered for Massachusetts Schedule VI and for the same schedules as he or she is registered with the Drug Enforcement Administration.

(1) Any physician, dentist, podiatrist or veterinarian who is not registered with the Drug Enforcement Administration shall be automatically registered to dispense controlled substances but only for Massachusetts Schedule VI.

(2) The Commissioner may periodically recall registrations to dispense controlled substances issued to practitioners, in accordance with M.G.L. c. 94C, § 7(f), and may issue a new registration upon verification that the practitioner continues to be duly authorized to practice his or her profession in Massachusetts.

(E) Time for Application and Term of Registration. No person required to be registered shall engage in any activity for which registration is required until he or she is registered for that activity.

(1) Any person who is registered with the Commissioner may apply to be re-registered on a form provided by the Commissioner not more than 60 days before the expiration date of his or her registration.

(2) Any registration issued by the Commissioner other than a registration to conduct research activities with Schedule I controlled substances or a registration to dispense automatically issued shall be effective for one year from the date of issuance.

(3) A registration issued to conduct research with Schedule I controlled substances shall be for such period, not to exceed one year, as may be specified by the Commissioner.

(4) Any person who is registered may at any time apply to modify his or her registration to change the contact information.

(F) Separate Registrations Required for Separate Locations. A separate registration is required at each place of business or professional practice where the applicant or registrant manufactures, distributes or dispenses controlled substances, or uses controlled substances in research, teaching, or chemical analysis.

700.004: continued

(1) The following locations are deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(a) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered.

(b) An office used by an agent of a registrant where sales of controlled substances are solicited, made or supervised but which neither contains such substances, nor serves as a distribution point for filling sales orders.

(c) An office or registered hospital or other registered health facility which is used by a registered individual practitioner, pharmacist or optometrist who is registered at another location which is his principal place of professional practice, provided that no controlled substances are maintained by such practitioner at any place where he or she is not registered.

(2) If a practitioner holds a current registration under 105 CMR 700.000: *Implementation of M.G.L. c. 94C*, a separate registration is not required for charitable or volunteer activities which do not exceed ten hours in a calendar month. For the purposes of this exemption, a charitable or volunteer activity is one for which the registrant receives no recompense or remuneration of any kind, and which is performed for or in association with a nonprofit group or organization offering medical services at no cost to patients.

(G) Limitations on Registration for Schedule I. No person other than a person proposing to manufacture controlled substances in Schedule I; or a person proposing to conduct research on research subjects involving controlled substances in Schedule I pursuant to M.G.L. c. 94C, § 8; or a person proposing to engage in qualitative or quantitative analysis of those controlled substances in Schedule I within a scientific laboratory shall be registered for activities involving the manufacture, distribution or dispensing of Schedule I controlled substances unless expressly authorized so to do by the Commissioner:

(1) Every applicant for registration for activities involving the manufacture, distribution or dispensing of controlled substances in Schedule I shall demonstrate to the satisfaction of the Commissioner, unless waived by the Commissioner:

(a) That he or she is registered by the Drug Enforcement Administration specifically to manufacture, or conduct research involving, or to conduct chemical analysis with, controlled substances in Schedule I; and

(b) That he or she has never had an application denied or suspended or revoked by the Drug Enforcement Administration or any predecessor agency for violation of any law or regulation; and

(c) That his or her physical security controls are specifically approved by the Drug Enforcement Administration; and

(d) That in the case of an application to conduct research with controlled substances in Schedule I, his or her protocol is attached to his or her application and satisfies the requirements of 105 CMR 700.009(H).

(H) Content and Form of Application. Each application for registration, renewal of a registration, or modification of a registration shall be on a form provided or approved by the Commissioner. The Commissioner may, in his or her judgment, require additional information.

(I) Application to Manufacture a New Controlled Substance. Any person who proposes to manufacture a controlled substance for which he or she is not registered with the Drug Enforcement Administration, shall file with the Commissioner a copy of DEA Form 130, which shall be treated as confidential by said Commissioner.

(1) He or she shall file a copy thereof at the time he or she files such form with the Drug Enforcement Administration or before he or she begins manufacture, whichever is earlier.

(2) The applicant need not disclose any technical detail of the process which he or she regards as a trade secret, however he or she must identify each substance used in or resulting from successive stages of manufacture, in order to notify the Commissioner of precursors and byproducts.

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(J) Termination of Registration. The registration of any person shall terminate if and when such person surrenders or otherwise discontinues an associated health professions license, or dies or ceases legal existence or discontinues business or professional practice in Massachusetts or changes his or her name or address as shown on the registration, or has his or her registration revoked by the Commissioner.

(1) In the event of a change in name or address, the person may apply for a new registration up to 90 days in advance of the effective date of such change.

(2) Any registrant whose registration will terminate under 105 CMR 700.004(J), other than by death, shall notify the Commissioner at least 30 days before such event and shall surrender his or her Certificate of Registration by mailing it to the Commissioner on the day of such event.

(3) If a registrant dies, the executor or administrator of the registrant's estate shall be responsible for fulfilling the requirements of 105 CMR 700.004 as soon as reasonably feasible.

(K) Transfer of Registration Prohibited. No registration or any authority conferred thereby shall be assigned or otherwise transferred.

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

700.005: Security Requirements

(A) Physical Security Requirements. All applicants and registrants shall provide effective physical security controls against theft and other diversion of controlled substances. All applicants and registrants shall provide physical security controls which meet the conditions set forth in guidelines issued by the Department.

(B) Personnel Security Requirements. All applicants and registrants shall screen before employment new employees who may work in or around areas where controlled substances are handled.

(1) Such screening shall be made solely for the purpose of determining whether the prospective employee is a responsible person who can be trusted to work in and around controlled substances. Documentation of such screening shall be made available by applicants and registrants to the Commissioner upon his or her request.

(2) No registrant shall knowingly employ any agent or employee who has had an application for registration denied for violation of any law or regulation or has had his or her registration revoked for violation of any law or regulation at any time.

(C) Security of Mail. Every registrant shall ensure that mail which can reasonably be believed to contain controlled substances and which is addressed to any person at the registrant's place of business or professional practice, is safeguarded until delivered directly to the addressee, or immediately returned to the sender.

(D) Report of Theft, Loss or Suspected Tampering. A registrant shall report the theft, loss or suspected tampering of any controlled substances to the designated agent of the Commissioner within 24 hours of discovery of such theft, loss or suspected tampering, by submitting to the Commissioner the form provided or approved by the Commissioner for such purpose.

700.006: Requirements for Records, Inventories, and Reports

(A) Records Required, Generally. Every person registered with the Commissioner shall keep records, maintain inventories, and make reports in conformance with the requirements of the Federal *Comprehensive Drug Prevention and Control Act of 1970* and the Federal Food, Drug and Cosmetic Act, and 105 CMR 700.006.

(B) Time for Keeping Records. A registrant shall keep for at least two years from the date of preparation, every report, inventory and record he or she is required to keep by 105 CMR 700.000.

700.006: continued

(C) Central Record Keeping. Any registrant may keep central records if he or she holds a valid permit to keep central records issued by the Drug Enforcement Administration and notifies the Commissioner thereof. The registrant must keep records in a manner that makes them easily available for inspection upon request of the Commissioner.

(D) Exemptions from Record Keeping. A registered person who uses any controlled substance in research or teaching at a registered institution which maintains records, is exempt from the requirement to keep his or her own records, if he or she has notified the Drug Enforcement Administration and the Commissioner of the name, address and registration number of the institution registered by the Drug Enforcement Administration, which maintains his or her records; and a registered chemical analyst employed by a scientific laboratory which maintains records, is exempt from the requirement to keep his or her own records if he or she has notified the Commissioner of the name, address and registration number of the scientific laboratory which maintains his or her records.

(E) Inventory Requirements. Every registrant shall take an initial inventory and biennial inventories thereafter.

(1) Every registrant required to take inventories under Federal Law and Regulations shall follow those requirements, which are deemed to include Schedules I, II, III, IV, and V only.

(2) Every registrant shall take an initial inventory of all his or her controlled substances in Schedules II through V on the day he or she first engages in the manufacture, distribution, or dispensing of controlled substances.

(3) Every registrant shall take a new inventory of all stocks of controlled substances in Schedules II through V every two years following the date on which either the Federal or State initial inventory was taken, as applicable:

(a) On the day of the year on which the initial inventory was taken;

(b) On the registrant's regular physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date and which would otherwise apply; or

(c) Any other fixed date which does not vary by more than six months from the biennial date which would otherwise apply.

(4) A registrant who elects to take his or her biennial inventory on his or her regular general physical inventory date or another fixed date, shall inform the Commissioner of this election and of the date on which he or she will take his biennial inventory upon request.

(5) Whenever the Commissioner by regulation adds to any schedule a controlled substance which was not immediately prior to that date listed in a schedule on which a registrant was required to keep records, a registrant who possesses that substance shall:

(a) Take, on the effective date of the regulation, an inventory of all stocks of that substance on hand and;

(b) Thereafter, include such substance in each inventory made by such registrant.

(F) Additional Records and Inventories Required of Practitioners. All registered individual practitioners and pharmacists shall maintain records and inventories in accordance with 105 CMR 700.000, with respect to all controlled substances in Schedules II through V which he or she dispenses or administers in any manner, any exemptions for individual practitioners in Federal law and regulations notwithstanding.

(1) All registered individual practitioners shall include in their inventories of controlled substances that they dispense or administer in any manner, in Schedules II through V, the following information:

(a) For each controlled substance in finished form:

1. The name of the substance; and

2. The size of each finished form in metric weight or volume; and

3. The number of units or volume of each finished form.

(b) For each controlled substance not in finished form:

1. The name of the substance; and

2. The total quantity of the substance to the nearest metric unit of weight.

700.006: continued

(2) Records maintained by registered individual practitioners and pharmacists shall be closed to the public, and shall not be used in the criminal prosecution of any person in connection with his or her treatment as a patient by such individual practitioner or pharmacist nor shall they be admissible in evidence against any such patient in connection with such treatment in any criminal, civil, legislative or administrative proceeding.

(3) Records for Schedules II through V. A registered individual practitioner and pharmacist shall maintain on a current basis, separately for each registration he or she possesses, a complete and accurate record of each substance in Schedules II through V received, distributed, administered, dispensed, and otherwise disposed of as follows:

- (a) The name of the substance and the form of the substance; and
- (b) The size of each finished form in metric weight or volume; and
- (c) The number of units or volume of each finished form received from other persons; the date received; and the name, address, and Drug Enforcement Administration registration number of the person from whom the substance was received; and
- (d) The name, dosage and strength per dosage unit of each controlled substance administered or dispensed; the name and address of the person for whom the controlled substance was administered or dispensed and whether administered or dispensed by delivery or dispensed by prescription; the date of the administration or dispensing, and the written or typewritten name or initials of the person who administered or dispensed the substance; and
- (e) The number of units or volume of such finished forms disposed of in any other way by the registrant, including the date and manner of disposal.

(4) Records for Schedule VI. A registered individual practitioner, including an optometrist, who dispenses, other than by prescribing and administering, Schedule VI sample medications shall maintain a record, which may be kept in the patient's medical record, of the following information:

- (a) the name, dosage and strength of the substance dispensed;
- (b) the volume of units dispensed;
- (c) the date of the dispensing; and
- (d) the name and address of the person to whom the medication was dispensed.

(5) Record Keeping Requirements for Schools Registered for Fluoride Programs. Schools shall keep for a period of two years such records concerning the administration of fluoride tablets and mouth rinse as the Commissioner may require.

(G) Additional Reporting Required by Manufacturers. Each registered manufacturer shall submit to the Commissioner on forms approved or supplied by him or her, a quarterly report, on or before the 15th day of the month succeeding the period for which such report is submitted, accounting for all stocks of non-narcotic controlled substances appearing in Schedules I, II, and III on hand at the beginning and at the end of the quarter, and for all receipts, dispositions, manufacturing and packaging of such controlled substances. Such reports shall be made in a form as similar as possible to the Federal reporting requirements for narcotic controlled substances appearing in Schedules I, II, and III. Each registered manufacturer shall make available to the Commissioner the required Federal reports for narcotic controlled substances in Schedules I, II, and III.

(H) Disposition upon Discontinuance of Business or Professional Practice. Any registrant who desires to cease legal existence or discontinues business or professional practice or moves his or her principal place of business or professional practice from the Commonwealth shall notify the Commissioner in writing at least 30 days before such event, and shall inform the Commissioner how he or she proposes to dispose of all the controlled substances in his or her possession associated with the discontinued professional practice. If the Commissioner does not notify the registrant by the date the registrant has proposed to dispose of such substances that he or she should postpone or cancel such disposal, he or she may proceed as he or she proposed to the Commissioner. Any such registrant whose registration has expired, the executor of the estate of any deceased person in possession of controlled substances, any registrant in possession of controlled substances which are safeguarded for or intended to be dispensed to any patient who has died, or been transferred from the jurisdiction of the registrant without such controlled substances being transferred, and any other person in possession of controlled substances for which he or she is not registered:

700.006: continued

- (1) Shall dispose of all controlled substances in his or her possession:
 - (a) Under the authorization and instructions of the Regional Director of the Drug Enforcement Administration by transfer to a person registered to possess the controlled substances; or
 - (b) By delivery to an agent of the Drug Enforcement Administration; or
 - (c) By delivery to an expressly authorized agent of the Commissioner; or
 - (d) By destruction of the substances in the presence of an agent of the Drug Enforcement Administration; or
 - (e) By destruction of the substances in the presence of an expressly authorized agent of the Commissioner; or
 - (f) By such other means as said Regional Director may determine; and
- (2) May transfer such controlled substances in accordance with 105 CMR 700.006(H)(1) without being registered to do so; and
- (3) Upon the completion of such disposition, shall file with the Commissioner on a form approved or provided by him a final report of such disposition.

(I) Filing of Prescriptions by Pharmacies in Registered Health Facilities. Every pharmacy located in a health facility registered with the Commissioner shall file prescriptions for controlled substances as follows:

- (1) Prescriptions for controlled substances listed in Schedules I and II shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedules I and II only;
- (2) Prescriptions for controlled substances listed in Schedules III, IV, and V shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedule III, IV and V only; and
- (3) Prescriptions for controlled substances listed in Schedule VI and prescriptions for non-controlled substances shall be filed separately from all other prescriptions of the pharmacy in a file identified for controlled substances listed in Schedule VI and non-controlled substances.

700.007: Inspection of Premises

(A) Notice of Inspection Required. The Commissioner or any expressly authorized agent of the Commissioner may carry out an inspection relating to any provision of the chapter of a registrant or applicant for registration, upon stating his or her purpose, presenting his or her appropriate credentials, and, if requested, presenting a Notice of Inspection to the owner, operator or agent in charge of the premises to be inspected, if he or she is given the consent of such owner, operator or agent in charge.

(B) Notice of Inspection Form. The Notice of Inspection Form shall be supplied by the Commissioner and shall contain:

- (1) The name and title of the registrant;
- (2) The name and title of the owner, operator or agent in charge if different from the registrant;
- (3) The name, if any, and address of the controlled premises;
- (4) The date and time of the inspection;
- (5) A statement that the Notice of Inspection is given pursuant to M.G.L. c. 94C;
- (6) A reproduction of the pertinent parts of M.G.L. c. 94C;
- (7) The signature of the inspector;
- (8) Provision for acknowledgment in writing by the owner, operator or agent in charge of the controlled premises that he or she has given his or her informed consent. Such acknowledgment shall contain a statement for the owner, operator or agent in charge that he or she has been informed:
 - (a) Of his or her constitutional right not to have an administrative inspection of the premises without an administrative inspection warrant;
 - (b) Of his or her right to refuse such an inspection;
 - (c) Of the possibility that anything of an incriminating nature which may be found may be used against him or her;
 - (d) That he or she has been presented with a Notice of Inspection in accordance with 105 CMR 700.000;

700.007: continued

- (e) That the consent given by him or her is voluntary and without threats of any kind; and
- (f) That he or she may withdraw his or her consent at any time during the course of inspection.

(C) Notice of Inspection Distribution. The Notice of Inspection and acknowledgment of informed consent shall be made in duplicate and one copy shall be retained by the Commissioner and the duplicate shall be given to the person inspected.

(D) Confidentiality of Trade Information. Unless the owner, operator, or agent in charge of a controlled premises so consents in writing, no inspection authorized by 105 CMR 700.000 shall extend to:

- (1) Financial data; or
- (2) Sales data, other than shipping data; or
- (3) Pricing data; or
- (4) Technical details of production processes other than as specified in 105 CMR 700.004(I).

700.009: Research Involving Controlled Substances

(A) Persons Covered. No person shall carry out any research projects or studies involving any research drug unless the researcher for the research project or study applies to the Commissioner for authorization. In the case of a research study involving an investigational new drug, as defined in 21 CFR 312.3, the researcher shall be the principal investigator, as required therein. The researcher shall supply the Commissioner with:

- (1) satisfactory evidence of compliance with any applicable Federal law; and
- (2) such information regarding the research project or study as the Commissioner requires, including a list of all research drugs and other controlled substances involved in the research project or study.

(B) Information to Be Submitted. The application to carry out a research project or study covered by M.G.L. c. 94C, § 8 shall be submitted by the researcher on a form provided or approved by the Commissioner. The Commissioner may, in his or her judgment, require additional information. A researcher may include multiple research projects or studies in a single application, provided all required information is included for each study or project.

(C) Evidence of Compliance with Applicable Federal Law. Satisfactory evidence of compliance with applicable Federal Law shall consist of:

- (1) Any of the following which are required by the Federal Food and Drug Administration:
 - (a) Notice of Claimed Investigational Exemption for a New Drug (Form FD 1571); and
 - (b) Statement of Investigator (Clinical Pharmacology) (Form FD 1572); and
 - (c) Statement of Investigator (Form FD 1573); and
- (2) A copy of the Drug Enforcement Administration Registration of each person required to be registered by the Drug Enforcement Administration.

(D) Requirement of Confidentiality. Records maintained by researchers, including every "Statement of Informed Consent", shall be closed to the public, and shall not be used in the criminal prosecution of any research subject in connection with his or her participation as a research subject, nor shall they be admissible in evidence against any such research subject in connection with such participation in any criminal, civil, legislative or administrative proceeding.

(E) Request to Inspect Protocol. If a request is made to inspect and/or release one of the protocols on file with the Department, the Department shall promptly notify the researcher and the pharmaceutical company(nies) sponsoring the clinical trial of the request, by telephone and followed up by written notification by certified mail. Such notification shall not include the identity of the person requesting inspection unless otherwise required by law, but may, in the discretion of the Department, include any known connection of the requesting party to organizations or entities with a competing commercial interest. In the case of a general request for inspection involving more than a specified researcher, protocol, drug or pharmaceutical company, and association representing pharmaceutical manufacturers and/or researchers may be notified in *lieu* of individual researchers and pharmaceutical manufacturers. Notification shall be at least eight calendar days prior to inspection.

700.010: Dispensing and Labeling of Sample Medications by Practitioners

(A) A registered individual practitioner may, in the course of professional practice, dispense to an ultimate user the following:

- (1) A Schedule VI sample medication in a single dose or in such quantity as is in the opinion of the registered individual practitioner appropriate for the treatment of the patient but not exceeding a 30-day supply per dispensing; provided, however that this quantity may be increased to a 90-day supply if dispensed as part of an indigent patient drug program and deemed appropriate in the professional judgement of the practitioner;
- (2) A Schedule II through V sample medication in a single dose or in such quantity as in the opinion of the registered individual practitioner is essential for the immediate treatment of the patient.

(B) All sample medications dispensed by a registered individual practitioner shall be properly labeled.

- (1) Whenever a sample medication is dispensed by a registered individual practitioner, a label shall be affixed to the outside of the package, and shall include the following information:
 - (a) a registered individual practitioner's name and address;
 - (b) date of dispensing; and
 - (c) name of the patient, unless a veterinary product.
- (2) In addition, the following information must be included on the label unless already provided for on the manufacturer's packaging of the sample medication:
 - (a) name, dosage form and strength of the sample medication;
 - (b) clear, simple and brief directions for use and any necessary cautionary statements; and
 - (c) date on which the medication will expire.
- (3) Information provided to the patient under 105 CMR 700.010(B)(2) shall be, in the professional judgement of the registered individual practitioner, presented in a manner which can be easily understood by the patient. A combination of written information, labeling and counseling may be used to meet this requirement, based upon the individual needs of each patient.
- (4) If multiple packages of the same sample medication are dispensed at the same time to the same patient, the samples may be placed in a larger container to which the label containing applicable information required by 105 CMR 700.010 has been affixed.

700.011: Issuance of Prescriptions or Medication Orders for Implantable Infusion Pumps Containing Schedule II or Schedule III Controlled Substance

A prescription or medication order for an implantable infusion pump containing a Schedule II or Schedule III controlled substance may be filled for a maximum of a 90 day supply.

700.012: Prescription Monitoring Program

(A) Pharmacy Reporting Requirements.

- (1) The reporting requirement of 105 CMR 700.012 shall apply to every pharmacy 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 as outlined in 105 CMR 700.012, 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, transmit to the Department or its agent the pharmacy identifier, customer identification number and associated information as specified in the PMP Dispensing Guide issued by the Commissioner.
- (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.

700.012: continued

(3) A pharmacy that dispenses a controlled substance subject to the requirements in 105 CMR 700.012 must require that a customer identifier is presented whenever a controlled substance in Schedules II through V, or an additional drug is dispensed. The pharmacy may dispense a controlled substance in Schedules II through V or an additional drug without reviewing the customer identifier if the pharmacy has reason to believe that the failure to dispense the controlled substance or additional drug would result in a serious hardship for the ultimate user or agent of the ultimate user, and documents the reason; and the ultimate user or agent of the ultimate user prints his or her name and address on the reverse side of the prescription and signs his or her name thereto, or in the case of an electronic prescription, provides an electronic signature; and the pharmacy provides to the Department those informational fields required by the Department.

(4) The Commissioner may waive or modify the requirements in 105 CMR 700.012(A) for a pharmacy to report customer information as specified by the Commissioner.

(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 by the end of the next business day and shall include data for all controlled substances dispensed since the previous transmission or report 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.

(6) If a pharmacy is not able to submit dispensing information by electronic means, the Commissioner 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 Medical Review Group.

(1) The Commissioner may establish the Prescription Monitoring Program Medical Review Group to 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.

(C) Privacy, Confidentiality and Disclosure.

(1) Except where otherwise provided by judicial order, statute or regulation including, but not limited to 105 CMR 700.012(C)(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, 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 or to review his or her own professional prescribing history for the purpose of practice improvement;

(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; meets all applicable requirements of M.G.L. c. 94C, § 24A(f); and such requesting 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.

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- (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) PMP data provided to prescribers pursuant to 105 CMR 700.012(C)(2)(a) may be accessed directly through the MassPAT, or through a secure electronic medical record or other secure electronic system which complies with 21 CFR 1311, Subpart C, and other federal regulations applicable to the safety and security of healthcare information and prescriptive practice, as authorized in a written agreement with the Department pursuant to 105 CMR 700.012(E)(1) and in accordance with Departmental guidance. Such agreement may allow the creation and maintenance of a summary or description of patient-specific data collected pursuant to 105 CMR 700.012 in that patient's electronic medical record as a clinical note associated with a specific clinical encounter; provided however, that such data may be used only for the purpose of diagnosis, treatment or coordinating care, and shall not be retained separately from said clinical note.
- (4) 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(E) and shall be made in accordance with procedures established by the Commissioner to ensure compliance with the requirements of 105 CMR 700.012(C) and (D).
- (5) The Commissioner 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 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 or she 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.
- (6) (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 pursuant to 105 CMR 700.012(C)(4) and (5) shall be in conformance with any protocols established by the Commissioner, 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.
- (7) The Commissioner may provide de-identified data to a public or private entity for statistical research or educational purposes.
- (8) The Commissioner may determine that a drug is an "additional drug" for purposes of 105 CMR 700.012, because it carries a *bona fide* potential for abuse based on factors including, but not limited to, the following:
- (a) A risk of addiction exists when used alone or in combination with a Schedule II through IV drug;
 - (b) The drug is known to be used recreationally;
 - (c) The drug is known to be regularly diverted for misuse; or
 - (d) The drug has been known to contribute to overdose or be regularly present in the bloodstream of individuals who have experienced overdose.

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Upon making such a determination, the Commissioner shall notify all dispensers that they must begin to report the dispensing of such additional drug pursuant to prescription as directed in 105 CMR 700.012(A).

(9) 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 700.012C.

(D) 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(C) 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.

(E) 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(C)(2)(a) through (c), or a designee of such individual as approved by the Commissioner, to use the secure electronic transmission system established pursuant to 105 CMR 700.012(E)(1) in accordance with security protocols established by the Commissioner.

(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.

(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(J) or other state law.

(6) The Department may enter into data use agreements with healthcare facilities permitting healthcare facilities to integrate secure software or other information systems with their electronic medical record for the purpose of performing compilation, data analysis or visualization of data collected pursuant to 105 CMR 700.012(A). Such data use agreements must comply with Department guidelines including security protocols and terms and conditions of use established by the Commissioner, and 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts*. Notwithstanding 105 CMR 700.012(E)(3), use of prescription monitoring data received and retained pursuant to 105 CMR 700.012(E) shall be limited to performing data analysis, compilation, or visualization for the purposes of diagnosis, treatment or coordinating care of the practitioner's patient.

(F) Automatic Authorization to Utilize the Prescription Monitoring Program.

(1) 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(E).

(2) If the licensure or registration of a practitioner is suspended, the Department shall suspend the practitioner's access to the prescription monitoring program.

(3) If the licensure or registration of a practitioner is voided or terminated, the Department shall terminate the practitioner's access to the prescription monitoring program.

(G) 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 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 practitioner issues a prescription to a patient for any narcotic drug in Schedule II or III or a benzodiazepine.

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- (3) 105 CMR 700.012(G)(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 through V during that encounter;
 - (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 younger than 96 months old;
 - (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.

(H) Waiver of Requirement to Utilize the Prescription Monitoring Program.

- (1) The Department may temporarily waive the requirements established in 105 CMR 700.012(G)(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(H)(2).
- (2) A request for a waiver of the requirements in 105 CMR 700.012(G)(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.

(I) 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 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.

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(J) 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 one or more of the following actions:

(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;

(d) Share information with the appropriate board of registration; and

(e) Take action pursuant to 105 CMR 700.115.

(4) If the Department takes action under 105 CMR 700.012(J)(3), the participant may contest the Department's action, 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 105 CMR 700.000;

(2) 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;

(3) has had his or her 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;

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- (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 suspends, revokes, or refuses to renew a registration, the affected person shall be notified in writing of the reasons for the Department's action and of his or 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 801 CMR 1.01: *Formal Rules*.

(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.

700.140: Waiver of Requirements Imposed on Registrants

The Commissioner may waive the applicability to a particular registrant of one or more of the requirements imposed on registrants in 105 CMR 700.000: *Implementation of M.G.L. c. 94C* upon a finding that:

- (A) Compliance would cause undue hardship to the registrant;
- (B) The registrant's noncompliance does not jeopardize the health or safety of individuals or the public;
- (C) The registrant has instituted compensating measures that are acceptable to the Commissioner; and
- (D) The registrant provides to the Commissioner, or his or her designee, written documentation supporting its request for a waiver.

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.

REGULATORY AUTHORITY

105 CMR 700.000: M.G.L. c. 94C, §§ 2, 6, 24 and 24A; M.G.L. c. 17, § 13; M.G.L. c. 28A, § 10; M.G.L. c. 30a; M.G.L. c. 111, § 201; M.G.L. c. 111C, §§ 6 and 9; M.G.L. c. 111O; M.G.L. c. 112, §§ 1 through 12CC, 9E, 9I, 23R through 23BB, 24, 24G, 51, 66, 66B, 74, 80B, 212 and 265.