

105 CMR 725.000: IMPLEMENTATION OF AN ACT FOR THE HUMANITARIAN  
MEDICAL USE OF MARIJUANA

- 725.001: Purpose
- 725.002: Scope
- 725.003: Authority
- 725.004: Definitions
- 725.005: Registration of Certifying Physicians
- 725.010: Certifying Physician's Certification of a Debilitating Medical Condition for a Qualifying Patient
- 725.015: Registration of Qualifying Patients
- 725.020: Registration of Personal Caregivers
- 725.025: Responsibilities of Personal Caregivers
- 725.030: Registration of Dispensary Agents
- 725.035: Hardship Cultivation Registration
- 725.100: Registration of Medical Marijuana Treatment Centers
- 725.105: Operational Requirements for Medical Marijuana Treatment Centers
- 725.110: Security Requirements for Medical Marijuana Treatment Centers
- 725.200: Confidentiality
- 725.300: Inspection of Medical Marijuana Treatment Centers
- 725.305: Deficiency Statements
- 725.310: Plan of Correction
- 725.400: Medical Marijuana Treatment Center: Grounds for Denial of Initial Application for Registration
- 725.405: Medical Marijuana Treatment Center Registration: Grounds for Denial of Renewal Applications and Revocation
- 725.410: Void Medical Marijuana Treatment Center Registration
- 725.415: Medical Marijuana Treatment Center Registration: Limitation of Sales by Medical Marijuana Treatment Centers
- 725.420: Medical Marijuana Treatment Center Registration: Limitation of Sales by Medical Marijuana Treatment Centers Pending Hearing and Final Agency Decision
- 725.425: Denial of a Registration Card or Hardship Cultivation Registration
- 725.430: Revocation of a Registration Card or Hardship Cultivation Registration
- 725.435: Revocation of a Certifying Physician Registration
- 725.440: Void Certifying Physician Registration
- 725.445: Void Registration Cards
- 725.450: Summary Cease and Desist Order and Quarantine Order
- 725.455: Summary Suspension Order
- 725.500: Administrative Review: Non-Selection of Medical Marijuana Treatment Center's Application for Initial Registration
- 725.505: Hearings
- 725.510: Effect of Denial of Renewal or Revocation of Medical Marijuana Treatment Center Registration, Revocation of Dispensary Agent Registration, and Surrender of a Registration
- 725.600: Municipal Requirements
- 725.700: Waivers

105 CMR: Department of Public Health

725.800: Severability

725.001: Purpose

The purpose of 105 CMR 725.000 is to implement Chapter 369 of the Acts of 2012, An Act for the Humanitarian Medical Use of Marijuana.

725.002: Scope

105 CMR 725.000 applies to every person who:

(A) Seeks to register and/or registers with the Department as a certifying physician, registered qualifying patient, personal caregiver, or for hardship cultivation;

(B) Is a physician who seeks to certify and/or certifies that a person has a debilitating medical condition;

(C) Seeks to register and/or registers with the Department as a medical marijuana treatment center (MMTC), or dispensary agent, including such center's board members, directors, employees, executives, managers, owners, or volunteers.

725.003: Authority

105 CMR 725.000 is promulgated pursuant to Chapter 369 of the Acts of 2012, An Act for the Humanitarian Medical Use of Marijuana.

725.004: Definitions

For the purposes of 105 CMR 725.000, the following terms shall have the following meanings:

Act means Chapter 369 of the Acts of 2012, An Act for the Humanitarian Medical Use of Marijuana.

Arming Station means a device that allows control of a security alarm system.

Automatic Voice Dialer means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio, or other communication system, to a law enforcement, public safety, or emergency services agency, requesting dispatch.

Bona Fide Physician-Patient Relationship means a relationship between a certifying physician, acting in the usual course of his or her professional practice, and a patient in which the physician has conducted a clinical visit, completed and documented a full assessment of the patient's medical history and current medical condition, has explained the potential benefits and risks of marijuana use, and has a role in the ongoing care and treatment of the patient.

Card Holder means a registered qualifying patient, a personal caregiver, or a dispensary agent of a medical marijuana treatment center who has been issued and possesses a valid registration card.

Certificate of Registration means the certificate issued by the Department that confirms that a MMTC has met all requirements pursuant to the Act and 105 CMR 725.000 and is registered by the Department.

Certifying Physician means a Massachusetts licensed physician (Medical Doctor or Doctor of Osteopathy) who certifies that in his or her professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks for a qualifying patient.

Commissioner means the Commissioner of Public Health or the Commissioner's designee.

Debilitating means causing weakness, cachexia, wasting syndrome, intractable pain, or nausea, or impairing strength or ability, and progressing to such an extent that one or more major life activities are substantially limited.

Debilitating Medical Condition means cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, and multiple sclerosis (MS), when such diseases are debilitating, and other debilitating conditions as determined in writing by a qualifying patient's certifying physician.

Department means the Massachusetts Department of Public Health.

Dispensary Agent means a board member, director, employee, executive, manager, owner, or volunteer of a MMTC, who is at least 21 years of age and who is registered with the Department.

Duress Alarm means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system.

Edible Marijuana-Infused Products (edible MIPs) means Marijuana-Infused Products (MIPs) that are to be consumed by eating or drinking.

Enclosed, Locked Facility means a closet, room, greenhouse, or other area equipped with locks or other security devices, accessible only to dispensary agents, registered qualifying patients, or personal caregivers.

Executive means the chair of a board of directors, chief executive officer, executive director, president, senior director, owner, and any other executive leader of a MMTC.

Flowering means the gametophytic or reproductive state of marijuana in which the plant produces flowers, trichomes, and cannabinoids characteristic of marijuana.

Hardship Cultivation Registration means a registration issued to a registered qualifying patient under the requirements of 105 CMR 725.000.

Holdup Alarm means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress.

Life-Limiting Illness means a debilitating medical condition that does not respond to curative treatments, where reasonable estimates of prognosis suggest death may occur within six months.

Limited Access Area means a building, room, or other area on the registered premises of a MMTC where marijuana, marijuana-infused products, or marijuana by-products are cultivated, stored, weighed, packaged, processed, or disposed, under control of a MMTC, with access limited to only those dispensary agents designated by the MMTC.

Marijuana or Marihuana means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; and resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin extracted therefrom, fiber, oil, or cake or the sterilized seed of the plant which is incapable of germination.

Massachusetts Resident means a person whose primary residence is located in Massachusetts.

Marijuana-Infused Product (MIP) means a product infused with marijuana that is intended for use or consumption other than by smoking or vaporizing, including but not limited to edible products, ointments, aerosols, oils, and tinctures. These products, when created or sold by a registered MMTC, shall not be considered a food or a drug as defined in M.G.L. c. 94, s. 1.

Medical Marijuana Treatment Center (MMTC) means a not-for-profit entity registered under 105 CMR 725.000, that acquires, cultivates, possesses (including development of related products such as edible MIPs, tinctures, aerosols, oils, or ointments), processes, transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to registered qualifying patients or their personal caregivers who have designated such entity as the patient's registered MMTC. Unless otherwise specified, MMTC refers to the site(s) of dispensing, cultivation, and preparation of any marijuana products, including MIPs, if any.

Panic Alarm means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response.

Paraphernalia means "drug paraphernalia" as defined in M.G.L. c. 94C, s. 1.

Person means an individual or a non-profit entity.

Personal Caregiver means a person, registered by the Department, who is at least 21 years old who has agreed to assist with a registered qualifying patient's medical use of marijuana, and is not the registered qualifying patient's certifying physician. Where a registered qualifying patient is under 18 years of age, he or she must have a personal caregiver who is his or her parent or legal guardian. An employee of a hospice provider, nursing, or medical facility providing care to a qualifying patient may serve as a personal caregiver, including to patients under 18 years of age.

Propagation means the reproduction of marijuana plants by seeds, cuttings, or grafting.

Production Area means any limited access area within the MMTC where marijuana or MIPs are handled or produced in preparation for sale.

Qualifying Patient means a Massachusetts resident 18 years of age or older who has been diagnosed by a Massachusetts licensed certifying physician as having a debilitating medical condition, or a Massachusetts resident under 18 years of age who has been diagnosed by two Massachusetts licensed certifying physicians, at least one of whom is a board-certified pediatrician, with a debilitating life-limiting illness.

Registered Qualifying Patient means a qualifying patient who has applied for and received a registration card from the Department.

Registrant means the holder of a registration card or a certificate of registration, or a certifying physician registered with the Department pursuant to 105 CMR 725.005.

Registration Card means an identification card issued by the Department to a registered qualifying patient, personal caregiver, or dispensary agent. The registration card verifies either that a certifying physician has provided a written certification to the qualifying patient and the patient has been registered with the Department, that the patient has designated the individual as a personal caregiver, that the patient has been granted a hardship cultivation registration, that a MMTC has met the terms of sections 9 and 10 of the Act, or that a dispensary agent has been registered with the Department and is authorized to work at a MMTC. The registration card confers entry into role-appropriate elements of a Department-supported, interoperable database in which detailed information regarding certifications and possession criteria are stored. The registration card identifies for the Department and law enforcement those individuals who are exempt from Massachusetts criminal and civil penalties for the medical use of marijuana in compliance with 105 CMR 725.000 and the Act.

Sixty-Day Supply means that amount of marijuana that a registered qualifying patient would reasonably be expected to need over a period of 60 calendar days for his or her personal medical use, which is ten ounces, subject to 105 CMR 725.010(I).

Usable Marijuana means the dried leaves and flowers of the female marijuana plant and any mixture or preparation thereof, including ointments and tinctures, but does not include the seedlings, seeds, stalks, or roots of the plant.

Vegetation means the sporophytic state of the marijuana plant, which is a form of asexual reproduction in plants during which plants do not produce resin or flowers and are bulking up to a desired production size for flowering.

Verified financial hardship means that an individual is a recipient of MassHealth, or Supplemental Security Income, or the individual's income does not exceed 133% of the federal poverty level, adjusted for family size.

Written Certification means a form submitted to the Department by a Massachusetts licensed certifying physician, describing the patient's pertinent symptoms, specifying the patient's debilitating medical condition, and stating that in the physician's professional opinion the potential benefits of the medical use of marijuana would likely outweigh the health risks for the qualifying patient.

725.005: Registration of Certifying Physicians

- (A) A physician who wishes to issue a written certification for a qualifying patient shall have at least one established place of practice in Massachusetts and shall hold:
  - (1) An active full license, with no prescribing restriction, to practice medicine in Massachusetts; and
  - (2) A Massachusetts Controlled Substances Registration from the Department.
- (B) To register as a certifying physician, a physician shall submit, in a form and manner determined by the Department, the physician's:
  - (1) Full name and business address;
  - (2) License number issued by the Massachusetts Board of Registration in Medicine;
  - (3) Massachusetts Controlled Substances Registration number; and
  - (4) Any other information required by the Department.
- (C) Once registered, a certifying physician will retain indefinitely a registration to certify a debilitating medical condition for a qualifying patient unless:
  - (1) The physician's license to practice medicine in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts;
  - (2) The physician's Massachusetts Controlled Substances Registration is suspended or revoked;
  - (3) The physician has fraudulently issued a written certification of a debilitating medical condition; or
  - (4) The physician has certified a qualifying patient for a debilitating medical condition on or after January 1, 2014, without appropriate completion of continuing professional development credits pursuant to 105 CMR 725.010(A).
- (D) After registering, a certifying physician is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any changes to the physician's information.

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

- (A) A certifying physician issuing a written certification for a qualifying patient, on or after January 1, 2014, must have completed a minimum of 2.0 Category 1 continuing professional development credits as defined in 243 CMR 2.06(6)(a)1 (AMA PRA Category 1 Credit, AAFP Prescribed credit, or AOA Category 1-A) from an organization accredited by the Accreditation Council for Continuing Medical Education (ACCME), American Osteopathic Association, American Academy of Family Physicians, or a state medical society recognized by the ACCME. Such program must explain the proper use of marijuana, including contraindications, side effects, and dosage, and shall also include information on substance abuse recognition, diagnosis, and treatment related to marijuana.
- (B) A certifying physician issuing a written certification of a debilitating medical condition for a qualifying patient for purposes of obtaining marijuana shall comply with generally accepted standards of medical practice, including regulations of the Board of Registration in Medicine at 243 CMR 1.00, 2.00, and 3.00.
- (C) A certifying physician may not delegate authority to certify a debilitating medical condition to any other health care professional or any other person.
- (D) A certifying physician may issue a written certification for a debilitating medical condition only for a qualifying patient with whom the physician has a bona fide physician-patient relationship.
- (E) Before certifying a qualifying patient, a certifying physician must utilize the Massachusetts Prescription Monitoring Program unless otherwise specified by the Department, to review the qualifying patient's prescription and medical marijuana certification history.
- (F) A patient who has had a diagnosis of a debilitating medical condition in the past but does not have active disease and is not undergoing treatment for such condition is not suffering from a debilitating medical condition for which the medical use of marijuana is authorized.
- (G) Initial certifications submitted in the absence of a clinical visit are not permissible.
- (H) A certification must indicate the time period for which the certification is valid, and shall not be less than 15 calendar days nor longer than one year.
- (I) A certifying physician may determine and certify that a qualifying patient requires an amount of marijuana exceeding ten ounces as a 60-day supply and shall document the amount and the rationale in the medical record and in the written certification. For that qualifying patient, that amount of marijuana constitutes a 60-day supply.

- (J) A certifying physician, and such physician's co-worker, employee, spouse, parent, or child, shall not:
- (1) Have ever directly or indirectly accepted, solicited, or offered anything of value from or to a MMTC, a board member or executive of a MMTC, any personnel or any other person associated with a MMTC, or a personal caregiver;
  - (2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular personal caregiver or MMTC;
  - (3) Examine or counsel a patient at a MMTC;
  - (4) Have a direct or indirect financial interest in a MMTC; or
  - (5) Directly or indirectly benefit from a patient obtaining a written certification, which shall not prohibit the physician from charging an appropriate fee for the clinical visit.
- (K) A certifying physician shall not issue a written certification for himself or herself.
- (L) A certifying physician issuing a written certification for his or her family members, employees, or co-workers shall do so in accordance with 105 CMR 725.000, including conducting a clinical visit, completing and documenting a full assessment of the patient's medical history and current medical condition, explaining the potential benefits and risks of marijuana use, and maintaining a role in the ongoing care and treatment of the patient.
- (M) A certification shall be issued in a form and manner determined by the Department.

725.015: Registration of Qualifying Patients

- (A) To obtain a registration card, a qualifying patient shall submit, in a form and manner determined by the Department, the following:
- (1) The qualifying patient's full name, date of birth, address, telephone number, and email address if any, and a statement indicating his or her age and that his or her primary residence is in Massachusetts;
    - (a) If the qualifying patient is under 18 years of age, an attestation from a parent or legal guardian granting permission for the child to register with the Department; and
    - (b) If the qualifying patient is under 18 years of age, that qualifying patient must designate a personal caregiver, who shall be his or her parent or legal guardian.
  - (2) Written certification(s) for the qualifying patient from the qualifying patient's certifying physician(s);
  - (3) Full name, address, and telephone number of the qualifying patient's certifying physician(s);
  - (4) Full name, date of birth, and address of the qualifying patient's personal caregiver(s), if any;
  - (5) The name and address of the designated MMTC from which the qualifying patient or his or her personal caregiver will purchase marijuana, unless the qualifying patient will be applying for a hardship cultivation registration;

- (6) A copy of the qualifying patient's Massachusetts driver's license, Massachusetts issued identification card, or other verifiable identity document acceptable to the Department;
  - (7) A registration fee. If the fee poses a verified financial hardship, the qualifying patient may request a waiver of the fee in a form and manner determined by the Department;
  - (8) Written acknowledgement of the limitations on his or her authorization to cultivate, possess, and use marijuana for medical purposes in the Commonwealth;
  - (9) An attestation that the registered qualifying patient will not engage in the diversion of marijuana; and
  - (10) Any other information required by the Department.
- (B) A registration card will be valid for five years from the date of issue, and may be renewed, in a form and manner determined by the Department, by meeting the requirements in 105 CMR 725.015(A).
- (C) A qualifying patient who received written certification from a physician prior to the effective date of 105 CMR 725.000, and who used that written certification as his or her qualifying patient registration card, must apply for a registration card according to the procedures set out in 105 CMR 725.015 no later than January 1, 2014; however the initial certification will remain valid until the application for the registration card is approved or denied by the Department.
- (D) After obtaining a registration card, a qualifying patient is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any change to his or her information or if the registration card has been lost or stolen.
- (E) A registered qualifying patient may change his or her designated MMTC once in a 120-day period. A registered qualifying patient must notify the Department of his or her change of designated MMTC in a manner and form determined by the Department. The Department's interoperable on-line database shall notify each MMTC of a registered qualifying patient who designates or ceases to designate the MMTC. .

725.020: Registration of Personal Caregivers

- (A) To obtain a registration card for a personal caregiver, a qualifying patient shall submit, in a form and manner determined by the Department, the following:
- (1) The personal caregiver's full name, date of birth, address, telephone number, and email address if any, and a statement that the individual is at least 21 years of age;
  - (2) Full name, date of birth, and address of the qualifying patient for whom the personal caregiver will be providing assistance with the use of medical marijuana;
  - (3) A copy of the personal caregiver's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Department;

105 CMR: Department of Public Health

- (4) A statement of whether the caregiver will be cultivating marijuana for the patient, and at what address, if the patient has been granted a hardship cultivation registration;
  - (5) Written acknowledgement by the personal caregiver of the limitations on his or her authorization to cultivate, possess, and dispense to his or her registered qualifying patient, marijuana for medical purposes in the Commonwealth;
  - (6) An attestation that the personal caregiver will not engage in the diversion of marijuana; and
  - (7) Any other information required by the Department.
- (B) An individual must be granted a registration card by the Department prior to serving as a personal caregiver for any registered qualifying patient.
- (C) A personal caregiver who registered with the Department prior to the effective date of 105 CMR 725.000 must apply for a registration card according to the procedures set out in 105 CMR 725.020 no later than January 1, 2014.
- (D) Except in the case of an employee of a hospice provider, nursing facility, medical facility providing care to a qualifying patient admitted to or residing at that facility, or a parent or guardian of more than one qualifying patient, an individual may not serve as a personal caregiver for more than one qualifying patient at one time.
- (E) A registered qualifying patient may designate up to two personal caregivers. However, only one caregiver may cultivate marijuana on behalf of the registered qualifying patient if the registered qualifying patient has been granted a hardship cultivation registration.
- (F) A registered qualifying patient may add a second caregiver or change personal caregiver(s) by providing notification in a form and manner determined by the Department, and providing the information required in 105 CMR 725.020(A) for registration of personal caregivers. The Department's interoperable on-line database shall notify a MMTC when one of its registered qualifying patient adds or changes a personal caregiver, together with necessary identifying information about the personal caregiver(s).
- (G) A personal caregiver may not receive payment or other compensation for services rendered as a personal caregiver. In the case of an employee of a hospice provider, nursing facility, or medical facility, or a visiting nurse, personal care attendant, or home health aide serving as a personal caregiver, such employee may not receive payment or compensation above and beyond the employee's regular wages.
- (H) A registration card will be valid for five years from the date of issue, and may be renewed, in a form and manner determined by the Department, by meeting the requirements in 105 CMR 725.020(A).
- (I) After obtaining a registration card, the personal caregiver is responsible for notifying the Department, in a form and manner determined by the Department, within five business

days after any change to his or her information or if the registration card has been lost or stolen.

725.025: Responsibilities of Personal Caregivers

- (A) A personal caregiver may do the following:
- (1) Transport a registered qualifying patient to and from a MMTC;
  - (2) Obtain and transport marijuana from a MMTC on behalf of a registered qualifying patient;
  - (3) Cultivate marijuana on behalf of a registered qualifying patient who has obtained a hardship cultivation registration;
  - (4) Prepare marijuana for consumption by a registered qualifying patient; and
  - (5) Administer marijuana to a registered qualifying patient.
- (B) A personal caregiver may not do the following:
- (1) Consume, by any means, marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;
  - (2) Sell, provide, or otherwise divert marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;
  - (3) Cultivate marijuana for the personal caregiver's own use, unless the personal caregiver is also a registered qualifying patient who has obtained a hardship cultivation registration; or
  - (4) Cultivate marijuana for purposes of selling or providing marijuana to anyone other than the registered qualifying patient.
- (C) An employee of a hospice provider, nursing facility, or medical facility serving as a personal caregiver for a registered qualifying patient admitted to or residing at that facility may not cultivate marijuana for that patient.

725.030: Registration of Dispensary Agents

- (A) A MMTC shall apply for registration of all dispensary agents who are associated with that MMTC. All dispensary agents must:
- (1) Be at least 21 years old; and
  - (2) Have not been convicted of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority.
- (B) An application for registration of a dispensary agent, in a form and manner determined by the Department, shall include the full name, date of birth, and address of the dispensary agent, written acknowledgement by the dispensary agent of the limitations on his or her authorization to cultivate, possess, and dispense marijuana for medical purposes in the Commonwealth, and any other information required by the Department.
- (C) A MMTC executive registered with the Department of Criminal Justice Information Systems pursuant to 105 CMR 725.100(A)(7) must submit to the Department a Criminal

Offender Record Information (CORI) report for each dispensary agent applicant, obtained within 30 calendar days prior to submission.

- (D) A MMTC must notify the Department within one business day after a dispensary agent ceases to be associated with the MMTC. Whether or not such notice is submitted, the dispensary agent's registration shall be immediately void when he or she is no longer associated with the MMTC.
- (E) A registration card will be valid for one year from the date of issue, and may be renewed, in a form and manner determined by the Department, on an annual basis by meeting the requirements in 105 CMR 725.030 (A)-(C).
- (F) After obtaining a registration card for a dispensary agent, a MMTC is responsible for notifying the Department, in a form and manner determined by the Department, as soon as possible, but in any event, within five business days after any changes to the cardholder's information or if the registration card has been lost or stolen.

725.035: Hardship Cultivation Registration

- (A) A qualifying patient registered with the Department pursuant 105 CMR 725.015 may apply for a hardship cultivation registration if such patient can demonstrate that his or her access to a MMTC is limited by:
  - (1) Verified financial hardship,; or
  - (2) Physical incapacity to access reasonable transportation, as demonstrated by an inability to use public transportation or drive oneself, lack of a personal caregiver with a reliable source of transportation, and lack of a MMTC that will deliver marijuana to the patient's or personal caregiver's primary address; or
  - (3) Lack of a MMTC within a reasonable distance of the patient's residence and lack of a MMTC that will deliver marijuana to the patient's or personal caregiver's primary address.
- (B) To obtain a hardship cultivation registration, a registered qualifying patient shall, in a form and manner determined by the Department, submit the following:
  - (1) A registration fee, unless waived pursuant to 105 CMR 725.015(A)(7);
  - (2) Information supporting a claim that access is limited due to one or more of the circumstances listed in 105 CMR 725.035 (A) (1)-(3)
  - (3) An explanation including lack of feasible alternatives to mitigate the limitation claimed under 105 CMR 725.035(A);
  - (4) A description and address of the single location that shall be used for the cultivation of marijuana;
  - (5) A written explanation of how the qualifying patient will cultivate marijuana in accordance with the requirements of 105 CMR 725.035;
  - (6) A description of the device or system that will be used to ensure security and prevent diversion of the marijuana plants being cultivated;

- (7) Written re-acknowledgement of the limitations on his or her authorization to cultivate, possess, and use marijuana for medical purposes in the Commonwealth; and
  - (8) Any other information required by the Department.
- (C) The Department shall review and approve or deny an application for a hardship cultivation registration within 30 calendar days of receipt of a completed application.
- (D) A registered qualifying patient with a hardship cultivation registration may cultivate at one single location, which shall be either the qualifying patient's or personal caregiver's primary residence.
- (E) Only one hardship cultivation registration may be issued for a given location, absent proof that more than one registered qualifying patient resides at the location.
- (F) A hardship cultivation registration will be valid for one year from the date of issue, and may be renewed, in a form and manner determined by the Department, on an annual basis by meeting the requirements in 105 CMR 725.035(B).
- (G) A hardship cultivation registration shall allow the registered qualifying patient or his or her personal caregiver to cultivate a limited number of plants sufficient to maintain a 60-day supply of marijuana solely for that patient's use.
- (H) Cultivation and storage of marijuana shall be in a secure, enclosed, locked area accessible only to the registered qualifying patient or his or her personal caregiver. Marijuana shall not be visible from the street or other public areas.
- (I) A registered qualifying patient cultivating marijuana pursuant to a hardship cultivation registration shall adhere to industry best practices in the cultivation of marijuana plants and storage of finished product, and any standards specified by the Department.
- (J) A registered qualifying patient is prohibited from selling, bartering, giving away or distributing in any manner marijuana, MIPs, or paraphernalia.
- (K) The Department may inspect the cultivation site of a registered qualifying patient with a hardship cultivation registration, or the cultivation site of his or her personal caregiver, at any time.
- (L) A registered qualifying patient who received written certification of a debilitating medical condition from a physician prior to enactment of 105 CMR 725.000, and who used that written certification as a limited cultivation registration, must apply for a hardship cultivation registration according to the procedures set out in 105 CMR 725.035(B) no later than January 1, 2014, if he or she intends to continue to cultivate marijuana; however the initial limited cultivation registration will remain valid until the application for the hardship cultivation registration card is approved or denied by the Department.

- (M) After obtaining a hardship cultivation registration, a registered qualifying patient is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any change to his or her information or his or her personal caregiver's information. .

725.100: Registration of Medical Marijuana Treatment Centers

(A) General Requirements

- (1) No more than three MMTCs may be owned or controlled directly or indirectly by the same entity, or by any executive of the MMTC, or by any other entity owned or controlled by one or more of such executives.
- (2) A MMTC is required to incorporate pursuant to chapter 180 of the Massachusetts General Laws and to maintain the corporation in good standing with the Massachusetts Secretary of State. A MMTC must operate on a not-for-profit basis for the benefit of registered qualifying patients who have designated the MMTC to supply marijuana to them.
- (3) A MMTC must make vaporizers available for sale to registered qualifying patients.
- (4) A MMTC may cultivate marijuana, only at either its principal place of business or at an alternate location in Massachusetts, but not both.
- (5) All officers, executives, and board members of the MMTC must meet all requirements for dispensary agents under 105 CMR 725.030.
- (6) A MMTC must have a program to provide reduced cost or free marijuana, and MIPs if applicable, to patients with documented verified financial hardship.
- (7) At least one executive of a non-profit entity seeking registration as a MMTC must register with the Massachusetts Department of Criminal Justice Information Services on behalf of the entity as an organization user of iCORI.

(B) Application Requirements

- (1) Phase 1 – Request to Submit Application: As necessary, the Department shall publish a Notice of Application Opportunity (Notice) for entities that seek authority to apply for a certificate of registration. Every entity responding to the Notice shall file a response in a form and manner specified by the Department, and must at a minimum provide:
  - (a) Documentation that it is a non-profit organization incorporated in Massachusetts;
  - (b) Documentation that it has at least \$500,000 deposited in an escrow account, to ensure that the entity has sufficient resources to operate;
  - (c) Documentation that no officer, director, or board member of the entity, and no prospective employee or volunteer of the MMTC, has been convicted of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority;

- (d) A description of any legal or enforcement actions in another state against any officer, executive, director, or board member of the entity, or any other entity owned or controlled in whole or in part by them, or by an entity that directly or indirectly owns or controls the entity in whole or in part, related to the cultivation, processing, distribution, or sale of medical marijuana;
- (e) An attestation signed by an authorized designee of the entity that if the entity is allowed to proceed to Phase 2 of the application process, the entity is prepared to pay a non-refundable application fee as specified in the Notice;
- (f) The requisite application fee;
- (g) A description of the proposed location for the MMTC; and
- (h) Any other information required by the Department.

(2) Action on Phase 1 Submissions: The Department shall notify each entity that responded to the Notice in a timely manner whether or not it may proceed to Phase 2 of the application process.

(3) Phase 2 – Application: Within 30 days after receipt of an invitation to submit an application pursuant to 105 CMR 725.100(B)(2), each entity that proceeds to Phase 2 shall submit an application in a form and manner specified by the Department, which includes:

- (a) A non-refundable application fee;
- (b) Detailed information regarding the non-profit entity, including the legal name, a copy of the articles of incorporation and bylaws, and the physical address of the proposed MMTC;
- (c) If marijuana will not be cultivated at the dispensing location of the proposed MMTC, the physical address of the one additional location where marijuana will be cultivated, including a guarantee that cultivation of, or sale of, marijuana is permissible on the property;
- (d) Evidence of sufficient interest in the subject property and the additional cultivation location, if any. Sufficient interest means one of the following:
  - 1. Clear legal title to the proposed site;
  - 2. An option to purchase the proposed site;
  - 3. A lease for at least five years;
  - 4. A lease for at least one year with options to renew for not less than four additional years
  - 5. A legally enforceable agreement to give such title under 105 CMR 725.100 (B)(3)(d)1. or 2., or such lease under 105 CMR 725.100 (B)(3)(d)3. or 4., in the event the Department determines that the applicant qualifies for registration as a MMTC; or
  - 6. Binding permission to use the premises for a period of at least five years.
- (e) Evidence that the MMTC is or will be compliant with requirements of the Americans with Disabilities Act (ADA) Accessibility Guidelines;
- (f) Evidence of compliance with local codes, ordinances, and bylaws for the physical address of the MMTC and for the physical address of the additional location, if any, including any demonstration of support or non-opposition furnished by the local municipality;

- (g) Evidence that the MMTC will be ready to operate within 120 days of notification by the Department that the entity qualifies for registration;
- (h) The name, address, date of birth, and résumés of each officer and board member of the non-profit entity, along with a photocopy of their driver's licenses or other government-issued identification cards, and CORI reports obtained from the Department of Criminal Justice Information Services (DCJIS) within 30 days prior to submission to the Department, pursuant to the MMTC's registration with DCJIS under M.G.L. c. 6 § 172;
- (i) The name, address, and date of birth of all dispensary agents that the MMTC intends to employ, to the extent that they are known;
- (j) A list of all persons or entities having direct or indirect authority over the management or policies of the MMTC, and a list of all persons or entities having 5% or more ownership in the MMTC, whether or not the interest is in the land or buildings, including owners of any entity which owns all or part of the land or buildings;
- (k) The identity of any creditor holding a security interest in the premises of the MMTC or the additional cultivation location, if any;
- (l) A copy of the MMTC's liability insurance policy, if any;
- (m) A detailed floor plan of the premises of the proposed MMTC that identifies the square footage available and describes the functional areas of the MMTC, and, if applicable, such information for the single allowable off-premises location in Massachusetts where marijuana will be cultivated or MIPs will be prepared;
- (n) Detailed information regarding the business plan for the MMTC;
- (o) An operational plan for the cultivation of marijuana, including policies and procedures;
- (p) If the MMTC intends to produce MIPs, a description of the types and forms of MIPs that the MMTC intends to produce, and the methods of production;
- (q) Detailed operating procedures for the MMTC, which shall include but not be limited to provisions for security, prevention of diversion, storage of marijuana and MIPs, transportation of marijuana or MIPs if applicable, inventory procedures, procedures for quality control and testing of product for potential contaminants, procedures for maintaining confidentiality as required by law, personnel policies, dispensing procedures, record-keeping procedures, plans for patient education, and any plans for patient or personal caregiver home-delivery;
- (r) Detailed description of the MMTC's policies and procedures for the provision of marijuana and MIPs to registered qualifying patients with verified financial hardship without charge or at less than the market price, as required by 105 CMR 725.100 (A)(6);
- (s) An analysis of the projected patient population and projected need in the service area of the proposed MMTC;
- (t) A detailed description of all intended training(s) for dispensary agents;
- (u) Evidence that the applicant is responsible and suitable to maintain a MMTC. A negative determination with respect to any one of the following factors constitutes an adequate ground for deeming an applicant unsuitable to establish or maintain a MMTC. No person whose application has been denied because the applicant is unsuitable may make another application for at least one year after the

date of denial. Information including but not limited to the following factors shall be considered in determining the responsibility and suitability of the applicant to maintain a MMTC include but are not limited to the following:

1. Demonstrated experience running a non-profit organization or other business;
2. History of providing medical marijuana services or other health care services, including provision of services in other states;
3. Denial, suspension, or revocation of a license or registration, or the denial of a renewal of a license or registration, for any type of business or profession, by any federal, state, or local government, or any foreign jurisdiction, including denial, suspension, revocation, or refusal to renew certification for Medicaid or Medicare or failure to follow non-profit registration procedures or rules;
4. History of response to correction orders issued under the laws or regulations of Massachusetts or other states;
5. Whether the applicant is in compliance with all laws of the Commonwealth relating to taxes and child support and whether the applicant has workers compensation and professional and commercial insurance coverage;
6. Any criminal action under the laws of the Commonwealth, or any like action of the laws of another state whether a felony or misdemeanor, the United States or a military, territorial, or Indian tribal authority against any of the officers, executives, or board members of the applicant, including but not limited to action against any medical marijuana or health care facility in which those individuals either owned shares of stock or served as corporate officers, and which resulted in conviction, or guilty plea, or plea of nolo contendere, or admission of sufficient facts;
7. Any civil action under the laws of the Commonwealth, or any like action under the laws of another state, the United States or a military, territorial, or Indian tribal authority relating to any officer's, executive's, or board member's profession or occupation, drugs, devices, or fraudulent practices, including but not limited to fraudulent billing practices;
8. Discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or a like action or complaint by another state, the United States or a military, territorial, or Indian tribal authority with regard to any professional license or registration of an officer, executive, or board member;
9. Abuse or excessive use of drugs, including alcohol, by any officer, executive, or board member;
10. Possession, use, prescription for use, or distribution of controlled substances or legend drugs by any officer, executive, or board member, except for therapeutic or other proper medical or scientific purpose;

11. Any attempt to obtain a registration, license, or approval to operate in any state by fraud, misrepresentation, or the submission of false information; and
12. Any other factors required by the Department.

(4) Failure of the applicant to adequately address all required items in its application will result in the application being evaluated as submitted.

(5) Action on Phase 2 Submissions

- (a) The Department shall not consider an application that is submitted after the due date specified.
- (b) The Department may conduct a site visit to the proposed location of the MMTC, to determine the appropriateness of the site(s).
- (c) A selection committee constituted by the Department shall evaluate and score applications for the purpose of granting registrations. Decisions will be based on the thoroughness and quality of the applicants' responses to the required criteria, and the applicants' ability to meet the overall health needs of registered qualifying patients and the safety of the public.
- (d) For purposes of ranking, the Department may take into account desired geographical distribution of MMTCs (i.e., convenience for and proximity to Massachusetts residents, and avoidance of clustering of MMTCs in one area), local support for the MMTC application, the presence of a home-delivery system and other mechanisms to ensure appropriate patient access, as well as other factors as described in the application form.
- (e) The Department shall grant registrations within the context of appropriate allocation of resources and based upon ensuring that the needs of the Commonwealth are met with regard to access, quality, and community safety.
- (f) Nothing in 105 CMR 725.000 is intended to confer a property or other right or interest entitling an applicant to a hearing before an application may be denied.

(C) MMTC Certificate of Registration

- (1) The Department shall issue a certificate of registration to each approved applicant to operate a MMTC, in the name of the non-profit entity.
- (2) No person shall operate a MMTC without a certificate of registration issued by the Department.
- (3) A certificate of registration may not be assigned or transferred.
- (4) A registration shall be immediately null and void if the MMTC ceases to operate, or if, without the permission of the Department, it relocates.
- (5) Acceptance of a certificate of registration constitutes an agreement by the MMTC that it will adhere to the practices, policies, and procedures that are described in its application materials, as well as all relevant laws, regulations, and any conditions imposed by the Department as part of registration.

- (6) The MMTC shall post the certificate of registration in a conspicuous location on the premises.
  - (7) The MMTC shall conduct all authorized activities at the address(es) identified on the certificate of registration issued by the Department. Except for the one permitted off-site cultivation location, no operations are permitted at any other locations, except surveillance activities in accordance with 105 CMR 725.110(D).
- (D) The MMTC must be operational within 120 days after registration by the Department.
- (E) Expiration and Renewal of Registration. The MMTC's certificate of registration shall expire one year after the date of issuance and may be renewed as follows:
- (1) No later than 60 days prior to the expiration date, a MMTC shall submit a completed renewal application to the Department in a form and manner determined by the Department, as well as the required fee.
  - (2) The MMTC shall update as needed, and ensure the accuracy of, all information that it submitted on its initial application for a certificate of registration.
- (F) Notification to Department and Department Approval of Changes
- (1) Prior to changing dispensary or cultivation location, the MMTC shall submit a request for such change to the Department and shall pay the appropriate fee. No such change shall be permitted until approved by the Department.
  - (2) Prior to any modification, remodeling, expansion, reduction, or other physical, non-cosmetic alteration of the MMTC, the MMTC shall submit an application for such change to the Department and shall pay the appropriate fee. No such change shall be permitted until approved by the Department.
  - (3) Prior to changing its name, the MMTC shall notify the Department and shall pay the appropriate fee. No such change shall be permitted until approved by the Department.
  - (4) When an MMTC intends to change its manager, it shall notify the Department.
  - (5) The MMTC shall keep current all information required by 105 CMR 725.000 or otherwise required by the Department. The MMTC shall report any changes in or additions to the content of the information contained in any document to the Department within 10 days after such change or addition.

725.105: Operational Requirements for Medical Marijuana Treatment Centers

- (A) Every MMTC shall have and follow a set of detailed written operating procedures, which shall include but need not be limited to the following. If the MMTC has a separate cultivation facility, it shall develop and follow a set of such operating procedures for that facility.

105 CMR: Department of Public Health

- (1) Security measures in compliance with 105 CMR 725.110;
- (2) Employee security policies, including personal safety and crime prevention techniques;
- (3) A description of the MMTC's:
  - (a) Hours of operation and after-hours contact information; and
  - (b) Price list for marijuana, MIPs, and any other available products, and alternate price lists for patients with documented verified financial hardship as required by 105 CMR 725.100(A)(6);
- (4) Storage of marijuana in compliance with 105 CMR 725.105(D);
- (5) Description of the various strains of marijuana to be cultivated and dispensed, and the form(s) in which marijuana will be dispensed;
- (6) Procedures to ensure accurate recordkeeping, including inventory protocols;
- (7) Plans for quality control, including product testing for contaminants in compliance with 105 CMR 725.105(C)(2);
- (8) A staffing plan and staffing records in compliance with 105 CMR 725.105(I)(6);
- (9) Emergency procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;
- (10) Alcohol, smoke, and drug-free workplace policies;
- (11) A plan describing how confidential information will be maintained in accordance with 105 CMR 725.200; and
- (12) A description of the MMTC's patient education activities in accordance with 105 CMR 725.105(K).

**(B) Cultivation Requirements**

- (1) Only a MMTC is permitted to cultivate marijuana, with the exception of a registered qualifying patient granted a hardship cultivation registration or that patient's personal caregiver. Each registered MMTC may have only one cultivation site.
- (2) A cultivation location of a MMTC may cultivate marijuana for only that MMTC, and up to two additional MMTCs under common ownership.
- (3) All phases of the cultivation of marijuana shall take place in designated, locked, limited access areas that are monitored by a surveillance camera system in accordance with 105 CMR 725.110(D)(1)(d)–(i).

- (4) Application of any pesticide in the cultivation of marijuana is prohibited. All cultivation must adhere to U.S. Department of Agriculture organic requirements at 7 CFR Part 205.
  - (5) Soil for cultivation shall meet the U.S. Agency for Toxic Substances and Disease Registry's Environmental Media Evaluation Guidelines for residential soil levels.
  - (6) The cultivation process shall use best practices to limit contamination, including but not limited to mold, fungus, bacterial diseases, rot, pests, pesticides, mildew, and any other contaminant identified as posing potential harm.
- (C) Requirements for Handling Marijuana and for Production of Marijuana-Infused Products
- (1) Except for a registered qualifying patient or personal caregiver, who are not subject to 105 CMR 725.105, only a registered MMTC is permitted to produce MIPs.
  - (2) The MMTC is responsible for testing marijuana and MIPs for contaminants as specified by the Department, including but not limited to mold, mildew, heavy metals, and the presence of pesticides. The MMTC shall maintain the results of all testing for no less than one year. The Department may require additional testing.
    - (a) The MMTC must have and follow a policy and procedure for responding to results indicating contamination, which shall include destruction of contaminated product and assessment of the source of contamination. Such policy shall be available to registered qualifying patients and personal caregivers.
    - (b) The test results and date of testing shall be placed on the label of the product.
  - (3) All marijuana and MIPs in the process of development, production, transport, or analysis shall be stored in such a manner as to prevent diversion, theft, or loss.
    - (a) Such items shall be accessible only to the minimum number of specifically authorized dispensary agents essential for efficient operation.
    - (b) Such items shall be returned to a secure location immediately after completion of the process or at the end of the scheduled business day.
    - (c) If a manufacturing process cannot be completed at the end of a working day, the processing area or tanks, vessels, bins, or bulk containers containing marijuana shall be securely locked inside an area or building that affords adequate security.
  - (4) A MMTC shall process marijuana in a safe and sanitary manner.
    - (a) A MMTC shall process the dried leaves and flowers of the female marijuana plant only, which shall be:
      - 1. Well cured and free of seeds and stems;
      - 2. Free of dirt, sand, debris, or other foreign matter; and
      - 3. Free of mold, rot, other fungus, or bacterial diseases.
    - (b) The dried product shall be handled on food-grade stainless steel tables.
    - (c) Marijuana shall be packaged in a secure area adjacent to the production area.
  - (5) Production of edible MIPs shall take place in compliance with the following:

105 CMR: Department of Public Health

- (a) All edible MIPs shall be developed, handled, and stored in compliance with the sanitation requirements in 105 CMR 500.000: Good Manufacturing Practices for Food, and with the requirements for food handlers specified in 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements.
- (b) Any edible MIP that is made to resemble a typical food or beverage product must be packaged in an opaque package and labeled as required by 105 CMR 725.105(E)(3).
- (6) All MMTCs, including those that develop or process non-edible MIPs, shall comply with the following sanitary requirements.
- (a) Any dispensary agent whose job includes contact with marijuana or non-edible MIPs, including cultivation, production, or packaging, is subject to the requirements for food handlers specified in 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements.
- (b) Any dispensary agent working in direct contact with preparation of marijuana or non-edible MIPs shall conform to sanitary practices while on duty, including:
1. Maintaining adequate personal cleanliness; and
  2. Washing hands thoroughly in an adequate hand-washing area before starting work, and at any other time when hands may have become soiled or contaminated.
- (c) Hand-washing facilities shall be adequate and convenient and shall be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the MMTC in production areas and where good sanitary practices require employees to wash and/or sanitize their hands, and shall provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices.
- (d) There shall be sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations.
- (e) Litter and waste shall be properly removed, disposed of so as to minimize the development of odor, and minimize the potential for the waste attracting and harboring pests. The operating systems for waste disposal shall be maintained in an adequate manner pursuant to 105 CMR 725.105(J).
- (f) Floors, walls, and ceilings shall be constructed in such a manner that they may be adequately kept clean and in good repair.
- (g) There shall be adequate safety lighting in all processing and storage areas, as well as areas where equipment or utensils are cleaned.
- (h) Buildings, fixtures, and other physical facilities shall be maintained in a sanitary condition.
- (i) All contact surfaces, including utensils and equipment, shall be maintained in a clean and sanitary condition. Such surfaces shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the U.S. Environmental Protection Agency (EPA), in accordance with labeled instructions. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable.

- (j) All toxic items shall be identified, held, and stored in a manner that protects against contamination of marijuana and MIPs.
- (k) A MMTC's water supply shall be sufficient for necessary operations. Any private water source shall be capable of providing a safe, potable, and adequate supply of water to meet the MMTC's needs.
- (l) Plumbing shall be of adequate size and design, and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the MMTC. Plumbing shall properly convey sewage and liquid disposable waste from the MMTC. There shall be no cross-connections between the potable and waste water lines.
- (m) A MMTC shall provide its employees with adequate, readily accessible toilet facilities that are maintained in a sanitary condition and in good repair.
- (n) Products that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.
- (o) Storage and transportation of finished products shall be under conditions that will protect them against physical, chemical, and microbial contamination as well as against deterioration of them or their container.

(D) MMTC Storage Requirements

- (1) A MMTC shall provide adequate lighting, ventilation, temperature, humidity, space, and equipment, in accordance with applicable provisions of 105 CMR 725.000.
- (2) A MMTC shall have separate areas for storage of marijuana and MIPs that are outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until such products are destroyed.
- (3) MMTC storage areas shall be maintained in a clean and orderly condition.
- (4) MMTC storage areas shall be free from infestation by insects, rodents, birds, or pests of any kind.
- (5) MMTC storage areas shall be maintained in accordance with the security requirements of 105 CMR 725.110.

(E) Packaging and Labeling

- (1) Marijuana and MIPs shall be packaged in plain, opaque, child-proof containers without depictions of the product, cartoons, or images other than the MMTC's logo.
- (2) Labeling of Marijuana. The MMTC shall place a legible, firmly affixed label on which the wording is no less than 1/16 inch in size on each package of marijuana that it prepares for dispensing, containing at a minimum the following information:
  - (a) The registered qualifying patient's Department-issued registration number;
  - (b) The name and registration number of the MMTC that produced the marijuana, together with the MMTC's telephone number and mailing address, and website information, if any;
  - (c) The quantity of usable marijuana contained within the package;

- (d) The date that the MMTC packaged the contents;
- (e) A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;
- (f) The cannabinoid profile of the marijuana contained within the package, including THC level;
- (g) The tests performed to detect contaminants, test results, and date of testing in accordance with 105 CMR 725.105(C)(2); and
- (h) This statement, including capitalization: “This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Do not drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.”

(3) Labeling of Marijuana-Infused Products (MIPs). The MMTC shall place a legible, firmly affixed label on which the wording is no less than 1/16 inch in size on each MIP that it prepares for dispensing, containing at a minimum the following information:

- (a) The registered qualifying patient’s Department-issued registration number;
- (b) The name and registration number of the MMTC that produced the MIP, together with the MMTC’s telephone number and mailing address, and website information, if any;
- (c) The name of the product;
- (d) The quantity of usable marijuana contained within the product as measured in ounces;
- (e) A list of ingredients, including the cannabinoid profile of the marijuana contained within the product, including the THC level;
- (f) The date of product creation and the recommended “use by” or expiration date;
- (g) A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;
- (h) Directions for use of the product if relevant;
- (i) The tests performed to detect contaminants, test results, and date of testing in accordance with 105 CMR 725.105(C)(2);
- (j) A warning if nuts or other known allergens are contained in the product; and
- (k) This statement, including capitalization: “This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Do not drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.”

(F) Dispensing Marijuana and Marijuana-Infused Products

- (1) Registered qualifying patients and personal caregivers shall be identified as follows:
  - (a) A MMTC shall refuse to sell marijuana or MIPs to any registered qualifying patient or personal caregiver who is unable to produce a Department-issued registration card and valid proof of identification, or who does not have a valid certification in the Department-supported interoperable database. The identification must contain a name, photograph, and date of birth, and shall be limited to the following:
    - 1. A drivers license;

2. A government-issued identification card;
3. A military identification card; and
4. A passport.

(b) Upon entry into a MMTC by a registered qualifying patient or personal caregiver, a dispensary agent shall immediately inspect the patient's or caregiver's Department-issued registration card and proof of identification.

(2) A MMTC may dispense only to a registered qualifying patient who has designated that MMTC as his or her source of supply, or to his or her personal caregiver. Pursuant to 105 CMR 725.010 (H), a certifying physician shall define the length of valid certification of a qualifying patient.

(a) For a registered qualifying patient certified for less than 60 days, the amount of marijuana dispensed, including marijuana contained in MIPs, shall be no more than the appropriate proportion of a 60-day supply, as defined in 105 CMR 725.004 (e.g. a patient certified for 15 days may receive up to 2.5 ounces of marijuana).

(b) For a registered qualifying patient certified for 60 days or longer, the amount of marijuana dispensed, including marijuana contained in MIPs, shall be no more than a 60-day supply in each 60-day period as defined in 105 CMR 725.004 (e.g. a patient certified for 90 days may receive up to ten ounces in the first 60 days and five ounces in the remaining 30 days, while a patient certified for 180 days may receive up to ten ounces in each 60-day period).

(c) For a registered qualifying patient whose certifying physician has determined that he or she requires a 60-day supply in excess of 10 ounces in accordance with 105 CMR 725.010 (I), the amount of marijuana dispensed, including marijuana contained in MIPs, pursuant to 105 CMR 725.105(F)(2)(a) or (b) shall be adjusted accordingly.

(3) A MMTC shall make interpreter services available that are appropriate to the population served. Such services may be provided by a telephone interpreting service.

(4) Consumption of marijuana or MIPs on the premises or grounds of any MMTC is prohibited.

(5) A MMTC may refuse to dispense to a registered qualifying patient or personal caregiver if in the opinion of the dispensary agent, the patient or the public would be placed at risk. In any instance of denial, a MMTC must notify the patient's certifying physician within 24 hours.

**(G) Inventory**

(1) A MMTC must limit its inventory of seeds, plants, and useable marijuana to reflect current registered qualifying patient needs as identified by the number of patients designating the MMTC as their source of marijuana, plus an additional supply, not to exceed a reasonable amount needed to enable the MMTC to meet the demand of new registered qualifying patients.

- (2) Real-time inventory shall be maintained as specified by the Department and in 105 CMR 725.105 (G)(3) and (4), including, at a minimum, an inventory of marijuana plants; marijuana plant-clones in any phase of development such as propagation, vegetation, and flowering; marijuana ready for dispensing; all MIPs; and all damaged, defective, expired, or contaminated marijuana and MIPs awaiting disposal.
  - (3) A MMTC shall:
    - (a) Establish inventory controls and procedures for the conduct of inventory reviews, and comprehensive inventories of marijuana and MIPs. in the process of cultivation and finished, stored marijuana.
    - (b) Conduct a monthly inventory of marijuana in the process of cultivation and finished, stored marijuana.
    - (c) Conduct a comprehensive annual inventory at least once every year after the date of the previous comprehensive inventory.
    - (d) Promptly transcribe inventories taken by use of an oral recording device.
  - (4) The record of each inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the names, signatures, and titles of the individuals who conducted the inventory.
  - (5) A MMTC shall tag and track all marijuana seeds, plants, and products, using a seed-to-sale methodology.
- (H) Dispensary Agent Training. MMTCs shall ensure that all dispensary agents complete training as specified by the Department.
- (I) Record Keeping. Records of a MMTC must be available for inspection by the Department, upon request. Written records that are required and are subject to inspection include but are not necessarily limited to all records required in any section of 105 CMR 725.000, in addition to the following:
- (1) Operating procedures as required by 105 CMR 725.105(A);
  - (2) The standards and procedures by which the MMTC determines the price it charges for marijuana and MIPs, and a record of the prices charged;
  - (3) Inventory records as required by 105 CMR 725.105(G);
  - (4) Seed-to-sale tracking records for all marijuana and MIPs;
  - (5) Written policies and procedures for the production and distribution of marijuana and MIPs, which shall include but not be limited to:
    - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories;
    - (b) A procedure for handling voluntary and mandatory recalls of marijuana and MIPs. Such procedure shall be adequate to deal with recalls due to any action initiated at the request or order of the Department, and any voluntary action by a

MMTC to remove defective or potentially defective marijuana or MIPs from the market, as well as any action undertaken to promote public health and safety; and (c) A procedure for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated marijuana or MIPs are segregated from other marijuana or MIPs and destroyed. This procedure shall provide for written documentation of the disposition of the marijuana or MIPs;

(6) The following personnel records:

- (a) Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;
- (b) A personnel record for each dispensary agent. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with the MMTC and shall include, at a minimum, the following:
  - 1. An application for employment or to volunteer, including an attestation that the individual has never been convicted of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority;
  - 2. A copy of his or her current Department-issued dispensary agent registration card, and a copy of his or her driver's license or other government-issued identification card;
  - 3. Documentation of verification of references;
  - 4. Documentation of CORI check(s);
  - 5. The job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision;
  - 6. Documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time, and place he or she received said training and the topics discussed, including the name and title of presenters;
  - 7. A copy of the application that the MMTC submitted to the Department on behalf of any prospective dispensary agent;
  - 8. Documentation of periodic performance evaluations; and
  - 9. A record of any disciplinary action taken.
- (c) A staffing plan that will demonstrate accessible business hours and safe cultivation conditions;
- (d) Personnel policies and procedures, including a requirement for immediate dismissal of any dispensary agent who has:
  - 1. Diverted marijuana or MIPs, which shall be reported to law enforcement authorities, or
  - 2. Engaged in unsafe practices with regard to operation of the MMTC, which shall be reported to the Department; and
- (e) All CORI reports obtained in accordance with 105 CMR 725.030(C), M.G.L. c.6, § 172 and 803 CMR 2.00 et seq.;

(7) Business records, which shall include manual or computerized records of:

- (a) Assets and liabilities;

- (b) Monetary transactions;
- (c) Books of accounts, which shall include journals, ledgers, and supporting documents; agreements; checks; invoices; and vouchers;
- (d) Sales records that indicate the name of the registered qualifying patient or personal caregiver to whom marijuana and MIPs have been dispensed, including the quantity, form, and cost; and
- (e) Salary and wages paid to each employee, stipend paid to each board member, and any executive compensation or bonus, benefit, or item of value paid to any individual affiliated with a MMTC.

- (8) When marijuana or MIPs are disposed of, the MMTC must create and maintain a written record of the date, the quantity disposed of, the manner of disposal, and the persons present during the disposal, with their signatures. MMTCs shall keep disposal records for at least two years.
- (9) Following closure of a MMTC, all records must be kept for at least 2 years at the expense of the owner of the MMTC and in a form and location acceptable to the Department.

(J) Waste Disposal

- (1) All waste, including waste composed of or containing finished marijuana and MIPs, shall be stored, secured, and managed in accordance with applicable state and local statutes, ordinances, and regulations.
- (2) Liquid waste containing marijuana or by-products of marijuana processing shall be disposed in compliance with requirements for discharge into surface water, 314 CMR 3.00; groundwater, 314 CMR 5.00; and sewers, 314 CMR 7.00.
- (3) Solid waste generated at a MMTC shall be disposed of through incineration in a municipal waste combustor in Massachusetts. No fewer than two dispensary agents must witness and document destruction.
- (4) A MMTC must accept unused, excess, or contaminated marijuana or MIPs from a registered qualifying patient or personal caregiver, and shall destroy it as provided in 105 CMR 725.105 (J) and maintain a written record of such disposal in accordance with 105 CMR 725.105(I)(8).

(K) Patient Education. A MMTC shall provide educational materials about marijuana to registered qualifying patients and their personal caregivers. A MMTC must have an adequate supply of up-to-date educational material available for distribution. Educational materials must be available in languages accessible to all patients served by the MMTC, and made available for inspection by the Department upon request. The educational material must include at least the following:

- (1) A warning that marijuana and MIPs have not been analyzed or approved by FDA, that there is limited information on side effects, and that there may be health risks associated with using them;

- (2) A warning that when under the influence of marijuana or MIPs, driving is prohibited by M.G.L. c. 90, s. 24, , and machinery should not be operated;
  - (3) Information to assist in the selection of marijuana and MIPs, describing the potential differing effects of various strains of marijuana, as well as various forms and routes of administration;
  - (4) Materials offered to registered qualifying patients and their personal caregivers to enable them to track the strains used and their associated effects;
  - (5) Information describing proper dosage and titration for different routes of administration. Emphasis shall be on using the smallest amount possible to achieve the desired effect. The impact of potency must also be explained;
  - (6) A discussion of tolerance, dependence, and withdrawal;
  - (7) Facts regarding substance abuse signs and symptoms, as well as referral information for substance abuse treatment programs;
  - (8) A statement that registered qualifying patients may not distribute marijuana or MIPs to any other individual, and that they must return unused, excess, or contaminated product to the MMTC from which they purchased the product, for disposal; and
  - (9) Any other information required by the Department.
- (L) Marketing and Advertising Applicable to MMTCs
- (1) A MMTC may develop a logo to be used in labeling, signage, and other materials. Use of medical symbols, images of marijuana, related paraphernalia, and colloquial references to cannabis and marijuana are prohibited from use in this logo.
  - (2) MMTC external signage shall be no more than 16 x 18 inches and shall not be illuminated at any time.
  - (3) A MMTC shall not display on the exterior of the facility advertisements for marijuana or any brand name, and may only identify the building by the registered name.
  - (4) A MMTC shall not utilize graphics related to marijuana or paraphernalia on the exterior of the MMTC or the building in which the MMTC is located.
  - (5) A MMTC shall not advertise the price of marijuana or MIPs, except that it shall provide a catalogue or a printed list of the prices and strains of marijuana and MIPs available at the MMTC to registered qualifying patients and personal caregivers.
  - (6) Marijuana, MIPs, and associated products shall not be displayed or clearly visible to a person from the exterior of a MMTC.

- (7) A MMTC shall not produce any items for sale or promotional gifts, such as T-shirts or novelty items, bearing a symbol of or references to marijuana or MIPs, including the logo of the MMTC.
- (8) All advertising materials and materials produced by a MMTC and disseminated pursuant to 105 CMR 725.105(K) or (L) are prohibited from including:
- (a) Any statement, design, representation, picture, or illustration that encourages or represents the use of marijuana for a condition other than a debilitating medical condition;
  - (b) Any statement, design, representation, picture, or illustration that encourages or represents the recreational use of marijuana;
  - (c) Any statement, design, representation, picture, or illustration related to the safety or efficacy of marijuana unless supported by substantial evidence or substantial clinical data with appropriate scientific rigor; or
  - (d) Any statement, design, representation, picture, or illustration portraying anyone under the age of 18.
- (9) Inside the MMTC, all marijuana and MIPs shall be kept in locked, opaque cabinets or containers, with the exception of displays allowable under 105 CMR 725.105(L)(10).
- (10) A MMTC may display, in secure, locked cases, no more than one sample of each product offered for sale. These display cases may be transparent.
- (11) The Department shall maintain and make available a list of all MMTCs, their location, and their contact information.
- (M) Reports to the Department. The Department may require ongoing reporting on operational, quality, and financial information in a form and manner determined by the Department.
- (N) Prohibitions
- (1) A MMTC may not dispense, deliver, or otherwise transfer marijuana to a person other than a registered qualifying patient who has designated the MMTC to cultivate marijuana for him or her, or to his or her personal caregiver.
  - (2) A MMTC may not acquire marijuana or marijuana plants except through the cultivation of marijuana by that MMTC.
  - (3) A MMTC may not contract for the cultivation of seeds, seedlings, or small plants or for the cultivation, production, or preparation of marijuana or MIPs for medical use.
  - (4) A MMTC is prohibited from acquiring, possessing, cultivating, delivering, transferring, transporting, supplying, or dispensing marijuana for any purpose except to assist registered qualifying patients who have designated the MMTC to cultivate marijuana for them.
  - (5) A MMTC shall not give away or allow use of any samples of marijuana or MIPs.

(6) A MMTC shall not sell or distribute marijuana or MIPs over the Internet or by mail order.

(O) Requirements Upon Expiration, Revocation, or Voiding of Certificate of Registration of MMTC.

(1) If a registration to operate expires without being renewed, is revoked, or becomes void, the MMTC shall:

- (a) Immediately discontinue cultivation and production of marijuana and MIPs;
- (b) Weigh and inventory all unused marijuana in all stages of cultivation and all MIPs in any stage of production, and create and maintain a written record of all such items;
- (c) Dispose of the unused marijuana and MIPs in accordance with Department guidelines and a plan approved by the Department in accordance with 105 CMR 725.105(J); and
- (d) Maintain all records as required by 105 CMR 725.105(I)(9).

(2) If the MMTC does not comply with the requirements of 105 CMR 725.105(O)(1), the Department shall have the authority to, at the owner of the MMTC's expense, secure the MMTC, and after a period of thirty days, seize and destroy the inventory and equipment and contract for the storage of MMTC records.

(P) Access to the Department of Public Health, Emergency Responders, and Law Enforcement

The following individuals shall have access to a MMTC or MMTC transportation vehicle without restriction:

- (1) Representatives of the Department;
- (2) Emergency responders; and
- (3) Authorized law enforcement personnel.

725.110: Security Requirements for Medical Marijuana Treatment Centers

(A) General Requirements. A MMTC shall implement appropriate security measures to deter and prevent unauthorized entrance into areas containing marijuana and theft of marijuana at the MMTC. Security measures to protect the premises, registered qualifying patients, personal caregivers, and dispensary agents of the MMTC must include but are not limited to the following. The MMTC must:

(1) Allow only registered qualifying patients, personal caregivers, and dispensary agents, and, subject to the requirements of 105 CMR 725.110(C)(4), outside vendors, contractors, and visitors, access to the MMTC;

(2) Prevent individuals from remaining on or near the premises of the MMTC if they are not engaging in activity expressly or by necessary implication permitted by the Act and 105 CMR 725.000.

- (3) Dispose of marijuana in excess of the quantity required for normal, efficient operation in accordance with 105 CMR 725.105(J);
  - (4) Establish limited access areas accessible only to specifically authorized personnel, which shall include only the minimum number of employees essential for efficient operation;
  - (5) Store all finished marijuana and MIPs in a secure, locked safe or vault and in such a manner as to prevent diversion, theft, or loss;
  - (6) Keep all safes, vaults, and any other equipment or areas used for the production, cultivation, harvesting, processing, or storage of marijuana and MIPs securely locked and protected from entry, except for the actual time required to remove or replace marijuana or MIPs;
  - (7) Keep all locks and security equipment in good working order;
  - (8) Prohibit keys from being left in the locks, or stored or placed in a location accessible to persons other than specifically authorized personnel;
  - (9) Prohibit accessibility of security measures, such as combination numbers, passwords, or electronic or biometric security systems, to persons other than specifically authorized personnel;
  - (10) Ensure that the outside perimeter of the MMTC is sufficiently lit to facilitate surveillance;
  - (11) Ensure that trees, bushes, and other foliage outside of the MMTC do not allow for a person or persons to conceal themselves from sight;
  - (12) Develop emergency policies and procedures for securing all product following any instance of diversion, theft, or loss of marijuana or MIPs, and conduct an assessment to determine whether additional safeguards are necessary;
  - (13) Immediately dispose of the entire stock of marijuana and MIPs under conditions approved by the Department upon revocation or non-renewal of the MMTC's registration. Such disposal shall be considered to be in the best interests of the general public, and the Department shall not be held liable in any way for any loss of revenue; and
  - (14) Develop sufficient additional safeguards as required by the Department for MMTCs that present special security concerns.
- (B) Alternate Security Provisions. If a MMTC has provided other safeguards that can be regarded as an adequate substitute for a security requirement specified in 105 CMR 725.110(A), such added protection may be taken into account by the Department in

evaluating overall required security measures.

(C) Limited Access Areas

- (1) All limited access areas must be identified by the posting of a sign that shall be a minimum of 12" X 12" and which states: "Do Not Enter – Limited Access Area – Access Limited to Authorized Personnel Only" in lettering no smaller than ½ inch in height.
- (2) All limited access areas shall be clearly described by the filing of a diagram of the registered premises, in the form and manner determined by the Department, reflecting walls, partitions, counters, and all areas of entry and exit. Said diagram shall also show all propagation, vegetation, flowering, processing, production, storage, disposal, and retail sales areas.
- (3) A dispensary agent in a limited access area shall visibly display an identification badge issued by the MMTC at all times.
- (4) All outside vendors, contractors, and visitors must obtain a visitor identification badge prior to entering a limited access area, and shall be escorted at all times by a dispensary agent authorized to enter the limited access area. The visitor identification badge must be visibly displayed at all times while the visitor is in any limited access area. All visitors must be logged in and out, and that log shall be available for inspection by the Department at all times. All visitor identification badges shall be returned to the MMTC upon exit.

(D) Security Alarm Systems

- (1) A MMTC shall have an adequate security system to prevent and detect diversion, theft, or loss of marijuana or unauthorized intrusion, utilizing commercial grade equipment, which shall, at a minimum, include:
  - (a) A perimeter alarm on all entry points and perimeter windows;
  - (b) A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the MMTC within five minutes after the failure, either by telephone, email, or text message;
  - (c) A duress alarm, panic alarm, holdup alarm, or automatic voice dialer;
  - (d) Video cameras in all areas that may contain marijuana, at all points of entry and exit, and in any parking lot, which shall be appropriate for the normal lighting conditions of the area under surveillance. The cameras shall be directed at all safes, vaults, sales areas, and areas where marijuana or MIPs are harvested, processed, prepared, stored, handled, or dispensed. Cameras shall be angled so as to allow for the capture of clear and certain identification of any person entering or exiting the MMTC or area;
  - (e) Twenty-four hour recordings from all video cameras that are available for immediate viewing by the Department upon request and that are retained for at

least 90 days. Recordings shall not be destroyed or altered, and shall be retained as long as necessary if the MMTC is aware of a pending criminal, civil, or administrative investigation, or legal proceeding for which the recording may contain relevant information;

(f) The ability to immediately produce a clear, color, still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

(g) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture;

(h) The ability to remain operational during a power outage; and

(i) A video recording that allows for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place.

Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal.

(2) All security system equipment and recordings shall be maintained in a secure location so as to prevent theft, loss, destruction, and alterations.

(3) In addition to the requirements listed in 105 CMR 725.110(D)(1) and (2), the MMTC shall have a back-up alarm system provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(4) Access to surveillance areas shall be limited to persons that are essential to surveillance operations, law enforcement agencies, security system service personnel, and the Department. A current list of authorized employees and service personnel that have access to the surveillance room must be available to the Department upon request. If on-site, surveillance rooms shall remain locked and shall not be used for any other function.

(5) All security equipment shall be in good working order and shall be inspected and tested at regular intervals, not to exceed 30 days from the previous inspection and test.

(E) Medical Marijuana Treatment Center Transportation of Marijuana and MIPs

(1) Only a dispensary agent may transport marijuana or MIPs on behalf of a MMTC, whether between MMTC sites or to registered qualifying patients or personal caregivers.

(2) A MMTC shall:

(a) Weigh, inventory, and account for on video all marijuana and MIPs to be transported prior to their leaving the origination location;

(b) Re-weigh, re-inventory, and account for on video all marijuana and MIPs transported, within eight hours after arrival at the destination MMTC except in the case of home delivery pursuant to 105 CMR 725.110(E)(11);

(c) Document and report any discrepancy in weight or inventory to the Department and local law enforcement within 24 hours;

- (d) Complete a shipping manifest in a form and manner determined by the Department, for retention by the origination location, and carry a copy of said manifest with the products being transported; and
- (e) Securely transmit a copy of the manifest to the receiving MMTC prior to transport except in the case of home delivery pursuant to 105 CMR 725.110(E)(11).

- (3) A MMTC shall retain all shipping manifests for no less than one year and make them available to the Department upon request.
- (4) A MMTC shall ensure that marijuana and MIPs are:
  - (a) Transported in a secure, locked storage compartment that is part of the vehicle transporting the marijuana and MIPs;
  - (b) Not visible from outside the vehicle; and
  - (c) Transported in a vehicle that bears no markings that indicate that the vehicle is being used to transport marijuana or MIPs nor indicates the name of the MMTC.
- (5) Any vehicle transporting marijuana or MIPs shall travel directly to the receiving MMTC and shall not make any stops except in the case of home delivery pursuant to 105 CMR 725.110(E)(11).
- (5) A MMTC shall ensure that all delivery times and routes are randomized.
- (7) A MMTC shall staff all transport vehicles with a minimum of two dispensary agents. At least one dispensary agent shall remain with the vehicle at all times that the vehicle contains marijuana or MIPs.
- (8) Each dispensary agent shall have access to a secure form of communication with personnel at the sending site at all times that the vehicle contains marijuana or MIPs.
- (9) Each dispensary agent shall carry his or her Department-issued registration card at all times when transporting marijuana or MIPs and shall produce it to the Department's authorized representative or law enforcement official upon request.
- (10) A MMTC shall report to the Department and local law enforcement any vehicle accidents, diversions, losses, or other reportable incidents pursuant to 105 CMR 725.110(F), that occur during transport, within 24 hours.
- (11) Home delivery of medical marijuana to a registered qualifying patient or a personal caregiver shall be conducted in accordance with 105 CMR 725.105(F) and 105 CMR 725.110(E).

(F) Incident Reporting

- (1) A MMTC shall immediately notify appropriate law enforcement authorities and the Department within 24 hours after discovering the following:
  - (a) Discrepancies identified during inventory, diversion, theft, loss, and any

criminal action involving the MMTC or a dispensary agent;

(b) Any suspicious act involving the sale, cultivation, distribution, processing, or production of marijuana or MIPs by any person;

(c) Unauthorized destruction of marijuana or MIPs;

(d) Any loss or unauthorized alteration of records related to marijuana, MIPs, or registered qualifying patients;

(e) An alarm activation or other event that requires response by public safety personnel;

(f) The failure of any security alarm system due to a loss of electrical power or mechanical malfunction that is expected to last longer than eight hours; and

(g) Any other breach of security.

(2) A MMTC shall, within ten days, provide written notice to the Department of any incident described in 105 CMR 725.110(F)(1), by submitting an incident report in the form and manner determined by the Department which details the circumstances of the event, any corrective actions taken, and confirmation that the local authorities were notified.

(3) All documentation related to an incident that is reportable pursuant to 105 CMR 725.110(F)(1) shall be maintained by a MMTC for no less than one year and made available to the Department and authorized law enforcement officials upon request.

(G) A MMTC must, on an annual basis, undergo a security system audit by a vendor approved by the Department. A report of such audit must be submitted, in a form and manner determined by the Department, no later than 30 days after the audit is conducted. If the audit identifies concerns related to the MMTC's security system, the MMTC will also submit a plan to mitigate those concerns within 14 days of submitting the plan.

#### 725.200: Confidentiality

(A) Information held by the Department about applicants for registration as, a qualifying patient, personal caregiver, or dispensary agent, and registered qualifying patients, personal caregivers, and dispensary agents is confidential and exempt from the provisions of M.G.L. c. 66.

(B) Information held by the Department about applicants for registration as, a qualifying patient, personal caregiver, or dispensary agent, and registered qualifying patients, personal caregivers, and dispensary agents may be released by the Department to:

(1) The data subject or the data subject's authorized representative, pursuant to M.G.L. c. 66A;

(2) Department staff for the purpose of carrying out their official duties with regard to the medical marijuana program;

(3) An individual or entity pursuant to an order from a court of competent jurisdiction;

(4) Law enforcement personnel for the sole purpose of verifying a cardholder's registration and certification; and

(5) The Board of Registration in Medicine when necessary in connection with referrals to said Board concerning violations of 105 CMR 725.000.

- (C) Applications, supporting information, and other information regarding a MMTC are not confidential, except for information that identifies a specific registered qualifying patient or personal caregiver.
- (D) Information held by a MMTC about registered qualifying patients and personal caregivers is confidential and shall not be disclosed without the written consent of the individual to whom the information applies, provided however, the Department may to access this information to carry out official duties with regard to the medical marijuana program.

725.300: Inspection of Medical Marijuana Treatment Centers

- (A) The Department or its agents may inspect a MMTC at any time without prior notice in order to determine the MMTC's compliance with the Act and 105 CMR 725.000. All areas of a MMTC, all dispensary agents and activities, and all records are subject to such inspection. Acceptance of a certificate of registration by a MMTC constitutes permission for such inspection.
- (B) A MMTC shall immediately upon request make available to the Department all information that may be relevant to a Department inspection, or an investigation of any incident or complaint.
- (C) A MMTC shall make all reasonable efforts to facilitate the Department's inspection, or investigation of any incident or complaint, and to facilitate the Department's interviews of MMTC dispensary agents.
- (D) An inspection or other investigation may be made prior to the issuance of a certificate of registration or renewal of registration. Additional inspections may be made whenever the Department deems it necessary for the enforcement of the Act and 105 CMR 725.000.
- (E) During an inspection, the Department may direct a MMTC to test marijuana or MIPs for contaminants as specified by the Department, including but not limited to mold, mildew, heavy metals, and the presence of pesticides.

725.305: Deficiency Statements

After an inspection in which a violation of 105 CMR 725.000 is observed, the Department shall issue a Deficiency Statement citing every violation identified, a copy of which shall be left with or sent to the MMTC.

725.310: Plan of Correction

- (A) A MMTC shall submit to the Department a written Plan of Correction for any violations cited in the Deficiency Statement issued pursuant to 105 CMR 725.305 within 10 days after receipt of the Deficiency Statement.

- (B) Every Plan of Correction shall state, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 105 CMR 725.000 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.
- (C) The Department shall review the Plan of Correction for compliance with the requirements of 105 CMR 725.000 and shall notify the MMTC of either the acceptance or rejection of the Plan. An unacceptable Plan must be amended and resubmitted within five days after receipt of such notice.

725.400: Medical Marijuana Treatment Center: Grounds for Denial of Initial Application for Registration

Each of the following, in and of itself, constitutes full and adequate grounds for denying the initial application for a MMTC registration.

- (A) Information provided by the applicant was misleading, incorrect, false, or fraudulent.
- (B) The application received a low score, indicating the inability to maintain and operate a MMTC in compliance with the requirements of the Act and 105 CMR 725.000.
- (C) The application received a lower score than other applications.
- (D) The applicant has been determined to be either not responsible or suitable pursuant to 105 CMR 725.100(B)(3)(u).

725.405: Medical Marijuana Treatment Center Registration: Grounds for Denial of Renewal Applications and Revocation

Each of the following, in and of itself, constitutes full and adequate grounds for denying the renewal application for registration or revoking registration.

- (A) The MMTC is not operational within 120 days of registration by the Department.
- (B) Information provided by the MMTC was materially inaccurate, incomplete, or fraudulent.
- (C) The MMTC has failed to comply with any requirement of the Act or 105 CMR 725.000 or any applicable law or regulation, including laws and regulations of the Commonwealth relating to taxes, child support, workers compensation, and professional and commercial insurance coverage.
- (D) The MMTC has failed to submit a Plan of Correction as required or to implement a Plan of Correction as submitted pursuant to 105 CMR 725.310.
- (E) The MMTC has assigned or attempted to assign its certificate of registration to another entity.

- (F) There has been a lack of responsible operation of the MMTC, as shown by but not limited to one or more of the following:
- (1) Incompetent or negligent operation;
  - (2) Failure to maintain the MMTC in a clean, orderly, and sanitary fashion; or
  - (3) Permitting a person to use a registration card belonging to a different person.
- (G) The MMTC does not have sufficient financial resources to meet the requirements of the Act or 105 CMR 725.000.
- (H) The financial management of the MMTC has resulted in the filing of a petition for bankruptcy or receivership related to the financial solvency of the MMTC.
- (I) The owner entity or entities and executives of a MMTC have maintained a substandard level of compliance with the statutory and regulatory requirements for the operation of a medical marijuana facility or a health care facility in another jurisdiction, including, but not limited to, failure to correct deficiencies, a limitation upon or a suspension, revocation, or refusal to grant or renew a medical marijuana registration or health care facility license to operate, or certification for Medicaid or Medicare.
- (J) A dispensary agent of a MMTC has a history of criminal conduct as evidenced by any criminal proceedings against such individual or against medical marijuana facilities or other health care facilities in which such individual either owned shares of stock or served as a corporate officer, and which resulted in conviction, guilty plea, plea of nolo contendere, or admission to sufficient facts.
- (K) The MMTC has committed, permitted, aided, or abetted any illegal practices in the operation of any MMTC.
- (L) The MMTC has failed to cooperate or give information to a law enforcement official related to any matter arising out of conduct at any MMTC.
- (M) The conduct or practices of the MMTC have been detrimental to the safety, health, or welfare of registered qualified patients, personal caregivers, or the public.
- (N) The conduct and/or practices of the MMTC demonstrate a lack of responsibility or suitability as specified in 105 CMR 725.100(B)(3)(u).

725.410: Void Medical Marijuana Treatment Center Registration

A MMTC registration is void if the MMTC transfers its location without Department approval or ceases to operate.

725.415: Medical Marijuana Treatment Center Registration: Limitation of Sales by Medical Marijuana Treatment Centers

- (A) If the Commissioner determines that a MMTC does not substantially comply with applicable provisions of 105 CMR 725.000 or the Act, the Commissioner, in lieu of revoking or refusing renewal of a MMTC's registration, may order that the MMTC shall not sell marijuana or MIPs after a date specified, to registered qualifying patients or their personal caregivers who have not previously obtained marijuana or MIPs from the MMTC.
- (B) The Commissioner shall not make such a determination until a MMTC has been notified that the MMTC does not substantially comply with applicable provisions of 105 CMR 725.000 or the Act, that an order to limit sales is contemplated, and that the MMTC has a reasonable opportunity to correct the deficiencies.
- (C) An order that a MMTC shall not sell marijuana or MIPs pursuant to 105 CMR 725.415(A) may be rescinded when the Commissioner finds that the MMTC is in substantial compliance with the applicable provisions of 105 CMR 725.000.

725.420: Medical Marijuana Treatment Center Registration: Limitation of Sales by Medical Marijuana Treatment Centers Pending Hearing and Final Agency Decision

Prior to a hearing, following any action initiated by the Department under 105 CMR 725.415, the Commissioner may order that a MMTC immediately limit the sale of marijuana or MIPs, after a date specified, to registered qualifying patients or their personal caregivers who have previously obtained marijuana or MIPs from the MMTC.

725.425: Denial of a Registration Card or Hardship Cultivation Registration

Each of the following, in and of itself, constitutes full and adequate grounds for denial of a registration card for registered qualifying patients, personal caregivers, and dispensary agents, or a hardship cultivation registration:

- (A) Failure to provide the information required in 105 CMR 725.000 for a registration card or hardship cultivation registration;
- (B) Provision of misleading, incorrect, false, or fraudulent information on the application;
- (C) Failure to meet the requirements set forth in 105 CMR 725.000 for a registration card or hardship cultivation registration;
- (D) Revocation or suspension of a registration card or hardship cultivation registration in the previous six months; or
- (E) Failure to pay all applicable fees.

725.430: Revocation of a Registration Card or Hardship Cultivation Registration

105 CMR: Department of Public Health

- (A) Each of the following, in and of itself, constitutes full and adequate grounds for revocation of a registration card issued to a registered qualifying patient, personal caregiver, dispensary agent, or a hardship cultivation registration:
- (1) Submission of misleading, incorrect, false, or fraudulent information in the application or renewal application;
  - (2) Violation of the requirements of the Act or 105 CMR 725.000;
  - (3) Fraudulent use of a registration card;
  - (4) Selling, distributing, or giving marijuana or MIPs to any other person;
  - (5) Tampering, falsifying, altering, modifying, duplicating, or allowing another person to use, tamper, falsify, alter, modify, or duplicate a registration card or hardship cultivation registration;
  - (6) Failure to notify the Department within five business days after becoming aware that the registration card has been lost, stolen, or destroyed; or
  - (7) Failure to notify the Department within five business days after a change in the registration information contained in the application.
- (B) In addition to the grounds in 105 CMR 725.430(A), each of the following, in and of itself, shall be adequate grounds for the revocation of a registration card issued to a registered qualifying patient:
- (2) The qualifying patient is no longer a resident of the Commonwealth;
  - (3) The qualifying patient, taking into account the amounts of marijuana or MIPs obtained by his or her personal caregiver if applicable, seeks to obtain or obtains more of such amounts than is allowable under 105 CMR 725.105(F)(2)(a)-(c); or
  - (4) The qualifying patient has used marijuana in a manner that puts others at risk of their health, safety, or welfare, or has failed to take reasonable precautions to avoid putting others at such risk.
- (C) In addition to the grounds in 105 CMR 725.430(A), a conviction of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority shall be adequate grounds for the revocation of a dispensary agent's registration card.

725.435: Revocation of a Certifying Physician Registration

Each of the following, in and of itself, constitutes full and adequate grounds for revoking a certifying physician registration:

- (A) The physician fraudulently issued a written certification of a debilitating medical condition;

- (B) The physician failed to comply with the requirements of the Act or any applicable provisions of 105 CMR 725.000; or
- (C) The physician certified a qualifying patient for a debilitating medical condition on or after January 1, 2014, without completion of continuing professional development credits pursuant to 105 CMR 725.010(A).

725.440: Void Certifying Physician Registration

- (A) When a certifying physician's license to practice medicine in Massachusetts is no longer active, or is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts, or the physician's Massachusetts controlled substances registration is suspended or revoked, the physician's registration to certify a debilitating medical condition for a qualifying patient is immediately void.
- (B) A void certifying physician registration is inactive and invalid.

725.445: Void Registration Cards

- (A) A registration card issued to a dispensary agent shall be void when the agent has ceased to be associated with the MMTC that applied for and received the dispensary agent's registration card;
- (B) A registration card that has been issued to a qualifying patient, including a hardship cultivation registration, shall be void when:
  - (1) The card has not been surrendered upon the issuance of a new registration card based on new information;
  - (2) The qualifying patient is no longer a resident of Massachusetts; or
  - (3) The patient is deceased.
- (C) A registration card issued to a personal caregiver is void when:
  - (1) The registered qualifying patient has notified the Department that the individual registered as the personal caregiver is no longer the personal caregiver for that patient. or
  - (2) The qualifying patient is no longer registered with the Department.
- (D) A void registration card is inactive and invalid.

725.450: Summary Cease and Desist Order and Quarantine Order

A summary cease and desist order or quarantine order may be imposed by the Commissioner prior to a hearing, in order immediately to stop or restrict operations by a MMTC, to protect the public health, safety, or welfare. The Commissioner may rescind or amend a summary cease and desist order or quarantine order.

- (A) If, based upon inspection, affidavits, or other evidence, the Commissioner determines that a

MMTC or the products prepared by a MMTC pose an immediate or serious threat to the public health, safety, or welfare, the Commissioner may:

- (1) Issue a cease and desist order and/or quarantine order, requiring cessation or restriction of any or all MMTC operations, and prohibiting the use of marijuana or MIPs produced by that MMTC; or
- (2) Issue a cease and desist order placing restrictions on a MMTC, to the extent necessary to avert a continued threat, pending final investigation results.

(B) The requirements of the cease and desist order or the quarantine order shall remain in effect until the Commissioner rescinds or amends such requirements or until such time as the Department takes final action on any related pending complaint and issues a final decision.

725.455: Summary Suspension Order

The Commissioner may summarily suspend any registration card or certificate of registration issued pursuant to 105 CMR 725.000, pending further proceedings for denial of renewal or revocation of a registration, whenever the Commissioner finds that the continued registration poses an imminent danger to the public health, safety, or welfare.

725.500: Administrative Review: Non-Selection of Medical Marijuana Treatment Center's Application for Initial Registration

- (A) The Department shall provide written notice of non-selection to an applicant.
- (B) Applicants may request copies of the application scores and any documentation supporting the scoring process for all applications.
- (C) Applicants may request an informal briefing from the Department limited to a discussion of the scoring of their application.
- (D) The written notice of denial is a final agency action subject to judicial review in Superior Court in an action for certiorari relief under G.L. c.249, s.4.

725.505: Hearings

- (A) Upon written request, a registrant shall be afforded a hearing no later than 28 calendar days after the effective date of a summary cease and desist order or quarantine order issued pursuant to 105 CMR 725.450. At the hearing, the Department must prove by a preponderance of the evidence that there existed immediately prior to, or at the time of the order, an immediate or serious threat to the public health, safety, or welfare.
- (B) Upon written request, a registrant shall be afforded a hearing no later than 14 calendar days after the effective date of a summary suspension order issued pursuant to 105 CMR 725.455. At the hearing, the Department must prove by a preponderance of the evidence that there existed immediately prior to, or at the time of the suspension, an imminent danger to the public health, safety, or welfare.

- (C) With the exception of the provisions for cease and desist orders and quarantine orders pursuant to 105 CMR 725.450, and summary suspension orders pursuant to 105 CMR 725.455, the Department shall provide written notice, and shall provide a hearing if a hearing is requested in writing within 21 calendar days, prior to:
- (1) Denying a renewal application for a registration card;
  - (2) Revoking a registration card for a registered qualifying patient, personal caregiver, or dispensary agent;
  - (3) Denying a renewal application for or revoking a hardship cultivation registration;
  - (4) Denying a renewal application of a MMTC;
  - (5) Revoking the registration certificate of a MMTC;
  - (6) Limiting sales of marijuana or MIPs by a MMTC; or
  - (7) Revocation of a certifying physician registration.
- (D) The written notice shall provide the registrant with a statement of the grounds for the action and of the right to request a hearing.
- (E) If a request for a hearing is made, the hearing shall be conducted by the Division of Administrative Law Appeals in accordance with the Adjudicatory Rules of Practice and Procedure, 801 CMR 1.02.
- (F) At the hearing, the Department must prove the basis for the action by a preponderance of the evidence.
- (G) A final decision after a hearing is a final agency action subject to judicial review in Superior Court pursuant to M.G.L. c. 30A.
- (H) If a hearing pursuant to 105 CMR 725.505 is not requested within the required time, the right to a hearing is waived.

725.510: Effect of Denial of Renewal or Revocation of Medical Marijuana Treatment Center Registration, Revocation of Dispensary Agent Registration, and Surrender of a Registration

- (A) A MMTC that has had its application for renewal registration denied or its registration revoked is disqualified from future registration as a MMTC.
- (B) A dispensary agent whose registration card has been revoked is disqualified from serving as a dispensary agent or from having any financial interest in a MMTC.

105 CMR: Department of Public Health

- (C) The surrender of a certificate of registration or a registration card shall not prevent the Department from revoking, or imposing other penalties with respect to, such certificate of registration or registration card.

725.600: Municipal Requirements

- (A) A MMTC and other registered persons shall comply with all local rules, regulations, ordinances, and bylaws.
- (B) The Department does not mandate any involvement by municipalities or local boards of health in the regulation of MMTCs, qualifying patients with hardship cultivation registrations, or any other aspects of medical marijuana. However, nothing in 105 CMR 725.000 shall be construed so as to prohibit appropriate, lawful local oversight and regulation, including fee requirements, that does not conflict or interfere with the operation of 105 CMR 725.000.

725.700: Waivers

The Commissioner may waive the applicability of one or more of the requirements imposed by 105 CMR 725.000 upon finding that:

- (A) Compliance would cause undue hardship to the registrant;
- (B) If applicable, the registrant's non-compliance does not jeopardize the health or safety of any patient or the public;
- (C) The registrant has instituted compensating features that are acceptable to the Department; and
- (D) The registrant provides to the Commissioner written documentation supporting its request for a waiver.

725.800: Severability

The provisions of 105 CMR 725.000 are severable. If a court of competent jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY: Massachusetts General Laws Chapter 111, Sections 2 and 3, and Chapter 369 of the Acts of 2012