

935 CMR 501.000: MEDICAL USE OF MARIJUANA

Section

- 501.001: Purpose
- 501.002: Definitions
- 501.003: Colocated Marijuana Operations (CMOs)
- 501.005: Fees
- 501.006: Registration of Certifying Physicians
- 501.007: Registration of Certifying Certified Nurse Practitioners
- 501.008: Registration of Certifying Physician Assistants
- 501.010: Written Certification of a Debilitating Medical Condition for a Qualifying Patient
- 501.015: Temporary and Annual Registration of Qualifying Patients
- 501.020: Temporary and Annual Registration of Personal Caregivers
- 501.021: Registration of Caregiving Institutions
- 501.022: Registration of Institutional Caregivers
- 501.025: Responsibilities of Caregivers
- 501.027: Hardship Cultivation Registration
- 501.029: Registration and Conduct of Independent Testing Laboratory Agents
- 501.030: Registration of Medical Marijuana Treatment Center Agents
- 501.031: Denial of a Registration Card or Hardship Cultivation Registration
- 501.032: Revocation of a Registration Card or Hardship Cultivation Registration
- 501.033: Void Registration Cards
- 501.034: Revocation of a Certifying Healthcare Provider Registration
- 501.035: Void Certifying Physician Registration
- 501.040: Leadership Rating Program for Medical Marijuana Treatment Centers
- 501.050: Medical Marijuana Treatment Centers (MTCs)
- 501.052: Independent Testing Laboratories
- 501.100: Application for Licensing of Medical Marijuana Treatment Centers (MTCs)
- 501.101: Application Requirements
- 501.102: Action on Applications
- 501.103: Licensure and Renewal
- 501.104: Notification and Approval of Changes
- 501.105: General Operational Requirements for Medical Marijuana Treatment Centers
- 501.110: Security Requirements for Medical Marijuana Treatment Centers
- 501.120: Additional Operational Requirements for the Cultivation, Acquisition, and Distribution of Marijuana.
- 501.130: Additional Operational Requirements for Handling and Testing Marijuana and for Production of MIPs
- 501.140: Additional Operational Requirements for Patient Sales
- 501.145: Home Delivery
- 501.150: Edibles
- 501.160: Testing of Marijuana and Marijuana Products
- 501.170: Municipal Requirements
- 501.200: Counties of Dukes County and Nantucket
- 501.300: Complaints Process
- 501.301: Inspection and Compliance
- 501.302: Compliance Examination
- 501.303: Unannounced Purchase for Purpose of Investigative Testing (Secret Shopper Program)
- 501.310: Deficiency Statements
- 501.320: Plans of Correction
- 501.321: Administrative Hold
- 501.330: Limitation of Sales
- 501.335: Removal and Prohibition of Marijuana and Marijuana Products
- 501.340: Quarantine Order
- 501.350: Cease and Desist Order and Summary Suspension Order
- 501.360: Fines
- 501.370: Orders to Show Cause
- 501.400: Medical Marijuana Treatment Center License: Grounds for Denial of Application for Licensure
- 501.415: Void Medical Marijuana Treatment Center License
- 501.450: Medical Marijuana Treatment Center Registration or License: Grounds for Suspension, Revocation, and Denial of Renewal Applications

Section: continued

- 501.500: Hearings and Appeals of Actions on Registrations or Licenses
- 501.800: Suitability Standard for Licensure and Registration
- 501.801: Suitability Standard for Licensure
- 501.802: Suitability Standard for Registration as a Medical Marijuana Treatment Center Agent
- 501.803: Suitability Standard for Registration as a Laboratory Agent
- 501.820: Confidentiality
- 501.830: Petitions for the Adoption, Amendment or Repeal of Regulations
- 501.840: Nonconflict with Other Laws
- 501.850: Waivers
- 501.860: Notice
- 501.900: Severability

501.001: Purpose

The purpose of 935 CMR 501.000 is to implement St. 2017, c. 55: *An Act to Ensure Safe Access to Marijuana*; M.G.L. c. 94G and M.G.L. c. 94I.

501.002: Definitions

For the purposes of 935 CMR 501.000, the following terms shall have the following meanings:

Administrative Hold means a hold requiring temporary isolation of Marijuana, Marijuana Products, or Marijuana-infused Products (MIPs), by a Licensee or Registrant pending further investigation.

Adult-use Cannabis or Marijuana means Marijuana that is cultivated, Processed, Transferred, tested or sold to adults 21 years of age or older pursuant to M.G.L. c. 94G.

Adult-use Cannabis or Marijuana Products means Marijuana Products that are Processed Manufactured, Transferred, tested or sold to adults 21 years of age or older pursuant to M.G.L. c. 94G.

Advanced Core Curriculum means the advanced training curriculum taught by a Responsible Vendor Trainer that may be taken by MTC Agents after completing the Basic Core Curriculum under 935 CMR 501.105(2)(b).

Advertising means a form of marketing communication that employs a sponsored, nonpersonal message to sell or promote an MTC' Brand Name, MTC Branded Good, service, product or idea.

Affixed means the attachment of a label or other packaging material so that it is not easily removed or lost.

Agent Registration Card means an identification card currently and validly issued by the Commission to a Marijuana Establishment, MTC or Laboratory Agent. The Agent Registration Card allows access into Commission supported databases. The registration card facilitates verification of an individual Registrant's status including, but not limited to, identification by the Commission and Law Enforcement Authorities of those individuals exempt from Massachusetts criminal and civil penalties under M.G.L. c. 94G and 94I, and 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000.

Area of Disproportionate Impact means a geographic area identified by the Commission for the purposes identified in M.G.L. c. 94G, § 4(a½)(iv), and 935 CMR 500.040: *Leadership Rating Program for Marijuana Establishments and Marijuana-related Businesses* and 500.101: *Application Requirements*, and which has had historically high rates of arrest, conviction, and incarceration related to Marijuana crimes.

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

501.002: continued

Assignment for the Benefit of Creditors means a contractual agreement with a third-party by which the Licensee assigns all of its assets and liabilities to such third-party in order to satisfy the Licensee's obligations to its creditors by liquidating the assets.

Basic Core Curriculum means the foundational training curriculum required of all MTC Agents taught by a Responsible Vendor Trainer under 935 CMR 501.105(2)(b).

Beverage means a liquid intended for drinking.

Bona Fide Healthcare Provider – Patient Relationship means a relationship between a Certifying Healthcare Provider, acting in the usual course of their professional practice, and a Patient in which the healthcare provider 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.

Brand Name means a brand name (alone or in conjunction with any other word), registered trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other identifiable marker associated with an MTC.

Brand Name Sponsorship means the payment by an MTC in exchange for use of a Brand Name:

- (a) to sponsor an athletic, musical, artistic, or other social or cultural event; or
- (b) to identify, advertise, or promote such event or an entrant or participant of such an event.

Cannabinoid means any of several compounds produced by Marijuana plants that have medical and psychotropic effects.

Cannabinoid Profile means the amounts, expressed as the dry-weight percentages, of delta-nine-tetrahydrocannabinol, cannabidiol, tetrahydrocannabinolic acid and cannabidiolic acid in a Marijuana Product. Amounts of other Cannabinoids may be required by the Commission.

Cannabis means Marijuana as defined in 935 CMR 501.002.

Canopy means an area to be calculated in square feet and measured using clearly identifiable boundaries of all areas(s) that will contain Flowering and/or Vegetative plants larger than eight inches tall and eight inches wide at any point in time, including all of the space(s) within the boundaries. Canopy may be noncontiguous, but each unique area included in the total Canopy calculations shall be separated by an identifiable boundary which includes, but is not limited to: interior walls, shelves, Greenhouse walls, hoop house walls, garden benches, hedge rows, fencing, garden beds, or garden plots. If Flowering and/or Vegetative plants larger than eight inches tall and eight inches wide are being cultivated using a shelving system, the surface area of each level shall be included in the total Canopy calculation.

Card Holder means a Registered Qualifying Patient, Personal Caregiver, Marijuana Establishment Agent, Medical Marijuana Treatment Center (MTC) Agent, or Laboratory Agent who holds a valid Patient or Agent Registration Card.

Caregiver means a Personal Caregiver or Institutional Caregiver.

Caregiving Institution means a hospice program, long-term care facility, or hospital duly registered currently and validly by the Commission, providing care to a Registered Qualifying Patient on the premises of the facility or through a hospice program.

Cease and Desist Order means an order to stop or restrict operations including, but not limited to, cultivation, product manufacturing, Transfer, sale, delivery, or testing, of Marijuana, Marijuana Products, or Marijuana-infused Products (MIPs) by a Licensee or Registrant to protect the public health, safety or welfare.

501.002: continued

Ceases to Operate means a Marijuana Establishment, Medical Marijuana Treatment Center (MTC) or Independent Testing Laboratory that closes and does not transact business for a period greater than 60 days with no substantial action taken to reopen. The Commission may determine that an establishment has Ceased to Operate based on its actual or apparent termination of operations.

Certificate of Licensure means the certificate issued by the Commission that confirms that an MTC or Independent Testing Laboratory has met all applicable requirements pursuant to M.G.L. c. 94I, and 935 CMR 501.000 and is currently and validly licensed by the Commission. An MTC or Independent Testing Laboratory may be eligible for a provisional or final Certificate of Licensure.

Certificate of Registration means a certificate currently and validly issued by the Commission, that confirms an individual or entity has met all applicable requirements pursuant to M.G.L. c. 94I, and 935 CMR 501.000 and is registered by the Commission.

Certifying Certified Nurse Practitioner (CNP) means a Massachusetts licensed certified nurse practitioner licensed pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing*, who certifies that in their professional opinion, the potential benefits of the medical use of Marijuana would likely outweigh the health risks for a Qualifying Patient.

Certifying Healthcare Provider means a Certifying CNP, a Certifying Physician or a Certifying Physician Assistant.

Certifying Physician means a Massachusetts licensed physician (Medical Doctor or Doctor of Osteopathy), who certifies that in their professional opinion, the potential benefits of the medical use of Marijuana would likely outweigh the health risks for a Qualifying Patient.

Certifying Physician Assistant means a Massachusetts physician assistant licensed pursuant to 263 CMR 3.00: *Licensure of Individual Physician Assistants*, who certifies that in their professional opinion, the potential benefits of the medical use of Marijuana would likely outweigh the health risks for a Qualifying Patient.

Clinical Visit means an in-person or telehealth visit during which a Certifying Healthcare Provider establishes a *Bona Fide* Healthcare Provider Patient Relationship and conducts a full assessment of the Patient's medical history and current medical condition, including the Debilitating Medical Condition, and explains the potential benefits and risks of Marijuana use. A Clinical Visit for an initial Certificate of Registration shall be performed in-person.

Clone means a clipping from a Cannabis or Marijuana plant that can be rooted and grown.

Close Associate means a Person who holds a relevant managerial, operational or financial interest in the business of an applicant or Licensee and, by virtue of that interest or power, is able to exercise a significant influence over the corporate governance of a Marijuana Establishment, an MTC or Independent Testing Laboratory licensed under 935 CMR 500.000: *Adult Use of Marijuana*. A Close Associate is deemed to be a Person or Entity Having Direct or Indirect Control.

Colocated Marijuana Operations (CMO) means an MTC operating under a License pursuant to 935 CMR 501.000 and a Marijuana Establishment operating under at least one License pursuant to 935 CMR 500.000: *Adult Use of Marijuana*, on the same Premises. Colocated Marijuana Operations pertain to cultivation, product manufacturing, and retail licenses, but not any other adult-use License.

Commission means the Massachusetts Cannabis Control Commission, as established by M.G.L. c. 10, § 76, or its representatives. The Commission has authority to implement the state Marijuana laws, which include, but are not limited to, St. 2016, c. 334: *The Regulation and Taxation of Marijuana Act*, as amended by St. 2017, c. 55: *An Act to Ensure Safe Access to Marijuana*; M.G.L. 10, § 76; M.G.L. c. 94G; M.G.L. c. 94I; 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000.

501.002: continued

Commission Delegee(s) means other state or local officials or agencies working in cooperation with the Commission by agreement, to carry out the Commission's responsibilities and to ensure compliance with the adult-use and medical-use laws, and any other applicable federal or state laws.

Confidential Application Materials means any electronic or written document, communication or other record pertaining to an application for licensure or registration that is required to be confidential or protected from disclosure by law, which includes, but is not limited to, personally identifiable information concerning an applicant, Registrant, or Licensee; background check information or Criminal Offender Record Information (CORI) as defined by 803 CMR 2.02: *Definitions*, or Criminal History Record Information (CHRI) as defined by 803 CMR 7.02: *Definitions*; and information that implicates security concerns.

Confidential Database means the Commission database that holds data concerning:

- (a) Qualifying Patients issued a Registration Card for medical use of Marijuana;
- (b) healthcare professionals registered to issue Written Certifications;
- (c) MTCs;
- (d) quantity of medical-use Marijuana dispensed to a Card Holder; and
- (e) any other pertinent information.

Confidential Information means information that is legally required to be kept confidential, or that is protected from disclosure by a legally recognized privilege. This includes, but is not limited to, M.G.L. c. 4, § 7, cl. 26 and M.G.L. c. 94I, §§ 2(e) and 3.

Confidential Investigatory Materials means any electronic or written document, communication or other record pertaining to an investigation which concerns:

- (a) a possible violation of a statute, regulation, rule, practice or procedure, or professional or industry standard, administered or enforced by the Commission;
- (b) an ongoing investigation that could alert subjects to the activities of an investigation;
- (c) any details in witness statements, which if released create a grave risk of directly or indirectly identifying a private citizen who volunteers as a witness;
- (d) investigative techniques the disclosure of which would prejudice the Commission's future investigative efforts or pose a risk to the public health, safety or welfare; or
- (e) the background of any person the disclosure of which would constitute an unwarranted invasion of personal privacy.

Confidential Records means any electronic or written record required to be kept confidential or protected from disclosure by law which includes, but is not limited to, Confidential Application Materials, Confidential Social Equity Application Materials, Confidential Investigatory Materials, and Protected Patient Records (as defined in 935 CMR 501.002: Protected Patient Records).

Confidential Social Equity Application Materials means any electronic or written document, communication or other record pertaining to an application for the Social Equity Program that is required to be confidential or protected from disclosure by law which includes, but is not limited to, CORI as defined by 803 CMR 2.02: *Definitions*, or CHRI as defined in 803 CMR 7.02: *Definitions*.

Consumer means a person who is 21 years of age or older.

Court Appointee shall mean a person or entity appointed by a court of competent jurisdiction to exercise court oversight with respect to the property, assets, management, or operations of a Licensee or Person or Entity Having Direct or Indirect Control over a Licensee including, without limitation, a receiver, custodian, guardian, trustee, and executor or administrator of estate. This could include a person or entity preapproved or recommended by the Commission or its delegee appointed by the court.

Court Supervised Proceeding shall mean a proceeding where a court of competent jurisdiction supervises the property, assets, management, or operations of a Licensee or Person or Entity Having Direct or Indirect Control over a Licensee through a Court Appointee.

501.002: continued

Craft Marijuana Cooperative means a Marijuana Cultivator comprised of residents of the Commonwealth and organized as a limited liability company, limited liability partnership, or cooperative corporation under the laws of the Commonwealth. A cooperative is licensed to cultivate, obtain, Manufacture, Process, package, brand and Transfer Marijuana or Marijuana Products to Marijuana Establishments, but not to Consumers.

Criminal Offender Record Information (CORI) shall have the same meaning as defined by 803 CMR 2.02: *Definitions*.

Cultivation Batch means a collection of Cannabis or Marijuana plants from the same seed or plant stock that are cultivated and harvested together, and receive an identical Propagation and cultivation treatment including, but not limited to: growing media, ambient conditions, watering and light regimes and agricultural or hydroponic inputs. Clones that come from the same plant are one batch. The Licensee shall assign and record a unique, sequential alphanumeric identifier to each Cultivation Batch for the purposes of production tracking, product labeling and product recalls.

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 of a patient's major life activities is 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 healthcare provider.

Delivery Agreement means a contract between a licensed Marijuana Establishment and a Delivery Licensee or Marijuana Establishment with a Delivery Endorsement to deliver Marijuana or Marijuana Products from the Marijuana Establishment directly to Consumers and as permitted, Marijuana Couriers to Patients and Caregivers, under the provisions of a Delivery License.

Delivery Endorsement means authorization granted to Licensees in categories of Marijuana Establishments identified by the Commission to perform deliveries directly from the establishment to Consumers.

Delivery Items means Finished Marijuana Products, Marijuana Accessories, and Marijuana Establishment Branded Goods.

Delivery Licensee means an entity that is authorized to deliver Marijuana and Marijuana Products directly to Consumers and as permitted, Marijuana Couriers to Patients and Caregivers.

Department of Agricultural Resources (MDAR) means the Massachusetts Department of Agricultural Resources, unless otherwise specified. MDAR has jurisdiction over Hemp and Pesticides.

Department of Criminal Justice Information Services (DCJIS) means the Massachusetts Department of Criminal Justice Information Services, unless otherwise specified. DCJIS shall have the same meaning as defined in 803 CMR 2.02: *Definitions*.

Department of Public Health (DPH) means the Massachusetts Department of Public Health, unless otherwise specified. DPH is the agency that administered the Medical Use of Marijuana Program prior to 2019.

Department of Revenue (DOR) means the Massachusetts Department of Revenue, unless otherwise specified.

Department of Unemployment Assistance (DUA) means the Massachusetts Department of Unemployment Assistance, unless otherwise specified.

501.002: continued

Duress Alarm means a silent security alarm signal generated by the entry of a designated code into an Arming Station that signals an alarm user is under duress and turns off the system.

Economic Empowerment Priority Applicant means an applicant who as an entity or through an individual certified by the Commission in 2018, meets and continues to meet three or more of the following six criteria, at least one of which shall be a majority-equity-ownership criterion:

(a) Majority Equity Ownership Criteria:

1. A majority (more than 50%) of ownership belongs to people who have lived for five of the preceding ten years in an Area of Disproportionate Impact, as determined by the Commission.
2. A majority (more than 50%) of ownership has held one or more previous positions where the primary population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision or empowerment to disproportionately impacted individuals or communities.
3. A majority (more than 50%) of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent.

(b) Additional Criteria:

1. At least 51% of current employees or subcontractors reside in Areas of Disproportionate Impact and by the first day of business, the ratio will meet or exceed 75%.
2. At least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises.
3. Other significant articulable demonstration of past experience in, or business practices that promote, economic empowerment in Areas of Disproportionate Impact.

This applicant has priority for the purposes of the review of its license application.

Edibles means a Marijuana Product that is to be consumed by humans by eating or drinking. These products, when created or sold by a Marijuana Establishment or an MTC, shall not be considered a food or a drug as defined in M.G.L. c. 94, § 1.

Electronic Certification means a document signed or executed electronically by a Certifying Healthcare Provider, stating that in the healthcare professional's professional opinion, the potential benefits of the medical use of Marijuana would likely outweigh the health risks for the Qualifying Patient. Such certification shall be made only in the course of a *Bona Fide* Healthcare Provider Patient Relationship and shall specify the Qualifying Patient's Debilitating Medical Condition. Electronic Certifications, on submission by a Certifying Healthcare Provider to the Commission, shall automatically generate a temporary registration.

Enclosed Area means an indoor or outdoor area equipped with locks or other security devices, which is accessible only to Qualifying Patients, MTC Agents, Registered Qualifying Patients, or Caregivers.

Equity Holder means a person or entity that holds, or may hold as a result of one or more of the following including, without limitation, vesting, conversion, exercising an option, a right of first refusal, or any agreement that would trigger an automatic transfer of or conversion to equity, any amount of equity in a Marijuana Establishment or an MTC.

Executive means members of the board of directors, executive officers, executive director, manager, or their equivalent, of a Marijuana Establishment, MTC, or Independent Testing Laboratory.

Executive Office of Energy and Environmental Affairs (EOEEA) means the Massachusetts Executive Office of Energy and Environmental Affairs, unless otherwise specified.

Existing Licensee Transporter means an entity that is otherwise licensed by the Commission and also licensed to purchase, obtain, and possess Marijuana or Marijuana Products solely for the purpose of transporting, temporary storage, sale and distribution on behalf of other Marijuana Establishments or MTCs to other establishments, but not to Consumers.

501.002: continued

Expedited Applicant means an applicant for a Marijuana Microbusiness, Marijuana Craft Cooperative, Independent Testing Laboratory, or Outdoor Marijuana Cultivator license; a Social Equity Participant; a minority, woman, and/or veteran-owned business; eligible for expedited review prior to other General Applicants.

Fingerprint-based Background Check Trust Fund means a fund established under M.G.L. c. 29, § 2HHH, in which fees for fingerprint background checks are deposited.

Finished Marijuana means Usable Marijuana, Cannabis resin or Cannabis concentrate.

Finished Marijuana Product means a Marijuana Product that is completely manufactured and ready for retail sale and shall include Finished Marijuana that has been separated into individual packages or containers for sale.

Flowering means the gametophytic or reproductive state of Cannabis or Marijuana in which the plant produces flowers, trichomes, and Cannabinoids characteristic of Marijuana.

Food and Drug Administration (FDA) means the United States Food and Drug Administration.

General Applicant means an applicant that has not been certified as an Economic Empowerment Priority Applicant or an MTC Priority Applicant; and is not eligible to be an Expedited Applicant.

Greenhouse means a structure or thermally isolated Enclosed Area of a building that maintains a specialized sunlit environment used for and essential to the cultivation, protection or maintenance of plants.

Hardship Cultivation Registration means a registration issued to a Registered Qualifying Patient under the requirements of 935 CMR 501.027.

Healthcare Clinician or Provider means a Certifying Physician, Certifying Certified Nurse Practitioner or Certifying Physician Assistant qualified under 935 CMR 501.000 to issue Written Certifications for the medical-use of Marijuana.

Hemp means the plant of the genus Cannabis or any part of the plant, whether growing or not, with a delta-9-tetrahydrocannabinol concentration that does not exceed 0.3% on a dry weight basis of any part of the plant of the genus Cannabis, or per volume or weight of Marijuana Product, or the combined percent of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid in any part of the plant of the genus Cannabis, regardless of moisture content. MDAR has jurisdiction over Hemp.

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

Horticultural Lighting Equipment (HLE) means any lighting equipment (*e.g.*, fixtures, bulbs, ballasts, controls, *etc.*) that uses energy for the cultivation of plants, at any stage of growth (*e.g.*, germination, cloning/Mother Plants, Propagation, Vegetation, Flowering, and harvest).

Horticulture Lighting Square Footage (HLSF) means an area to be calculated in square feet and measured using clearly identifiable boundaries of all areas(s) that will contain plants at any point in time, at any stage of growth, including all of the space(s) within the boundaries, HLSF may be noncontiguous, but each unique area included in the total HLSF calculations shall be separated by an identifiable boundary which includes, but is not limited to: interior walls, shelves, Greenhouse walls, hoop house walls, garden benches, hedge rows, fencing, garden beds, or garden plots. If plants are being cultivated using a shelving system, the surface area of each level shall be included in the total HLSF calculation.

Host Community means a municipality in which a Marijuana Establishment, MTC or Independent Testing Laboratory is located or in which an applicant has proposed locating an establishment.



501.002: continued

Immature Plant means a rooted plant in the Vegetation stage of development that is no taller than eight inches, no wider than eight inches, and is in a growing/cultivating container.

Immediate Family Member means a spouse, parent, child, grandparent, grandchild, or sibling, including in-laws.

Impassible Barrier means, for the purposes of determining the 500 foot buffer zone, a highway, public or private way or path, inaccessible structure, body of water, or other obstruction that renders any part of the 500-foot straight-line distance between an MTC Entrance and a School Entrance inaccessible by a pedestrian or automobile.

Independent Testing Laboratory means a laboratory that is licensed or registered by the Commission and is:

- (a) Currently and validly licensed under 935 CMR 500.101: *Application Requirements*, or formerly and validly registered by the Commission;
- (b) Accredited to ISO 17025:2017 or the International Organization for Standardization 17025 by a third-party accrediting body that is a signatory to the International Laboratory Accreditation Accrediting Cooperation mutual recognition arrangement or that is otherwise approved by the Commission;
- (c) Independent financially from any MTC, Marijuana Establishment or Licensee; and
- (d) Qualified to test Marijuana and Marijuana Products, including MIPs, in compliance with M.G.L. c. 94C, § 34; M.G.L. c. 94G, § 15; 935 CMR 500.000: *Adult Use of Marijuana*; 935 CMR 501.000; and Commission protocol(s).

Individual Order means a delineated amount of Finished Marijuana Products to be delivered by a Delivery Licensee or a Marijuana Establishment with a Delivery Endorsement to an individual Consumer and as permitted, a Marijuana Courier to a Patient or Caregiver, and not to exceed the individual possession amount limits as determined by statute.

Inducement means money or any other thing of substantial value intended to persuade or influence a person or entity to take an action or refrain from taking an action.

Informed Consent means the consent obtained by a Research Licensee from potential participants in a research project that explains to potential participants the risks and potential benefits of a study, and the rights and responsibilities of the parties involved.

Informed Consent Form means the document provided to potential participants in a research project that explains to potential participants the risks and potential benefits of a study, and the rights and responsibilities of the parties involved.

Institutional Caregiver means an employee of a hospice program, long-term care facility, or hospital providing care to a Registered Qualifying Patient on the Premises of a long-term care facility, hospital or through a hospice program.

Institutional Review Board means a specifically constituted administrative body established or designated by a Marijuana Research Facility Licensee to review and oversee the design and methods of a research project and, where human or animal subject are a component of the research, to protect the rights and welfare of persons recruited to participate in research.

Known Allergen means milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, or such other allergen identified by the U.S. Food and Drug Administration (FDA).

Laboratory Agent means an employee of an Independent Testing Laboratory who transports, possesses or tests medical-use Marijuana or MIPs in compliance with 935 CMR 501.000. For the purposes of testing for the medical-use program, a Laboratory Agent may register under 935 CMR 501.029 or 935 CMR 500.029: *Registration and Conduct of Laboratory Agents*.

Law Enforcement Authorities means local law enforcement including, but not limited to, the local police and fire departments within the municipality where the Licensee is sited, unless otherwise indicated.

501.002: continued

License means the certificate issued by the Commission that confirms that an MTC or Independent Testing Laboratory has met all applicable requirements pursuant to St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, and 935 CMR 501.000. An MTC or Independent Testing Laboratory may hold a provisional or final License.

Licensee means a person or entity on the application and licensed by the Commission to operate an MTC or Independent Testing Laboratory under St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, and 935 CMR 501.000. Any person or entity that solely provides initial capital to establish or operate the establishment and to whom, in return for the initial capital, requires only repayment of the loan and does not have any ownership or direct or indirect authority to control the MTC or Independent Testing Laboratory, will not be a Licensee.

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 two years.

Lighting Power Density (HLPD) means a measure of total watts of Horticultural Lighting Equipment per total Horticulture Lighting Square Footage, (HLE/HLSF = HLPD) expressed as number of watts per square foot.

Limitation on Sales means a limitation on the sales of Marijuana, Marijuana Products, or MIPs by a Licensee or Registrant arising from the regulations and until substantial compliance by a Licensee or Registrant with a law, regulation, guidance or other requirement for licensure or registration.

Limited Access Area means an indoor or outdoor area on the Premises of an MTC where Marijuana or MIPs, or their byproducts are cultivated, stored, weighed, packaged, Processed, or disposed, under the control of an MTC, with access limited to only to those MTC Agents and Laboratory Agents designated by the MTC after receipt of a Final License.

Local Authorities means local municipal authorities unless otherwise indicated.

Manufacture means to compound, blend, extract, infuse or otherwise make or prepare a Marijuana Product.

Marijuana (or Cannabis) means all parts of any plant of the genus Cannabis, not excepted in 935 CMR 501.002: Marijuana (a) through (c) and whether growing or not; the seeds thereof; and resin extracted from any part of the plant; Clones of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinol as defined in M.G.L. c. 94G, § 1; provided that Cannabis shall not include:

- (a) 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, fiber, oil, or cake made from the seeds of the plant or the sterilized seed of the plant that is incapable of germination;
- (b) Hemp; or
- (c) The weight of any other ingredient combined with Cannabis or Marijuana to prepare topical or oral administrations, food, drink or other products.

Marijuana Accessories (or Cannabis Accessories) means equipment, products, devices or materials of any kind that are intended or designed for use in planting, Propagating, cultivating, growing, harvesting, Manufacturing, compounding, converting, producing, Processing, preparing, testing, analyzing, packaging, Repackaging, storing, containing, ingesting, inhaling or otherwise introducing Cannabis or Marijuana into the human body.

501.002: continued

Marijuana Courier means an entity licensed to deliver Finished Marijuana Products, Marijuana Accessories and Branded Goods directly to Consumers from a Marijuana Retailer, or directly to Registered Qualifying Patients or Caregivers from an MTC, but is not authorized to sell Marijuana or Marijuana Products directly to Consumers, Registered Qualifying Patients or Caregivers and is not authorized to Wholesale, Warehouse, Process, Repackage, or White Label. A Marijuana Courier is an additional license type under M.G.L. c. 94G, § 4(b)(1) that allows for limited delivery of Marijuana or Marijuana Products to Consumers; and shall not be considered to be a Marijuana Retailer under 935 CMR 500.002: *Definitions* or 935 CMR 500.050: *Marijuana Establishments* and shall be subject to 935 CMR 500.050(1)(b): *Control Limitations*.

Marijuana Cultivator means an entity licensed to cultivate, Process and package Marijuana, and to Transfer Marijuana to other Marijuana Establishments, but not to Consumers. A Craft Marijuana Cooperative is a type of Marijuana Cultivator.

Marijuana Establishment means a Marijuana Cultivator (Indoor or Outdoor), Craft Marijuana Cooperative, Marijuana Product Manufacturer, Marijuana Microbusiness, Independent Testing Laboratory, Marijuana Retailer, Marijuana Transporter, Delivery Licensee, Marijuana Research Facility Licensee (as defined in 935 CMR 501.002: Marijuana Research Facility Licensee), Social Consumption Establishment (as defined in 935 CMR 501.002: Social Consumption Establishment), or any other type of licensed Marijuana-related business, except a Medical Marijuana Treatment Center (MTC).

Marijuana Establishment Agent means any Owner, employee, Executive, or volunteer of a Marijuana Establishment, who shall be 21 years of age or older. Employee includes a consultant or contractor who provides on-site services to a Marijuana Establishment related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of Marijuana.

Marijuana-infused Product (MIP) means a Marijuana Product infused with Marijuana that is intended for use or consumption including, but not limited to, Edibles, ointments, aerosols, oils, and Tinctures. A Marijuana-infused Product (MIP), when created or sold by a Marijuana Establishment or an MTC, shall not be considered a food or a drug as defined in M.G.L. c. 94, § 1. MIPs are a type of Marijuana Product.

Marijuana Products (or Cannabis Products) means Marijuana and its products, unless otherwise indicated Marijuana Products includes products that have been Manufactured and contain Cannabis, Marijuana or an extract from Cannabis or Marijuana, including concentrated forms of Marijuana and products composed of Marijuana and other ingredients that are intended for use or consumption, including Edibles, Beverages, topical products, ointments, oils and Tinctures. Marijuana Products include Marijuana-infused Products (MIPs) defined in 935 CMR 501.002: Marijuana-infused Products.

Marijuana Product Manufacturer means an entity licensed to obtain, Manufacture, Process and package Marijuana or Marijuana Products and to Transfer these products to other Marijuana Establishments, but not to Consumers.

Marijuana Regulation Fund means the fund established under M.G.L. c. 94G, § 14, in which fees, fines, and other monies collected by the Commission are deposited, except for fees collected by the Commission on behalf of other state agencies.

Marijuana Research Facility means the Premises at which a Marijuana Research Facility Licensee is approved to conduct research.

Marijuana Research Facility Licensee or Research Licensee means an academic institution, nonprofit corporation or domestic corporation or entity authorized to do business in the Commonwealth, including a licensed Marijuana Establishment or MTC, that is licensed to conduct research.

501.002: continued

Marijuana Retailer means an entity licensed to purchase, Repackage, White Label, and transport Marijuana or Marijuana Product from Marijuana Establishments and to Transfer or otherwise Transfer this product to Marijuana Establishments and to sell to Consumers. Unless licensed, retailers are prohibited from offering Marijuana or Marijuana Products for the purposes of on-site social consumption on the Premises of a Marijuana Establishment.

Marijuana Transporter means an entity, not otherwise licensed by the Commission, that is licensed to possess Marijuana Products solely for the purpose of transporting, temporary storage, sale and distribution to Marijuana Establishments or MTCs, but not to Consumers. Marijuana Transporters may be an Existing Licensee Transporter or Third-party Transporter.

Marijuana Vaporizer Device means a product containing concentrated marijuana oil that is converted into inhalable marijuana aerosolized vapors.

Massachusetts Resident means a person whose primary Residence is in Massachusetts.

Medical Marijuana Treatment Center (MTC), formerly known as a Registered Marijuana Dispensary (RMD)), means an entity licensed under 935 CMR 501.101 that acquires, cultivates, possesses, Processes (including development of related products such as Edibles, MIPs, Tinctures, aerosols, oils, or ointments), Repackages, transports, sells, distributes, delivers, dispenses, or administers Marijuana, products containing Marijuana, related supplies, or educational materials to Registered Qualifying Patients or their Personal Caregivers for medical use. Unless otherwise specified, MTC refers to the site(s) of dispensing, cultivation, and preparation of Marijuana for medical use.

Medical-use Marijuana (or Medical-use Cannabis) means Marijuana that is cultivated, Processed, Transferred, tested or sold in compliance with M.G.L. c. 94I, and 935 CMR 501.000.

Medical-use Marijuana or Marijuana Products means Marijuana Products that are Manufactured, Transferred, tested or sold in compliance with M.G.L. c. 94I, and 935 CMR 501.000.

Member means a member of a nonprofit entity incorporated pursuant to M.G.L. c. 180.

Microbusiness means an entity that can be either a Tier 1 Marijuana Cultivator or Marijuana Product Manufacturer or both, in compliance with the operating procedures for each License and, if in receipt of a Delivery Endorsement issued by the Commission, may deliver Marijuana or Marijuana Products produced at the licensed location directly to Consumers in compliance with established regulatory requirements for retail sale as it relates to delivery. A Microbusiness that is a Marijuana Product Manufacturer may purchase no more than 2,000 pounds of Marijuana per year from other Marijuana Establishments for the purpose of Marijuana Product manufacturing by the Licensee.

Mother Plant means a marijuana plant that is grown or maintained for the purpose of generating Clones, and that will not be used to produce plant material for sale to another Marijuana Establishment or Medical Marijuana Treatment Center.

MTC Agent means any Owner, employee, Executive, or volunteer of an MTC, who shall be 21 years of age or older. Employee includes a consultant or contractor who provides on-site services to an MTC related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of Marijuana or Marijuana Products for medical purposes.

MTC Branded Good means a merchandise item offered for sale by an MTC, and identifiable as being of a particular MTC, distinct from those of other entities, by having the MTC's Brand Name. An MTC Branded Good does not include Marijuana, Marijuana Products, or Marijuana Accessories. It may include apparel, water bottles or other similar non-Edible merchandise.

MTC Entrance means the entrance or entrances that provides ingress and egress to Consumers, Registered Qualifying Patients and Caregivers, to the MTC.

501.002: continued

MTC Priority Applicant means a Medical Marijuana Treatment Center (MTC) (previously, Registered Marijuana Dispensary (RMD)) certified by the Commission as an MTC Priority Applicant in 2018 upon demonstrating that it had at least a provisional Certification of Registration prior to April 1, 2018. This applicant has priority for the purposes of the review of its license application.

Mycotoxin means a secondary metabolite of a microfungus that is capable of causing death or illness in humans and other animals. For purposes of 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000, Mycotoxin shall include aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A.

Order to Show Cause means an order issued by the Commission or a Commission Delegee on a determination that there are grounds to suspend or revoke a License or registration.

Other Jurisdiction means the United States, another state, or foreign jurisdiction, or a military, territorial or Native American tribal authority.

Outdoor Cultivation shall mean the cultivation of mature Cannabis without the use of artificial lighting in the Canopy area at any point in time. Artificial lighting is permissible only to maintain Immature or Vegetative Mother Plants.

Owner means any Equity Holder that possesses 10% equity or more in a Marijuana Establishment, MTC or Independent Testing Laboratory.

Panic Alarm means an audible security alarm signal generated by the manual activation of a device that signals a life threatening or emergency situation and calls for a law enforcement response.

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

Patient Registration Card means a temporary or an annual Registration Card currently and validly issued by the Commission to a Registered Qualifying Patient. The Patient Registration Card facilitates verification of an individual Registrant's status including, but not limited to, identification by the Commission and Law Enforcement Authorities, of those individuals who are exempt from Massachusetts criminal and civil penalties under M.G.L. c. 94I, and 935 CMR 501.000 through Commission-supported databases. A Temporary Patient Registration issued to a Qualifying Patient shall be deemed a Registration Card.

Person means an individual or entity under the laws of the Commonwealth.

Person or Entity Having Direct Control means any person or entity having direct control over the operations of an MTC, which satisfies one or more of the following criteria:

- (a) An Owner that possesses a financial interest in the form of equity of 10% or greater in an MTC;
- (b) A Person or Entity that possesses a voting interest of 10% or greater in an MTC or a right to veto significant events;
- (c) A Close Associate;
- (d) A Person or Entity that has the right to control, or authority through contract, or otherwise including, but not limited to:
  - 1. To make decisions regarding operations and strategic planning, capital allocations, acquisitions and divestments;
  - 2. To appoint more than 50% of the directors or their equivalent;
  - 3. To appoint or remove Corporate-level officers or their equivalent;
  - 4. To make major marketing, production, and financial decisions;
  - 6. To earn 10% or more of the profits or collect more than 10% of the dividends.
  - 5. To execute significant (in aggregate of \$10,000 or greater) or exclusive contracts; or
- (e) A Court Appointee or assignee pursuant to an agreement for a general assignment or Assignment for the Benefit of Creditors; or
- (f) A Third-party Technology Platform Provider that possesses any financial interest in a Delivery Licensee including, but not limited to, a Delivery Agreement or other agreement for services.

501.002: continued

Person or Entity Having Indirect Control means any person or entity having indirect control over operations of MTC. It specifically includes any Person or Entity Having Direct Control over an indirect holding or parent company of the applicant, and the chief executive officer and executive director of those companies, or any person or entity in a position indirectly to control the decision-making of MTC.

Personal Caregiver means a person, registered by the Commission, who shall be 21 years of age or older, who has agreed to assist with a Registered Qualifying Patient's medical use of Marijuana, and is not the Registered Qualifying Patient's Certifying Healthcare Provider. A visiting nurse, personal care attendant, or home health aide providing care to a Registered Qualifying Patient may serve as a Personal Caregiver, including as a second Personal Caregiver to patients younger than 18 years old.

Personal Caregiver Registration Card means a temporary or an annual Registration Card currently and validly issued by the Commission to a Personal Caregiver. The Registration Card allows access into Commission supported databases. The Registration Card facilitates verification of an individual Registrant's status including, but not limited to, identification by the Commission and Law Enforcement Authorities of those individuals who are exempt from Massachusetts criminal and civil penalties under M.G.L. c. 94I, and 935 CMR 501.000. A temporary registration issued to a Personal Caregiver shall be deemed a Registration Card.

Pesticide means a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; provided that Pesticide shall not include any article that is a "new animal drug" within the meaning of § 201(v) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 321(v)), or that has been determined by the Secretary of the United States Department of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an "animal feed" within the meaning of § 201(w) of such act (21 U.S.C. § 32(w)).

Preapproved Court Appointee means a person or entity preapproved by the Commission pursuant to 935 CMR 500.104(3)(c) to serve as a Court Appointee over a Licensee or its delegee which may be recommended to a court of competent jurisdiction.

Pre-certification Application means an application reviewed by the Commission for pre-certification prior to provisional licensure. The Pre-certification Application may be available in a form and manner determined by the Commission.

Pre-verification means the process of an MTC examining the identification presented by an individual Registered Qualifying Patient to confirm that the identification is valid and matches the individual presenting it and collecting the information required by 935 CMR 501.000 prior to that Registered Qualifying Patient being able to receive deliveries of Marijuana or Marijuana Products to the Registered Qualifying Patient or Caregiver's Residence.

Premises means any indoor or outdoor location over which an MTC or Independent Testing Laboratory or its agents may lawfully exert substantial supervision or control over entry or access to the property or the conduct of persons.

Priority Applicant means an MTC Priority Applicant (formerly a Registered Marijuana Dispensary or RMD Priority Applicant) or an Economic Empowerment Priority Applicant.

Process or Processing means to harvest, dry, cure, trim and separate parts of the Cannabis or Marijuana plant by manual or mechanical means, except it shall not include Manufacture as defined in 935 CMR 501.002: Manufacture.

Product Database means a Commission-operated technology platform displaying information about Marijuana Products produced by licensed Marijuana Product Manufacturers and sold by a licensed Marijuana Retailer or Delivery Operator pursuant to 935 CMR 500.000: *Adult Use of Marijuana* or an MTC pursuant to 935 CMR 501.000.

501.002: continued

Production Area means a Limited Access Area within the MTC where Cannabis or Marijuana is handled or produced in preparation for sale.

Production Batch means a batch of finished plant material, Cannabis resin, Cannabis concentrate, or Marijuana-infused Product made at the same time, using the same methods, equipment and ingredients. The Licensee shall assign and record a unique, sequential alphanumeric identifier to each Production Batch for the purposes of production tracking, product labeling and product recalls. All Production Batches shall be traceable to one or more Cannabis or Marijuana Cultivation Batches.

Program Transfer means the transfer of the medical use of Marijuana program pursuant to St. 2017, c. 55, §§ 64 through 71, and 82, and M.G.L. c. 94I.

NON-TEXT PAGE



501.002: continued

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

Protected Patient Records means any document, record or electronic or written communication related to their care provided by a medical-use Marijuana Licensee or establishment or by a Certifying Healthcare Provider that is required to be confidential or protected from disclosure by law.

Provisional Medical Marijuana Treatment Center License means a License issued by the Commission confirming that an MTC has completed the application process and satisfied the qualifications for initial licensure.

Qualifying Patient means:

- (a) a Massachusetts Resident or a non-Massachusetts Resident receiving end-of-life or palliative care or cancer treatment in Massachusetts as determined by a Certifying Healthcare Provider, who is 18 years of age or older who has been diagnosed by a Certifying Healthcare Provider as having a Debilitating Medical Condition; or
- (b) a Massachusetts Resident, or a non-Massachusetts Resident receiving end-of-life or palliative care or cancer treatment in Massachusetts as determined by a Certifying Healthcare Provider, who is younger than 18 years old who has been diagnosed by two Massachusetts licensed Certifying Physicians, at least one of whom is a board-certified pediatrician, pediatric subspecialist, oncologist, neurologist, or family physician as having a Debilitating Medical Condition that is also a Life-limiting Illness, subject to 935 CMR 501.010(10).

Quality Control Sample means a sample of Marijuana or Marijuana Product developed by a Marijuana Cultivator, a Marijuana Product Manufacturer, a Microbusiness, or a Craft Marijuana Cooperative that is provided internally to employees for purposes of ensuring product quality and making determinations about whether to sell the Marijuana or Marijuana Product.

Quarantine Order means an order to quarantine or otherwise restrict the sales or use of Marijuana, Marijuana Products, or MIPs by a Licensee or Registrant to protect the public health, safety, or welfare.

Registered Qualifying Patient means a Qualifying Patient who is currently and validly issued a temporary or an annual Registration Card by the Commission.

Registrant means the holder of a Registration Card currently and validly registered with the Commission.

Registration Card means an identification card currently and validly issued by the Commission, to a Registered Qualifying Patient, Personal Caregiver, Institutional Caregiver, MTC or Laboratory Agent. The Registration Card allows access into Commission supported databases. The Registration Card facilitates verification of an individual Registrant's status including, but not limited to, the identification by the Commission and Law Enforcement Authorities of those individuals who are exempt from Massachusetts criminal and civil penalties under St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, and 935 CMR 501.000.

Removal of Product means an order issued against an MTC to remove and prohibit sales of categories of products, product types, specific product types or specific brands of products after notice and on a determination that the Marijuana or Marijuana Product poses a substantial risk to the public health, safety or welfare including, but not limited to, when the product is especially appealing to persons younger than 21 years old.

Repackage means to uniformly wrap or seal Marijuana that has already been wrapped or sealed, into a ready-made product for retail sale, without combining, infusing, or changing the chemical composition of the Marijuana.

501.002: continued

Research Permit means a certificate indicating Commission approval to conduct a specified research project over a specified and finite period. To the extent that a Research Licensee is subject to other IRB, institutional, industry, or professional standards, they shall demonstrate compliance with those standards.

Residence means a house, condominium or apartment, and excludes, unless otherwise authorized by law, dormitories or other on-campus college or university housing; bed-and-breakfast establishments, hotels, motels or other commercial hospitality operations; and federal public housing identified at <https://resources.hud.gov/>, shelters or residential programs.

Residual Solvent means a volatile organic chemical used in the Manufacture of a Marijuana Product that is not completely removed by practical manufacturing techniques.

Responsible Vendor means an MTC that the Commission has determined to have completed the initial training requirements and has maintained its training requirement under 935 CMR 501.105(2).

Responsible Vendor Trainer means an independent business entity certified by the Commission to provide Responsible Vendor Training Program courses. No owner, manager, or employee of a Responsible Vendor Trainer may be a Person or Entity Having Direct or Indirect Control of an MTC.

Responsible Vendor Training (RVT) Program means a mandatory program that provides training courses taught by a Responsible Vendor Trainer for MTC Agents in order to satisfy the minimum training hours required under 935 CMR 501.105(2).

School Entrance means the entrance(s) that provide ingress and egress to students of the pre-existing public or private or private school providing education in kindergarten or any grades 1 through 12 at the time of the newspaper publication of the proposed MTC's community outreach meeting under 935 CMR 501.101(1)(a)9.a.

SDO means the Supplier Diversity Office of the Massachusetts Operational Services Division (OSD).

Second Confirmatory Test means a second full panel of tests performed for reanalysis of a sample of Marijuana or Marijuana Products that failed an initial test for contaminants.

Seed-to-sale Electronic Tracking System means a system designated by the Commission as the system of record (Seed-to-sale SOR) or a secondary electronic tracking system used by a Marijuana Establishment or an MTC or an Independent Testing Laboratory. This system shall capture everything that happens to an individual Marijuana plant, from seed and cultivation, through growth, harvest and Manufacture of Marijuana Products and MIPs, including transportation, if any, to final sale of finished products. Seed-to-sale Electronic Tracking System shall utilize a unique-plant identification and unique-batch identification. It will also be able to track agents' and Registrants' involvement with the Marijuana Product. Any secondary system used by the Marijuana Establishment or an MTC or an Independent Testing Laboratory shall integrate with the SOR in a form and manner determined by the Commission.

Seed-to-sale-System of Record (Seed-to-sale SOR) means the electronic tracking system designated and required by the Commission to perform a process.

Shelf-stable means able to be safely stored at room temperature in a sealed container. Shelf-stable does not include "Time/Temperature Controlled for Safety Food" as it is defined in the 2013 *Food Code* as adopted under 105 CMR 590.001(A).

Small Business means, for the purposes of 935 CMR 500.005(1)(b), an applicant or Licensee that:

- (a) currently employs a combined total of 50 or fewer full-time equivalent employees in all locations or employees work less than a combined total of 2,600 hours per quarter; and

501.002: continued

(b) has gross revenues of \$5 million or less, as reported to the Massachusetts Department of Revenue the year prior to the date of the Licensee's renewal application or as otherwise demonstrated in a form and manner determined by the Commission.

Social Consumption Establishment means an entity licensed to sell Marijuana or Marijuana Products and allow Consumers to consume Marijuana or Marijuana Products solely on its Premises.

Social Consumption Pilot Program means a limited number of Social Consumption Establishments, specifically Social Consumption Establishments, in certified municipalities.

Social Equity Program Participant means an individual who qualified to participate in the Social Equity Program and is designated as a program participant by the Commission.

Substantial Modification means a material change to a term of a contract that a reasonable person would understand alters the relationship between the parties. A Substantial Modification shall include, but is not limited to, shifting responsibility for the performance of a contract term or increasing or decreasing the amount of consideration being paid for performance of the contract above an amount that is *de minimis*.

Summary Suspension means the suspension of any License or registration issued under 935 CMR 501.000 and the cessation of all operations in order to protect the public health, safety and welfare.

Temporary Patient Registration means an interim registration document for patients and their Personal Caregivers generated automatically upon the Commission's receipt of a Certifying Healthcare Provider's Electronic Certification. The temporary registration document shall constitute a Registration Card for patients and their Personal Caregivers to access an MTC. Temporary registration shall expire 14 days after the Commission issues the Registration Card or on the issuance and receipt of an annual Registration Card, whichever occurs first.

Third-party Technology Platform Provider means an individual or entity that provides or hosts an internet-based application or group of applications developed for the facilitation of ordering and delivering Finished Marijuana Products, Marijuana Accessories and Branded Goods for sale or delivery by a Marijuana Courier or an MTC to a Registered Qualifying Patient or Caregiver. A proprietary application developed by a Licensee exclusively for that Licensee's use shall not be considered to be a Third-party Technology Platform Provider. A Third-party Technology Platform Provider may not be an investor in a Delivery Licensee.

Tincture means a Cannabis-infused alcohol or oils concentrate administered orally in small amounts using a dropper or measuring spoon. Tinctures are not considered an Edibles under 935 CMR 501.000.

Transfer means the sale of Marijuana or Marijuana Products from a Marijuana Establishment to a separate Marijuana Establishment, Independent Testing Laboratory or MTC (but not to Consumers) subject to entry of the transaction in the Commission's Seed-to-sale SOR.

United States (US) means the United States of America.

Unreasonably Impracticable means that the measures necessary to comply with the regulations, ordinances or bylaws adopted pursuant to St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. c. 94I, 935 CMR 500.000: *Adult Use of Marijuana* or 935 CMR 501.000 subject Licensees to unreasonable risk or require such a high investment of risk, money, time or any other resource or asset that a reasonably prudent businessperson would not operate a Marijuana Establishment.

Usable Marijuana means the fresh or dried leaves and flowers of the female Marijuana plant and any mixture or preparation thereof, including Marijuana, Marijuana Products or MIPs, but does not include the seedlings, seeds, stalks, roots of the plant, or Marijuana rendered unusable in accordance with 935 CMR 501.105(12).

501.002: continued

Vault means a secured, limited access storage room within an MTC that is outfitted with adequate security features for the purposes of storing Marijuana or Marijuana Products or cash. A vault must be adequately sized to store inventory that is not being actively handled for purposes of dispensing, packaging, processing or transportation.

Vegetation means the sporophytic state of the Cannabis or 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.

Vegetative Plant means a plant in a stage of Vegetation.

Vendor Sample means a sample of Marijuana or Marijuana Product developed by a Marijuana Cultivator or a Marijuana Product Manufacturer licensed under the provisions of 935 CMR 500.000: *Adult Use of Marijuana*, that is provided to a Marijuana Product Manufacturer, a Marijuana Retailer or a Delivery Operator to promote product awareness.

Verified Financial Hardship means that an individual is a recipient of MassHealth, or Supplemental Security Income, or the individual's income does not exceed 300% of the federal poverty level, adjusted for family size.

Veteran means a person who served in the active military, naval, air, or space service of the United States and who was discharged or released under conditions other than dishonorable.

Visitor means an individual, other than an MTC Agent or Laboratory Agent, authorized by the MTC or Independent Testing Laboratory to be on the Premises of an MTC for a purpose related to its operations and consistent with the objectives of M.G.L. c. 94I, and 935 CMR 501.000.

Visitor Identification Badge means a badge issued by an MTC, Marijuana Establishment or the Commission to be used at all times while on the Premises of a Marijuana Establishment or an MTC or Independent Testing Laboratory. These identification badges shall be issued in a form and manner determined by the Commission.

Waiver of Consent means the document signed by potential participants or the legal guardians of potential participants that waives one or more elements of consent.

Written Certification means a form submitted to the Commission by a Massachusetts licensed Certifying Healthcare Provider describing the Qualifying 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 patient.

14-day Supply means that amount of Marijuana, or equivalent amount of Marijuana in MIPs, that a Registered Qualifying Patient would reasonably be expected to need over a period of 14 calendar days for the Patient's personal medical use, which is 2.5 ounces, subject to 935 CMR 501.010(9), unless otherwise determined by a Certifying Healthcare Provider.

60-day Supply means that amount of Marijuana, or equivalent amount of Marijuana in MIPs, 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 935 CMR 501.010(9), unless otherwise determined by a Certifying Healthcare Provider.

501.003: Colocated Marijuana Operations (CMOs)

An MTC may also be licensed to conduct adult-use operations as a Cultivator, Product Manufacturer and Retailer, as defined in 935 CMR 500.002: Cultivator, Product Manufacturer, and Retailer. Unless otherwise specified, a CMO shall comply with the requirements of each the adult-use and medical-use license located on the Premises of the CMO.

935 CMR: CANNABIS CONTROL COMMISSION

501.005: Fees

(1) Each Qualifying Patient is subject to the following nonrefundable fees. 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 Commission.

Patients	Fee
Medical Use ID Card Replacement	\$10

(2) Each of the individuals and entities identified below is subject to the following nonrefundable fees.

**Medical Marijuana Treatment Center (MTC):**

MTC Agent Registration, Annual	\$500
MTC Application Fee	\$3,500
MTC Initial and Annual License Fee	\$50,000

**Caregiving and Caregiving Institutions:**

Registration of Caregiving Institutions	None
Registration of Institutional Caregivers	None

(3) Other Fees (Cost per License).

Change in Name Fee	\$1,000
Change in Location Fee	\$10,000
Change in Building Structure Fee	\$1,000
Change in Ownership or Control Fee (involving at least one entity gaining ownership/control)	\$5000 per entity, per License
Change in Ownership or Control Fee (involving individuals, e.g., change of Board Member)	\$500 per person
Architectural Review Request Fee	\$1,500
Packaging and Labeling Preapproval Application Fee	\$50 per product

(4) These fees do not include the costs associated with the Seed-to-sale SOR, which includes a monthly program fee and fees for plant and package tags. These fees do not include the costs associated with criminal background checks as required under 935 CMR 501.000. These fees do not include the costs associated with packaging and label approval.

(5) All persons required to complete a background check pursuant to 935 CMR 501.101(1)(b) shall be responsible for reimbursement and/or payment of fees relating to criminal and background investigations as necessary for the purpose of evaluating Licensees, agents and applicants for licensure in accordance with 935 CMR 501.101(1)(b).

(6) For CMOs, an applicant or Licensee shall pay the applicable fees for each Marijuana Establishment set forth in 935 CMR 500.005: *Fees* and MTC set forth in 935 CMR 501.005.

501.005: continued

(7) Preapproved Court Appointees.

- (a) Each applicant seeking to be Preapproved Court Appointee shall pay a nonrefundable application fee of \$500 with any such application.
- (b) A Preapproved Court Appointee seeking to renew its designation shall pay a renewal fee of \$400.

501.006: Registration of Certifying Physicians

(1) 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:

- (a) An active full license, with no prescribing restriction, to practice medicine in Massachusetts; and
- (b) A Massachusetts Controlled Substances Registration from the DPH.

(2) To register as a Certifying Physician, a physician shall submit, in a form and manner determined by the Commission, the physician's:

- (a) Full name and business address;
- (b) License number issued by the Massachusetts Board of Registration in Medicine;
- (c) Massachusetts Controlled Substances Registration number; and
- (d) Any other information required by the Commission.

(3) Once registered by the Commission, a Certifying Physician will retain indefinitely a registration to certify a Debilitating Medical Condition for a Qualifying Patient, unless:

- (a) 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;
- (b) The physician's Massachusetts Controlled Substances Registration is suspended or revoked;
- (c) The physician has fraudulently issued a Written Certification of a Debilitating Medical Condition;
- (d) The physician has certified a Qualifying Patient for a Debilitating Medical Condition without appropriate completion of continuing professional development credits pursuant to 935 CMR 501.010(1); or
- (e) The physician surrenders his or her registration.

(4) After registering, a Certifying Physician is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any changes to the physician's information.

501.007: Registration of Certifying Certified Nurse Practitioners

(1) A Certifying CNP 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:

- (a) An active full license, with no prescribing restriction, to practice nursing in Massachusetts;
- (b) A board authorization by the Massachusetts Board of Registration in Nursing to practice as a CNP; and
- (c) A Massachusetts Controlled Substances Registration from the DPH.

(2) To register as a Certifying CNP, a CNP shall submit, in a form and manner determined by the Commission, the Certifying CNP's:

- (a) Full name and business address;
- (b) License number issued by the Massachusetts Board of Registration in Nursing;
- (c) Board Authorization by the Massachusetts Board of Registration in Nursing;
- (d) Massachusetts Controlled Substances Registration number;
- (e) An attestation by the supervising physician for the CNP that the CNP is certifying patients for medical use of Marijuana pursuant to the mutually agreed upon guidelines between the CNP and physician supervising the CNP's prescriptive practice; and
- (f) Any other information required by the Commission.

501.007: continued

- (3) Once registered by the Commission, a Certifying CNP will retain indefinitely a registration to certify a Debilitating Medical Condition for a Qualifying Patient, unless:
- (a) The CNP's license to practice nursing in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the CNP has voluntarily agreed not to practice nursing in Massachusetts;
  - (b) The CNP's Board Authorization to practice as an advanced practice nurse in Massachusetts is suspended, revoked or restricted with regard to prescribing;
  - (c) The CNP's Massachusetts Controlled Substances Registration is suspended or revoked;
  - (d) The CNP has fraudulently issued a Written Certification of a Debilitating Medical Condition;
  - (e) The CNP has certified a Qualifying Patient for a Debilitating Medical Condition without appropriate completion of continuing professional development credits pursuant to 935 CMR 501.010(1); or
  - (f) The CNP surrenders his or her registration.
- (4) After registering, a Certifying CNP is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any changes to the CNP's information including, but not limited to, changes to his or her supervising physician.

501.008: Registration of Certifying Physician Assistants

- (1) A Certifying Physician Assistant 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:
- (a) An active full license, with no prescribing restriction, to practice as a physician assistant in Massachusetts;
  - (b) A board authorization by the Massachusetts Board of Registration of Physician Assistants to practice as a physician assistant; and
  - (c) A Massachusetts Controlled Substances Registration from the DPH.
- (2) To register as a Certifying Physician Assistant, a physician assistant shall submit, in a form and manner determined by the Commission, the Certifying Physician Assistant's:
- (a) Full name and business address;
  - (b) License number issued by the Massachusetts Board of Registration of Physician Assistants;
  - (c) Board Authorization by the Massachusetts Board of Registration of Physician Assistants;
  - (d) Massachusetts Controlled Substances Registration number;
  - (e) An attestation by the supervising physician for the physician assistant that the physician assistant is certifying patients for medical use of Marijuana pursuant to the mutually agreed upon guidelines between the physician assistant and physician supervising the physician assistant's prescriptive practice; and
  - (f) Any other information required by the Commission.
- (3) Once registered by the Commission, a Certifying Physician Assistant will retain indefinitely a registration to certify a Debilitating Medical Condition for a Qualifying Patient, unless:
- (a) The physician assistant's license to practice as a physician assistant in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician assistant has voluntarily agreed not to practice medicine in Massachusetts;
  - (b) The physician assistant's Board Authorization to practice as a physician assistant in Massachusetts is suspended, revoked or restricted with regard to prescribing;
  - (c) The physician assistant's Massachusetts Controlled Substances Registration is suspended or revoked;
  - (d) The physician assistant has fraudulently issued a Written Certification of a Debilitating Medical Condition;
  - (e) The physician assistant has certified a Qualifying Patient for a Debilitating Medical Condition on or after the effective date of the transfer of the program, without appropriate completion of continuing professional development credits pursuant to 935 CMR 501.010(1); or
  - (f) The physician assistant surrenders his or her registration.

501.008: continued

(4) After registering, a Certifying Physician Assistant is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any changes to the physician assistant's information including, but not limited to, changes to the Certifying Physician Assistant's license to practice or to his or her supervising physician.

501.010: Written Certification of a Debilitating Medical Condition for a Qualifying Patient

(1) A Certifying Healthcare Provider shall complete a program that explains the proper use of Marijuana, including side effects, dosage, and contraindications, including with psychotropic drugs, as well as on substance abuse recognition, diagnosis, and treatment related to Marijuana, which includes, but is not limited to, the following:

(a) A Certifying Physician issuing a Written Certification shall have completed a minimum of 2.0 Category 1 continuing professional development credits as defined in 243 CMR 2.06(6)(a)1.

(b) A Certifying CNP issuing a Written Certification shall have completed a minimum of one program meeting the requirements of 244 CMR 5.00: *Continuing Education* and 244 CMR 6.00: *Approval of Nursing Education Programs and the General Conduct Thereof*.

(c) A Certifying Physician Assistant issuing a Written Certification shall have completed a minimum of one program meeting the requirements of 263 CMR 3.05(3).

(2) A Certifying Healthcare Provider shall issue a Written Certification that complies with generally accepted standards of medical practice including, but not limited to, the following:

(a) A Certifying Physician issuing a Written Certification shall comply with generally accepted standards of medical practice, including regulations of the Board of Registration in Medicine at 243 CMR 1.00 through 3.00, pursuant to M.G.L. c. 112, § 5, and M.G.L. c. 111, § 203.

(b) A Certifying CNP issuing a Written Certification shall comply with generally accepted standards of nursing practice, including the regulations of the Board of Registration in Nursing at 244 CMR 9.00: *Standards of Conduct*.

(c) A Certifying Physician Assistant issuing a Written Certification shall comply with generally accepted standards of practice for physician assistants, including regulations of the Board of Registration of Physician Assistants at 263 CMR 5.09: *Standards of Conduct for Physician Assistants*.

(3) A Certifying Healthcare Provider may not delegate to any other healthcare professional or any other person, authority to diagnose a patient as having a Debilitating Medical Condition.

(4) A Certifying Healthcare Provider shall have a program to provide a discount to patients with documented Verified Financial Hardship. The plan shall outline the goals, programs, and measurements the Certifying Healthcare Provider will pursue as part of the plan. A Certifying Healthcare Provider may apply for a waiver under 935 CMR 501.850 to waive this requirement by demonstrating that the Certifying Healthcare Provider does not have control over the costs to its patients.

(5) A Certifying Healthcare Provider may issue a Written Certification only for a Qualifying Patient with whom the healthcare provider has a *Bona Fide* Healthcare Provider Patient Relationship.

(6) Before issuing a Written Certification, a Certifying Healthcare Provider shall utilize the Massachusetts Prescription Monitoring Program, unless otherwise specified by the Commission, to review the Qualifying Patient's prescription history.

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



501.010: continued

- (8) An initial or renewal Written Certification submitted before a Clinical Visit is prohibited.
- (a) A Clinical Visit may occur in-person or by telehealth means, provided that a Clinical Visit for issuing an initial Certificate of Registration must be conducted in-person.
  - (b) If a Clinical Visit is conducted by telehealth means, the Certifying Healthcare Provider shall ensure that there is an ability to deliver the service using telehealth with the same standard of care and in compliance with licensure and registration requirements as is applicable to in-person services to patients and shall comply with any additional requirements established by the Commission.
- (9) A certification shall indicate the time period for which the certification is valid, and may not be less than 15 calendar days or longer than one year, except that in the following circumstances, the certification may be valid for two years:
- (a) A Certifying Healthcare Provider verifies and represents to the Commission that a Qualifying Patient is receiving Social Security Disability Insurance or Supplemental Security Income; or
  - (b) A Certifying Healthcare Provider diagnoses a Qualifying Patient after an in-person Clinical Visit with a terminal illness, or permanent disability and certifies the patient for two years.
- (10) A Certifying Healthcare Provider may determine and certify that a Qualifying Patient requires an amount of Marijuana other than 2.5 ounces as a 14-day Supply or 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 14-day Supply or 60-day Supply.
- (11) A Qualifying Patient who is younger than 18 years old and has been diagnosed by two Massachusetts licensed Certifying Physicians, at least one of whom is a board certified pediatrician, pediatric subspecialist, oncologist, neurologist, or family physician, with a debilitating Life-limiting Illness, may receive a Written Certification; provided however, that the physicians may certify a Qualifying Patient who is younger than 18 years old who has a Debilitating Medical Condition that is not a Life-limiting Illness if those physicians determine that the benefits of the medical use of Marijuana outweigh the risks. This shall include a discussion of the potential negative impacts on neurological development with the parent or legal guardian of the Qualifying Patient, written consent of the parent or legal guardian, and documentation of the rationale in the medical record and the Written Certification.
- (12) A Certifying Healthcare Provider, and such healthcare provider's co-worker, employee, or Immediate Family Member, may not:
- (a) Have ever directly or indirectly accepted or solicited from, or offered to an MTC, a board member or Executive of an MTC, any MTC personnel, or any other individual associated with an MTC, or a Personal Caregiver, anything of value;
  - (b) 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 MTC;
  - (c) Examine or counsel a patient, or issue a Written Certification, at an MTC;
  - (d) Be a Person or Entity Having Direct or Indirect Control for an MTC; or
  - (e) Directly or indirectly benefit from a patient obtaining a Written Certification, which may not prohibit the healthcare provider from charging an appropriate fee for the Clinical Visit.
- (13) A Certifying Healthcare Provider may not issue a Written Certification for himself or herself or for his or her Immediate Family Members.
- (14) A Certifying Healthcare Provider issuing a Written Certification for their employees or coworkers shall do so in accordance with 935 CMR 501.010 of a Debilitating Medical Condition for a Qualifying Patient, 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.

501.015: Temporary and Annual Registration of Qualifying Patients

(1) A Qualifying Patient shall apply for a temporary or annual registration according to the procedures set out in 935 CMR 501.015, unless otherwise provided by the Commission.

(2) To obtain a temporary or an annual Registration Card, a Qualifying Patient shall first obtain electronic or Written Certification(s) from the Qualifying Patient's Certifying Healthcare Provider(s).

(3) Temporary Registration Card. A patient's Certifying Healthcare Provider(s) shall provide a Qualifying Patient who has not been issued a temporary Patient Registration Card in the 365-day period preceding the date of certification, a temporary registration in a form and a manner determined by the Commission, which will include, but not be limited to, the following:

(a) To generate a temporary Registration Card, a Certifying Healthcare Provider shall obtain from a Qualifying Patient, and electronically submit the information required by the Commission as part of the temporary electronic certification process;

(b) At a minimum, a Certifying Healthcare Provider shall submit the information required in 935 CMR 501.015(5)(a) through (d) and (f);

(c) On submission of the requisite information, the provider shall provide a packet of information for the patient, which includes:

1. A temporary Patient Registration Card;
2. A caregiver authorization form and instructions;
3. Guidance on patient confidentiality;
4. Written instructions in a form and manner determined by the Commission that the patient needs to complete the registration process with the Commission in order to obtain an annual Registration card; and
5. If requested, a paper copy of the Commission registration form for an annual Registration Card.

(d) The temporary Registration Card shall constitute a Registration Card for patients for the purposes of accessing MTCs and purchasing medical-use Marijuana and MIPs;

(e) A temporary Registration Card shall expire either 14 days after the issuance of the temporary Registration Card or on the issuance and receipt of an annual Registration Card, whichever occurs first;

(f) A patient is limited to one 14-day temporary registration during any 365-day period, unless otherwise approved by the Commission;

(g) No more than 2.5 ounces of Marijuana may be dispensed by an MTC to a Qualifying Patient with a 14-day temporary registration except a Certifying Healthcare Provider may determine and certify that a Qualifying Patient requires an amount of Marijuana other than 2.5 ounces as a 14-day Supply and shall document the amount and the rationale in the medical record and in the Written Certification;

(h) It is the obligation of the MTC to track and dispense only the amount allowed for a 14-day Supply; and

(i) To obtain an annual Registration Card after receiving a temporary Registration Card, a Qualifying Patient shall comply with 935 CMR 501.015(5): *Annual Patient Registration Card* and complete the registration process for review by the Commission.

(4) To access MTCs and obtain medical-use Marijuana and MIPs, the patient shall present their temporary Registration Card in addition to a government-issued identification card. MTCs are responsible for ensuring that patients present proper documentation and verifying that the temporary Registration Card is valid, before the patient accesses the MTC and purchases Marijuana, Marijuana Products, or MIPs.

(5) Annual Patient Registration Card. To obtain an annual Registration Card, a Qualifying Patient shall submit or verify, in a form and manner determined by the Commission, the following information:

(a) 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:

1. If the Qualifying Patient is younger than 18 years old, an attestation from a parent or legal guardian granting permission for the child to register with the Commission; and
2. If the Qualifying Patient is younger than 18 years old, that Qualifying Patient shall have a designated Personal Caregiver, who shall be his or her parent or legal guardian.

501.015: continued

- (b) Electronic or Written Certification(s) for the Qualifying Patient from the Qualifying Patient's Certifying Healthcare Provider(s);
- (c) name, address, and telephone number of the Qualifying Patient's Certifying Healthcare Provider(s);
- (d) Full name, date of birth, and address of the Qualifying Patient's Personal Caregiver(s), if any;
- (e) A copy of the Qualifying Patient's government-issued identification card or other verifiable identity document acceptable to the Commission, except in the case of a Qualifying Patient younger than 18 years old who does not have to comply with such requirement;
- (f) Written acknowledgement of the limitations on his or her authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth;
- (g) An attestation that the Registered Qualifying Patient shall not engage in the diversion of Marijuana and that the patient understands that protections conferred by M.G.L. c. 94I, for possession of Marijuana for medical use are applicable only within Massachusetts; and
- (h) Any other information required by the Commission.

(6) After obtaining a Registration Card, a Qualifying Patient is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any change to the information that he or she was previously required to submit to the Commission, or after he or she discovers that his or her Registration Card has been lost or stolen.

(7) A Registered Qualifying Patient shall carry his or her Registration Card at all times while in possession of medical-use Marijuana or MIPs.

#### 501.020: Temporary and Annual Registration of Personal Caregivers

(1) A Personal Caregiver shall apply for a temporary or annual Registration Card according to the procedures set out in 935 CMR 501.020, unless otherwise provided by the Commission. An individual shall be granted a temporary or an annual Registration Card prior to serving as a Personal Caregiver for any Registered Qualifying Patient.

#### (2) Temporary Caregiver Registration Authorization.

(a) A temporary caregiver authorization will allow the Caregiver, during the interim period during which the patient has an effective and valid temporary Patient Registration Card, to serve as a caregiver to a Qualifying Patient and access MTCs and obtain medical-use Marijuana, Marijuana Products and MIPs on behalf of a patient before the patient and Caregiver are issued annual Registration Cards by the Commission.

(b) During the time a Qualifying Patient has a temporary Patient Registration Card pursuant to 935 CMR 501.015(3), the patient may authorize a Personal Caregiver, who is 21 years of age or older, as their temporary caregiver. To authorize an individual as a temporary caregiver, the patient shall complete the temporary caregiver authorization form, generated by the patient's healthcare provider or printed from the electronic patient portal by the patient, sign the form, and provide the authorization form to the designated caregiver.

(c) To access MTCs and obtain medical-use Marijuana, Marijuana Products and MIPs on behalf of a patient, the Caregiver shall present the patient's temporary Registration Card, a completed and signed temporary caregiver authorization form, and a government-issued identification document.

(d) MTCs are responsible for ensuring that Caregivers present proper documentation and verifying that the temporary Registration Card is valid, before the Caregiver accesses the MTC and purchases Marijuana, Marijuana Products or MIPs.

(e) It is the obligation of the MTC to track and dispense only the amount allowed for a 14-day Supply.

(f) To obtain an annual Registration Card after receiving a temporary Registration Card, a caregiver shall comply with 935 CMR 501.020(3) and complete the electronic registration process for review by the Commission.

(3) Annual Caregiver Registration Card. To obtain an annual Registration Card for a Personal Caregiver, a Registered Qualifying Patient shall submit, in a form and manner determined by the Commission, the following:

501.020: continued

- (a) The Personal Caregiver's full name, date of birth, address, telephone number, and email address if any, and a statement that the individual is 21 years of age or older;
- (b) Full name, date of birth, and address of the Registered Qualifying Patient for whom the Personal Caregiver will be providing assistance with the use of Marijuana for medical purposes;
- (c) A copy of the Personal Caregiver's driver's license, government issued identification card, or other verifiable identity document acceptable to the Commission;
- (d) A statement of whether the Caregiver will be cultivating Marijuana for the patient, and at what address;
- (e) Written acknowledgment 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;
- (f) An attestation by the Personal Caregiver that he or she shall not engage in the diversion of Marijuana and that he or she understands that protections conferred by M.G.L. c. 94I, for possession of Marijuana for medical use are applicable only within Massachusetts; and
- (g) Any other information required by the Commission.

(4) An annual Registration Card will be valid for one year from the date of issue of the temporary Registration Card, unless otherwise specified by the Commission, and may be renewed, in a form and manner determined by the Commission, which includes, but is not limited to, meeting the requirements in 935 CMR 501.020(3). The Commission will accept Registration Cards validly issued prior to the Program Transfer. This Registration Card will remain valid until its one-year anniversary date or until a new Registration Card is issued by the Commission, whichever occurs first. On the issuance of a new Registration Card, the holder of the Registration Card shall destroy any previously issued Registration Card(s) in a responsible manner that would prevent it from being used as an identification or Registration Card.

(5) Except in the case of a visiting nurse, home health aide, personal care attendant, or Immediate Family Member of more than one Registered Qualifying Patient, an individual may not serve as a Personal Caregiver for more than five Registered Qualifying Patient at one time. If a Personal Caregiver wants to serve more than five patients, the Personal Caregiver must seek a waiver pursuant to 935 CMR 501.850.

(6) A Registered Qualifying Patient may designate up to two Personal Caregivers. A Personal Caregiver(s) may cultivate Marijuana on behalf of the Registered Qualifying Patient at only one location. Cultivation pursuant to a Hardship Cultivation Registration by a Personal Caregiver constitutes agreement to comply with the requirements of Hardship Cultivation Registration under 935 CMR 501.027.

(7) A Personal Caregiver may cultivate a limited number of plants sufficient to maintain a 60-day supply of marijuana for each Registered Qualifying Patient solely for that patient's use, except that under no circumstances may a Personal Caregiver cultivate plants in excess of 500 square feet of Canopy.

(8) 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 Commission, and providing the information required in 935 CMR 501.020(3) for registration of Personal Caregivers.

(9) After obtaining a Registration Card, the Personal Caregiver is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any change to the information that his or her Registered Qualifying Patient was previously required to submit to the Commission, or after the Personal Caregiver discovers that their Registration Card has been lost or stolen.

(10) A Personal Caregiver shall carry his or her temporary or annual Registration Card at all times while in possession of Marijuana.

501.021: Registration of Caregiving Institutions

(1) Prior to facilitating the medical use of Marijuana to a Registered Qualifying Patient, a hospice program, long term care facility, or hospital shall obtain a Certificate of Registration as a Caregiving Institution. To obtain a Certificate of Registration as a Caregiving Institution, the institution shall submit, in a form and manner determined by the Commission, the following:

- (a) The name, address and telephone number of the institution, as well as the telephone number and email address for the primary contact for that Caregiving Institution;
- (b) A copy of the Caregiving Institution's current facility licensure or certification from the Commonwealth of Massachusetts;
- (c) Written acknowledgement by the authorized signatory of the Caregiving Institution of the limitations on the institution's authorization to cultivate, possess, and dispense to Registered Qualifying Patients, Marijuana for medical purposes in the Commonwealth;
- (d) An attestation by the authorized signatory of the Caregiving Institution that employees of the Caregiving Institution shall not engage in the diversion of Marijuana and that he or she understands that protections conferred by M.G.L. c. 94I, for possession of Marijuana for medical use are applicable only within Massachusetts; and
- (f) Any other information required by the Commission.

(2) A Caregiving Institution shall be granted a Certificate of Registration by the Commission prior to serving as a Caregiving Institution for any Registered Qualifying Patient. The Commission will accept certificates of registration validly issued prior to the Program Transfer. This certificate will remain valid until a new certificate is issued by the Commission. On the issuance of a new certificate, the holder of the certificate shall destroy any previously issued certificate in a responsible manner that would prevent it from being used as a certificate.

(3) An employee of the Caregiving Institution may serve as a Caregiver for more than one Registered Qualifying Patient at one time.

(4) An employee of the Caregiving Institution may not cultivate Marijuana for a Registered Qualifying Patient under the care of the Caregiving Institution.

(5) A Caregiving Institution shall maintain records on all Marijuana received by the institution on behalf of a Registered Qualifying Patient and the administration of such Marijuana to the Registered Qualifying Patient, and such records should be produced to the Commission upon request as permitted by law.

(6) A Certificate of Registration for a Caregiving Institution will remain valid, unless and until the Caregiving Institution's current facility licensure or certification from the Commonwealth of Massachusetts is no longer active, or is suspended, revoked, or restricted.

501.022: Registration of Institutional Caregivers

(1) A Caregiving Institution shall apply for an Institutional Caregiver registration for all employees that will be facilitating a Registered Qualifying Patient's use of Marijuana for medical purposes. All such individuals shall be 21 years of age or older.

(2) A Caregiving Institution seeking registration of an Institutional Caregiver shall file an application, in a form and manner determined by the Commission, which shall include:

- (a) The full name, date of birth and address of the individual;
- (b) Written acknowledgment by the individual of the limitations on his or her authorization to possess, transport, and facilitate the use of Marijuana for medical purposes in the Commonwealth;
- (c) Written acknowledgment by the individual of the prohibition against cultivation in his or her role as an Institutional Caregiver;
- (d) A copy of the Institutional Caregiver's driver's license, government issued identification card, or other verifiable identity document acceptable to the Commission;
- (e) An attestation that the individual shall not engage in the diversion of Marijuana;
- (f) A nonrefundable application fee, as required by the Commission; and
- (g) Any other information required by the Commission.

## 501.022: continued

(3) A Caregiving Institution shall notify the Commission no more than one business day after an Institutional Caregiver ceases to be associated with the Caregiving Institution. The Institutional Caregiver's registration shall be immediately void when he or she is no longer associated with the Caregiving Institution.

(4) A Registration Card for an Institutional Caregiver will be valid for one year from the date of issue, and may be renewed, in a form and manner determined by the Commission, on an annual basis by meeting the requirements in 935 CMR 501.022(1) and (2). The Commission will accept Registration Cards validly issued prior to the Program Transfer. This Registration Card will remain valid until its one-year anniversary date or until a new Registration Card is issued by the Commission, whichever occurs first. On the issuance of a new Registration Card, the holder of the Registration Card shall destroy any previously issued Registration Card(s) in a responsible manner that would prevent it from being used as a registration or identification card.

(5) An Institutional Caregiver shall apply for registration according to the procedures set out in 935 CMR 501.022, unless otherwise provided by the Commission.

(6) After obtaining a Registration Card for an Institutional Caregiver, a Caregiving Institution is responsible for notifying the Commission, in a form and manner determined by the Commission, as soon as possible, but in any event, within five business days after any changes to the information that the Caregiving Institution was previously required to submit to the Commission, or after discovery that a Registration Card has been lost or stolen.

(7) An Institutional Caregiver shall carry his or her Registration Card at all times while in possession of Marijuana.

(8) An Institutional Caregiver affiliated with multiple Caregiving Institutions shall be registered as an Institutional Caregiver by each Caregiving Institution.

501.025: Responsibilities of Caregivers(1) Personal Caregivers.

## (a) A Personal Caregiver may:

1. Transport a Registered Qualifying Patient to and from an MTC;
2. Obtain and transport Marijuana from an MTC on behalf of a Registered Qualifying Patient;
3. Cultivate Marijuana, subject to the plant limitations of 935 CMR 501.027(8), on behalf of a maximum of one Registered Qualifying Patient who has not obtained a Hardship Cultivation Registration, unless the Personal Caregiver is a visiting nurse, personal care attendant, or home health aide serving as a Personal Caregiver;
4. Cultivate Marijuana on behalf of one or more Registered Qualifying Patients who have obtained a Hardship Cultivation Registration, unless the Personal Caregiver is a visiting nurse, personal care attendant, or home health aide serving as a Personal Caregiver;
5. Prepare Marijuana for consumption by a Registered Qualifying Patient; and
6. Administer Marijuana to a Registered Qualifying Patient.
7. Receive reimbursement for reasonable expenses incurred in the provision of services as a Caregiver, including transportation and cultivation expenses directly related to the care of a Registered Qualifying Patient, so long as the expenses are documented and available for inspection by the Commission on request. A Caregiver may not receive reimbursement or payment for the Caregiver's time. In the case of an individual who serves as a Personal Caregiver for more than one Registered Qualifying Patient, the individual may receive partial reimbursement from multiple patients so long as the total reimbursement received does not exceed the Caregiver's total documented expenses.

## (b) A Personal Caregiver may not:

1. Consume, by any means, Marijuana that has been dispensed to or cultivated on behalf of a Registered Qualifying Patient;
2. Sell or otherwise divert Marijuana that has been dispensed to or cultivated on behalf of a Registered Qualifying Patient;

501.025: continued

3. Unless otherwise authorized by law or by the Commission, cultivate Marijuana for the Personal Caregiver's own use;
  4. Unless otherwise authorized by law, cultivate Marijuana for purposes of selling or providing Marijuana to anyone other than the Registered Qualifying Patient;
  5. Allow a Registered Qualifying Patient who is younger than 18 years old to possess Marijuana at any time when not in the presence of the Personal Caregiver;
  6. Cultivate Marijuana for Registered Qualifying Patient if the Personal Caregiver is a visiting nurse, personal care attendant, or home health aide serving as a Personal Caregiver;
  7. Offer a discount or any other thing of value to a Registered Qualifying Patient based on the representation that a patient will use a particular product or MTC;
  8. Directly or indirectly accept or solicit from an MTC, a board member or Executive of an MTC, any MTC personnel, or any other individual associated with an MTC, anything of value based on the representation that a Registered Qualifying Patient will use a particular product or MTC;
  9. Receive payment or other compensation for services rendered as a Personal Caregiver other than reimbursement for reasonable expenses incurred in the provision of services as a Caregiver; provided however, that a caregiver's time is not considered a reasonable expense. In the case of a visiting nurse, personal care attendant, or home health aide serving as a Personal Caregiver, such individual may not receive payment or compensation above and beyond their regular wages; or
  10. Participate in paid advertising.
- (c) A Personal Caregiver shall notify the Commission within five calendar days upon the death of a Personal Caregiver's Registered Qualifying Patient.
- (d) A Personal Caregiver engaging in cultivation for a Registered Qualifying Patient shall
1. Maintain a log of the costs associated with growing and make that log available to the Commission upon request;
  2. Provide annual written notice of the Personal Caregiver's cultivation conditions to the Registered Qualifying Patient and additional written notice of any change to those conditions.
- (e) A Personal Caregiver engaging in Hardship Cultivation shall comply with all applicable municipal or state requirements for electrical usage and fire safety, and shall document its fire safety plan and electrical and fire inspections.
- (2) Institutional Caregivers.
- (a) An Institutional Caregiver may:
1. Receive Marijuana delivered to the Caregiving Institution for a Registered Qualifying Patient;
  2. Prepare Marijuana for consumption by a Registered Qualifying Patient; and
  3. Administer Marijuana to a Registered Qualifying Patient or facilitate consumption of Marijuana for medical use by the Qualifying Patient.
- (b) An Institutional Caregiver may not:
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 a Registered Qualifying Patient;
  4. Allow a Registered Qualifying Patient who is younger than 18 years old to possess Marijuana at any time when not in the presence of a Caregiver;
  5. Receive payment or compensation above and beyond his or her regular wages; or
  6. Participate in paid advertising
- (c) An Institutional Caregiver shall notify their employing Caregiving Institution of any changes in his or her registration information within 24 hours of the change.

501.027: Hardship Cultivation Registration

- (1) A Qualifying Patient registered with the Commission pursuant to 935 CMR 501.015 may apply for a Hardship Cultivation Registration if such patient can demonstrate that his or her access to an MTC is limited by:

501.027: continued

- (a) Verified financial hardship;
  - (b) 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 an MTC that will deliver Marijuana to the patient's or Personal Caregiver's primary address;
  - (c) Lack of an MTC within a reasonable distance of the patient's primary residence and lack of an MTC that will deliver Marijuana to the patient's or Personal Caregiver's primary address; or
  - (d) Lack of access to a medicine essential for the Qualifying Patient's treatment plan.
- (2) To obtain a Hardship Cultivation Registration, a Registered Qualifying Patient shall, in a form and manner determined by the Commission, submit the following:
  - (a) Information supporting a claim that access is limited due to one or more of the circumstances listed in 935 CMR 501.027(1);
  - (b) An explanation, including lack of feasible alternatives, to mitigate the limitation claimed under 935 CMR 501.027(1);
  - (c) A description and address of the single location that shall be used for the cultivation of Marijuana, which shall be either the Registered Qualifying Patient's or one Personal Caregiver's primary residence;
  - (d) A written explanation of how the Registered Qualifying Patient will cultivate Marijuana in accordance with the requirements of 935 CMR 501.027;
  - (e) A description of the device or system that will be used to ensure security and prevent diversion of the Marijuana plants being cultivated;
  - (f) Written acknowledgment of the limitations on their authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth; and
  - (g) Any other information required by the Commission.
- (3) The Commission shall review and approve or deny an application for a Hardship Cultivation Registration within 30 calendar days of receipt of a completed application.
- (4) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their Personal Caregiver(s), may cultivate only at the location specified in the application approved by the Commission.
- (5) A Hardship Cultivation Registration will be valid for one year from the date of issue. On the issuance of a new certificate, the holder of the certificate shall destroy any previously issued certificate in a responsible manner that would prevent it from being used as a certificate.
- (6) A Hardship Cultivation Registration may be renewed, in a form and manner determined by the Commission, on an annual basis, which includes, but is not limited to, meeting the requirements in 935 CMR 501.027(2).
- (7) A Hardship Cultivation Registration shall allow the Registered Qualifying Patient or their Personal Caregiver(s) to cultivate a limited number of plants sufficient to maintain a 60-day Supply of Marijuana solely for that patient's use.
- (8) A Registered Qualifying Patient is prohibited from possessing or cultivating more than 12 Flowering plants and 12 Vegetative plants, excluding Clones, without a Hardship Cultivation Registration.
- (9) Cultivation and storage of Marijuana shall be in an enclosed, locked area accessible only to the Registered Qualifying Patient or their Personal Caregiver(s), subject to 935 CMR 501.840. Marijuana may not be visible from the street or other public areas.
- (10) A Registered Qualifying Patient engaging in Hardship Cultivation shall comply with all applicable municipal or state requirements for electrical usage and fire safety, and shall document its fire safety plan and electrical and fire inspections.



501.027: continued

(11) A Registered Qualifying Patient or their Personal Caregiver(s) cultivating Marijuana pursuant to a Hardship Cultivation Registration shall adhere to any standards specified by the Commission.

(12) A Registered Qualifying Patient and their Personal Caregiver(s) are prohibited from selling, bartering, giving away or distributing in any manner Marijuana cultivated pursuant to a Hardship Cultivation Registration.

(13) The Commission may inspect the cultivation site of a Registered Qualifying Patient with a Hardship Cultivation Registration, or the cultivation site of their Personal Caregiver(s), at a reasonable time, with reasonable notice as defined by the Commission, taking into consideration the circumstances of the Registered Qualifying Patient. Acceptance of a Hardship Cultivation Registration by a Registered Qualifying Patient constitutes consent for such inspection of the cultivation site. The Commission may not provide notice in cases of suspected diversion, where the Commission is working with Law Enforcement Authorities.

(14) Registration for hardship cultivation may be available in a form and manner determined by the Commission. If, prior to the Program Transfer, a Registered Qualifying Patient received Written Certification of a Debilitating Medical Condition from a physician and used that Written Certification as a limited cultivation registration, the initial limited cultivation registration will remain valid until the application for the Hardship Cultivation Registration card is approved or denied by the Commission.

(15) After obtaining a Hardship Cultivation Registration, a Registered Qualifying Patient is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any change to the information that they or their Personal Caregiver(s) was previously required to submit to the Commission.

(16) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their Personal Caregiver(s) if applicable, shall have the registration available at the site of cultivation. The Commission may make such registration available on request of the Registered Qualifying Patient or other government agency acting within their lawful authority.

501.029: Registration and Conduct of Independent Testing Laboratory Agents

(1) An Independent Testing Laboratory providing testing services for an MTC or Marijuana Establishment in compliance with 935 CMR 501.000, or 935 CMR 500.000: *Adult Use of Marijuana*, shall apply for Laboratory Agent registration for any of its employees, consultants or volunteers that will be in possession of Marijuana for medical use on behalf the Independent Testing Laboratory.

(2) An application for registration of a Laboratory Agent, submitted to the Commission by an Independent Testing Laboratory, shall include:

- (a) The full name, date of birth and address of the individual;
- (b) All aliases used previously or currently in use by the individual, including maiden name, if any;
- (c) Written acknowledgment signed by the applicant of the limitations on his or her authorization to possess, test, Transfer, or Process Marijuana or Marijuana Products in the Commonwealth;
- (d) A copy of the applicant's driver's license, government issued identification card, or other verifiable identity document acceptable to the Commission;
- (e) An attestation signed by the applicant that the applicant will not engage in the diversion of Marijuana and Marijuana Products;
- (f) A nonrefundable application fee, as required by the Commission; and
- (g) Any other information required by the Commission.

501.029: continued

(3) An Independent Testing Laboratory Person Having Direct Control registered with the Massachusetts DCJIS pursuant to 803 CMR 2.04: *iCORI Registration* shall submit to the Commission a CORI report and any other background check information required by the Commission for each individual for whom the Independent Testing Laboratory seeks a Laboratory Agent registration, obtained within 30 calendar days prior to submission.

(4) An Independent Testing Laboratory shall notify the Commission no more than one business day after a Laboratory Agent ceases to be associated with the Independent Testing Laboratory. The Laboratory Agent's registration shall be immediately void when the agent is no longer associated with the Independent Testing Laboratory.

(5) A Registration Card shall be valid for one year from the date of issue. The Commission will accept Registration Cards validly issued prior to the Program Transfer. A Registration Card will remain valid until its one-year anniversary date or until a new Registration Card is issued by the Commission, whichever occurs first. On the issuance of a new Registration Card, the holder of the Registration Card shall be destroyed any previously issued Registration Card(s) in a responsible manner that would prevent it from being used as an identification or Registration Card.

(6) A Registration Card may be renewed on an annual basis on a determination by the Commission that the applicant for renewal continues to be suitable for registration based on satisfaction of the requirements included in 935 CMR 501.800 and 935 CMR 501.801 or 935 CMR 501.803.

(7) After obtaining a Registration Card for a Laboratory Agent, an Independent Testing Laboratory is responsible for notifying the Commission, in a form and manner determined by the Commission, as soon as possible, but in any event, within five business days of any changes to the information that the Independent Testing Laboratory was previously required to submit to the Commission or after discovery that a Registration Card has been lost or stolen.

(8) A Laboratory Agent shall always carry the Registration Card associated with the appropriate Independent Testing Laboratory while in possession of Marijuana Products, including at all times while at an Independent Testing Laboratory, or while transporting Marijuana or Marijuana Products.

501.030: Registration of Medical Marijuana Treatment Center Agents

(1) An MTC shall apply for MTC agent registration for all its, employees, Executives, Owners, and volunteers who are associated with that MTC. The Commission shall issue an Agent Registration Card to each individual determined to be suitable for registration. All such individuals shall:

- (a) Be 21 years of age or older;
- (b) Have not been convicted of an offense in the Commonwealth involving the distribution of controlled substances to minors, or a like violation of the laws of other jurisdictions; and
- (c) Be determined suitable for registration consistent with the provisions of 935 CMR 501.800 and 935 CMR 501.801 or 935 CMR 501.802.

(2) An application for registration of an MTC agent shall include:

- (a) The full name, date of birth and address of the individual;
- (b) All aliases used previously or currently in use by the individual, including maiden name, if any;
- (c) A copy of the applicant's driver's license, government-issued identification card, liquor purchase identification card issued pursuant to M.G.L. c. 138, § 34B, or other verifiable identity document acceptable to the Commission;
- (d) An attestation that the individual will not engage in the diversion of Marijuana or Marijuana Products;

501.030: continued

- (e) Written acknowledgment by the individual of the limitations on their authorization to cultivate, harvest, prepare, package, possess, transport, and dispense marijuana for medical purposes in the Commonwealth;
  - (f) background information including, as applicable:
    - 1. A description and the relevant dates of any criminal action under the laws of the Commonwealth, or an Other Jurisdiction, whether for a felony or misdemeanor and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;
    - 2. A description and the relevant dates of any civil or administrative action under the laws of the Commonwealth, or an Other Jurisdiction, relating to any professional or occupational or fraudulent practices;
    - 3. A description and relevant dates of any past or pending 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;
    - 4. A description and relevant dates of any past discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or an Other Jurisdiction, with regard to any professional license or registration held by the applicant; and
  - (g) A nonrefundable application fee paid by the MTC with which the MTC Agent will be associated; and
  - (h) Any other information required by the Commission
- (3) An MTC Executive registered with DCJIS pursuant to 803 CMR 2.04: *iCORI Registration*, shall submit to the Commission a CORI report and any other background check information required by the Commission for each individual for whom the MTC seeks an MTC agent registration, obtained within 30 calendar days prior to submission.
- (a) The CORI report obtained by the MTC shall provide information authorized under Required Access Level 2 pursuant to 803 CMR 2.05(3)(a)2.
  - (b) The MTC's collection, storage, dissemination and usage of any CORI report or background check information obtained for MTC Agent registrations shall comply with 803 CMR 2.00: *Criminal Offender Record Information (CORI)*.
- (4) An MTC shall notify the Commission no more than one business day after an MTC agent ceases to be associated with the MTC. The registration shall be immediately void when the agent is no longer associated with the MTC.
- (5) An Agent Registration Card shall be valid for one year from the date of issue and may be renewed thereafter on a triennial basis on a determination by the Commission that the applicant for renewal continues to be suitable for registration.
- (6) After obtaining a Registration Card for an MTC agent, an MTC is responsible for notifying the Commission, in a form and manner determined by the Commission, as soon as possible, but in any event, within five business days of any changes to the information that the MTC was previously required to submit to the Commission, or after discovery that a Registration Card has been lost or stolen.
- (7) An MTC agent shall always carry a Registration Card associated with the appropriate Marijuana Establishment while in possession of Marijuana or Marijuana Products, including at all times while at an MTC or while transporting Marijuana or Marijuana Products.
- (8) An Agent working in a CMO may only perform tasks and duties permitted by the license under which they are registered and may only perform both medical- and adult-use tasks and duties if registered under both 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000.

501.031: 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 temporary or an annual Registration Card for a Registered Qualifying Patient or Personal Caregiver, or a Registration Card for an MTC agent, including Laboratory Agents, or a Hardship Cultivation Registration:

- (1) Failure to provide the information required in 935 CMR 501.027, 935 CMR 501.029 or 935 CMR 501.030 for an Agent Registration Card or Hardship Cultivation Registration;
- (2) Provision of information on the application that is deceptive, misleading, false, or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure;
- (3) Failure to meet the requirements set forth in 935 CMR 501.027, 935 CMR 501.029 or 501.030 for an Agent Registration Card or Hardship Cultivation Registration;
- (4) Revocation or suspension of an Agent Registration Card or Hardship Cultivation Registration in the previous six months;
- (5) Failure by the MTC to pay all applicable fees; or
- (6) Other grounds, as the Commission may determine in the exercise of its discretion, that are directly related to the applicant's ability to serve as an MTC agent, or that make the applicant unsuitable for registration; however, the Commission will provide notice to the applicant of the grounds prior to the denial of the Agent Registration Card and a reasonable opportunity to correct these grounds.
  - (a) The Commission may delegate Registrants' suitability determinations to the Executive Director, who may appoint a Suitability Review Committee, in accordance with 935 CMR 501.800. Suitability determinations shall be based on credible and reliable information.
  - (b) The Executive Director may institute a suitability review based on a recommendation from Enforcement staff that background check information would result in or could support an adverse suitability determination. All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 501.800.

501.032: Revocation of a Registration Card or Hardship Cultivation Registration

(1) Each of the following, in and of itself, constitutes full and adequate grounds for revocation of a temporary or an annual Registration Card issued to a Registered Qualifying Patient or Personal Caregiver or a Registration Card issued to an MTC agent, Laboratory Agent or a Hardship Cultivation Registration:

- (a) Submission of information in the application or renewal application that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure;
- (b) Violation of the requirements of the state Marijuana laws, including 935 CMR 501.000;
- (c) Fraudulent use of a Registration Card including, but not limited to, tampering, falsifying, altering, modifying, duplicating, or allowing another person to use, tamper, falsify, alter, modify, or duplicate an Agent Registration Card or Hardship Cultivation Registration;
- (d) Selling, Transferring, distributing, or giving Marijuana to any unauthorized person;
- (e) Failure to notify the Commission within five business days after becoming aware that the Agent Registration Card has been lost, stolen, or destroyed;
- (f) Failure to notify the Commission within five business days after a change in the registration information contained in the application or required by the Commission to have been submitted in connection with the application an Agent Registration Card, including open investigations or pending actions as delineated in 935 CMR 501.802, as applicable, that may otherwise affect the status of the suitability for registration of the MTC agent;
- (g) Conviction, guilty plea, plea of *nolo contendere*, or admission to sufficient facts of a felony drug offense involving distribution to a minor in the Commonwealth, or a like violation of the laws of an Other Jurisdiction; or

501.032: continued

(h) Conviction, guilty plea, plea of *nolo contendere* or admission to sufficient facts in the Commonwealth, or a like violation of the laws of another state, to an offense as delineated in 935 CMR 501.802 or 501.803, as applicable, that may otherwise affect the status of the suitability for registration of the MTC agent.

(2) In addition to the grounds in 935 CMR 501.032(1), each of the following, in and of itself, shall be adequate grounds for the revocation of a Patient Registration Card:

- (a) The Qualifying Patient is no longer a resident of the Commonwealth;
- (b) The Qualifying Patient, taking into account the amounts of Marijuana, Marijuana Products or MIPs obtained by his or her Personal Caregiver, if applicable, knowingly and intends to subvert, seeks to obtain or obtains more of such amounts than is allowable under 935 CMR 501.105; or
- (c) The Qualifying Patient has used Marijuana in a manner that puts at risk the health, safety, or welfare of others, or has failed to take reasonable precautions to avoid putting others at such risk.

(3) In addition to the grounds in 935 CMR 501.032(1), a conviction of a felony drug offense in the Commonwealth, or a like violation of the laws of an Other Jurisdictions shall be adequate grounds for the revocation of an MTC Agent Registration Card.

(4) In addition to the applicable grounds in 935 CMR 501.032(1) through (3), any other ground that serves the purposes of M.G.L. c. 94I, or 935 CMR 501.000 shall be sufficient to revoke a Registration Card or Hardship Cultivation Registration.

(5) Other grounds as the Commission may determine in the exercise of its discretion, that are directly related to the applicant's ability to serve as an MTC agent, that make the Registrant unsuitable for registration. The Commission will provide notice to the Registrant of the grounds prior to the revocation of an Agent Registration Card and a reasonable opportunity to correct these grounds.

- (a) The Commission may delegate Registrants' suitability determinations to the Executive Director, who may appoint a Suitability Review Committee, in accordance with 935 CMR 500.801. Suitability determinations shall be based on credible and reliable information.
- (b) The Executive Director may institute a suitability review based on a recommendation from Enforcement staff that background check information would result in or could support an adverse suitability determination. All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 501.800.

501.033: Void Registration Cards

(1) A Registration Card validly issued prior to the Program Transfer shall be void on the issuance of a new Registration Card.

(2) A Registration Card issued to an MTC agent shall be void when:

- (a) The agent has ceased to be associated with the MTC or Independent Testing Laboratory that applied for and received the agent's Registration Card;
- (b) The card has not been surrendered on the issuance of a new Registration Card based on new information; or
- (c) The MTC agent is deceased.

(3) A Patient Registration Card, including a Hardship Cultivation Registration, shall be void when:

- (a) The card has not been surrendered upon the issuance of a new Registration Card;
- (b) The Qualifying Patient is no longer a resident of Massachusetts; or
- (c) The Patient is deceased.

501.033: continued

- (4) A Personal Caregiver Registration Card is void:
  - (a) When the Registered Qualifying Patient has notified the Commission that the individual registered as the Personal Caregiver is no longer the Personal Caregiver for that Patient;
  - (b) When the sole Registered Qualifying Patient for whom the Personal Caregiver serves as such is no longer registered with the Commission; or
  - (c) Five days after the death of the Registered Qualifying Patient, to allow for appropriate disposal of Marijuana pursuant to 935 CMR 501.105.
- (5) A void temporary or annual Registration Card is inactive and invalid.

501.034: Revocation of a Certifying Healthcare Provider Registration

- (1) Each of the following, in and of itself, constitutes full and adequate grounds for revoking a Certifying Healthcare Provider registration:
  - (a) The Certifying Healthcare Provider fraudulently issued a Written Certification;
  - (b) The Certifying Healthcare Provider failed to comply with the requirements of M.G.L. c 94I, or any applicable provisions of 935 CMR 501.000;
  - (c) The Certifying Healthcare Provider issued a Written Certification without completion of continuing professional development credits pursuant to 935 CMR 501.010(1); or
  - (d) Any other ground that serves the purposes of M.G.L. c. 94I, or 935 CMR 501.000.

501.035: Void Certifying Physician Registration

- (1) When a Certifying Healthcare Provider's license to practice medicine or nursing, as applicable, in Massachusetts is no longer active, or is summarily suspended, suspended, revoked, or restricted with regard to prescribing, or the Certifying Healthcare Provider has voluntarily agreed not to practice medicine, or nursing, in Massachusetts, as applicable, or the Certifying Healthcare Provider's Massachusetts controlled substances registration is suspended or revoked, the Certifying Healthcare Provider's registration to certify a Debilitating Medical Condition for a Qualifying Patient is immediately void.
- (2) When a Certifying Healthcare Provider surrenders his or her registration, the registration is void.
- (3) A void Certifying Healthcare Provider registration is inactive and invalid.

501.040: Leadership Rating Program for Medical Marijuana Treatment Centers

- (1) Leadership Rating Categories. In a time and manner to be determined by the Commission, Licensees will be eligible to earn leadership ratings in the following categories:
  - (a) Social Justice Leader;
  - (b) Local Employment Leader;
  - (c) Energy and Environmental Leader;
  - (d) Compliance Leader; and
  - (e) Medical Treatment Center Leader.
- (2) Leadership Rating Application.
  - (a) MTCs annually submit information, in a time and manner determined by the Commission, demonstrating their eligibility for the applicable leadership rating.
  - (b) All information submitted is subject to verification and audit by the Commission prior to the award of a leadership rating.
  - (c) Award of a leadership rating in one year does not entitle the applicant to a leadership rating for any other year.
- (3) Leadership Rating Criteria.
  - (a) Social Justice Leader. In the year preceding the date of application for a leadership rating, a licensee satisfies at least two of the following:
    1. Upon the Legislature's establishment of a dedicated Social Equity or Technical Assistance Fund (Fund) or a similar fund, 1% of the MTC's gross revenue is donated to the Fund. This requirement will not go into effect until such a Fund is created; and

501.040: continued

2. The Licensee has conducted 50 hours of educational seminars targeted to residents of Areas of Disproportionate Impact in one or more of the following: Marijuana cultivation, Marijuana Product manufacturing, Marijuana retailing, or Marijuana business training;
3. The Licensee can demonstrate that a majority of employees have a conviction or continuance without a finding for an offense under M.G.L. c. 94C or an equivalent conviction in Other Jurisdictions;
4. 66% or more of the Licensee's employees are people of color, women, Veterans, persons with disabilities, and LGBTQ+ people;
5. The Licensee has developed, and can demonstrate execution of, a Diversity Plan or Positive Impact Plan recognized as exemplary by the Commission in its discretion; and
6. The Licensee can demonstrate that in a year, at least one percent of its gross revenue or a minimum of 20 hours of each staff member's paid time is contributed to supporting Qualifying Patients and Caregivers.

A Social Justice Leader may use a logo or symbol created by the Commission to indicate its leadership status.

(b) Local Employment Leader. In the year preceding the date of application for a leadership rating:

1. 51% or more of the Licensee's employees have been a Massachusetts Resident for 12 months or more, as determined by the Commission; and
2. 51% or more of the Licensee's Executives have been a Massachusetts Resident for 12 months or more, as determined by the Commission.
3. 51% or more of ancillary business service expenditures purchased by the Licensee have been from businesses with its primary place of businesses within Massachusetts.

(c) Energy and Environmental Leader. In the year preceding the date of application for a leadership rating, the licensee has met the energy and environmental goals in one or more subcategories in compliance with criteria published as Appendix B in the Energy & Environment Compiled Guidance:

1. Energy;
2. Recycling and Waste Disposal;
3. Transportation;
4. Water Usage; and
5. Soil Sampling;

(d) Compliance Leader. In the year preceding the date of application for a leadership rating:

1. All Licensee employees have completed all required trainings for their positions within 90 days of hire;
2. The Licensee has no unresolved written deficiency statements;
3. The Licensee has not been the subject of a Cease and Desist Order or a Quarantine Order;
4. The Licensee has not had its license suspended; and
5. The Licensee has met all timelines required by the Commission.

(e) Medical Marijuana Treatment Center Leader. In the year preceding the date of application for a leadership rating:

1. The MTC has met or exceeded their goals outlined in their submitted verified financial hardship program according to 935 CMR 501.050(1)(h).
2. Demonstrated a consistent availability of Marijuana-infused Products in serving sizes above 5mg of THC and greater than 100mg of THC per package.
3. Maintained a consistent Patient supply as per 935 CMR 501.140(13) and reserved a quantity and variety of Marijuana and Marijuana Products beyond what is required.
4. Demonstrated accessibility in multiple forms including foreign languages, developmental disabilities, Patients with mental and/or physical disabilities, homebound Patients, pediatric Patients, and Patients on hospice.
5. Conducted community outreach to Qualifying Patient communities to educate those communities on the benefits of registering with the medical program.
6. Has no disciplinary actions related to treatment of Qualifying Patients.
7. Offers meaningful pediatric Patient programs or specializes in collaboratively working with families/Patients that need specialized Marijuana and Marijuana Products.

(f) Leadership ratings will be taken into consideration by the Commission in assessing fines pursuant to 935 CMR 501.360 and disciplinary action pursuant to 935 CMR 501.450.

501.050: Medical Marijuana Treatment Centers (MTCs)

(1) General Requirements.

- (a) An MTC is required to be registered to do business in the Commonwealth as a domestic business corporation or another domestic business entity in compliance with 935 CMR 501.000 and to maintain the corporation or entity in good standing with the Secretary of the Commonwealth, DOR, and DUA.
- (b) Control Limitations.
  - 1. No Person or Entity Having Direct or Indirect Control shall be granted, or hold, more than three MTC Licenses.
  - 2. An Independent Testing Laboratory or Standards Laboratory Licensee, or any associated Person or Entity Having Direct or Indirect Control, may not have a License in any other class.
  - 3. To the extent that persons or entities seek to operate a testing facility in the Counties of Dukes County and Nantucket, 935 CMR 501.200 applies.
  - 4. The Commission shall receive notice of any such interests as part of the application pursuant to 935 CMR 501.101.
  - 5. Any Person or Entity Having Direct or Indirect Control, or Licensee, shall be limited to a total of 100,000 square feet of Canopy distributed across no more than three cultivation Licenses under 935 CMR 500.000: *Adult Use of Marijuana* and three MTC Licenses.
- (c) At least one Executive of the entity seeking licensure as an MTC shall register with DCJIS on behalf of the entity as an organization user of iCORI.
- (d) An MTC applicant shall demonstrate initial capital resources of \$500,000 for its first application for licensure as an MTC. An MTC applicant shall demonstrate initial capital resources of \$400,000 for its subsequent application(s) for licensure as an MTC.
- (e) Under a single License, an MTC may not operate more than two locations in Massachusetts at which Marijuana is cultivated, MIPs are prepared, and Marijuana is dispensed.
- (f) An MTC shall operate all activities authorized by the License only at the address(es) reported to the Commission for that license.
- (g) All agents of the MTC shall be registered with the Commission pursuant to 935 CMR 501.030.
- (h) An MTC shall have a program to provide reduced cost or free Marijuana to Patients with documented Verified Financial Hardship. The plan shall outline the goals, programs, and measurements the MTC will pursue as part of the plan.

(2) Cultivation Operations.

- (a) An MTC may perform cultivation operations only at the address approved to do so by the Commission. At the cultivation location, MTCs may cultivate, Process, and package Marijuana, to transport Marijuana to MTCs and to Transfer Marijuana to other MTCs, but not to Patients.
- (b) MTCs shall select a cultivation tier in their initial application for licensure, or if one has not been previously selected, shall do so in their next application for License renewal. Cultivation tiers are based on the square footage of Canopy:
  - 1. Tier 1: up to 5,000;
  - 2. Tier 2: 5,001 to 10,000;
  - 3. Tier 3: 10,001 to 20,000;
  - 4. Tier 4: 20,001 to 30,000;
  - 5. Tier 5: 30,001 to 40,000;
  - 6. Tier 6: 40,001 to 50,000;
  - 7. Tier 7: 50,001 to 60,000;
  - 8. Tier 8: 60,001 to 70,000;
  - 9. Tier 9: 70,001 to 80,000;
  - 10. Tier 10: 80,001 to 90,000; or
  - 11. Tier 11: 90,001 to 100,000.



501.050: continued

(c) Tier Expansion. An MTC may submit an application, in a time and manner determined by the Commission, to change the tier in which it is classified. An MTC may change tiers to either expand or reduce production. If an MTC is applying to expand production, it shall demonstrate that while cultivating at the top of its production tier, it has sold 85% of its product consistently over the six months preceding the application for expanded production for an indoor cultivator, or during the harvest season, prior to the application for expanded production for an outdoor cultivator.

(d) Tier Relegation. In connection with the License renewal process for MTC, the Commission will review the records of the MTC during the six months prior to the application for renewal for an indoor cultivator or during the harvest season prior to the application for renewal for an outdoor cultivator. The Commission may reduce the Licensee's maximum Canopy to a lower tier if the Licensee sold less than 70% of what it produced during the six months prior to the application for renewal for an indoor cultivator or during the harvest season prior to the application for renewal for an outdoor cultivator.

(e) Tier Factors. When determining whether to allow expansion or relegate a Licensee to a different tier, the Commission may consider factors including, but not limited to:

1. Cultivation and production history, including whether the plants/inventory suffered a catastrophic event during the licensing period;
2. Transfer, sales, and excise tax payment history;
3. Existing inventory and inventory history;
4. Sales contracts; and
5. Any other factors relevant to ensuring responsible cultivation, production, and inventory management.

(3) Product Manufacturing Operations. An MTC may perform manufacturing operations only at the address approved to do so by the Commission. At the Processing location, MTCs may obtain, Manufacture, Process and package Marijuana Products, to transport Marijuana Products to MTCs and to Transfer Marijuana Products to other MTCs, but not to Patients.

(4) Dispensing Operations.

(a) An MTC may perform dispensing operations only at the address approved to do so by the Commission. At the dispensing location, the MTC may purchase and transport Marijuana Products from MTCs and transport, sell, Repackage or otherwise transfer Marijuana Products to MTCs and to Registered Qualifying Patients.

(b) MTCs may perform home deliveries to Registered Qualifying Patients or Personal Caregivers from their dispensing location if approved by the Commission to do so. An MTC shall only deliver to an Institutional Caregiver at their Caregiving Institution.

#### 501.052: Independent Testing Laboratories

(1) An Independent Testing Laboratory shall apply for licensure in the manner prescribed in 935 CMR 500.101: *Application Requirements*.

(2) The Commission will accept certificates of registration for Independent Testing Laboratories validly issued prior to the Program Transfer. A certificate will remain valid until the certificate expires or the laboratory is licensed pursuant to 935 CMR 500.101: *Application Requirements*, whichever occurs first.

(3) An Independent Testing Laboratory may not cultivate Marijuana.

(4) An Independent Testing Laboratory may not possess, transport or Process Marijuana other than that necessary for the purposes of testing in compliance with 935 CMR 500.000: *Adult Use of Marijuana* and 935 CMR 501.000. Laboratories registered prior to the Program Transfer and that have not been licensed pursuant to 935 CMR 500.101: *Application Requirements*, are limited to possessing, transporting or Processing Marijuana for the purposes of testing in compliance with 935 CMR 501.000.

(5) An Executive or Member of an MTC is prohibited from being a Person or Entity Having Direct or Indirect Control in an Independent Testing Laboratory providing testing services for any MTC, except as otherwise provided in 935 CMR 501.200.

501.052: continued

(6) No individual employee of a laboratory providing testing services for MTCs may receive direct or indirect financial compensation from any MTC, except as otherwise provided in 935 CMR 501.200.

501.100: Application for Licensing of Medical Marijuana Treatment Centers (MTCs)

501.101: Application Requirements

(1) New Applicants. An MTC applicant shall file, in a form and manner specified by the Commission, an application for licensure as an MTC. The application requirements outlined in 935 CMR 501.101(1) will apply to all MTC applications submitted on or after November 1, 2019. The application shall consist of three sections: Application of Intent; Background Check; and Management and Operations Profile, except as otherwise provided. The applicant may complete any section of the application in any order. Once all sections of the application have been completed, the application may be submitted. Application materials, including attachments, may be subject to release pursuant to M.G.L. c. 66, § 10 and M.G.L. c. 4, § 7, cl. 26.

(a) Application of Intent. An applicant for licensure as an MTC shall submit the following as part of the Application of Intent:

1. Documentation that the MTC is an entity registered to do business in Massachusetts and a list of all Persons or Entities Having Direct or Indirect Control. In addition, the applicant shall submit any contractual, management, or other written document that explicitly or implicitly conveys direct or indirect control over the MTC to the listed person or entity pursuant to 935 CMR 501.050(1)(b);
2. A disclosure of an interest of each individual named in the application in any Marijuana Establishment or MTC application for licensure or Licensee in Massachusetts;
3. Documentation disclosing whether any individual named in the application have past or present business interests in Other Jurisdictions;
4. Documentation detailing the amounts and sources of capital resources available to the applicant from any individual or entity that will be contributing capital resources to the applicant for purposes of establishing or operating the identified MTC for each License applied for. If any person or entity contributing initial capital, either in cash or in kind, would be classified as a Person or Entity Having Direct or Indirect Control, in exchange for the initial capital, they shall also be listed pursuant to 935 CMR 501.101(1)(a)1. Information submitted shall be subject to review and verification by the Commission as a component of the application process. Required documentation shall include:
  - a. The proper name of any individual or registered business name of any entity;
  - b. The street address; provided however, that the address may not be a post office box;
  - c. The primary telephone number;
  - d. Electronic mail;
  - e. The amount and source of capital provided or promised;
  - f. A bank record dated within 60 days of the application submission date verifying the existence of capital;
  - g. Certification that funds used to invest in or finance the MTC were lawfully earned or obtained; and
  - h. Any contractual or written agreement pertaining to a loan of initial capital, if applicable.
5. Documentation of a bond or an escrow account in an amount set by 935 CMR 501.105(16);
6. Identification of the proposed address for the License;
7. Documentation of a property interest in the proposed address. The proposed MTC shall be identified in the documentation as the entity that has the property interest. Interest may be demonstrated by one of the following:
  - a. Clear legal title to the proposed site;
  - b. An option to purchase the proposed site;
  - c. A legally enforceable agreement to give such title; or
  - d. Documentation evidencing permission to use the Premises.

501.101: continued

8. Documentation in the form of a single-page certification signed by the contracting authorities for the municipality (or municipalities) and applicant evidencing that the applicant for licensure and host municipality in which the address of the MTC is located have executed a Host Community agreement;
  9. Documentation that the applicant has conducted a community outreach meeting consistent with the Commission's *Guidance for License Applicants on Community Outreach* within the six months prior to the application submission date. If the MTC will be located in two locations under this License, the applicant shall hold separate and distinct community outreach meetings in each municipality. Documentation shall include:
    - a. Copy of a notice of the time, place and subject matter of the meeting, including the proposed address of the MTC, that was published in a newspaper of general circulation in the city or town at least 14 calendar days prior to the meeting;
    - b. Copy of the meeting notice filed with the city or town clerk, the planning board, the contracting authority for the municipality and local cannabis licensing authority, if applicable;
    - c. Attestation that at least one meeting was held within the municipality where the MTC is proposed to be located;
    - d. Attestation that at least one meeting was held after normal business hours;
    - e. Attestation that notice of the time, place and subject matter of the meeting, including the proposed address of the MTC, was mailed at least seven calendar days prior to the community outreach meeting to abutters of the proposed address of the MTC, and residents within 300 feet of the property line of the petitioner as they appear on the most recent applicable tax list, notwithstanding that the land of any such Owner is located in another city or town;
    - f. Information presented at the community outreach meeting, which shall include, but not be limited to:
      - i. The proposed address of the MTC with the declaration that the proposed MTC is a "Medical Marijuana Treatment Center";
      - ii. Information adequate to demonstrate that the location(s) will be maintained securely;
      - iii. Steps to be taken by the MTC to prevent diversion to minors;
      - iv. A plan by the MTC to provide reduced cost or free Marijuana to Patients with documented Verified Financial Hardship, as defined by the Commission. The plan shall outline the goals, programs, and measurements the MTC will pursue once licensed;
      - v. A plan by the Marijuana Establishment to positively impact the community;
      - vi. Information adequate to demonstrate that the location will not constitute a nuisance as defined by law; and
      - vii. An attestation that community members were permitted to ask questions and receive answers from representatives of the MTC.
  10. A description of plans to ensure that the MTC is or will be compliant with local codes, ordinances, and bylaws for the physical address of the MTC, which shall include, but not be limited to, the identification of all local licensing requirements for the medical use of Marijuana;
  11. A plan by the MTC to positively impact Areas of Disproportionate Impact, as defined by the Commission, for the purposes established in M.G.L. c. 94G, § 4(a½)(iv). The plan shall outline the goals, programs, and measurements the MTC will pursue once licensed;
  12. The requisite nonrefundable application fee pursuant to 935 CMR 501.005; and
  13. Any other information required by the Commission.
- (b) **Background Check.** Prior to an application being considered complete, each applicant for licensure shall submit the following information:
1. The list of individuals and entities in 935 CMR 501.101(1)(a)1.;
  2. Information for each individual identified in 935 CMR 501.101(1)(a)1., which shall include:
    - a. the individual's full legal name and any aliases;
    - b. the individual's address;
    - c. the individual's date of birth;

501.101: continued

- d. a photocopy of the individual's driver's license or other government-issued identification card;
  - e. a CORI Acknowledgment Form, pursuant to 803 CMR 2.09: *Requirements for Requestors to Request CORI*, provided by the Commission, signed by the individual and notarized; and
  - f. any other authorization or disclosure, deemed necessary by the Commission, for the purposes of conducting a background check.
3. Relevant Background Check Information. All Persons and Entities Having Direct or Indirect Control, and those individuals and entities contributing 10% or more in the form of a loan, shall provide information detailing involvement in any of the following criminal, civil, or administrative matters:
- a. A description and the relevant dates of any criminal action under the laws of the Commonwealth, or an Other Jurisdiction, whether for a felony or misdemeanor including, but not limited to, action against any health care facility or facility for providing Marijuana for medical or adult-use purposes, in which those individuals either owned shares of stock or served as board member, Executive, officer, director or member, and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;
  - b. A description and the relevant dates of any civil action under the laws of the Commonwealth, or an Other Jurisdiction including, but not limited to, a complaint relating to any professional or occupational or fraudulent practices;
  - c. A description and relevant dates of any past or pending legal or disciplinary actions in the Commonwealth or any other state against an entity whom the applicant served as a Person or Entity Having Direct or Indirect Control, related to the cultivation, Processing, distribution, or sale of Marijuana for medical or adult-use purposes;
  - d. A description and the relevant dates of any administrative action including any complaint, order, stipulated agreement or settlement, or disciplinary action, by the Commonwealth, or like action in an Other Jurisdiction including, but not limited to:
    - i. The denial, suspension, or revocation, or other action with regard to of a professional or occupational license, registration, or certification or the surrender of a license;
    - ii. Administrative actions with regard to unfair labor practices, employment discrimination, or other prohibited labor practices; and
    - iii. Administrative actions with regard to financial fraud, securities regulation, or consumer protection.
  - e. A description and relevant dates of actions against a license to prescribe or distribute controlled substances or legend drugs held by any Person or Entity Having Direct or Indirect Control that is part of the applicant's application, if any; and
  - f. Any other information required by the Commission.
- (c) Management and Operations Profile. Each applicant shall submit, with respect to each application, a response in a form and manner specified by the Commission, which includes:
- 1. Detailed information regarding its business registration with the Commonwealth, including the legal name, a copy of the articles of organization and bylaws as well as the identification of any doing-business-as names;
  - 2. A certificate of good standing, issued within the previous 90 days from submission of an application, from the Corporations Division of the Secretary of the Commonwealth;
  - 3. A certificate of good standing or certificate of tax compliance issued within the previous 90 days from submission of an application, from the DOR;
  - 4. A certificate of good standing, issued within the previous 90 days from submission of an application, from the DUA, if applicable. If not applicable, a written statement to this effect is required;
  - 5. A proposed timeline for achieving operation of the MTC and evidence that the MTC will be ready to operate within the proposed timeline after notification by the Commission that the applicant qualifies for licensure;

501.101: continued

6. A description of the MTC's plan to obtain a liability insurance policy or otherwise meet the requirements of 935 CMR 501.105(10);
7. A detailed summary of the business plan for the MTC;
8. A detailed summary of operating policies and procedures for the MTC, which shall include, but not be limited to, provisions for:
  - a. Security;
  - b. Prevention of Diversion;
  - c. Storage of Marijuana;
  - d. Transportation of Marijuana;
  - e. Inventory procedures;
  - f. Procedures for quality control and testing of product for potential contaminants;
  - g. Personnel policies;
  - h. Dispensing procedures;
  - i. Recordkeeping procedures;
  - j. Maintenance of financial records; and
  - k. Diversity plans to promote equity among people of color, particularly Black, African American, Latinx, and Indigenous people, women, Veterans, persons with disabilities, and LGBTQ+ people, in the operation of the MTC. The plan shall outline the goals, programs, and measurements the MTC will pursue once licensed.
9. A detailed description of qualifications and intended training(s) for MTC agents who will be employees;
10. The Management and Operation Profile submitted in accordance with 935 CMR 501.101(1)(c) shall demonstrate compliance with the operational requirements set forth in 935 CMR 501.105 through 501.160, as applicable;
11. Disclosure of the proposed hours of operation, and the names and contact information for individuals that will be the emergency contacts for the MTC;
12. The identification of whether the MTC will perform home deliveries to Patients and Caregivers. If so, a detailed summary of the policies and procedures to ensure the safe delivery of Finished Marijuana Products to Patients and Caregivers, including procedures for how Individual Orders will be filled and procedures for reconciling Individual Orders at the close of the business day, shall be provided;
13. A detailed operation plan for the cultivation of Marijuana, including a detailed summary of policies and procedures for cultivation, consistent with state and local law including, but not limited to, the Commission's guidance in effect November 1, 2019;
14. A list of all products that MTC plans to produce, including the following information:
  - a. A description of the types and forms of Marijuana Products that the MTC intends to produce;
  - b. The methods of production;
  - c. A safety plan for the manufacture and production of Marijuana Products; and
  - d. A sample of any unique identifying mark that will appear on any product produced by the applicant as a branding device.
15. A detailed summary of the proposed program to provide reduced cost or free Marijuana to Patients with documented financial hardship; and
16. Any other information required by the Commission.

(2) Application Requirements for MTC Applicants that Submit an Application of Intent prior to November 1, 2019.

- (a) Application of Intent. An applicant for an MTC License shall submit the following as part of the Application of Intent:
  1. Documentation that it is an entity in good standing as specified in 935 CMR 501.050, as well as a list of all Executives of the proposed MTC, and a list of all members, if any, of the entity;
  2. Documentation that it has at least \$500,000 in its control and available, as evidenced by bank statements, lines of credit, or the equivalent, to ensure that the applicant has sufficient resources to operate. 935 CMR 501.101(2) may be fulfilled through demonstration of pooled resources among the individuals or entities affiliated with the applicant. If an entity is submitting more than one application, the capital requirement shall be \$400,000 for each subsequent application;

501.101: continued

3. An attestation signed by an authorized designee of the entity that if the entity is allowed to proceed to the Management and Operations Profile, the entity is prepared to pay a nonrefundable application fee as specified in the applicable notice;
  4. The requisite nonrefundable application fee; and
  5. Any other information required by the Commission.
- (b) Management and Operations Profile. Within 45 days after receipt of an invitation to the Management and Operations Profile, the applicant shall submit a response in a form and manner specified by the Commission, which includes:
1. Detailed information regarding entity, including the legal name, a copy of the articles of organization and bylaws;
  2. The name, address, date of birth, and resumés of each Executive of the applicant and of the members, if any, of the entity, along with a photocopy of their driver's licenses or other government-issued identification cards, and background check information in a form and manner determined by the Commission;
  3. List of all Persons or Entities Having Direct or Indirect Control over the management or policies of the MTC;
  4. A description of the MTC's plan to obtain a liability insurance policy or otherwise meet the requirements of 935 CMR 501.105(10);
  5. A detailed summary of the business plan for the MTC;
  6. An operational plan for the cultivation of Marijuana, including a detailed summary of policies and procedures for cultivation;
  7. If the MTC intends to produce MIPs, a description of the types and forms of MIPs that the MTC intends to produce, and the methods of production;
  8. A detailed summary of operating policies and procedures for the MTC, which shall include, but not be limited to, provisions for security, prevention of diversion, storage of Marijuana, transportation of Marijuana, inventory procedures, including plans for integrating any existing electronic tracking systems with the Seed-to-sale SOR, procedures for quality control and testing of product for potential contaminants, procedures for maintaining confidentiality as required by law, personnel policies, dispensing procedures, recordkeeping procedures, plans for patient education, and any plans for patient or Personal Caregiver home delivery;
  9. A detailed summary of the MTC's policies and procedures for the provision of Marijuana to Registered Qualifying Patients with Verified Financial Hardship without charge or at less than the market price, as required by 935 CMR 501.050(1)(h);
  10. A detailed description of all intended training(s) for MTC agents;
  11. Evidence that the applicant is responsible and suitable to maintain an MTC. Information including, but not limited to, the following factors shall be considered in determining the responsibility and suitability of the applicant to maintain an MTC:
    - a. Demonstrated experience running a business;
    - b. History of providing healthcare services or services providing Marijuana for medical purposes, including provision of services in other states;
    - c. History of response to correction orders issued under the laws or regulations of the Commonwealth or other states;
    - d. Whether the applicant complies with all laws of the Commonwealth relating to taxes and child support and whether the applicant will have workers' compensation and professional and commercial insurance coverage;
    - e. A description and the relevant dates of any criminal action under the laws of the Commonwealth, or Other Jurisdictions, whether for a felony or misdemeanor including, but not limited to, action against any health care facility or facility for providing Marijuana for medical- or adult-use purposes, in which those individuals either owned shares of stock or served as board member, Executive, officer, director or member, and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;
    - f. A description and the relevant dates of any civil action under the laws of the Commonwealth, or Other Jurisdictions including, but not limited to, a complaint relating to any professional or occupational or fraudulent practices;

## 501.101: continued

- i. Fraudulent billing practices;
  - ii. Past or pending legal or disciplinary actions in any other state against any officer, Executive, director, or board member of the applicant or its members, or against any other entity owned or controlled in whole or in part by them, related to the cultivation, Processing, distribution, or sale of Marijuana for medical purposes;
  - iii. Past or pending 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 the Commonwealth or Other Jurisdictions, including denial, suspension, revocation, or refusal to renew certification for Medicaid or Medicare;
  - iv. Past discipline by, or a pending disciplinary action or unresolved complaint by the Commonwealth, or a like action or complaint by Other Jurisdictions, with regard to any professional license or registration of an Executive of the applicant, as well as by any member of the entity, if any; or
  - g. A description and relevant dates of actions against a license to prescribe or distribute controlled substances or legend drugs held by any Person or Entity Having Direct or Indirect Control that is part of the applicant's application, if any; and
  - h. Any attempt to obtain a registration, license, or approval to operate in any state by fraud, misrepresentation, or the submission of false information;
12. Any other information required by the Commission.
- (c) Siting Profile. Within 12 months after receipt of an invitation to submit the Siting Profile, the applicant shall submit a response in a form and manner specified by the Commission, which includes:
- 1. The county, city or town in which the proposed MTC would be sited, and if known, the physical address of the proposed MTC. If Marijuana will be cultivated or MIPs will be prepared at any location other than the dispensing location of the proposed MTC, the physical address of the one additional location where Marijuana will be cultivated or MIPs will be prepared, if known;
  - 2. The applicant shall provide evidence of interest in the subject property or properties. Interest may be demonstrated by one of the following:
    - a. Clear legal title to the proposed site;
    - b. An option to purchase the proposed site;
    - c. A legally enforceable agreement to give such title; or
    - d. Documentation evidencing permission to use the premises;
  - 3. Documentation in the form of a single-page certification signed by the contracting authorities for the municipality (or municipalities) and applicant evidencing that the applicant for licensure and host municipality in which the address of the MTC is located have executed a Host Community agreement(s);
  - 4. A description of plans to ensure that the MTC is or shall be compliant with local codes, ordinances, and bylaws for the physical address of the MTC and for the physical address of the additional location, if any, including the identification of all local licensing bylaws or ordinances for the medical use of Marijuana;
  - 5. A proposed timeline for achieving operation of the MTC and evidence that the MTC will be ready to operate within the proposed timeline after notification by the Commission that the applicant qualifies for licensure; and
  - 6. Any other information required by the Commission.

(3) CMO License Requirements. MTC applicants seeking to operate a Marijuana Establishment shall also comply with 935 CMR 500.101: *Application Requirements*.

501.102: Action on Applications

- (1) Action on Each Application. The Commission shall grant Licenses with the goal of ensuring that the needs of the Commonwealth are met regarding access, quality, and community safety.
- (a) License applications shall be evaluated based on the applicant's:

501.102: continued

1. Demonstrated compliance with the laws and regulations of the Commonwealth;
  2. Suitability for licensure based on the provisions of 935 CMR 501.101(1), 501.800 and 501.801; and
  3. Evaluation of the thoroughness of the applicant's responses to the required criteria. The Commission shall consider each License application submitted by an applicant on a rolling basis.
- (b) The Commission shall notify each applicant in writing that:
1. The application has been deemed complete;
  2. The application has been deemed incomplete, and include the grounds for which it has been deemed incomplete; or
  3. The Commission requires further information within a specified period of time before the packet is determined to be complete.
- (c) Failure of the applicant to adequately address all required items in its application in the time required under 935 CMR 501.102 by the Commission will result in evaluation of the application as submitted. Nothing in 935 CMR 501.101 is intended to confer a property or other right or interest entitling an applicant to a meeting before an application may be denied.
- (d) On determination that the application is complete, a copy of the completed application, to the extent permitted by law, will be forwarded to the municipality in which the MTC will be located. The Commission shall request that the municipality respond within 60 days of the date of the correspondence that the applicant's proposed MTC complies with municipal bylaws or ordinances.
- (e) The applicant shall keep current all information required by 935 CMR 501.000 or otherwise required by the Commission. The applicant shall report any changes in or additions to the content of the information contained in the application to the Commission within five business days after such change or addition. If a material change occurs to an application deemed complete, the Commission may deem the application incomplete pending further review. If an application initially deemed complete, and later deemed incomplete, a notice will be provided to the applicant. An incomplete application must be fully evaluated pursuant to 935 CMR 501.102(1)(a) prior to being deemed complete again and submitted to the Commission pursuant to M.G.L. c. 94G, § 5(a).
- (2) Action on Completed Application.
- (a) The Commission shall review applications from applicants in the order they were submitted as determined by the Commission's electronic licensing system.
- (b) The Commission shall grant or deny a provisional License not later than 90 days following notification to the applicant that all required packets are considered complete. Applicants shall be notified in writing that:
1. the applicant shall receive a provisional License which may be subject to further conditions as determined by the Commission; or
  2. the applicant has been denied a License. Denial shall include a statement of the reasons for the denial.
- (c) Failure of the applicant to complete the application process within the time specified by the Commission in the application instructions shall be grounds for denial of a License.
- (3) Action on Application Submissions under 935 CMR 501.101(2).
- (a) The Commission shall not consider an application that is submitted after the due date specified.
1. An applicant that has submitted an Application of Intent shall be invited to the Management and Operations Profile phase within six months of November 1, 2019. Failure to do so will result in the expiration of the application.
  2. An applicant that has been invited to the Management and Operations Profile shall submit the Management and Operations Profile within 45 days of the invite. Failure to do so will result in the expiration of the application.
  3. An applicant that has been invited to the Management and Operations Profile shall be invited to submit a Siting Profile within 12 months of the invite to the Management and Operations Profile. Failure to do so will result in the expiration of the application.
  4. An applicant that has been invited to the Siting Profile shall obtain a provisional License within 12 months of the invite to the Siting Profile. Failure to do so will result in the expiration of the application.



## 501.102: continued

- (b) Once the Application of Intent and Management and Operations Profile have been submitted, respectively, and deemed complete, the applicant will be invited by notice to the next stage of the application.
- (c) Once the Siting Profile has been deemed complete, the applicant will receive notice. Notice and a copy of the completed application, to the extent permitted by law, will be forwarded to the municipality (or municipalities) in which the MTC will be located. The Commission shall request that the municipalities respond within 60 days of the date of the correspondence that the applicant's proposed MTC is in compliance with municipal bylaws or ordinances.
- (d) Failure of the applicant to adequately address all required items in its application will result in evaluation of the application as submitted. The applicant will not be permitted to provide supplemental materials, unless specifically requested by the Commission.
- (e) The Commission shall grant or deny a provisional License once the application, and all its sections, have been deemed complete and all third-party documentation has been reviewed. Applicants shall be notified in writing that:
  1. The applicant shall receive a provisional License which may be subject to further conditions as determined by the Commission; or
  2. The applicant has been denied a License. Denial shall include a statement of the reasons for the denial.
- (f) 935 CMR 501.103 shall apply to all applicants that are granted a provisional License under 935 CMR 501.101.

501.103: Licensure and Renewal

- (1) Provisional License. On selection by the Commission, an applicant shall submit the required License fee and subsequently be issued a provisional License to develop an MTC, in the name of the entity. Such provisional License shall be subject to reasonable conditions specified by the Commission, if any.
  - (a) The Commission shall review architectural plans for the building or renovation of an MTC. Construction or renovation related to such plans may not begin until the Commission has granted approval. Submission of such plans shall occur in a manner and form established by the Commission including, but not limited to, a detailed floor plan of the Premises of the proposed MTC that identifies the square footage available and describes the functional areas of the MTC, including areas for any preparation of Marijuana Products, and, if applicable, such information for the single allowable off-Premises location in Massachusetts where Marijuana will be cultivated or Marijuana Products will be prepared; and a description of plans to ensure that the MTC will be compliant with requirements of the Americans with Disabilities Act (ADA) Accessibility Guidelines.
 

To demonstrate compliance with 935 CMR 501.120(11), an MTC applicant shall also submit an energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation.
  - (b) An MTC shall construct its facilities in accordance with 935 CMR 501.000, conditions set forth by the Commission in its provisional License and architectural review, and any applicable state and local laws, regulations, permits or licenses.
  - (c) The Commission may conduct inspections of the facilities, as well as review all written materials required in accordance with 935 CMR 501.000.
  - (d) The applicable License fee shall be paid within 90 days from the date the applicant was approved for a provisional License by the Commission. Failure to pay the applicable License fee within the required time frame will result in the License approval expiring. If this occurs, a new License application will need to be completed pursuant to 935 CMR 501.101 and will require Commission approval.
  - (e) To the extent updates are required to the information provided for initial licensure, the MTC shall submit an updated energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with a renewal application submitted under 935 CMR 501.103(4).

501.103: continued

(2) Final License. On completion of all inspections required by the Commission, an MTC is eligible for a final License. All information described in 935 CMR 501.000 that is not available at the time of submission shall be provided to and approved by the Commission before an MTC may receive a final License. Such final Licenses shall be subject to reasonable conditions specified by the Commission, if any.

(a) No person or entity shall operate an MTC without a final License issued by the Commission.

(b) A provisional or final License may not be assigned or transferred without prior Commission approval.

(c) A provisional or final License shall be immediately void if the MTC Ceases to Operate or if, without the permission of the Commission, it relocates.

(d) Acceptance of a provisional or final License constitutes an agreement by the MTC 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 Commission as part of licensure.

(e) The MTC shall post the final License in a conspicuous location on the Premises at each Commission-approved location.

(f) The MTC shall conduct all activities authorized by 935 CMR 501.000 at the address(es) identified on the final License issued by the Commission.

(3) The MTC shall be operational within the time indicated in 935 CMR 501.101(1)(c)5. or as otherwise amended through the application process and approved by the Commission through the issuance of a final License.

(4) Expiration and Renewal of Licensure. The MTC's License, as applicable, shall expire one year after the date of issuance of the provisional License and annually thereafter, and may be renewed as follows, unless an action has been taken based on the grounds set forth in 935 CMR 501.450:

(a) No later than 60 calendar days prior to the expiration date, an MTC shall submit a completed renewal application to the Commission in a form and manner determined by the Commission, as well as the required License fee.

(b) The MTC shall submit as a component of the renewal application a report or other information demonstrating the establishment's efforts to comply with the plans required under 935 CMR 501.101(1), including 935 CMR 501.101(1)(a)11. and 935 CMR 501.101(1)(c)8.k., as applicable. The report will, at a minimum, have detailed, demonstrative, and quantifiable proof of the establishment's efforts, progress, and success of said plans.

(c) An MTC engaged in indoor cultivation shall include a report of the MTC's energy and water usage over the 12-month period preceding the date of the application.

(d) To the extent updates are required to the information provided for initial licensure, the MTC shall submit an updated energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with a renewal application submitted under 935 CMR 501.103(4).

(e) The MTC shall submit as a component of the renewal application certification of good standing from the Secretary of the Commonwealth, the DOR, and the DUA. Certificates of good standing will be accepted if issued within 90 days of the submittal of the renewal application.

(f) A MTC shall submit, as a component of the renewal application documentation that the establishment requested from its Host Community, the records of any cost to a city or town reasonably related to the operation of the establishment, which would include the city's or town's anticipated and actual expenses resulting from the operation of the establishment in its community. The applicant shall provide a copy of the electronic or written request, which should include the date of the request, and either the substantive response(s) received or an attestation that no response was received from the city or town. The request should state that in accordance with M.G.L. c. 94G, § 3(d), any cost to a city or town imposed by the operation of a Marijuana Establishment or MTC shall be documented and considered a public record as defined by M.G.L. c. 4, § 7, cl. 26.

(g) The MTC shall update as needed, and ensure the accuracy of, all information that it submitted on its initial application for a License.

501.103: continued

- (h) The MTC shall comply with the requirements of 935 CMR 501.104(1) in accordance with that section separately from the renewal application.
- (i) The Commission shall issue a renewal License within 30 days of receipt of a renewal application and renewal License fee from an MTC to a Licensee, if the Licensee:
  1. Is in good standing with the Secretary of the Commonwealth, DOR, and DUA;
  2. Provided documentation demonstrating substantial effort or progress towards achieving its goals submitted as part of its plans required under 935 CMR 501.101(1), including 935 CMR 501.101(1)(a)11. and 501.101(1)(c)8.k., as applicable; and
  3. No new information submitted as part of the renewal application, or otherwise obtained, presents suitability issues for any individual or entity listed on the application or License.
- (j) CMO Marijuana Retailers shall submit the following information pertaining to patient supply of marijuana:
  1. The licensee's policy and the procedures (*e.g.*, data points, formulas) relied on to determine what constitutes a sufficient quantity and variety of marijuana products consistent with 935 CMR 501.140(13); and
  2. The licensee's policy and procedures for determining what qualifies as a reasonable substitution for a medical marijuana product under 935 CMR 501.140(13) and its policy for communicating reliance on the substitution to Patients.

501.104: Notification and Approval of Changes

- (1) Prior to making the following changes, an MTC shall submit a request for such change to the Commission and pay the appropriate fee. No such change shall be permitted until approved by the Commission or in certain cases, the Commission has delegated authority to approve changes to the Executive Director. Failure to obtain approval of such changes may result in a License being suspended, revoked, or deemed void.
  - (a) Location Change. Prior to changing its location, the MTC shall submit a request for such change to the Commission.
  - (b) Ownership or Control Change.
    1. Ownership Change. Prior to any change in ownership, where an Equity Holder acquires or increases its ownership to 10% or more of the equity or contributes 10% or more of the initial capital to operate the MTC, including capital that is in the form of land or buildings, the MTC shall submit a request for such change to the Commission.
    2. Control Change. Prior to any change in control, where a new Person or Entity Having Direct or Indirect Control should be added to the License, the MTC shall submit a request for such change to the Commission prior to effectuating such a change. An individual, corporation, or entity shall be determined to be in a position to control the decision-making of an MTC if the individual, corporation, or entity falls within the definition of Person or Entity Having Direct or Indirect Control.
  - (c) Structural Change. Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of the MTC, the establishment shall submit a request for such change to the Commission.
  - (d) Name Change. Prior to changing its name, the MTC shall submit a request for such change to the Commission. Name change requests, and prior approval, shall apply to an establishment proposing a new or amending a current doing-business-as name.
  - (e) Court Supervised Proceedings. Notification and approval requirements with respect to Court Appointees and Court Supervised Proceedings are detailed in 935 CMR 501.104(3).
- (2) The Executive Director of the Commission may approve, provided the Executive Director gives the Commission timely notice of his or her decision:
  - (a) A Location Change;
  - (b) A Name Change;
  - (c) Any new equity owner, provided that the equity acquired is below 10%;
  - (d) Any new Executive or Director, provided that the equity acquired is below 10%;
  - (e) A reorganization, provided that the ownership and their equity does not change; and
  - (f) Court Appointees, as detailed in 935 CMR 501.104(3).

501.104: continued

(3) Court Supervised Proceedings.(a) Commission Petition.

1. The Commission or its delegee may seek to file a petition where there is an imminent threat or danger to the public health, safety or welfare, which may include one or more of the following:
  - a. Notice of violations of state or federal criminal statutes including, but not limited to, M.G.L. c. 94C, §§ 32 and 34;
  - b. Noncompliance with or violations of its statute or regulations such that the imposition of fines or other disciplinary actions would not be sufficient to protect the public;
  - c. Conditions that pose a substantial risk of diversion of Marijuana or Marijuana Products to the illicit market or to individuals younger than 21 years of age who do not possess a valid pediatric Patient Registration Card issued by the Commission;
  - d. Conditions that pose a substantial risk to Patients;
  - e. Violations of testing or inventory and transfer requirements such that the Commission cannot readily monitor Marijuana and Marijuana Products cultivated, manufactured, transported, delivered, transfer, or sold by a Licensee; or
  - f. Other circumstance that the Commission or its delegee determines possess an imminent threat or danger to public health, safety, or welfare exists.
2. The Commission or its delegee may seek to file a petition, intervene, or otherwise participate in a Court Supervised Proceeding or any other proceeding to secure its rights under M.G.L. c. 94G, § 19.
3. Nothing in 935 CMR 501.104(3) shall limit the Commission's authority under M.G.L. c. 94G, § 4(a)(v).

(b) Delegation. In accordance with M.G.L. c. 10, § 76(j), the Commission may delegate to the Executive Director the authority to appear on its behalf in Court Supervised Proceedings or any other proceeding, and to administer and enforce its regulations relative to such proceedings or Court Appointees which includes, but it not limited to, the following:

1. To determine the form and manner of the application process for a Preapproved Court Appointee;
2. To preapprove, recommend, disqualify, or discipline Court Appointees;
3. To approve the distribution of escrow funds under 935 CMR 501.105(10) or bond funds under 935 CMR 501.105(16) including, but not limited to, to cover the cost of a Court Appointee or the operations of an MTC under supervision subject to the receipt of a court order prior to the expenditure of such funds;
4. To approve the use of additional funds subject to the receipt of a court order prior to the expenditure of such funds;
5. To preapprove or approve certain transactions; provided, however, any change in the ownership or control under 935 CMR 501.104(1) shall be considered by the Commission; or
6. To impose fines or other disciplinary action under 935 CMR 501.500, however, any suspension or revocation of a License under 935 CMR 501.450 shall be considered by the Commission.

(c) Notice to the Commission.

1. A Licensee or Person or Entity Having Direct or Indirect Control over a Licensee shall provide notice to the Commission of a petition or Court Supervised Proceeding or any other proceeding implicating 935 CMR 501.000:
  - a. Five business days prior to the Licensee or Person or Entity Having Direct or Indirect Control filing a petition; or
  - b. On receipt of notice that a petition was filed or of an imminent threat of litigation that could lead to the appointment of a Court Appointee.
2. Notice to the Commission shall include a copy of the relevant communications, petition, pleadings and supporting documents, and shall be sent electronically to [Commission@CCCMass.Com](mailto:Commission@CCCMass.Com) and by mail to the Cannabis Control Commission at:

Cannabis Control Commission  
 ATTN: General Counsel - Court Appointees  
 Union Station  
 2 Washington Square  
 Worcester, MA 01604

501.104: continued

3. As soon as practicable, the Licensee or Person or Entity Having Direct or Indirect Control over a Licensee shall provide electronic and written notice to the Commission if the circumstances giving rise to the petition pose or may pose a threat to the public health, safety or welfare.
  4. As soon as practicable, the Licensee or Person or Entity Having Direct or Indirect Control over a Licensee shall provide notice to the court that it is licensed by the Commission and of the regulations relative to Court Supervised Proceedings and Court Appointees including, but not limited to, the qualifications for a Court Appointee established in 935 CMR 501.104(3)(d)1., and the list of Preapproved Court Appointees.
  5. A Licensee or Person or Entity Having Direct or Indirect Control over a Licensee that fails to comply with the requirements of 935 CMR 501.104(3) may be subject to disciplinary action including, but not limited to, revocation or suspension of any license or registration under 935 CMR 501.450.
- (d) Commission Qualifications for Court Appointees.
1. Qualifications. The Commission deems the following qualifications essential in a Court Appointee, subject to the court's discretion. At a minimum, an individual or entity seeking to be a Preapproved Court Appointee shall demonstrate the following qualifications consistent with the regulatory requirements for licensees. An applicant may seek a waiver of these qualifications under 935 CMR 501.850. The failure to maintain these qualifications may be a basis for disqualification.
    - a. Suitability. An applicant must demonstrate suitability under 935 CMR 501.801: *Table A*.
    - b. Ownership and Control Limits. A person or entity named as a Court Appointee shall, prior to and as a result of being a Court Appointee, be in compliance with the control limitations set forth in 935 CMR 501.050(1)(b) or any other limitations on licensure set forth in 935 CMR 501.000.
  2. Application Process for Preapproved Court Appointees. The Commission or its delegee may preapprove, recommend, disqualify, or discipline Preapproved Court Appointees. A person or entity seeking to be a Preapproved Court Appointee shall pay a fee established in 935 CMR 501.005(7)(a) and submit the following information and make the necessary disclosures:
    - a. Qualifications. An applicant shall demonstrate the qualifications set forth in 935 CMR 501.104(3)(d)1.
    - b. Credentials. An applicant shall demonstrate sufficient training, knowledge and experience, to ensure a Licensee under their or its supervision shall comply with Commissions statutory and regulatory requirements.
    - c. Affiliated Individuals or Entities. An applicant shall identify any person or entity that may exert control or influence over the Preapproved Court Appointee, whether or not such individuals or entities are can exercise the authority of a Court Appointee.
    - d. Engaged Individuals or Entities. An applicant shall identify an person or entity that the applicant intends to engage in conducting the work of a Court Appointee, whether or not such individuals or entities are exercising the authority of a Court Appointee.
    - e. Financial Information. An applicant shall make such financial disclosures necessary to determine its ability to serve as a Court Appointee.
    - f. Licenses. The applicant shall submit any professional or occupational licenses and represent that these licenses are in good standing.
    - g. Good Standing. If the applicant is an entity, it shall submit a valid Certificate of Good Standing issued each by the Secretary of the Commonwealth and the Department of Revenue.
    - h. Limitations. The applicant shall identify any limitations on the ability to serve as a Court Appointee including, but not limited to, capacity, qualifications, credentials, conflicts of interest, and financial requirements.
    - i. An applicant shall submit any additional information the Commission or its delegee may request, in its sole discretion.
    - j. Suitability. An applicant shall demonstrate suitability to operate a Licensee. If the applicant is an entity, each individual exercising the authority of a Court Appointee shall demonstrate suitability as provided in 935 CMR 501.000. An applicant shall demonstrate suitability by:

501.104: continued

- i. Submitting to a criminal background check in accordance with 935 CMR 501.030, 935 CMR 501.101 and 935 CMR 501.105; or
    - ii. Submitting an attestation under the pains and penalties of perjury that the applicant is suitable to operate a Licensee.
  - 3. Application requirements in this 935 CMR 501.104(3)(d)2., shall apply only to persons and entities acting as a Court Appointee.
  - 4. Renewal. In order to remain as Preapproved Court Appointee, each Preapproved Court Appointee, on the anniversary of their preapproval, shall annually attest to the Commission under the pains and penalties of perjury that there has been no material change to the information and disclosures submitted as part of the initial application or provide updated information and disclosures with respect to those that have changed, and pay the fee identified in 935 CMR 501.005(7)(b).
  - (e) Licensee's Obligations. A Licensee placed under the oversight or a Court Appointee shall:
    - 1. Continue to comply with all legal and regulatory requirements applicable to a Licensee, except as otherwise determined pursuant a court order or a waiver granted pursuant to 935 CMR 501.850.
    - 2. Provide the Commission with any documents requested by the Commission.
    - 3. Cooperate with the Commission's efforts to intervene as an interested party in any Court proceeding pursuant to which a Court Appointee is sought.
    - 4. Comply with the requirements of 935 CMR 501.104(1) upon final disposition of the License(s) subject to oversight by a Court Appointee.
    - 5. When a Licensee files a petition, it shall propose in such petition a Court Appointee with the qualifications identified in 935 CMR 501.104(3)(d)1. and/or may choose from the Commission's list of Preapproved Court Appointees.
  - (f) Applicability of 935 CMR 104(3).
    - 1. All Licensees and Persons or Entities having Direct or Indirect Control shall comply with the notice requirements established in 935 CMR 501.104(3)(c).
    - 2. A Person or Entity Having Direct or Indirect Control that has its ownership or control interest placed under the oversight of a Court Appointee shall be exempt from the requirements of subsection 935 CMR 501.104(3)(b) and (d) through (f); provided however, that upon final disposition of the interest in question, the Licensee shall comply with the requirements of 935 CMR 501.104(1), as applicable.
- (4) Assignment for the Benefit of Creditors. A Licensee must seek Commission approval, in a form or manner determined by the Commission, prior to effectuating an Assignment for the Benefit of Creditors. The Commission may delegate authority to approve such agreements to the Executive Director; provided however, that any transfer of a License shall be subject to Commission Approval.
- (5) The MTC shall keep current all information required by 935 CMR 501.000 or otherwise required by the Commission. The MTC shall report any changes in or additions to the content of the information contained in any document to the Commission within five business days after such change or addition.

501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (1) Written Operating Procedures. Every MTC shall have and follow a set of detailed written operating procedures. If the MTC has an additional location, it shall develop and follow a set of such operating procedures for that facility. A CMO shall have written operating procedures that comply with both 935 CMR 501.105(1) and 500.105(1): *Written Operating Procedures* and may do so by having two sets of written operating procedures applicable to each medical-use and adult-use operations or having one set of written operating procedures, provided it complies with both medical-use and adult-use requirements. Operating procedures shall include, but need not be limited to, the following:
- (a) Security measures in compliance with 935 CMR 501.110.
  - (b) Employee security policies, including personal safety and crime prevention techniques.
  - (c) A description of the MTC's hours of operation and after hours contact information, which shall be provided to the Commission, made available to Law Enforcement Authorities on request, and updated pursuant to 935 CMR 501.101(1)(c)11.

501.105: continued

- (d) Storage and waste disposal of Marijuana in compliance with 935 CMR 501.105(11) and 501.105(12).
- (e) Description of the various strains of Marijuana to be cultivated and dispensed, and the form(s) in which Marijuana will be dispensed.
- (f) Price list for Marijuana, MIPs, and any other available products, and alternate price lists for Patients with documented Verified Financial Hardship as required by 935 CMR 501.050(1)(h).
- (g) Procedures to ensure accurate recordkeeping, including inventory protocols for Transfer and inventory and procedures for integrating a secondary electronic system with the Seed-to-sale SOR.
- (h) Plans for quality control, including product testing for contaminants in compliance with 935 CMR 501.160.
- (i) A staffing plan and staffing records in compliance with 935 CMR 501.105(9)(d).
- (j) Emergency procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies.
- (k) Alcohol, smoke, and drug free workplace policies.
- (l) A plan describing how Confidential Information and other records required to be maintained confidentially will be maintained.
- (m) A policy for the immediate dismissal of any MTC Agent who has:
  1. Diverted Marijuana, which shall be reported to Law Enforcement Authorities and to the Commission;
  2. Engaged in unsafe practices with regard to operation of the MTC, which shall be reported to the Commission; or
  3. Been convicted or entered a guilty plea, plea of *nolo contendere*, or admission to sufficient facts of a felony drug offense involving distribution to a minor in the Commonwealth, or a like violation of the laws of any Other Jurisdiction.
- (n) A list of all board of directors, members and Executives of an MTC, and Members, if any, of the Licensee, shall be made available on request by any individual. This requirement may be fulfilled by placing this information on the MTC's website.
- (o) Policies and procedure for the handling of cash on MTC Premises including, but not limited to, storage, collection frequency, and transport to financial institution(s), to be available on inspection.
- (p) The standards and procedures by which the MTC determines the price it charges for Marijuana, and a record of the prices charged, including the MTC's policies and procedures for the provision of Marijuana to Registered Qualifying Patients with Verified Financial Hardship without charge or at less than the market price, as required by 935 CMR 501.050(1)(h).
- (q) Policies and procedures for energy efficiency and conservation that shall include:
  1. Identification of potential energy use reduction opportunities (including, but not limited to, natural lighting, heat recovery ventilation and energy efficiency measures), and a plan for implementation of such opportunities;
  2. Consideration of opportunities for renewable energy generation including, where applicable, submission of building plans showing where energy generators could be placed on the site, and an explanation of why the identified opportunities were not pursued, if applicable;
  3. Strategies to reduce electric demand (such as lighting schedules, active load management and energy storage); and
  4. Engagement with energy efficiency programs offered pursuant to M.G.L. c. 25, § 21, or through municipal lighting plants.
- (r) Policies and procedures to promote workplace safety consistent with the standards set forth under the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651, *et seq.*, including the general duty clause whereby each employer:
  1. shall furnish to each of its employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees;
  2. shall comply with occupational safety and health standards promulgated under 29 U.S.C. § 651, *et seq.* Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to 29 U.S.C. § 651, *et seq.*, which are applicable to the employee's own actions and conduct.

501.105: continued

All current and updated regulations and references at 29 CFR Parts 1903, 1904, 1910, 1915, 1917, 1918, 1926, 1928, and 1977 are incorporated by reference, and applicable to all places of employment covered by 935 CMR 501.000.

(s) A description of the MTC's patient education activities in accordance with 935 CMR 501.140(6).

(2) MTC Agent Training.

(a) MTCs and Independent Testing Laboratories shall ensure that all MTC Agents and Laboratory Agents complete minimum training requirements prior to performing job functions.

1. At a minimum, MTC Agents shall receive a total of eight hours of training annually. The eight-hour total training requirement shall be tailored to the roles and responsibilities of the job function of each MTC Agent.

2. A minimum of four hours of training shall be from Responsible Vendor Training Program courses established under 935 CMR 501.105(2)(b). Any additional RVT hours over the four-hour RVT requirement may count toward the eight-hour total training requirement.

3. Non-RVT training may be conducted in-house by the MTC or by a third-party vendor engaged by the MTC. Basic on-the-job training MTCs provide in the ordinary course of business may be counted toward the eight-hour total training requirement.

4. Agents responsible for tracking and entering product into the Seed-to-sale SOR shall receive training in a form and manner determined by the Commission. At a minimum, staff shall receive eight hours of on-going training annually.

5. MTCs shall maintain records of compliance with all training requirements noted above. Such records shall be maintained for four years and MTCs shall make such records available for inspection on request.

6. An individual who is both a Marijuana Establishment Agent and MTC Agent at a CMO location shall receive the training required for each license under which the agent is registered including, without limitation, with respect to patient privacy and confidentiality requirements, which may result in instances that would require such an agent to participate in more than eight hours of training.

(b) Responsible Vendor Training.

1. All current MTC Agents, including Laboratory Agents, involved in the handling or sale of Marijuana for medical use at the time of licensure or renewal of licensure, as applicable, shall have attended and successfully completed a Responsible Vendor Training Program to be designated a "Responsible Vendor".

a. MTC Agents shall first take the Basic Core Curriculum.

b. On completing the Basic Core Curriculum, an MTC Agent is eligible to take the Advanced Core Curriculum.

c. Exception for Administrative Employees. MTC Agents who serve as administrative employees and do not handle or sell Marijuana are exempt from the four-hour RVT requirement but may take a Responsible Vendor Training Program course on a voluntary basis as part of fulfilling the eight-hour total training requirement.

2. Once an MTC is designated a Responsible Vendor, all MTC Agents employed by the MTC that are involved in the handling or sale of Marijuana for medical use shall successfully complete the Basic Core Curriculum within 90 days of hire.

3. After successful completion of the Basic Core Curriculum, each MTC Agent involved in the handling or sale of Marijuana for medical use shall fulfill the four-hour RVT requirement every year thereafter for the MTC to maintain designation as a Responsible Vendor. Failure to maintain Responsible Vendor status is grounds for action by the Commission.

4. Responsible Vendor Trainer Certification.

a. No owner, manager or employee of a Responsible Vendor Trainer may be a Person or Entity Having Direct or Indirect Ownership or Control of an MTC.

b. Responsible Vendor Trainers shall submit their program materials to the Commission prior to offering courses, every two years following for Commission certification of the Responsible Vendor Trainer and Responsible Vendor Training Program curriculum, and on request. The process for certification will be in a form and manner determined by the Commission.



501.105: continued

- c. Responsible Vendor Training Program courses shall consist of at least two hours of instruction time.
  - d. Except as provided in 935 CMR 501.105(2)(b)4.e., Responsible Vendor Training Program courses shall be taught in a real-time, interactive, virtual or in-person classroom setting in which the instructor is able to verify the identification of each individual attending the program and certify completion of the program by the individual.
  - e. Responsible Vendor Training Program courses may be presented in a virtual format that is not taught in a real-time, provided that the Responsible Vendor Trainer, as part of its application for certification, can demonstrate means:
    - i. To verify the identification of each trainee participating in the program course and certify completion by the individual.
    - ii. To track trainees' time needed to complete the course training;
    - iii. To allow for the trainees to ask questions of the Responsible Vendor Trainer, for example, by email, virtual discussion board, or group/class discussion; and
    - iv. To evaluate each trainee's proficiency with course material.
  - f. Responsible Vendor Trainers shall seek certification for each Basic Core Curriculum and Advanced Core Curriculum. Applications for Advanced Core Curriculum certification will be open on or before July 1, 2022.
  - g. Responsible Vendor Trainers shall maintain its training records at its principal place of business for four years.
  - h. Responsible Vendor Trainers shall make the records available for inspection by the Commission and any other applicable licensing authority on request during normal business hours.
  - i. Responsible Vendor Trainers shall provide to the appropriate MTC and MTC Agent written documentation of attendance and successful evaluation of proficiency, such as passage of a test on the knowledge of the required curriculum for each attendee.
  - j. Trainees who can speak and write English fluently shall successfully demonstrate proficiency, such as passing a written test with a score of 70% or better.
  - k. MTC Agents who cannot speak or write English may be offered a verbal evaluation or test, provided that the same questions are given as are on the written test and the results of the verbal test are documented with a passing score of 70% or better.
  - l. Responsible Vendor Trainers shall solicit effectiveness evaluations from MTC Agents who have completed their program(s).
5. Basic Core Curriculum. The Basic Core Curriculum shall cover the following subject matter:
- a. Marijuana's effect on the human body, including:
    - i. Scientifically based evidence on the physical and mental health effects based on the type of Marijuana Product;
    - ii. The amount of time to feel impairment;
    - iii. Visible signs of impairment; and
    - iv. Recognizing the signs of impairment.
  - b. Diversion prevention and prevention of sales to minors, including best practices.
  - c. Compliance with all tracking requirements.
  - d. Acceptable forms of identification. Training shall include:
    - i. How to check identification;
    - ii. Spotting and confiscating fraudulent identification;
    - iii. Patient registration cards currently and validly issued by the Commission;
    - iv. Common mistakes made in identification verification; and
    - v. Prohibited purchases and practices, including purchases by persons younger than 21 years old in violation of M.G.L. c. 94G, § 13.
  - e. How to engage and work with persons with disabilities.
  - f. Other key state laws and rules affecting MTC Agents, which shall include:
    - i. Conduct of MTC Agents;
    - ii. Permitting inspections by state and local licensing and enforcement authorities;

501.105: continued

- iii. Local and state licensing and enforcement, including registration and license sanctions;
  - iv. Incident and notification requirements;
  - v. Administrative, civil, and criminal liability;
  - vi. Health and safety standards, including waste disposal;
  - vii. Patrons prohibited from bringing marijuana and Marijuana Products onto licensed premises;
  - viii. Permitted hours of sale;
  - ix. Licensee responsibilities for activities occurring within licensed premises;
  - x. Maintenance of records, including confidentiality and privacy; and
  - g. Such other areas of training determined by the Commission to be included in a Responsible Vendor Training Program.
6. Advanced Core Curriculum.
- a. Each Advanced Core Curriculum class shall be approved by the Commission prior to being offered. The curriculum shall build on the knowledge, skills, and practices covered in the Basic Core Curriculum.
  - b. An Advanced Core Curriculum class shall include standard and best practices in one or more of the following areas
    - i. Cultivation;
    - ii. Product Manufacturing;
    - iii. Retail;
    - iv. Transportation;
    - v. Social Consumption;
    - vi. Laboratory Science;
    - vii. Energy and Environmental Best Practices;
    - viii. Social Justice and Economically Reparative Practices;
    - ix. Implicit Bias and Diversity Training;
    - x. Worker Safety;
    - xi. Food Safety and Sanitation;
    - xii. Confidentiality and Privacy;
    - xiii. In depth coverage of any topic(s) taught in the Basic Core Curriculum; or
    - xiv. Such other topic as the Commission may approve in its sole discretion.
7. Delivery Core Curriculum. In addition to the Basic Core Curriculum, all MTC Agents acting as delivery employees of an MTC shall have attended and successfully completed the Delivery Core Curriculum prior to making a delivery, which shall, to the extent not covered in Basic Core Training include, without limitation, training on:
- a. Safely conducting deliveries;
  - b. Safe cash handling practices;
  - c. Strategies for de-escalating potentially dangerous situations;
  - d. Securing product following any instance of diversion, theft or loss of Finished Marijuana Products pursuant to 935 CMR 501.110(1)(m);
  - e. Collecting and communicating information to assist in investigations;
  - f. Procedures for checking identification;
  - g. Indications of impairment; and
  - h. Such other areas of training determined by the Commission to be included in a Responsible Vendor Training Program.
- (3) Handling of Marijuana.
- (a) An MTC shall Process Marijuana in a safe and sanitary manner. An MTC shall Process the 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, and other foreign matter;
    - 3. Free of contamination by mold, rot, other fungus, pests and bacterial diseases and satisfying the sanitation requirements in 105 CMR 500.000: *Good Manufacturing Practices for Food*, and if applicable, 105 CMR 590.000: *State Sanitary Code Chapter X: Minimum Sanitation Standards for Food Establishments*;
    - 4. Prepared and handled on food-grade stainless steel tables with no contact with MTC Agents' bare hands; and
    - 5. Packaged in a secure area.

501.105: continued

- (b) All MTCs, including those that develop, Repackage, or Process non-Edible MIPs, shall comply with the following sanitary requirements:
1. Any MTC 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*;
  2. Any MTC Agent working in direct contact with preparation of Marijuana or non-Edible MIPs shall conform to sanitary practices while on duty, including:
    - a. Maintaining adequate personal cleanliness; and
    - b. 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.
  3. Hand washing facilities shall be located in the MTC 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;
  4. There shall be sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations;
  5. 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 935 CMR 501.105(12);
  6. Floors, walls, and ceilings shall be constructed in such a manner that they may be adequately kept clean and in good repair;
  7. There shall be adequate safety lighting in all Processing and storage areas, as well as areas where equipment or utensils are cleaned;
  8. Buildings, fixtures, and other physical facilities shall be maintained in a sanitary condition;
  9. 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 US 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;
  10. All toxic items shall be identified, held, and stored in a manner that protects against contamination of Marijuana and MIPs. Toxic items may not be stored in an area containing products used in the cultivation of Marijuana. The Commission may require an MTC to demonstrate the intended and actual use of any toxic items found on the Premises;
  11. An MTC'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 MTC's needs;
  12. Plumbing shall be of adequate size and design, and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the MTC. Plumbing shall properly convey sewage and liquid disposable waste from the MTC. There shall be no cross-connections between the potable and wastewater lines;
  13. An MTC shall provide its employees with adequate, readily accessible toilet facilities that are maintained in a sanitary condition and in good repair;
  14. Products that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms;
  15. 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; and
  16. All vehicles and transportation equipment used in the transportation of Marijuana Products or Edibles requiring temperature control for safety shall be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the Marijuana Products or Edibles from becoming unsafe during transportation, consistent with applicable requirements pursuant to 21 CFR 1.908(c).

501.105: continued

(c) All MTCs shall comply with sanitary requirements during the development or Processing of Edibles. All Edibles shall be prepared, handled, and stored in compliance with the sanitation requirements in 105 CMR 590.000: *State Sanitary Code Chapter X - Minimum Sanitation Standards for Food Establishments*.

(d) All Marijuana in the process of cultivation, production, preparation, transport, or analysis shall be housed and stored in such a manner as to prevent diversion, theft, or loss.

1. Such items shall be accessible only to the minimum number of specifically authorized MTC Agents essential for efficient operation;

2. Such items shall be returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and

3. 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. Unless otherwise authorized by the Commission, a CMO shall comply with 935 CMR 500.105(3): *Requirements for the Handling of Marijuana* and 935 CMR 501.105(3).

(4) Advertising Requirements.

(a) Permitted Practices.

1. A Marijuana Establishment may develop a Brand Name to be used in labeling, signage, and other materials; provided however, that use of medical symbols, images of Marijuana or Marijuana Products, or related Paraphernalia, images that are appealing to persons younger than 21 years old, and colloquial references to Marijuana and Cannabis are prohibited from use in the Brand Name

2. Brand Name Sponsorship of a charitable, sporting or similar event, so long as the following conditions are met:

a. Sponsorship of the event is limited to the Brand Name.

b. Any advertising at or in connection with such an event is prohibited, unless such advertising is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching entrants or participants reasonably expected to be younger than 21 years old, as determined by reliable, current audience composition data; unless such advertising is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching entrants or participants reasonably expected to be younger than 21 years old, as determined by reliable, current audience composition data;

3. An MTC engaging in Brand Name Sponsorship under 935 CMR 501.105(4)(a)2. shall retain documentation of reliable, reasonable audience composition data that is the basis for allowing any such advertising or branding for a period of one year, or longer if otherwise required by the Commission, or a court or agency with jurisdiction.

4. An MTC may display, in secure, locked cases, samples of each product offered for sale and subject to the requirements of 935 CMR 501.110 for Marijuana Treatment Centers. These display cases may be transparent. An authorized MTC Agent may remove a sample of Marijuana from the case and provide it to the Registered Qualifying Patient for inspection, provided the Registered Qualifying Patient may not consume or otherwise use the sample, unless otherwise authorized in 935 CMR 501.000.

5. The MTC may post prices in the store and may respond to questions about pricing. The MTC shall provide a catalogue or a printed list of the prices and strains of Marijuana available at the MTC to Registered Qualifying Patients and may post the same catalogue or printed list on its website and in the retail store.

6. An MTC may engage in reasonable advertising practices that are not otherwise prohibited in 935 CMR 501.105(4)(b) that do not jeopardize the public health, welfare or safety of the general public or promote the diversion of Marijuana or Marijuana use in individuals younger than 21 years old or otherwise promote practices inconsistent with the purposes of M.G.L. c. 94G or 94I. Any such advertising created for viewing by the public shall include the statement "Please Consume Responsibly", in a conspicuous manner on the face of the advertisement and shall include a minimum of two of the following warnings in their entirety in a conspicuous manner on the face of the advertisement:

501.105: continued

- a. "This product may cause impairment and may be habit forming";
  - b. "Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug";
  - c. "There may be health risks associated with consumption of this product"; or
  - d. "Marijuana should not be used by women who are pregnant or breastfeeding".
- (b) Prohibited Practices. The following advertising activities are prohibited:
1. Advertising in such a manner that is deemed to be is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly or by omission or ambiguity;
  2. Advertising by means of television, radio, internet, mobile applications, social media, or other electronic communication, billboard or other outdoor advertising, or print publication, unless at least 85% of the audience is reasonably expected to be 21 years of age or older or comprised of individuals with debilitating conditions, as determined by reliable and current audience composition data;
  3. Advertising, including statements by a Licensee, that makes any false or statements concerning other Licensees and the conduct and products of such other Licensees that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly or by omission or ambiguity;
  4. Advertising on any billboards or any other public signage which fails to comply with all state laws and local ordinances;
  5. Installation of any illuminated signage or external signage beyond the period of 30 minutes before sundown until closing; provided however, that the Commission may further specify minimum signage requirements;
  6. The use of vehicles equipped with radio or loudspeakers for the advertising of Marijuana or Marijuana Products;
  7. The use of radio or loudspeaker equipment in any MTC for the purpose of attracting attention to the sale of Marijuana or Marijuana Products;
  8. Operation of any website of an MTC that fails to verify that the entrant is a Qualifying Patient or Caregiver or the entrant is 21 years of age or older;
  9. Use of unsolicited pop-up advertisements on the internet or text message; unless the advertisement is a mobile device application installed on the device by the owner of the device who is a Qualifying Patient or Caregiver or 21 years of age or older and includes a permanent and easy opt-out feature;
  10. Any advertising, including the use of Brand Names, of an improper or objectionable nature including, but not limited to, the use or language or images offensive or disparaging to certain groups;
  11. Any advertising solely for the promotion of Marijuana or Marijuana Products on MTC Branded Goods including, but not limited to, clothing, cups, drink holders, apparel accessories, electronic equipment or accessories, sporting equipment, novelty items and similar portable promotional items;
  12. Advertising on or in public or private vehicles and at bus stops, taxi stands, transportation waiting areas, train stations, airports, or other similar transportation venues including, but not limited to, vinyl-wrapped vehicles or signs or logos on transportation vehicles not owned by the MTC;
  13. The display of signs or other printed material advertising any brand or kind of Marijuana or Marijuana Products that are displayed on the exterior of any licensed Premises;
  14. Advertising of the price of Marijuana or Marijuana Products, except as permitted above pursuant to 935 CMR 501.105(4)(a)5.;
  15. Display of Marijuana or Marijuana Products so as to be clearly visible to a person from the exterior of an MTC;
  16. Advertising, marketing or branding including any statement, design, representation, picture, or illustration that encourages or represents the use of Marijuana for any purpose other than to treat a Debilitating Medical Condition or related symptoms;
- (c) The Commission shall maintain and make available a list of all MTCs, their dispensing location, and their contact information.
- (d) Nothing in 935 CMR 501.105(4) prohibits an MTC from using a mark provided by the Commission which uses images of Marijuana.

501.105: continued

(e) CMOs shall comply with the requirements of each 935 CMR 500.105(4): *Advertising Requirements* and 935 CMR 501.105(4) with respect to the applicable license. A CMO may develop a single marketing campaign; provided, however, it shall apply the most restrictive requirements applicable under either license.

(5) Labeling of Marijuana and Marijuana Products.

(a) Labeling of Marijuana Not Sold as a Marijuana Product. Prior to Marijuana being sold or Transferred, an MTC shall ensure the placement of a legible, firmly Affixed label on which the wording is no less than  $\frac{1}{16}$  of an inch in size on each package of Marijuana that it makes available for retail sale. The Affixed label shall contain at a minimum the following information, but may not include a Qualifying Patient's name:

1. The name and registration number, telephone number, email address of the MTC that produced the Marijuana, together with the retail Licensee's business telephone number, electronic mail address, and website information, if any;
2. The date that the MTC packaged the contents and a statement of which Licensee performed the packaging;
3. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
4. Net weight or volume in U.S. customary or metric units, listed in that order;
5. The full Cannabinoid Profile of the Marijuana contained within the package, including THC and other Cannabinoid levels;
6. A statement and a seal certifying that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L c. 94G, § 15;
7. 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. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";
8. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana:



9. The following symbol or other easily recognizable mark issued by the Commission that indicates that the product is harmful to children:



501.105: continued

10. 935 CMR 501.105(5)(a) may not apply to Marijuana packaged for transport of wholesale cultivated Marijuana in compliance with 935 CMR 501.105(13); provided however, that the MTC is responsible for compliance with 935 CMR 501.105(5) for all Marijuana Products sold or displayed to Patients.

(b) Labeling of Edibles. Prior to Edibles being sold or Transferred, the MTC shall place a legible, firmly Affixed label on which the wording is no less than  $\frac{1}{16}$  of an inch in size on each Edible that it prepares for retail sale or wholesale. The Affixed label shall contain at a minimum the following information, but may not include a Qualifying Patient's name:

1. The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address and website information, if any;
2. The name of the Marijuana Product;
3. Refrigeration of the product is required, as applicable;
4. Total net weight or volume in U.S. customary and metric units, listed in that order, of the Marijuana Product;
5. The number of servings in the Marijuana Product and the specific weight in milligrams of a serving size;
6. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
7. A list of ingredients, including the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta$ 9-THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume;
8. The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving;
9. The date of creation and the recommended "use by" or expiration date which may not be altered or changed;
10. A batch number, sequential serial number and bar codes when used, to identify the batch associated with manufacturing and Processing;
11. Directions for use of the Marijuana Product;
12. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
13. A warning if nuts or other Known Allergens are contained in the product;
14. This statement, including capitalization: "The impairment effects of edible products may be delayed by two hours or more. 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. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";
15. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana:



16. The following symbol or other easily recognizable mark issued by the Commission that indicates that the product is harmful to children:



501.105: continued

17. 935 CMR 501.105(5)(b) shall apply to Edibles produced by an MTC for transport to another Licensee in compliance with 935 CMR 501.105(8) and shall be in addition to any regulation regarding the appearance of Edibles under 935 CMR 501.150.

(c) Labeling of Marijuana Concentrates and Extracts. Prior to Marijuana concentrates or extracts being sold or Transferred, the MTC shall place a legible, firmly Affixed label on which the wording is no less than  $\frac{1}{16}$  of an inch in size on each Marijuana concentrate container that it prepares for retail sale or wholesale. The Affixed label shall contain at a minimum the following information, but may not include a Qualifying Patient's name:

1. The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number and e-mail address;
2. The name of the Marijuana Product;
3. Product identity, including the word "concentrate" or "extract", as applicable;
4. Total net weight or volume expressed in U.S. customary units and metric units, listed in that order, of a Marijuana Product;
5. If applicable, the number of servings in the Marijuana Product and the specific weight in milligrams of a serving size;
6. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
7. A list of ingredients including, but not limited to, the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta^9$ -THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume, and the amount of specific additives infused or incorporated during the manufacturing process, whether active or inactive including, but not limited to, thickening agents, thinning agents, and specific terpenes, expressed in absolute terms and as a percentage of volume;
  - a. For Marijuana Vaporizer Devices, identification of specific additives shall include, but not be limited to, any additives identified on the FDA's Inactive Ingredient Database for "Respiratory (inhalation)" or "Oral" routes of administration and based on dosage form as an aerosol product or inhalant. The FDA Inactive Ingredient Database is available at <https://www.fda.gov/media/72482/download>. If the FDA database or its equivalent is no longer available, licensees shall use the database identified by the Commission.
  - b. For Marijuana Vaporizer Devices produced using only cannabis-derived terpenes, the following statement: "This product was produced using only cannabis-derived terpenes."
  - c. For Marijuana Vaporizer Devices produced using terpenes other than cannabis-derived terpenes, the following statement: "This product was produced using terpenes derived from sources other than cannabis."
8. The date of creation and the recommended "use by" or expiration date;
9. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
10. Directions for use of the Marijuana Product;
11. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date(s) of testing in accordance with M.G.L. c. 94G, § 15. Marijuana Products that are required to undergo more than one screening shall list all applicable dates of testing;
12. A warning if nuts or other Known Allergens are contained in the product;
13. 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. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";



501.105: continued

14. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana:



15. The following symbol or other easily recognizable mark issued by the Commission that indicates that the product is harmful to children:



16. 935 CMR 501.105(5)(c) shall apply to Marijuana concentrates and extracts produced by an MTC for transport to another Licensee in compliance with 935 CMR 501.105(13).

(d) Labeling of Marijuana Infused Tinctures, Topicals or Other Non-edible Marijuana-infused Products. Prior to Marijuana-infused Tinctures, topicals or other non-edible Marijuana-infused Products being sold or Transferred the MTC shall place a legible, firmly Affixed label on which the wording is no less than  $\frac{1}{16}$  of an inch in size on each container of Marijuana-infused Product that it prepares for retail sale or wholesale. The Affixed label shall contain at a minimum the following information, but may not include a Qualifying Patient's name:

1. The name and registration number of the MTC that produced the Marijuana Product, together with the MTC's business telephone number, e-mail address and website information, if any;
2. The Marijuana Product's identity;
3. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
4. A list of ingredients, including the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta^9$ -THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume;
5. Total net weight or volume as expressed in U.S. customary units and metric units, listed in that order, of the Marijuana Product;
6. If applicable, the number of servings in the Marijuana Product and the specific weight in milligrams of a serving size;
7. The date of product creation;
8. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
9. Directions for use of the Marijuana Product;
10. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
11. A warning if nuts or other Known Allergens are contained in the product;
12. 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. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";

501.105: continued

13. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana:



14. The following symbol or other easily recognizable mark issued by the Commission that indicates that the product is harmful to children:



15. 935 CMR 501.105(5)(d) shall apply to Marijuana-infused Tinctures and topicals produced by an MTC for transport to another Licensee in compliance with 935 CMR 501.105(8).

(e) Labeling of Repackaged Marijuana. Prior to Repackaged Marijuana being sold, the Retailer shall place a legible, firmly Affixed label on which the wording is no less than  $\frac{1}{16}$  inch in size on each container of Marijuana that it prepares for retail sale.

1. The Affixed label shall contain at a minimum the following information, but may not include a Qualifying Patient's name:

- a. The name and registration number of the Cultivator that produced the Marijuana;
- b. Business or trade name of licensee that packaged the product, if different from the Cultivator;
- c. Date of Harvest;
- d. Type of Marijuana or name of strain;
- e. The full Cannabinoid Profile of the Marijuana contained within the Repackaged Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta$ 9-THC) and other Cannabinoids in the package;
- f. Weight in grams of usable marijuana used in product;
- g. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- h. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- i. 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. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";
- j. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana:



501.105: continued

k. The following symbol or other easily recognizable mark issued by the Commission that indicates that the product is harmful to children:



2. In circumstances where the labeling of the Marijuana Product is unreasonable or impractical, the MTC may include the labeling information on a peel-back label or may place the product in a sealed bag with an insert or additional, easily readable label firmly Affixed to that bag.

(f) In circumstances where the labeling of the Marijuana Product is unreasonable or impractical, the MTC may include the labeling information on a peel-back label or may place the product in a take-away bag with an insert or additional, easily readable placed within that bag.

(g) CMOs shall comply with the labeling requirements in 935 CMR 500.105(5) for all adult-use sales and 935 CMR 501.105(5) for all medical-use sales.

(6) Packaging of Marijuana and Marijuana Products.

(a) Child-resistant Packaging. MTCs engaged in product manufacturing operations shall ensure that all Marijuana and Marijuana Products that are provided for sale to Registered Qualifying Patients shall be sold in child-resistant packaging. To comply with 935 CMR 501.105(6), Licensees shall ensure:

1. That to the extent it is not Unreasonably Impracticable for the specific type of product, Marijuana Products are packaged in containers that are:

- a. Opaque and plain in design;
- b. Do not use bright colors, cartoon characters and other features designed to appeal to minors;
- c. Resealable for any Marijuana Product intended for more than a single use or containing multiple servings; and
- d. Certified by a qualified child-resistant packaging testing firm that the packaging complies with the most recent poison prevention packaging regulations of the U.S. Consumer Product Safety Commission as included at 16 CFR 1700.

2. That where compliance with the requirements of child-resistant packaging is deemed to be Unreasonably Impracticable or too challenging for Patients to maneuver, Marijuana Products shall be placed in an packaging that is:

- a. Capable of being resealed after it has been opened; and
- b. Includes the following statement, including capitalization, in at least ten-point Times New Roman, Helvetica or Arial font: "KEEP OUT OF REACH OF CHILDREN".

(b) Limits on Packaging Design. Packaging for Marijuana or Marijuana Products sold or displayed to Patients, including any label or imprint Affixed to any packaging containing Marijuana or Marijuana Products or any exit packages, may not be attractive to minors. Packaging is explicitly prohibited from:

1. Imitating or having a semblance to any existing branded consumer products, including foods and beverages, that do not contain Marijuana;
2. Featuring cartoons;
3. Featuring a design, brand or name that resembles a non-Cannabis consumer product of the type that is typically marketed to minors;
4. Featuring symbols or celebrities that are commonly used to market products to minors;
5. Featuring images of minors; and
6. Featuring words that refer to products that are commonly associated with minors or marketed to minors.

501.105: continued

(c) Packaging of Multiple Servings.

1. Packaging for Marijuana Products sold or displayed for Registered Qualifying Patients in multiple servings shall include the following statement on the exterior of the package in a printed font that is no smaller than ten-point Times New Roman, Helvetica or Arial, including capitalization: "INCLUDES MULTIPLE SERVINGS."

2. Packaging for Marijuana Products in solid form sold or displayed for Registered Qualifying Patients in multiple servings shall allow a Registered Qualifying Patient to easily perform the division into single servings.

a. Edibles in a solid form shall be easily and permanently scored to identify individual servings.

b. Notwithstanding 935 CMR 501.105(6)(c)2.a., where a product is unable, because of its form, to be easily and permanently scored to identify individual servings, the product shall be packaged in a single serving size. The determination of whether a product can be easily and permanently scored shall be decided by the Commission consistent with sub-regulatory guidelines established by the Commission and provided to Licensees.

(d) Each single serving of an Edible contained in a multiple-serving package may be marked, stamped or otherwise imprinted with the symbol issued by the Commission under 935 CMR 501.105(5) that indicates that the single serving is a Marijuana Product.

(e) Serving size shall be determined by the MTC.

(f) CMOs shall comply with the packaging requirements in 935 CMR 500.105(6): *Packaging of Marijuana and Marijuana Products* for adult use sales or 935 CMR 501.105(6) for medical use sales.

(7) Packaging and Labeling Pre-approval. Prior to Marijuana or Marijuana Product being sold at an MTC, a CMO, a Licensee or License Applicant may submit an application for packaging and label approval to the Commission. An application for preapproval may be submitted at any time prior to Marijuana or Marijuana Product being sold or at any time a substantive change is made to the packaging or labeling of Marijuana or Marijuana Product. The Commission shall charge a fee for packaging and labeling preapproval pursuant to 935 CMR 501.005.

(a) Packaging and labeling preapproval review shall be limited to the physical attributes of, and statutorily required warnings on, the packaging and label, including but not limited to legibility, but may not include a review of specific Independent Testing Laboratory test results required pursuant to 935 CMR 501.105(5). The packaging and labeling preapproval process shall be in addition to the requirements of 935 CMR 501.105(5) and (6).

(b) In addition to an application for packaging and labeling preapproval in a form and manner determined by the Commission, an applicant for preapproval shall submit electronic files of the following to the Commission:

1. For packaging preapproval, two images of the packaging, one depicting the front of the packaging and one depicting the back of the packaging. Photographs shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.

2. For labeling preapproval, one image of each label requested for review. Photographs shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.

(c) The Commission shall make every effort to make a preapproval determination based on information submitted. In the event that a preapproval determination is unable to be made conclusively based on submitted photographs, the Commission may request to view the packaging or label in person or through a video conference. Any such request by the Commission shall be made to the applicant electronically or in writing.

(8) Inventory.

(a) Subject to Marijuana or Marijuana Products being entered into the Seed-to-sale SOR, a Marijuana Establishment may Transfer product to an MTC, and an MTC may Transfer product to a Marijuana Establishment as long as there is no violation of the dosing limitations set forth in 935 CMR 500.150(4): *Dosing Limitations* or the limitations on total MTC inventory as set forth in 935 CMR 501.105(8)(m). Such Transfers cannot violate provisions protecting patient supply under 935 CMR 501.140(12). An MTC shall limit its Transfer of inventory of seeds, plants, and Usable Marijuana to reflect the projected needs of Registered Qualifying Patients.

501.105: continued

(b) Real-time inventory shall be maintained as specified by the Commission and in 935 CMR 501.105(8)(c) and (d) including, at a minimum, an inventory of Marijuana plants, Marijuana plant seeds and 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.

(c) An MTC shall:

1. 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;
2. Conduct a monthly inventory of Marijuana in the process of cultivation and finished, stored Marijuana;
3. Conduct a comprehensive annual inventory at least once every year after the date of the previous comprehensive inventory; and
4. Promptly transcribe inventories if taken by use of an oral recording device.

(d) 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.

(e) An MTC shall attach plant tags to all Marijuana, Clones, and plants and attach package tags to all Finished Marijuana and Marijuana Products, and track all Marijuana seeds, Clones, plants, and Marijuana Products, using a Seed-to-sale methodology in a form and manner to be approved by the Commission.

(f) The failure to enter inventory into the Seed-to-sale SOR may result in the suspension or revocation of an MTC License.

(g) The use of the Seed-to-sale SOR does not preclude an MTC from using a secondary electronic tracking system so long as it complies with 935 CMR 501.105(8). The MTC shall seek approval from the Commission, in a form and manner determined by the Commission, to integrate its secondary system with the Seed-to-sale SOR.

(h) Prior to the point of sale, an MTC shall specify the suggested retail price for any Marijuana or Marijuana Product intended for patient sale.

(i) An MTC shall limit its inventory of seeds, plants, and Usable Marijuana to reflect the projected needs of Registered Qualifying Patients.

(j) An MTC may acquire Marijuana and Marijuana Product from or distribute Marijuana or Marijuana Product to another MTC or Marijuana Establishment in accordance with 935 CMR 501.140(8) and subject to the following:

1. The distribution and acquisition of Marijuana and Marijuana Product, including MIPs, to and from all other MTCs does not exceed, cumulatively, 45% of the MTC's total annual inventory of Marijuana as measured by weight, or for Marijuana Product, including MIPs, as measured by its combined dry weight equivalent in Marijuana concentrate; except that such requirement shall not apply to CMOs; and
2. A documented emergency occurs such as loss of crop, vandalism, or theft, or other circumstance as approved by the Commission.

(k) Any distribution and acquisition of Marijuana and MIPs shall be tracked in the Seed-to-sale SOR in a form and manner determined by the Commission. Any distribution of Marijuana and MIPs that is not tracked in the Seed-to-sale SOR may result in the suspension or revocation of an MTC License or other administrative action.

(l) An MTC may not engage in a transfer of inventory that would violate the provisions protecting patient supply under 935 CMR 501.140(12).

(m) A CMO shall implement procedures for electronic separation of medical-and adult-use Marijuana, MIPs, and Marijuana Products in the Seed-to-sale SOR.

(n) A CMO shall designate whether Marijuana or MIPs, or Marijuana Products are intended for sale for adult use or medical use through the SOR. Products shall be transferred to the appropriate license within the Seed-to-sale SOR prior to sale. After the point of sale, there shall be a reconciliation of that inventory in the SOR.

(9) Recordkeeping. Records of an MTC shall be available for inspection by the Commission, on request. The financial records of an MTC shall be maintained in accordance with generally accepted accounting principles. Written records that are required and are subject to inspection include, but are not limited to, all records required in any section of 935 CMR 501.000 in addition to the following:

501.105: continued

- (a) Operating procedures as required by 935 CMR 501.105(1);
  - (b) Inventory records as required by 935 CMR 501.105(8)(d);
  - (c) Seed-to-sale Electronic Tracking System records for all Marijuana and MIPs as required by 935 CMR 501.105(8)(e);
  - (d) The following personnel records:
    - 1. Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;
    - 2. A personnel record for each MTC and Laboratory Agent. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with the MTC and shall include, at a minimum, the following:
      - a. All materials submitted to the Commission pursuant to 935 CMR 501.029 and 501.030;
      - b. Documentation of verification of references;
      - c. The job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision;
      - d. 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;
      - e. A copy of the application that the MTC submitted to the Commission on behalf of any prospective MTC agent;
      - f. Documentation of periodic performance evaluations;
      - g. Notice of completed Responsible Vendor Training Program and in-house training for MTC Agents required under 935 CMR 501.105(2); and
      - h. A record of any disciplinary action taken.
    - 3. A staffing plan that will demonstrate accessible business hours and safe cultivation conditions;
    - 4. Personnel policies and procedures, including, at a minimum, the following:
      - a. Code of ethics;
      - b. Whistle-blower policy; and
      - c. A policy which notifies persons with disabilities of their rights under <https://www.mass.gov/service-details/about-employment-rights> or a comparable link, and includes provisions prohibiting discrimination and providing reasonable accommodations; and
    - 5. All background check reports obtained in accordance with M.G.L. c. 6, § 172, 935 CMR 501.029, 935 CMR 501.030, and 803 CMR 2.00: *Criminal Offender Record Information (CORI)*;
  - (e) Business records, which shall include manual or computerized records of:
    - 1. Assets and liabilities;
    - 2. Monetary transactions;
    - 3. Books of accounts, which shall include journals, ledgers, and supporting documents, agreements, checks, invoices, and vouchers;
    - 4. Sales records that indicate the name of the Registered Qualifying Patient or Personal Caregiver to whom Marijuana has been dispensed, including the quantity, form, and cost;
    - 5. Salary and wages paid to each employee, stipend paid to each board of directors member, and any executive compensation, bonus, benefit, or item of value paid to any individual affiliated with an MTC, including Persons or Entities Having Direct or Indirect Control over the MTC.
  - (f) Waste disposal records as required under 935 CMR 501.105(12); and
  - (g) Following closure of an MTC, all records shall be kept for at least two years at the expense of the MTC and in a form and location acceptable to the Commission.
- (10) Liability Insurance Coverage or Maintenance of Escrow.
- (a) An MTC shall obtain and maintain general liability insurance coverage for no less than \$1,000,000 per occurrence and \$2,000,000 in aggregate, annually, and product liability insurance coverage for no less than \$1,000,000 per occurrence and \$2,000,000 in aggregate, annually, except as provided in 935 CMR 501.105(10)(b) or otherwise approved by the Commission. The deductible for each policy shall be no higher than \$5,000 per occurrence.

501.105: continued

(b) An MTC that documents an inability to obtain minimum liability insurance coverage as required by 935 CMR 501.105(10)(a) may place in escrow a sum of no less than \$250,000 or such other amount approved by the Commission, to be expended for coverage of liabilities.

(c) The escrow account required pursuant to 935 CMR 501.105(10)(b) shall be replenished within ten business days of any expenditure.

(d) Reports documenting compliance with 935 CMR 501.105(10) shall be made in a manner and form determined by the Commission pursuant to 935 CMR 501.000.

(e) A CMO shall maintain the insurance coverage or escrow account required under 935 CMR 500.105(10): *Liability Insurance Coverage or Maintenance of Escrow* or 501.105(10) per location.

(11) Storage Requirements.

(a) An MTC shall provide adequate lighting, ventilation, temperature, humidity, space, and equipment, in accordance with applicable provisions of 935 CMR 501.105 and 501.110.

(b) An MTC shall have separate areas for storage of Marijuana that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until such products are destroyed.

(c) MTC storage areas shall be maintained in a clean and orderly condition.

(d) MTC storage areas shall be free from infestation by insects, rodents, birds, and pests of any kind.

(e) MTC storage areas shall be maintained in accordance with the security requirements of 935 CMR 501.110.

(12) Waste Disposal.

(a) All recyclables and waste, including organic 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. All exterior waste receptacles located on the MTC's Premises shall be locked and secured to prevent unauthorized access.

(b) Liquid waste containing Marijuana or by-products of Marijuana Processing shall be disposed of in compliance with all applicable state and federal requirements including, but not limited to, for discharge of pollutants into surface water or groundwater (Massachusetts Clean Waters Act, M.G.L. c. 21, §§ 26 through 53; 314 CMR 3.00: *Surface Water Discharge Permit Program*; 314 CMR 5.00: *Groundwater Discharge Permit Program*; 314 CMR 12.00: *Operation, Maintenance and Pretreatment Standards for Wastewater Treatment Works and Indirect Dischargers*; the Federal Clean Water Act, 33 U.S.C. 1251 *et seq.*, the National Pollutant Discharge Elimination System Permit Regulations at 40 CFR Part 122, 314 CMR 7.00: *Sewer System Extension and Connection Permit Program*), or stored pending disposal in an industrial wastewater holding tank in accordance with 314 CMR 18.00: *Industrial Wastewater Holding Tank and Container Construction, Operation, and Record Keeping Requirements*.

(c) Organic material, recyclable material and solid waste generated at an MTC shall be redirected or disposed of as follows:

1. Organic and recyclable material shall be redirected from disposal in accordance with the waste disposal bans described at 310 CMR 19.017: *Waste Bans*.

2. To the greatest extent feasible:

a. Any recyclable material as defined in 310 CMR 16.02: *Definitions* shall be recycled in a manner approved by the Commission; and

b. Any Marijuana containing organic material as defined in 310 CMR 16.02: *Definitions* shall be ground up and mixed with other organic material as defined in 310 CMR 16.02 at the MTC such that the resulting mixture renders any Marijuana unusable for its original purpose. Once such Marijuana has been rendered unusable, the organic material may be composted or digested at an aerobic or anaerobic digester at an operation that complies with the requirements of 310 CMR 16.00: *Site Assignment Regulations for Solid Waste Facilities*.

501.105: continued

3. Solid waste containing Marijuana generated at an MTC shall be ground up and mixed with other solid waste at the MTC such that the resulting mixture renders any Marijuana unusable for its original purpose. Once such Marijuana has been rendered unusable, the resulting solid waste may be brought to a solid waste transfer facility or a solid waste disposal facility (*e.g.*, landfill or incinerator) that holds a valid permit issued by the Department of Environmental Protection or by the appropriate agency in the jurisdiction in which the facility is located.
  - (d) No fewer than two MTC Agents shall witness and document how the solid waste or organic material containing Marijuana is handled on-site including, but not limited to, the grinding up, mixing, storage and removal from the MTC in accordance with 935 CMR 501.105(12). When Marijuana Products or waste is disposed or handled, the MTC shall create and maintain an electronic record of the date, the type and quantity disposed or handled, the manner of disposal or other handling, the location of disposal or other handling, and the names of the two MTC Agents present during the disposal or other handling, with their signatures. An MTC shall keep these records for at least three years. This period shall automatically be extended for the duration of any disciplinary action and may be extended by an order of the Commission.
- (13) Transportation Between MTCs.
- (a) General Requirements.
    1. A licensed MTC shall be licensed to transport its Marijuana and Marijuana Products to other licensed establishments, including Marijuana Establishments, except as otherwise provided in 935 CMR 501.105(13).
    2. Marijuana Products may only be transported between licensed MTCs by registered MTC Agents.
    3. A Marijuana Transporter licensed pursuant to 935 CMR 500.050(9) may Transfer Marijuana and Marijuana Products to or from an MTC.
    4. The originating and receiving licensed MTCs shall ensure that all transported Marijuana Products are linked to the Seed-to-sale SOR. For the purposes of tracking, seeds and Clones will be properly tracked and labeled in a form and manner determined by the Commission.
    5. Any Marijuana Product that is undeliverable or is refused by the destination MTC shall be transported back to the originating establishment.
    6. All vehicles transporting Marijuana Products shall be staffed with a minimum of two MTC Agents. At least one agent shall always remain with the vehicle when the vehicle contains Marijuana or Marijuana Products.
    7. Prior to leaving an MTC for the purpose of transporting Marijuana Products, the originating MTC shall weigh, inventory, and account for, on video, all Marijuana Products to be transported.
    8. Within eight hours after arrival at the destination MTC, the destination MTC shall re-weigh, re-inventory, and account for, on video, all Marijuana Products transported.
    9. When videotaping the weighing, inventorying, and accounting of Marijuana Products before transportation or after receipt, the video shall show each product being weighed, the weight, and the manifest.
    10. Marijuana Products shall be packaged in sealed, labeled, and tamper or child-resistant packaging prior to and during transportation.
    11. In the case of an emergency stop during the transportation of Marijuana Products, a log shall be maintained describing the reason for the stop, the duration, the location, and any activities of personnel exiting the vehicle. Licensees shall comply with applicable requirements of 935 CMR 501.110(9).
    12. An MTC transporting Marijuana Products shall ensure that all transportation times and routes are randomized.
    13. An MTC transporting Marijuana Products shall ensure that all transport routes remain within the Commonwealth.
    14. All vehicles and transportation equipment used in the transportation of Cannabis Products or Edibles requiring temperature control for safety shall be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the Cannabis products or Edibles from becoming unsafe during transportation, consistent with applicable requirements pursuant to 21 CFR 1.908(c).



501.105: continued

15. All vehicles shall be equipped with a video system that includes one or more video cameras in the storage area of the vehicle and one or more video cameras in the driver area of the vehicle and which shall remain operational at all times during the entire transportation process and which shall have:
  - a. The ability to produce a clear color still photo whether live or recorded; and
  - b. A date and time stamp embedded in all recordings which shall always be synchronized and set correctly and may not significantly obscure the picture.
- (b) Reporting Requirements.
  1. MTC agents shall document and report any unusual discrepancy in weight or inventory to the Commission and Law Enforcement Authorities not more than 24 hours of the discovery of such a discrepancy.
  2. MTC agents shall report to the Commission and Law Enforcement Authorities any vehicle accidents, diversions, losses, or other reportable incidents that occur during transport, not more than 24 hours of such accidents, diversions, losses, or other reportable incidents.
- (c) Vehicles.
  1. A vehicle used for transporting Marijuana Products shall be:
    - a. Exclusively owned or leased by the MTC or otherwise licensed by the Commission as a Third-party Transporter;
    - b. Properly registered, inspected, and insured in the Commonwealth (documentation of such status shall be maintained as records of the MTC, and shall be made available to the Commission on request);
    - c. Equipped with an alarm system approved by the Commission; and
    - d. Equipped with functioning heating and air conditioning systems appropriate for maintaining correct temperatures for storage of Marijuana Products.
  2. Marijuana Products may not be visible from outside the vehicle.
  3. Any vehicle used to transport or deliver Marijuana or Marijuana Products must comply with applicable Massachusetts Registry of Motor Vehicles (RMV) requirements, but may not include any additional external marking that indicate the vehicle is being used to transport or deliver Marijuana or Marijuana Products.
  4. When transporting Marijuana Products, no other products may be transported or stored in the same vehicle.
  5. No firearms may be located within the vehicle or on an MTC Agent.
- (d) Storage Requirements.
  1. Marijuana Products shall be transported in a secure, locked storage compartment that is a part of the vehicle transporting the Marijuana Products.
  2. The storage compartment shall be sufficiently secure that it cannot be easily removed.
  3. If an MTC is transporting Marijuana Products for more than one licensed MTC at a time, the Marijuana Products for each Licensee shall be kept in a separate locked storage compartment during transportation and separate manifests shall be maintained for each MTC.
  4. If an MTC is transporting Marijuana Products to multiple other establishments, it may seek the Commission's permission to adopt reasonable alternative safeguards.
- (e) Communications.
  1. Any vehicle used to transport Marijuana Products shall contain a global positioning system (GPS) monitoring device that is:
    - a. Not a mobile device that is easily removable;
    - b. Attached to the vehicle at all times that the vehicle contains Marijuana Products;
    - c. Monitored by the MTC during transport of Marijuana Products; and
    - d. Inspected by the Commission prior to initial transportation of Marijuana Products, and after any alteration to the locked storage compartment.
  2. Each MTC Agent transporting Marijuana Products shall always have access to a secure form of communication with personnel at the originating location when the vehicle contains Marijuana and Marijuana Products.
  3. Secure types of communication include, but are not limited to:
    - a. Two-way digital or analog radio (UHF or VHF);
    - b. Cellular phone; or
    - c. Satellite phone.

501.105: continued

4. When choosing a type of secure communications, the following shall be taken into consideration:
    - a. Cellular signal coverage;
    - b. Transportation area;
    - c. Base capabilities;
    - d. Antenna coverage; and
    - e. Frequency of transportation.
  5. Prior to, and immediately after leaving the originating location, the MTC Agents shall use the secure form of communication to contact the originating location to test communications and GPS operability.
  6. If communications or the GPS system fail while on route, the MTC Agents transporting Marijuana Products shall return to the originating location until the communication system or GPS system is operational.
  7. The MTC Agents transporting Marijuana Products shall contact the originating location when stopping at and leaving any scheduled location, and regularly throughout the trip, at least every 30 minutes.
  8. The originating location shall have an MTC Agent assigned to monitoring the GPS unit and secure form of communication, who shall log all official communications with MTC Agents transporting Marijuana Products.
- (f) Manifests.
1. A manifest shall be filled out in triplicate, with the original manifest remaining with the originating MTC, a second copy provide to the destination MTC on arrival, and a copy to be kept with the licensed MTC Agent during transportation and returned to the MTC on completion of the transportation.
  2. Prior to transport, the manifest shall be securely transmitted to the destination MTC by facsimile or email.
  3. On arrival at the destination MTC, an MTC Agent at the destination MTC shall compare the manifest produced by the agents who transported the Marijuana Products to the copy transmitted by facsimile or email. This manifest shall, at a minimum, include:
    - a. The originating MTC name, address, and registration number;
    - b. The names and registration numbers of the agents who transported the Marijuana Products;
    - c. The name and registration number of the MTC Agent who prepared the manifest;
    - d. The destination MTC name, address, and registration number;
    - e. A description of the Marijuana Products being transported, including the weight and form or type of product;
    - f. The mileage of the transporting vehicle at departure from originating MTC and mileage on arrival at destination MTC, as well as mileage on return to originating MTC;
    - g. The date and time of departure from originating MTC and arrival at destination MTC for each transportation;
    - h. A signature line for the MTC Agent who receives the Marijuana Products;
    - i. The weight and inventory before departure and on receipt;
    - j. The date and time that the transported products were reweighed and re-inventoried;
    - k. The name of the MTC Agent at the destination MTC who reweighed and re-inventoried products; and
    - l. The vehicle make, model and license plate number.
  4. The manifest shall be maintained within the vehicle during the entire transportation process, until the delivery is completed.
  5. An MTC shall retain all transportation manifests for no less than one year and make them available to the Commission on request.
- (g) Requirements for Agents.
1. Each employee or agent transporting or otherwise handling Marijuana Products for an MTC shall be registered as an MTC Agent and have a driver's license in good standing issued by the Massachusetts Registry of Motor Vehicles for all classes of vehicle the MTC agent will operate for the MTC prior to transporting or otherwise handling Marijuana Products.

501.105: continued

2. An MTC Agent shall carry his or her Agent Registration Card at all times when transporting Marijuana Products and shall produce his or her Agent Registration Card to the Commission or Law Enforcement Authorities on request.
  - (h) MTCs engaged in transportation operations shall use best management practices to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts.
  - (i) A CMO can transport adult use and medical use Marijuana and Marijuana Products if it is appropriately licensed to do so. Where a CMO is transporting both adult use and medical use Marijuana, MIPs and Marijuana Products, the CMO shall comply with the more restrictive security provisions.
- (14) Access to the Commission, Emergency Responders, and Law Enforcement.
- (a) The following individuals shall have access to an MTC or MTC transportation vehicle:
    1. Representatives of the Commission as authorized by St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. c. 94I, and 935 CMR 501.000.
    2. Representatives of other state agencies of the Commonwealth; and
    3. Emergency responders while responding to an emergency.
  - (b) 935 CMR 501.000 may not be construed to prohibit access to authorized law enforcement personnel or local public health, inspectional services, or other permit-granting agents acting within their lawful jurisdiction
- (15) Energy Efficiency and Conservation. An MTC shall demonstrate consideration of the following factors as part of its operating plan and application for licensure:
- (a) Identification of potential energy use reduction opportunities (such as natural lighting and energy efficiency measures), and a plan for implementation of such opportunities;
  - (b) Consideration of opportunities for renewable energy generation including, where applicable, submission of building plans showing where energy generators could be placed on the site, and an explanation of why the identified opportunities were not pursued, if applicable;
  - (c) Strategies to reduce electric demand (such as lighting schedules, active load management, and energy storage); and
  - (d) Engagement with energy efficiency programs offered pursuant to M.G.L. c. 25, § 21, or through municipal lighting plants.
- (16) Bond.
- (a) Prior to commencing operations, an MTC shall provide proof of having obtained a surety bond in an amount equal to its licensure fee payable to the Marijuana Regulation Fund to ensure payment of the cost incurred for:
    1. the destruction of Cannabis goods necessitated by a violation of M.G.L. c. 94G, 94I, or 935 CMR 501.000;
    2. The costs and compensation of a Court Appointee;
    3. The cessation of operation of the MTC; or
    4. Such other uses that the Commission may authorize to ensure public health, safety and welfare
  - (b) All bonds required under 935 CMR 501.000 shall be issued by a corporate surety licensed to transact surety business in the Commonwealth.
  - (c) If the MTC is unable to secure a surety bond, as required by 935 CMR 501.105(16)(a) it may place in escrow a sum of no less than \$5,000 or such other amount approved by the Commission, to be expended for coverage of liabilities.
  - (d) The escrow account required pursuant to 935 CMR 501.105(16)(c) shall be replenished within ten business days of any expenditure required under 935 CMR 501.105, except if the MTC has ceased operations. Documentation of the replenishment shall be promptly sent to the Commission.
- (17) Reports to the Commission. The Commission may require ongoing reporting on operational, quality, and financial information in a form and manner determined by the Commission.

501.105: continued

(18) Requirements on the Expiration, Revocation, or Voiding of Certificate of Licensure of MTC.

(a) If a License to operate expires without being renewed, is revoked, or becomes void, the MTC shall:

1. Immediately discontinue cultivation and production of Marijuana;
2. 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;
3. Dispose of the unused Marijuana in accordance with 935 CMR 501.105(12) after approval by the Commission. Such disposal shall be in the public interest; and
4. Maintain all records as required by 935 CMR 501.105(9)(g).

(b) If the MTC does not comply with the requirements of 935 CMR 501.105(15)(a), the Commission shall have the authority to, at the MTC's expense, secure the MTC, and after a period of 30 calendar days, seize, and destroy the inventory and equipment and contract for the storage of MTC records.

(19) Prohibitions.

(a) Unless otherwise authorized by the Commission, an MTC may not dispense, deliver, or otherwise transfer Marijuana to a person other than a Registered Qualifying Patient or to his or her Personal Caregiver, to another MTC or to a laboratory as provided for in 935 CMR 501.105(13).

(b) Unless otherwise authorized by the Commission, an MTC may not acquire Marijuana or Marijuana plants, except through the cultivation of Marijuana by that MTC or another MTC as specified in 935 CMR 501.105(13); provided, however that an MTC may acquire Marijuana seeds, cuttings or genetic plant material. Cuttings or genetic plant material may only be acquired within 90 days of receiving a final Certificate of Licensure, or such other time period approved by the Commission and otherwise as authorized under 935 CMR 501.105(13).

(c) Unless authorized by the Commission, an MTC is prohibited from acquiring, possessing, cultivating, delivering, Transferring, transporting, supplying, or dispensing Marijuana for any purpose except to assist Registered Qualifying Patients.

(d) An MTC may not give away any Marijuana except as required pursuant to 935 CMR 501.050(1)(g). An MTC may not provide any samples of Marijuana.

(e) An MTC may not receive orders for Marijuana in any manner other than from a Registered Qualifying Patient or Personal Caregiver in person at the MTC, except in the cases of delivery, in which an order may be received by telephone or through a password-protected, internet-based platform.

(f) An MTC may not fill orders for Marijuana in any manner other than to a Registered Qualifying Patient or Personal Caregiver in person at the MTC, except in the case of delivery, in which an order may be delivered only to the Residence of a Registered Qualifying Patient or Personal Caregiver or the Caregiving Institution of a Registered Qualifying Patient. The Qualifying Patient or caregiver receiving the delivery shall possess a temporary or an annual Registration Card and valid photo identification as required pursuant to 935 CMR 501.140(2). An MTC is prohibited from delivering adult use Marijuana.

(g) Unless authorized by the Commission, an MTC may not sell any products other than Marijuana, including MIPs and Marijuana seeds, and other Marijuana Accessories and products such as vaporizers that facilitate the use of Marijuana for medical purposes.

(h) Consumption of Marijuana on the Premises or grounds of any MTC is prohibited; provided, however, that an MTC may administer medical use Marijuana for the purposes of teaching use of vaporizers, or demonstration of use of other products as necessary. An MTC is prohibited from administering adult use Marijuana.

(i) An MTC may not adulterate Marijuana, including with psychoactive additives or other illegal substances.

501.110: Security Requirements for Medical Marijuana Treatment Centers

(1) General Requirements. An MTC shall implement sufficient security measures to deter and prevent unauthorized entrance into areas containing Marijuana, theft of Marijuana and ensure the safety of MTC employees, Qualifying Patients and the general public. Security measures to protect the Premises, Registered Qualifying Patients, Personal Caregivers, and MTC agents of the MTC shall include, but are not limited to, the following:

- (a) Positively identifying and allowing only Registered Qualifying Patients, Personal Caregivers, MTC agents, Marijuana Courier agents, as applicable, and, subject to the requirements of 935 CMR 501.110(4)(e), outside vendors, contractors, and Visitors, access to the MTC;
- (b) Preventing individuals from remaining on the Premises of the MTC if they are not engaging in activity expressly or by necessary implication permitted by M.G.L. c. 94I, and 935 CMR 501.000;
- (c) Disposing of Marijuana in accordance with 935 CMR 501.105(12), in excess of the quantity required for normal, efficient operation as established within 935 CMR 501.105;
- (d) Securing all entrances to the MTC to prevent unauthorized access;
- (e) Establishing Limited Access Areas which, after receipt of a final License, shall be accessible only to specifically authorized personnel limited to include only the minimum number of employees essential for efficient operation;
- (f) Storing all finished Marijuana in a secure, locked safe or vault and in such a manner as to prevent diversion, theft, and loss;
- (g) Keeping all safes, vaults, and any other equipment or areas used for the production, cultivation, harvesting, Processing, or storage, including prior to disposal, of Marijuana and MIPs securely locked and protected from entry, except for the actual time required to remove or replace Marijuana;
- (h) Keeping all locks and security equipment in good working order;
- (i) Prohibiting keys, if any, from being left in the locks, or stored or placed in a location accessible to persons other than specifically authorized personnel;
- (j) Prohibit accessibility of security measures, such as combination numbers, passwords, or electronic or biometric security systems, to persons other than specifically authorized personnel;
- (k) Ensure that the outside perimeter of the MTC is sufficiently lit to facilitate surveillance;
- (l) Ensuring that all Marijuana Products are kept out of plain sight and are not visible from a public place, outside of the MTC, without the use of binoculars, optical aids or aircraft;
- (m) Develop emergency policies and procedures for securing all product following any instance of diversion, theft, or loss of Marijuana, and conduct an assessment to determine whether additional safeguards are necessary;
- (n) Develop sufficient additional safeguards as required by the Commission for MTCs that present special security concerns;
- (o) At MTCs where transactions are conducted in cash, establishing procedures for safe cash handling and cash transportation to financial institutions to prevent theft, loss and associated risks to the safety of employees, customers and the general public;
- (p) Sharing the MTC's floor plan or layout of the facility with Law Enforcement Authorities in a manner and scope as required by the municipality and identifying when the use of flammable or combustible solvents, chemicals or other materials are in use at the MTC;
- (q) Sharing the MTC's security plan and procedures with Law Enforcement Authorities, in the municipality where the MTC is located and periodically updating Law Enforcement Authorities if the plans or procedures are modified in a material way; and
- (r) Inside the MTC, all Marijuana shall be kept in a Limited Access Area inaccessible to any persons other than MTC agents, except for displays allowable under 935 CMR 501.105(4)(a)4. Inside the MTC, all Marijuana shall be stored in a locked, access-controlled space in a Limited Access Area during nonbusiness hours.

(2) Alternative Security Provisions.

- (a) Notwithstanding the requirements specified in 935 CMR 501.110(1) and (5) through (7), if an MTC has provided other, specific safeguards that may be regarded as an adequate substitute for those requirements, such measures may be taken into account by the Commission in evaluating the overall required security measures. For purposes of cash handling and cash transportation, only alternative safeguards that comply with the requirements of 935 CMR 501.110(7)(b) shall be considered to be adequate substitutes.

501.110: continued

(b) The applicant or Licensee shall submit a request for an alternative security provision to the Commission on a form as determined and made available by the Commission. Upon receipt of the form, the Commission shall submit the request to the chief law enforcement officer in the municipality where the MTC is located or will be located. The Commission shall request that the chief law enforcement officer review the request and alternative security provision requested and, within 30 days;

1. Certify the sufficiency of the requested alternate security provision; or
2. Provide the Commission with a statement of reasons why the alternative security provision is not sufficient in the opinion of the chief law enforcement officer.

(c) The Commission shall take the chief law enforcement officer's opinion under consideration in determining whether to grant the alternative security provision, provided that it may not be determinative. If no response is received from the chief law enforcement officer or a delegee within 30 days of submitting the request to the chief law enforcement officer, the Commission shall proceed with a determination.

(3) Buffer Zone. An MTC Entrance may not be closer than 500 feet from the nearest School Entrance, unless a city or town adopts an ordinance or bylaw that reduces the distance requirement.

(a) The buffer zone distance of 500 feet shall be measured in a straight line from the geometric center of the MTC Entrance to the geometric center of the nearest School Entrance unless there is an Impassable Barrier within those 500 feet; in these cases, the buffer zone distance shall be measured along the center of the shortest publicly-accessible pedestrian travel path from the geometric center of the MTC Entrance to the geometric center of the nearest School Entrance.

(b) The buffer zone distance of 500 feet may be reduced if a city or town adopts an ordinance or bylaw that reduces the distance requirement.

(4) Limited Access Areas.

(a) All Limited Access Areas shall 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 one inch in height.

(b) All Limited Access Areas shall be clearly described by the filing of a diagram of the licensed Premises, in the form and manner determined by the Commission, reflecting walls, partitions, counters, and all areas of entry and exit, including loading areas. Said diagram shall also show all Propagation, Vegetation, Flowering, Processing, production, storage, disposal, and retail sales areas.

(c) At all times following receipt of a final License, access to Limited Access Areas shall be limited to persons that are essential to operations in these areas and specifically permitted by the MTC, representatives of the Commission acting in accordance with their authority under the adult use, medical use and CMO laws; Commission Delegee(s); and local law enforcement authorities, fire safety personnel and emergency medical services acting within their lawful jurisdiction and official capacity.

(d) An MTC agent shall visibly display an identification badge issued by the MTC or the Commission at all times while at the MTC or transporting Marijuana.

(e) Following receipt of a final License, all outside vendors, contractors, and Visitors shall obtain a Visitor Identification Badge prior to entering a Limited Access Area, and shall be escorted at all times by an MTC agent authorized to enter the Limited Access Area. The Visitor Identification Badge shall be visibly displayed at all times while the Visitor is in any Limited Access Area. All Visitors shall be logged in and out, and that log shall be available for inspection by the Commission at all times. All Visitor Identification Badges shall be returned to the MTC upon exit.

(5) Security and Alarm Systems.

(a) An MTC 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:

1. A perimeter alarm on all entry and exit points and perimeter windows;
2. 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 designated employees of the MTC within five minutes after the failure, either by telephone, email, or text message;

501.110: continued

3. A Duress Alarm, Panic Alarm, or Holdup Alarm connected to local public safety or law enforcement authorities;
  4. Video cameras in all areas that may contain Marijuana, vaults or safes for the purpose of securing cash, 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 is cultivated, harvested, Processed, prepared, stored, handled, Transferred or dispensed, or where cash is kept and Processed. Cameras shall be angled to allow for the capture of clear and certain identification of any individual entering or exiting the MTC or area;
  5. 24-hour recordings from all video cameras that are available for immediate viewing by the Commission upon request and that are retained for at least 90 calendar days. Recordings may not be destroyed or altered, and shall be retained as long as necessary if the MTC is aware of a pending criminal, civil, or administrative investigation, or legal proceeding for which the recording may contain relevant information;
  6. The ability to immediately produce a clear, color, still image (live or recorded);
  7. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and may not significantly obscure the picture;
  8. The ability to remain operational during a power outage for a minimum of four hours and, if it appears likely that the outage will last for more than four hours, the MTC takes sufficient steps to ensure security on the premises in consultation with the Commission; and
  9. 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 be able 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.
- (b) All security system equipment and recordings shall be maintained in a secure location to prevent theft, loss, destruction, and alterations.
- (c) In addition to the requirements listed in 935 CMR 501.110(5), the MTC shall have a back-up alarm system, with all capabilities of the primary system, provided by a company supplying commercial grade equipment, which may not be the same company supplying the primary security system, or shall demonstrate to the Commission's satisfaction alternate safeguards to ensure continuous operation of a security system.
- (d) Access to surveillance areas shall be limited to persons that are essential to surveillance operations, law enforcement authorities acting within their lawful jurisdiction, fire safety personnel, security system service personnel, representatives of the Commission as authorized by M.G.L. c. 94I, and 935 CMR 501.000, and Commission Delegee(s).
- (e) A current list of authorized employees and service personnel that have access to the surveillance room shall be available to the Commission upon request. If on-site, surveillance rooms shall remain locked and may not be used for any other function.
- (f) All security equipment shall be in good working order and shall be inspected and tested at regular intervals, not to exceed 30 calendar days from the previous inspection and test.
- (g) Trees, bushes and other foliage outside of the MTC shall be maintained so as to prevent a person or persons from concealing themselves from sight.
- (6) Security and Alarm Requirements for MTCs Operating Outdoors.
- (a) An MTC that is an operating outdoors shall implement adequate security measures to ensure that outdoor areas are not readily accessible to unauthorized individuals and to prevent and detect diversion, theft or loss of Marijuana which shall, at a minimum, include:
    1. A perimeter security fence designed to prevent unauthorized entry to the cultivation facility with signs notifying observers that it is a Limited Access Area;
    2. Commercial-grade, nonresidential locks;
    3. A security alarm system that shall:
      - a. Be continuously monitored, whether electronically, by a monitoring company or other means determined to be adequate by the Commission; and
      - b. Provide an alert to designated employees of the MTC within five minutes after a notification of an alarm or a system failure, either by telephone, email or text message.

501.110: continued

4. Video cameras 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 is cultivated, harvested, Processed, prepared, stored, handled, Transferred or dispensed and for the purpose of securing cash. Cameras shall be angled so as to allow for the capture of clear and certain identification of any person entering or exiting the MTC or area;
  5. Recordings from all video cameras which shall be enabled to record 24 hours each day and be available for immediate viewing by the Commission on request for at least the preceding 90 calendar days or the duration of a request to preserve the recordings for a specified period of time made by the Commission, whichever is longer. Video cameras may use motion detection sensors to begin recording, so long as the motion detection sensor system provides an alert to designated employees of the MTC in a manner established in the MTC's written security procedures and approved by the Commission or a Commission Delegee. If an MTC receives notice that the motion detection sensor is not working correctly, it shall take prompt action to make corrections and document those actions. Recordings may not be destroyed or altered, and shall be retained as long as necessary if the MTC is aware of a pending criminal, civil or administrative investigation or legal proceeding for which the recording may contain relevant information;
  6. The ability to immediately produce a clear, color still image whether live or recorded;
  7. A date and time stamp embedded in all recordings, which shall be synchronized and set correctly at all times and may not significantly obscure the picture;
  8. The ability to remain operational during a power outage for a minimum of four hours and, if it appears likely that the outage will last for more than four hours, the MTC takes sufficient steps to ensure security on the premises in consultation with the Commission; and
  9. 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 may be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal.
- (b) All security system equipment and recordings shall be maintained in a secure location so as to prevent theft, loss, destruction and alterations.
- (c) In addition to the requirements listed in 935 CMR 501.110(5), the MTC shall have a back-up alarm system, with all capabilities of the primary system, provided by a company supplying commercial grade equipment, which may not be the same company supplying the primary security system, or shall demonstrate to the Commission's satisfaction alternate safeguards to ensure continuous operation of a security system.
- (d) Access to surveillance areas shall be limited to persons that are essential to surveillance operations, law enforcement authorities acting within their lawful jurisdiction, fire safety personnel, security system service personnel and the Commission. A current list of authorized employees and service personnel that have access to the surveillance room shall be available to the Commission on request. If the surveillance room is on-site of the MTC, it shall remain locked and may not be used for any other function.
- (e) All security equipment shall be in good working order and shall be inspected and tested at regular intervals, not to exceed 30 calendar days from the previous inspection and test.
- (f) Security plans and procedures shared with law enforcement authorities pursuant to 935 CMR 501.110(1)(q) shall include:
1. A description of the location and operation of the security system, including the location of the central control on the Premises;
  2. A schematic of security zones;
  3. The name of the security alarm company and monitoring company, if any;
  4. A floor plan or layout of the facility in a manner and scope as required by the municipality; and
  5. A safety plan for the manufacture and production of Marijuana Products as required pursuant to 935 CMR 501.101(1)(c).



501.110: continued

(7) Cash Handling and Transportation Requirements.

(a) An MTC with a contract to deposit funds with a financial institution that conducts any transaction in cash shall establish and implement adequate security measures and procedures for safe cash handling and cash transportation to financial institutions or Massachusetts Department of Revenue (DOR) facilities to prevent theft and loss, and to mitigate associated risks to the safety of employees, customers and the general public. Adequate security measures shall include:

1. An on-site secure locked safe or vault maintained in an area separate from retail sales areas used exclusively for the purpose of securing cash;
2. Video cameras directed to provide images of areas where cash is kept, handled and packaged for transport to financial institutions or DOR facilities, provided that the cameras may be motion-sensor activated cameras and provided, further, that all cameras be able to produce a clear, still image whether live or recorded;
3. A written process for securing cash and ensuring transfers of deposits to the MTC's financial institutions and DOR facilities on an incremental basis consistent with the requirements for deposit by the financial institution or DOR facilities;
4. Use of an armored transport provider that is licensed pursuant to M.G.L. c. 147, § 25 (watch, guard or patrol agency) and has been approved by the financial institution or DOR facility.

(b) Notwithstanding the requirement of 935 CMR 501.110(7)(a)4., an MTC may request an alternative security provision under 935 CMR 501.110(2) for purposes of cash transportation to financial institutions and DOR facilities. Any approved alternative security provision shall be included in the security plan shared with law enforcement in the municipality in which the MTC is licensed and periodically updated as required under 935 CMR 501.110(1)(q). To be determined to provide a sufficient alternative, any such alternative safeguard shall include, but may not be limited to:

1. Requiring the use of a locked bag for the transportation of cash from an MTC to a financial institution or DOR facility;
2. Requiring any transportation of cash be conducted in an unmarked vehicle;
3. Requiring two registered MTC Agents employed by the Licensee to be present in the vehicle at all times during transportation of deposits;
4. Requiring real-time GPS tracking of the vehicle at all times when transporting cash;
5. Requiring access to two-way communications between the transportation vehicle and the MTC;
6. Prohibiting the transportation of Marijuana or Marijuana Products at the same time that cash is being transported for deposit to a financial institution or DOR facility; and
7. Approval of the alternative safeguard by the financial institution or DOR facility.

(c) All written safety and security measures developed under this section shall be treated as security planning documents, the public disclosure of which would jeopardize public safety.

(8) Security Requirements for MTC Home Delivery Operations.

(a) An MTC authorized to perform home delivery (MTC) or a Marijuana Courier performing deliveries to Patients and Caregivers on behalf of an MTC, shall implement adequate security measures to ensure that each vehicle used for transportation of Marijuana and Marijuana Products are not readily accessible to unauthorized individuals and to prevent and detect diversion, theft or loss of Marijuana. Security measures shall, at a minimum, include for each operational delivery vehicle:

1. A vehicle security system that includes an exterior alarm;
2. A secure, locked storage compartment that is a part of the vehicle and not easily removable for the purpose of transporting the Marijuana or Marijuana Products.
3. A secure, locked storage compartment that is secured to the vehicle and not easily removable for the purpose of transporting and securing cash used as payment for deliveries of Marijuana or Marijuana Products.
4. A means of secure communication between each vehicle and the MTC's or Marijuana Courier's dispatching location which shall be capable of being monitored at all times that a vehicle is performing a delivery route. Means of communication shall include:
  - a. Two-way digital or analog radio (UHF or VHF);
  - b. Cellular phone; or
  - c. Satellite phone.

501.110: continued

5. A global positioning system (GPS) monitoring device that is:
    - a. Not a mobile device and that is attached to the vehicle at all times that the vehicle contains Marijuana or Marijuana Products; and
    - b. Monitored by the MTC or Marijuana Courier at a fixed location during the transportation of Marijuana or Marijuana Products for the purpose of home delivery with location checks occurring at least every 30 minutes. The MTC or Marijuana Courier may delegate monitoring of the GPS to the Third-party Technology Platform Provider with which the MTC or Marijuana Courier has a contract, provided that the MTC Licensee or Marijuana Courier shall be responsible for ensuring that monitoring occurs as required 935 CMR 501.110(8) and the contract is made available for inspection and on request, submitted to the Commission.
  6. A video system that includes one or more video cameras in the storage area of the vehicle and one or more video cameras in the driver area of the vehicle and which shall remain operational at all times during the entire transportation process and which shall have:
    - a. The ability to produce a clear color still photo whether live or recorded; and
    - b. A date and time stamp embedded in all recordings which shall be synchronized and set correctly at all times and may not significantly obscure the picture.
  7. All security equipment on vehicles shall be in good working order and shall be inspected and tested at regular intervals, no to exceed 30 calendar days from the previous inspection and test.
- (b) An MTC transporting Marijuana and Marijuana Products for home delivery shall ensure that all vehicles used for deliveries are staffed with a minimum of two MTC Agents. At least one MTC Agent shall remain with the vehicle at all times that the vehicle contains Marijuana or Marijuana Products.
- (c) The Commission may establish required training programs for MTC and Marijuana Courier Agents that shall be completed within a reasonable period of time and at the expense of the MTC or Marijuana Courier. Trainings shall include, but may not be limited to, the requirements of 935 CMR 501.105(2)(b)7.:
- (d) An MTC agent shall document and report any unusual discrepancy in inventory to the Commission and local law enforcement within 24 hours of the discovery of such a discrepancy.
- (e) An MTC shall report to the Commission and local law enforcement any vehicle accidents, diversions, losses, or other reportable incidents that occur during transport immediately and, under no circumstances, more than 24 hours of becoming aware of any accidents, diversions, losses, or other reportable incidents and shall otherwise comply with the incident reporting requirements set forth under 935 CMR 501.110(9).
- (f) The following individuals shall have access to MTC operations and vehicles, including video recordings:
1. Representatives of the Commission in the course of responsibilities authorized by 935 CMR 501.000;
  2. Representatives of other state agencies of the Commonwealth of Massachusetts acting within their jurisdiction; and
  3. Law Enforcement Authorities and emergency medical services in the course of responding to an emergency.
- (g) 935 CMR 501.000 may not be construed to prohibit access to authorized law enforcement personnel or local public health, inspectional services, or other permit-granting agents acting within their lawful jurisdiction.
- (h) All vehicles used by the MTC for home delivery are subject to inspection and approval by the Commission prior being put into use. It shall be the MTCs responsibility to make the Commission aware of its intent to introduce a new vehicle into operation and ensure an inspection of the vehicle prior to commencing operation.
- (i) Firearms are strictly prohibited from MTC vehicles and from MTC agents performing home deliveries.
- (9) Incident Reporting.
- (a) An MTC shall immediately notify appropriate Law Enforcement Authorities and the Commission any breach of security or other reportable incident defined herein immediately and, in no instance, more than 24 hours following discovery of the breach or incident. Notification shall occur, but not be limited to, during the following occasions:

501.110: continued

1. Discovery of inventory discrepancies;
  2. Diversion, theft, or loss of any Marijuana Product;
  3. Any criminal action involving the MTC or an MTC Agent or occurring on or in the MTC Premises;
  4. Any suspicious act involving the sale, cultivation, distribution, Processing, or production of Marijuana by any person;
  5. Unauthorized destruction of Marijuana;
  6. Any loss or unauthorized alteration of records related to Marijuana, Registered Qualifying Patients, Personal Caregivers, or MTC Agents;
  7. An alarm activation or other event that requires response by public safety personnel including, but not limited to, local law enforcement, municipal fire departments, public works or municipal sanitation departments, and municipal inspectional services department, or security personnel privately engaged by the MTC;
  8. 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;
  9. A significant motor vehicle crash that occurs while transporting or delivering Finished Marijuana Products and would require the filing of a Motor Vehicle Crash Operator Report pursuant to M.G.L. c. 90 § 26; provided however that a motor vehicle crash that renders the Licensee's vehicle inoperable shall be reported immediately to state and local law enforcement so that Marijuana or Marijuana Products may be adequately secured; or
  10. Any other breach of security.
- (b) An MTC shall, within ten calendar days, provide notice to the Commission of any incident described in 935 CMR 501.110(9)(a), by submitting an incident report in the form and manner determined by the Commission which details the circumstances of the event, any corrective actions taken, and confirmation that the appropriate Law Enforcement Authorities were notified.
- (c) All documentation related to an incident that is reportable pursuant to 935 CMR 501.110(9)(a) shall be maintained by an MTC for no less than one year or the duration of an open investigation, whichever is longer, and made available to the Commission and to Law Enforcement Authorities acting within their lawful jurisdiction upon request.

(10) Security Audits. An MTC shall, on an annual basis, obtain at its own expense a security system audit by a vendor approved by the Commission. A report of such audit shall be submitted, in a form and manner determined by the Commission, no later than 30 calendar days after the audit is conducted. If the audit identifies concerns related to the MTC's security system, the MTC shall also submit a plan to mitigate those concerns within ten business days of submitting the audit.

501.120: Additional Operational Requirements for the Cultivation, Acquisition, and Distribution of Marijuana

- (1) In addition to the general operational requirements for MTCs required under 935 CMR 501.105 and security requirements provided in 935 CMR 501.110, MTCs shall comply with additional operational requirements for the cultivation, acquisition, and distribution of Marijuana required under 935 CMR 501.120.
- (2) Except as authorized by 935 CMR 501.140(3)(c) and unless otherwise authorized by the Commission, only an MTC is permitted to cultivate medical-use Marijuana, except for a Registered Qualifying Patient granted a Hardship Cultivation Registration or that Patient's Personal Caregiver. Prior to commencing operations, MTCs shall disclose all growing media and plant nutrients intended to be used during the cultivation process. In all instances, MTCs shall disclose all growing media and plant nutrients being used upon request.
- (3) Unless otherwise authorized by the Commission, a cultivation location of an MTC may cultivate Marijuana for only that MTC, and up to two additional MTCs locations operated by the same entity Owner.

501.120: continued

(4) All phases of the cultivation of Marijuana shall take place in a designated, Limited Access Areas where Marijuana is not visible from a public place without the use of binoculars, aircraft or other optical aids. Marijuana is not visible if it cannot be reasonably identified.

(5) Application of Pesticides shall be performed in compliance with M.G.L. c. 132B, and 333 CMR 2.00: *General Information* through 333 CMR 14.00: *Protection of Children and Families from Harmful Pesticides*. Any testing results indicating noncompliance shall be immediately reported to the Commission, who may refer any such result to the MDAR.

(6) An MTC selling or otherwise Transferring Marijuana to another MTC or Marijuana Establishment shall provide documentation of its compliance, or lack thereof, with the testing requirements of 935 CMR 501.160.

(7) An MTC may label Marijuana and MIPS with the word "organic" only if all cultivation is consistent with US Department of Agriculture organic requirements at 7 CFR Part 205 and consistent with the MDAR requirements for Pesticide usage.

(8) Soil for cultivation shall meet federal standards identified by the Commission including, but not limited to, the US Agency for Toxic Substances and Disease Registry's Environmental Media Evaluation Guidelines for residential soil levels.

(9) The cultivation process shall use best practices to limit contamination including, but not limited to, mold, fungus, bacterial diseases, rot, pests, Pesticides not in compliance with 935 CMR 501.120(5), mildew, and any other contaminant identified as posing potential harm. Best practices shall be consistent with state and local law including, but not limited to, the Commission's Guidance on Integrated Pest Management.

(10) Any application of plant nutrient to land used for the cultivation of Marijuana shall comply with St. 2012, c. 262, as amended by St. 2013, c. 118, § 26, and 330 CMR 31.00: *Plant Nutrient Application Requirements for Agricultural Land and Non-agricultural Turf and Lawns*.

(11) MTC cultivation operations shall satisfy minimum energy efficiency and equipment standards established by the Commission and meet all applicable environmental laws, regulations, permits and other applicable approvals including, but not limited to, those related to water quality and quantity, wastewater, solid and hazardous waste management, and air pollution control, including prevention of odor and noise pursuant to 310 CMR 7.00: *Air Pollution Control* as a condition of obtaining a final License under 935 CMR 501.103(2) and as a condition of renewal under 935 CMR 501.103(4). MTC cultivation operations shall adopt and use additional best management practices as determined by the Commission, in consultation with the working group established under St. 2017, c. 55, § 78(b) or applicable departments or divisions of the EOEEA, to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts, and shall provide energy and water usage reporting to the Commission in a form determined by the Commission. Each License renewal application under 935 CMR 501.103(4) must include a report of the MTC cultivation operations' energy and water usage over the 12-month period preceding the date of application.

(12) MTC cultivation operations shall be subject to the following minimum energy efficiency and equipment standards:

(a) The building envelope for all facilities, except Greenhouses, shall meet minimum Massachusetts Building Code requirements and all Massachusetts amendments (780 CMR: *State Building Code*), International Energy Conservation Code (IECC) Section C.402 or The American Society of Heating, Refrigerating and Air-conditioning Engineers (ASHRAE) Chapters 5.4 and 5.5 as applied or incorporated by reference in 780 CMR: *State Building Code*, except that facilities using existing buildings may demonstrate compliance by showing that the envelope insulation complies with code minimum standards for Type Factory Industrial F-1, as further defined in guidelines issued by the Commission.

(b) Lighting used for MTC cultivation operations shall meet one of the following compliance paths:

501.120: continued

1. Horticulture Lighting Power Density may not exceed 36 watts per square foot, except for Tier 1 and Tier 2 which may not exceed 50 watts per square foot;
  2. All horticultural lighting used in a facility is listed on the current Design Lights Consortium Solid-State Horticultural Lighting Qualified Products List ("Horticultural QPL") or other similar list approved by the Commission as of the date of License application, and lighting Photosynthetic Photon Efficacy (PPE) is at least 15 % above the minimum Horticultural QPL threshold rounded up to the nearest 0.1  $\mu\text{mol/J}$  (micromoles per joule); or
  3. A facility seeking to use horticultural lighting not included on the Horticultural QPL or other similar list approved by the Commission shall seek a waiver pursuant to 935 CMR 501.850 and provide documentation of third-party certification of the energy efficiency features of the proposed lighting. All facilities, regardless of compliance path, shall provide third-party safety certification by an OSHA NRTL or SCC-recognized body, which shall certify that products meet a set of safety requirements and standards deemed applicable to horticultural lighting products by that safety organization.
- (c) Heating Ventilation and Air Conditioning (HVAC) and dehumidification systems shall meet Massachusetts State Building Code requirements and all Massachusetts amendments (780 CMR: *State Building Code*), IECC Section C.403 or ASHRAE Chapter 6 as applied or incorporated by reference in (780 CMR: *State Building Code*). As part of the documentation required under 935 CMR 501.120(11) an MTC engaged in cultivation operations shall provide a certification from a Massachusetts Licensed Mechanical Engineer that the HVAC and dehumidification systems meet Massachusetts building code as specified in 935 CMR 501.120(11) and that such systems have been evaluated and sized for the anticipated loads of the facility.
- (d) Safety protocols shall be established and documented to protect workers, Qualifying Patients, or Visitors (*e.g.*, eye protection near operating Horticultural Lighting Equipment).
- (e) The requirements in 935 CMR 501.120(12)(b) and (c) may not be required if an indoor MTC cultivation operation is generating 80% or more of the total annual on-site energy use for all fuels (expressed on a MWh basis) from an on-site clean or renewable generating source, or renewable thermal generation, as provided in M.G.L. c. 25A, §§ 11F and 11F $\frac{1}{2}$ . Additionally, the Licensee shall document that renewable energy credits or alternative energy credits representing the portion of the Licensee's energy usage not generated on-site have been purchased and retired on an annual basis.
- (f) Prior to final licensure, an MTC applicant shall demonstrate compliance with 935 CMR 501.120(11) by submitting an energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with submission of building plans under 935 CMR 501.103(1)(a). To the extent updates are required to the information provided for initial licensure, the MTC shall submit an updated energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with a renewal application submitted under 935 CMR 501.103(4).
- (g) A CMO with a final Certificate of Licensure issued before November 1, 2019 shall have until July 1, 2020 to comply with 935 CMR 501.120(11), except that any additions to or renovations to a facility shall comply with 935 CMR 501.120(11). An MTC with a final Certificate of Licensure issued before November 1, 2019 shall have until January 1, 2021 to comply with 935 CMR 501.120(11), except that any additions to or renovations to a facility shall comply with 935 CMR 501.120(11). An MTC subject to 935 CMR 501.120(12)(g) may apply for an additional six-month extension if it agrees to install meters to monitor energy usage, water usage and other data determined by the Commission as necessary in order to provide reports on energy usage, water usage, waste production and other data in a form and manner determined by the Commission.
- (h) For purposes of 935 CMR 501.120(11), the following terms shall have the following meanings:
1. Horticultural Lighting Equipment (HLE) means any lighting equipment (*e.g.* fixtures, bulbs, ballasts, controls, *etc.*) that uses energy for the cultivation of plants, at any stage of growth (*e.g.* germination, cloning/mother plants, Propagation, Vegetation, Flowering, and harvest).

501.120: continued

2. Horticulture Lighting Square Footage (HLSF) means an area to be calculated in square feet and measured using clearly identifiable boundaries of all areas(s) that will contain plants at any point in time, at any stage of growth, including all of the space(s) within the boundaries, HLSF may be noncontiguous, but each unique area included in the total HLSF calculations shall be separated by an identifiable boundary which includes, but is not limited to: interior walls, shelves, Greenhouse walls, hoop house walls, garden benches, hedge rows, fencing, garden beds, or garden plots. If plants are being cultivated using a shelving system, the surface area of each level shall be included in the total HLSF calculation.
  3. Lighting Power Density (HLPD) means a measure of total watts of Horticultural Lighting Equipment per total Horticulture Lighting Square Footage, (HLE/HLSF = HLPD) expressed as number of watts per square foot.
- (13) In addition to the written operating policies required under 935 CMR 501.105(1), MTC cultivation operations, including CMO Marijuana Cultivators, shall maintain written policies and procedures for the cultivation, production, Transfer or distribution of Marijuana, as applicable, which shall include, but not be limited to:
- (a) Methods for identifying, recording, and reporting diversion, theft, or loss, for correcting all errors and inaccuracies in inventories, and for maintaining accurate inventory. The policies and procedures, at a minimum, shall comply with 935 CMR 501.105(8);
  - (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by an MTC to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
  - (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, shall comply with 935 CMR 501.105(12);
  - (d) Policies and Procedures for Transportation. The policies and procedures, at a minimum, shall comply with 935 CMR 501.105(13);
  - (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, shall comply with 935 CMR 501.105(15) and 501.120(11);
  - (f) Policies and procedures for ensuring fire safety in cultivation activities including, but not limited to, the storage and processing of chemicals or fertilizers, in compliance with the standards set forth in 527 CMR 1.00: *Massachusetts Comprehensive Fire Code*; and
  - (g) Policies and procedures for the Transfer, acquisition, or sale of Marijuana between MTCs and Marijuana Establishments.

501.130: Additional Operational Requirements for Handling and Testing Marijuana and for Production of MIPs

- (1) In addition to the general operational requirements for MTCs required under 935 CMR 501.105 and security requirements provided in 935 CMR 501.110, MTCs shall comply with additional operational requirements required under 935 CMR 501.130.
- (2) Production of Edibles shall take place in compliance with the following:
  - (a) All Edibles shall be prepared, 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*; and
  - (b) Any Edible that is made to resemble a typical food or beverage product shall be packaged in an opaque package and labeled as required by 935 CMR 501.105(5)(c).

501.130: continued

(3) An MTC engaged in product manufacturing operations shall meet all applicable environmental laws, regulations, permits and other applicable approvals including, but not limited to, those related to water quality and quantity, wastewater, solid and hazardous waste management and air pollution control, including prevention of odor and noise pursuant to 310 CMR 7.00: *Air Pollution Control*, and to use additional best management practices as determined by the Commission in consultation with the working group established under St. 2017, c. 55, § 78(b) or applicable departments or divisions of the EOEEA to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts.

(4) An MTC selling or otherwise Transferring Marijuana to another MTC or Marijuana Establishment shall provide documentation of its compliance, or lack thereof, with the testing requirements of 935 CMR 501.160, and standards established by the Commission for the conditions, including time and temperature controls, necessary to protect Marijuana Products against physical, chemical, and microbial contamination as well as against deterioration of finished products during storage and transportation.

(a) An MTC shall retain all records of purchases from any manufacturer or supplier of any ingredient, additive, device, component part or other materials obtained by the MTC in relation to the manufacturing of Marijuana Vaporizer Devices and such records shall be made available to the Commission on request.

(b) An MTC shall maintain records of the name and business address of the manufacturer of any cartridge, battery, atomizer coil, hardware or other component of Marijuana Vaporizer Products manufactured by the Licensee. Further, the MTC shall, on request by the Commission, identify the materials used in the device's atomizer coil (*e.g.*, titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material) or state if such information cannot be reasonably ascertained.

(c) A copy of the Certificate of Analysis for each thickening agent, thinning agent or terpene infused or incorporated into a Marijuana Vaporizer Device during production shall be retained by an MTC and provided as a part of a wholesale transaction with any MTC or Marijuana Retailer.

(d) An MTC that wholesales Marijuana Vaporizer Devices to an MTC or Marijuana Retailer shall provide the recipient with the information insert required by 935 CMR 501.105(5)(c) or the necessary information to produce such an insert and the appropriate labeling information required by 935 CMR 501.000.

(5) Written policies and procedures for the production and distribution of Marijuana, 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. The policies and procedures, at a minimum, shall comply with 935 CMR 501.105(8);

(b) A procedure for handling voluntary and mandatory recalls of Marijuana. Such procedure shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by an MTC to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;

(c) A procedure for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana or Marijuana Products are segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana or Marijuana Products. The policies and procedures, at a minimum, shall comply with 935 CMR 501.105(12);

(d) Policies and procedures for transportation and Patient or Personal Caregiver home delivery;

(e) Policies and procedures for the Transfer, acquisition, or sale of Marijuana between MTCs, and if applicable, Marijuana Establishments and CMOs;

(f) Policies and procedures to ensure that all Edibles are prepared, 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*; and

501.130: continued

(g) Policies and procedures for ensuring safety in all processing activities and the related uses of extraction equipment in compliance with the standards set forth in 527 CMR 1.00: *Massachusetts Comprehensive Fire Code*.

(6) Product Database. An MTC engaged in product manufacturing operations, after receiving a Provisional License, but prior to receiving a Certificate to Commence Operations, shall provide the following information about the finished Marijuana Products it intends to produce prior to commencement of operations. This information may be used by the Commission for its Product Database.

(a) The MTC shall provide the following:

1. Marijuana Product type;
2. Marijuana Product brand name;
3. List of direct ingredients;
4. List of indirect ingredients;
5. Serving size, including a description of what constitutes a serving size for a product that is not already a single serving;
6. Potency;
7. A photograph of a finished Marijuana Product, against a white background, outside of but next to the Marijuana Product's packaging, including any external or internal packaging, provided however that where single servings of a multi-serving product are unable to be easily identified because of its form, a description of what constitutes a single serving shall be provided (*e.g.*, a single serving is a 1" x 1" square), and where an Edible cannot be stamped, for example, due to size or a coating, the photograph of the Edible outside of but next to its external and internal packaging, such as the wrapper, and labeling information for the Edible;
8. A photograph of the Marijuana Product, against a white background, inside the packaging; and
9. A list of Marijuana Products to be sold based on anticipated or executed agreements between the MTC and another MTC or Marijuana Establishment.

(b) Photographs shall be submitted in a form and manner determined by the Commission.

(c) An MTC shall provide the information required under 935 CMR 501.130(6)(a) for each Marijuana Product that it produces prior to the product being made available for sale and shall update the information whenever a substantial change to the product information occurs. Substantial changes, including changes to information listed in 935 CMR 501.130(6)(a)1. through 9., shall be submitted to the Commission for inclusion in the Product Database prior to the transfer of the Marijuana Product.

(7) Notwithstanding a stricter municipal or state regulation, an MTC shall identify the method of extraction (*e.g.*, Butane, Propane, CO<sub>2</sub>) on a physical posting at all entrances of the MTC. The Posting shall be a minimum of 12" x 12" and identify the method of extraction in lettering no smaller than one inch in height. An MTC shall post a copy of a permit to keep, store, handle or otherwise use flammable and combustible material at each place of operation within the facility.

(8) Except for a Registered Qualifying Patient or Personal Caregiver, who are not subject to 935 CMR 501.105, only a licensed MTC is permitted to produce MIPs. Unless otherwise authorized by the Commission, an MIP production facility of an MTC may produce MIPs for only that MTC, and up to two additional MTCs under an entity.

501.140: Additional Operational Requirements for Patient Sales

(1) In addition to the general operational requirements for MTCs required under 935 CMR 501.105 and security requirements provided in 935 CMR 501.110, MTCs engaged in patient sales shall comply with additional operational requirements for MTCs under 935 CMR 501.140.

(2) Verification of Patient and Caregiver Certification

(a) Upon entry into an MTC by a Registered Qualifying Patient or Personal Caregiver, or arrival at a residence for delivery to a Registered Qualifying Patient or Personal Caregiver, an MTC or Marijuana Courier Agent shall immediately inspect the Patient's or caregiver's temporary or annual Registration Card and proof of government-issued identification.



501.140: continued

1. The government-issued identification card shall contain a name, photograph, and date of birth, and shall be limited to one of the following:
    - a. A driver's license;
    - b. A government issued identification card;
    - c. A military identification card; or
    - d. A passport.
  2. An MTC may dispense only to a Registered Qualifying Patient who has a current valid certification with the Commission or Other Jurisdictions that permit the medical use of marijuana or their Personal Caregiver. Pursuant to 935 CMR 501.010(8), a Certifying Healthcare Provider shall have defined the calendar day length of valid certification of a Qualifying Patient.
  3. Qualifying Patients younger than 18 years old do not have to have a separate means of identification to enter an MTC.
  4. A Qualifying Patient younger than 18 years old cannot enter an MTC without their Caregiver.
- (b) An MTC shall make interpreter services available that are appropriate to the population served, including for the visually and hearing impaired. Such services may be provided by any effective means.
- (3) Patient Allotment.
- (a) 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 935 CMR 501.002 (*e.g.*, a Patient with a 60-day supply of ten ounces who is 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).
  - (b) For a Registered Qualifying Patient whose Certifying Healthcare Provider has determined that he or she requires a 60-day supply other than ten ounces in accordance with 935 CMR 501.010(9), the amount of Marijuana dispensed, including Marijuana contained in MIPs, shall be adjusted accordingly so that the amount of Marijuana dispensed, including Marijuana contained in MIPs, shall be no more than a 60-day supply as certified by the Certifying Healthcare Provider in each 60-day period.
  - (c) A Registered Qualifying Patient may possess up to 12 flowering plants and up to 12 Vegetative plants, excluding Clones and cuttings. If one or more Qualifying Patients collectively require more than this amount at one residence in order to maintain a 60-day supply, then a Hardship Cultivation Registration is required.
- (4) Unauthorized Sales and Right to Refuse Sales.
- (a) An MTC shall refuse to sell Marijuana to any Registered Qualifying Patient or Personal Caregiver who is unable to produce a temporary or an annual Registration Card and valid proof of identification, or who does not have a valid certification in the Commission supported interoperable database.
  - (b) An MTC shall refuse to dispense to a Registered Qualifying Patient or Personal Caregiver if in the opinion of the MTC agent, the Patient or the public would be placed at risk. In any instance of denial, an MTC shall notify the Patient's Certifying Healthcare Provider within 24 hours.
  - (c) An MTC may not sell to a Patient or caregiver an amount of Marijuana or Marijuana Products that would exceed the Patient's 60-day Supply.
  - (d) An MTC is prohibited from selling Marijuana Products containing nicotine.
  - (e) An MTC is prohibited from selling Marijuana Products containing alcohol, if sales of such alcohol would require licensure pursuant to M.G.L. c. 138.
- (5) Recording Sales.
- (a) An MTC shall only utilize a point-of-sale system approved by the Commission.
  - (b) A retailer is prohibited from utilizing software or other methods to manipulate or alter sales data.

501.140: continued

1. An MTC shall conduct a monthly analysis of its equipment and sales data to determine that no software has been installed that could be utilized to manipulate or alter sales data and that no other methodology has been employed to manipulate or alter sales data. The MTC shall use industry best practices to ensure its analysis does not compromise system security.
    - An MTC shall maintain records that it has performed the monthly analysis and produce it on request to the Commission. If a retailer determines that software has been installed for the purpose of manipulation or alteration of sales data or other methods have been utilized to manipulate or alter sales data:
      2. It shall immediately disclose the information to the Commission;
      3. It shall cooperate with the Commission in any investigation regarding manipulation or alteration of sales data; and
      4. Take such other action directed by the Commission to comply with 935 CMR 501.105.
  - (c) An MTC shall adopt separate accounting practices at the point-of-sale for Marijuana and Marijuana Product sales, and non-Marijuana sales.
  - (d) For non-Marijuana sales, an MTC shall comply with Massachusetts tax laws, and DOR rules and regulations including, but not limited to, 830 CMR 62C.25.1: *Record Retention*, and *DOR Directive 16-1* regarding recordkeeping requirements.
  - (e) At the point of sale, and in a form and manner determined by the Commission, an MTC shall comply with tracking requirements in 935 CMR 501.015(3) and (4) including, but not limited to, Qualifying Patient and, where applicable, Personal Caregiver information, and amount of medical-use Marijuana or MIPs sold.
  - (f) An MTC shall accurately track and maintain these records for no less than one year, except as otherwise provided in 935 CMR 501.140(5)(e) for taxable non-Marijuana sales, and shall be readily available to the Commission or its representatives on request. Such records shall include:
    1. Date and time of transaction;
    2. Name and agent registration number of the MTC Agent conducting the transaction;
    3. Specific name, strength, dose, quantity, and type of Marijuana and MIPs sold during the transaction;
    4. Name of Patient, and where applicable, Personal Caregiver, receiving the Marijuana, MIPs or Marijuana accessory or other taxable non-Marijuana item; and
    5. Any other additional information the Commission may deem necessary.
  - (g) The Commission may audit and examine the point-of-sale system used by an MTC in order to ensure compliance with 935 CMR 501.140(5);
- (6) Patient Education.
- (a) An MTC shall provide educational materials about Marijuana to Registered Qualifying Patients and their Personal Caregivers.
    1. An MTC shall have an adequate supply of up to date educational material available for distribution.
    2. Educational materials shall be available in languages accessible to all Patients served by the MTC, including for the visually and hearing impaired.
    3. Such materials shall be made available for inspection by the Commission upon request.
  - (b) The educational material shall include at least the following:
    1. A warning that Marijuana has not been analyzed or approved by the FDA, that there is limited information on side effects, that there may be health risks associated with using Marijuana, and that it should be kept away from children;
    2. A warning that when under the influence of Marijuana, driving is prohibited by M.G.L. c. 90, § 24, and machinery should not be operated;
    3. Information to assist in the selection of Marijuana, 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 shall also be explained;

.501.140: continued

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 to any other individual, and that they shall return unused, excess, or contaminated product to the MTC from which they purchased the product, for disposal; and
  9. Any other information required by the Commission.
- (c) The educational material cannot include:
1. Any statement, design, representation, picture, or illustration that encourages or represents the use of Marijuana for any purpose other than to treat a Debilitating Medical Condition or related symptoms;
  2. Any statement, design, representation, picture, or illustration that encourages or represents the recreational use of Marijuana;
  3. Advertising, marketing, and branding that asserts that its products are safe, or represent that its products have curative or therapeutic effects, other than labeling required pursuant to M.G.L. c. 94G, § 4(a½)(xxvi), unless supported by substantial evidence or substantial clinical data with reasonable scientific rigor as determined by the Commission; and
  4. Any statement, design, representation, picture, or illustration portraying anyone younger than 21 years old.

(7) Testing. No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 501.000. The product shall be deemed to comply with the standards required under 935 CMR 501.160.

Potency levels derived from the Cannabinoid Profile, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta$ 9-THC) and other Cannabinoids, contained within Finished Marijuana or Marijuana Product to be sold or otherwise marketed shall be recorded in the Seed-to-sale SOR.

(8) Repackaging. Repackaged Marijuana shall comply with the labeling and packaging requirements under 935 CMR 501.105(5) and 500.105(6).

(9) Advance Contactless Order Fulfillment.

(a) An MTC may allow for advance ordering of Marijuana and Marijuana Products by telephone, website or Third-party Platform, which shall be available for inspection prior to commencing operations and on request.

(b) MTCs may fulfill advance orders through contactless means by not requiring contact between a Qualified Patient or Personal Caregiver and Registered Marijuana Agent.

(c) Any physical unit used for the purpose of the fulfillment of an advance contactless order (order) shall ensure that access to orders of Marijuana or Marijuana Products is limited to the Qualifying Patient or Personal Caregiver who placed the advance order.

(d) Any physical unit used for the purpose of order fulfillment of Marijuana or Marijuana Products shall be located within the MTC building and bolted or otherwise permanently affixed to the MTC Premises.

(e) An MTC that adopts a contactless means of fulfilling orders shall have a written operations plan which shall be submitted to the Commission prior to commencing these operations and on request. The plan shall include a detailed description of how the MTC will ensure that advance contactless order fulfillment complies with the requirements of:

1. 935 CMR 501.105(3)(b) and (c) for the safe storage of Marijuana and Marijuana Products;
2. 935 CMR 501.110(1)(a) for the purposes of limiting access to Qualifying Patient or Personal Caregivers;
3. 935 CMR 501.110(5)(a)4. for the video surveillance of all advance contactless orders; and
4. 935 CMR 501.140(8).

(f) Orders placed in advance may not be retained in a physical unit used for the purpose of contactless order fulfillment overnight or outside of business hours.

501.140: continued

(10) Product Database. An MTC engaged in patient sales that purchases wholesale Marijuana Products from another licensed Marijuana Product Manufacturer for the purpose of Repackaging Marijuana Products for sale to a Qualifying Patient shall provide the Commission with the following information. This information may be used by the Commission for its Product Database.

(a) The MTC shall provide the following:

1. A photograph of a finished Marijuana Product outside of but next to the Marijuana Product's packaging; provided however, that where single servings of a multi-serving product are unable to be easily identified because of its form, a description of what constitutes a single serving shall be provided (*e.g.*, a single serving is a 1" x 1" square);
2. A photograph of the Marijuana Product inside packaging; and
3. The name of the MTC or Marijuana Establishment Product Manufacturer that produced the Marijuana Product.

(b) Photographs submitted shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.

(c) The MTC shall provide the information required under 935 CMR 501.140(8) for each Marijuana Product it Repackages for sale prior to the product being made available for sale and shall update the information whenever a substantial change to packaging or label of the Marijuana Product occurs. For purposes of 935 CMR 501.140(10)(c), a substantial change shall be a change to the physical attributes or content of the package or label.

(11) Sale of Marijuana Vaporizer Devices.

(a) MTCs offering Marijuana Vaporizer Devices for sale to Registered Qualifying Patients shall include signage at the point of sale, that is legible and enlarged and contains the following statements:

1. "Marijuana Vaporizer Devices have been tested for Vitamin E Acetate and other contaminants, with no adverse findings. WARNING: Vaporizer Devices may contain ingredients harmful to health when inhaled."
2. "Patients shall have access to the test results of Marijuana Vaporizer Devices including copies of any Certificates of Analysis provided by the device's manufacturer."

(b) MTCs shall provide a physical insert to Registered Qualifying Patients that accompanies all purchased Marijuana Vaporizer Devices that states, including capitalization and emphasis, the following: "Marijuana Vaporizer Devices have been tested for Vitamin E Acetate and other contaminants, with no adverse findings. WARNING: Vaporizer Devices may contain ingredients harmful to health when inhaled."

(c) The sale of disposable and reusable vaporizer pens and devices shall be accompanied by a product insert identifying the materials used in the vaporizer device's atomizer coil (*e.g.*, titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material), and manufacturer identification of the device hardware, cartridge, battery and other components;

(d) An MTC shall make available the information contained in 935 CMR 501.105(5)(c)6. in the product description at the point of sale and as part of any product list posted on the MTC's website or Third-party Technology Platforms or applications employed for preordering or delivery.

(e) An MTC shall retain all records of purchases from any supplier of any ingredient, additive, device, component part or other materials provided to the MTC about Marijuana Vaporizer Devices sold at MTCs. Such records shall be made available to the Commission upon request.

(12) Physical Separation of Marijuana and MIPs or Marijuana Products for Medical or Adult Use. A CMO shall provide for physical separation between medical and adult use sales areas. Separation may be provided by a temporary or semi permanent physical barrier, such as a stanchion, that, in the opinion of the Commission, adequately separates sales areas of MIPs for medical use from sales areas of Marijuana Products for adult use for the purpose of patient confidentiality.

(a) A CMO shall provide for separate lines for sales of Marijuana or MIPs for medical use from Marijuana Products for adult use within the sales area, provided that the holder of a patient registration card may use either line and may not be limited only to the medical use line, so long as the CMO can record the patient's transaction in accordance with 935 CMR 501.105(5)(d).

501.140: continued

(b) A CMO shall additionally provide a patient consultation area, an area that is separate from the sales floor that is enclosed to allow privacy and for confidential visual and auditory consultation with Qualifying Patients.

(c) A CMO's patient consultation area shall have signage stating, "Consultation Area". The private consultation area shall be separate from the sales area. It shall be accessible by a Qualifying Patient or caregiver without having to traverse a Limited Access Area.

(d) A CMO shall use best efforts to prioritize Patient and caregiver identification verification and physical entry into its retail area.

(13) Patient Supply.

(a) A CMO shall ensure access to a sufficient quantity and variety of Marijuana Products, including Marijuana, for Patients registered under 935 CMR 501.000.

1. Where the CMO has been open and dispensing for a period of less than six months, the license shall reserve 35% of the MTC's Marijuana Products.

2. Where the CMO has been open and dispensing for a period of six months or longer, the licensee shall maintain a quantity and variety of Marijuana Products for Patients registered under 935 CMR 501.000, sufficient to meet the demand indicated by an analysis of sales data collected by the Licensee during the preceding six months in accordance with 935 CMR 500.140(5): *Recording Sales* and 935 CMR 501.140(5).

(b) Marijuana products reserved for patient supply shall, unless unreasonably impracticable, reflect the actual types and strains of Marijuana Products documented during the previous six months. If a substitution shall be made, the substitution shall reflect as closely as possible the type and strain no longer available.

(c) On a biannual basis, the CMO shall submit to the Commission an inventory plan to reserve a sufficient quantity and variety of medical use Marijuana Products for Registered Qualifying Patients, based on reasonably anticipated patient needs as documented by sales records over the preceding six months. On each occasion that the supply of any product within the reserved patient supply is exhausted and a reasonable substitution cannot be made, the CMO shall submit a report to the Commission in a form determined by the Commission.

(d) Marijuana Products reserved for patient supply shall be either maintained on-site at the retailer or easily accessible at another location operated by the Licensee and transferable to the retailer location within 48 hours of notification that the on-site supply has been exhausted. CMOs shall perform audits of available patient supply on a weekly basis and retain those records for a period of six months.

(e) The Commission shall, consistent with 935 CMR 500.301 or 501.301, inspect and audit CMOs to ensure compliance with 935 CMR 500.140: *Additional Operating Requirements for Retail Sales*. The Commission may, in addition to the issuance of a deficiency statement under 935 CMR 500.310: *Deficiency Statements* or 935 CMR 501.310 and a plan of correction under 935 CMR 500.320: *Plans of Correction* or 935 CMR 501.320, demand that the CMO take immediate steps to replenish its reserved patient supply to reflect the amounts required under 935 CMR 500.140(15)(a) or 935 CMR 501.140(13)(a). Failure to adequately address a deficiency statement or follow a plan of correction shall result in administrative action by the Commission pursuant to 935 CMR 500.450: *Marijuana Establishment License: Grounds for Suspension, Revocation and Denial of Renewal Applications*, and 935 CMR 500.500: *Hearings and Appeals of Actions on Licenses* or 935 CMR 501.450 and 501.500.

(f) CMOs may transfer Marijuana Products reserved for medical-use to adult-use within a reasonable period of time prior to the date of expiration provided that the product does not pose a risk to health or safety.

(14) Prohibition on Monopolies.

(a) It shall be a violation of 935 CMR 501.000 for any MTC to monopolize or attempt to monopolize, or combine or conspire with any other person or entity including, but not limited, to a Third-party Technology Platform Provider, to monopolize any part of licensed activities authorized under 935 CMR 501.000.

501.140: continued

(b) It shall be a violation of 935 CMR 501.000 for any MTC engaged in activities authorized under 935 CMR 501.000 to make a contract for services with a Third-party Technology Platform Provider for the listing of a MTC's Marijuana or Marijuana Products on the condition, agreement or understanding that the parties to the contract shall not deal in Marijuana or Marijuana Products, either generally or specific brands or categories of Finished Marijuana Products, of a competitor or competitors of the parties where the effect of such contract or such condition, agreement or understanding may be to lessen substantially competition or tend to create a monopoly in any activity engaged in under 935 CMR. 501.000.

501.145: Home Delivery

(1) General Requirements.

(a) An MTC, or a Marijuana Courier acting on behalf of an MTC, shall obtain Commission approval prior to engaging in the delivery of Marijuana and Marijuana Products directly to a Registered Qualified Patient or Caregiver. An MTC shall comply with 935 CMR 501.110(8) and 935 CMR 501.110(9) and adhere to its policies and procedures for home delivery approved pursuant to 935 CMR 501.101(1)(c)12.

(b) All individuals delivering Marijuana and Marijuana Products for an MTC directly to Registered Qualifying Patients and Caregivers shall be employees of the MTC Licensee and shall hold a valid MTC agent registration; or, where a Marijuana Courier provides delivery services on behalf of an MTC, employees duly registered as agents of the Marijuana Courier.

(c) All Marijuana and Marijuana Products delivered by or on behalf of an MTC in fulfillment of an Individual Order shall be obtained from the MTC with which the Individual Order was placed. An MTC cannot pick up Marijuana or Marijuana Products from another MTC to fulfill an Individual Order.

(d) An MTC or Marijuana Courier may use a Third-party Technology Platform Provider to facilitate the ordering of Marijuana or Marijuana Products.

1. All agreements between an MTC or Marijuana Courier and a Third-party Technology Platform Provider shall be available for inspection and subject to the control limitations under 935 CMR 501.050(1)(b).

2. The Commission shall be notified in writing within five days of any Substantial Modification to an agreement between an MTC or Marijuana Courier and a Third-party Technology Platform Provider.

3. Any Third-party Technology Platform shall comply with privacy and patient protection standards established by the Commission.

4. The Commission shall be notified in writing on an ongoing basis of any new or additional or assigned agreements between an MTC or Marijuana Courier and a Third-party Technology Platform Provider within five days.

(e) The maximum retail value of Marijuana or Marijuana Products allowed in an MTC's vehicle at any one time shall be \$10,000 and each Marijuana Product shall be associated with a specific Individual Order. For purposes of 935 CMR 501.145(1)(e), "maximum retail value" shall mean the aggregate value of Marijuana and Marijuana Products as priced on the day of the order for delivery.

(f) All Marijuana and Marijuana Product deliveries shall be tracked using the Seed-to-sale SOR as designated by the Commission.

(g) Limitations on the time for delivery shall comply with all municipal bylaws and ordinances, provided however, that all deliveries of Marijuana or Marijuana Products shall be completed before 9:00 P.M. or the time determined by municipal bylaw or ordinance, whichever occurs first, and deliveries Marijuana may not occur between the hours of 9:00 P.M. and 8:00 A.M., unless otherwise explicitly authorized by municipal bylaw or ordinance.

(h) Every effort shall be made to minimize the amount of cash carried in an MTC or Marijuana Courier vehicle at any one time. MTCs and Marijuana Couriers shall use best efforts to implement platforms for the electronic payment of funds. Where cash is carried in an MTC vehicle, the storage and transport of cash shall comply with the requirements of 935 CMR 501.110(7).

501.145: continued

(2) Orders. All orders for deliveries made by an MTC or Marijuana Courier shall comply with the following requirements:

- (a) All Marijuana and Marijuana Products delivered by or on behalf of an MTC shall comply with 935 CMR 501.145(1)(c).
- (b) An MTC shall only deliver Marijuana or Marijuana Products for which it has received a specific order from a Registered Qualifying Patient or Caregiver. MTCs are prohibited from delivering Marijuana or Marijuana Products without a specific order destined for an identified Qualifying Patient or Caregiver. An order may be generated directly through the MTC or through a Third-party Technology Platform identified to the Commission under 935 CMR 501.145(1)(d).
- (c) MTCs shall deliver Marijuana or Marijuana Products only to the primary residence and be prohibited from delivering Marijuana or Marijuana Products to college or university-designated dormitories or housing, federally-subsidized housing, shelters or residential programs. An Institutional Caregiver shall only receive delivery at their Caregiving Institution.
- (d) Orders for home delivery shall be received by the MTC and completed after confirmation of the Registered Qualifying Patient's or Personal Caregiver's Residence.
- (e) MTCs shall only deliver one Individual Order, per Qualifying Patient or Caregiver, during each delivery.
- (f) Only Marijuana and Marijuana Products that are Shelf-stable may be delivered. Products that are perishable, or time and temperature controlled to prevent deterioration may not be allowed to be delivered by or on behalf of an MTC.
- (g) For home delivery, each order shall be labeled and packaged in accordance with 935 CMR 501.105(5) and (6).
- (h) Any Marijuana or Marijuana Product that is undeliverable or is refused by the Qualifying Patient or Caregiver shall be transported back to the originating MTC that provided the product once all other deliveries included on a delivery manifest have been made. It shall be the responsibility of the MTC, or the MTC in conjunction with the Marijuana Courier performing the delivery, to ensure that any undelivered product is returned to the MTC's physical location and stored in accordance with 935 CMR 501.105(11). A process for ensuring that undelivered Marijuana and Marijuana Products can be returned to the MTC by the Marijuana Courier shall be a term of the Delivery Agreement.

(3) Vehicle and Transport Requirements for Home Delivery.

- (a) Vehicles used for home delivery by an MTC or Marijuana Courier shall be owned or leased by the MTC or Marijuana Courier and shall be properly registered as commercial vehicles, inspected and insured in the Commonwealth of Massachusetts.
- (b) Vehicles and transportation operations of an MTC or Marijuana Courier shall comply with 935 CMR 501.105(13) and 501.110(7).
- (c) The MTC or Marijuana Courier shall maintain a separate log for each vehicle in use for home deliveries. For each delivery, the MTC or Marijuana Courier shall record:
  1. The location of the originating MTC and date and time the vehicle leaves the location;
  2. The mileage of the transporting vehicle at departure from the MTC, mileage on arrival at each Registered Qualifying Patient or Caregiver destination, and mileage on return to the MTC;
  3. The date and time of departure from the MTC and arrival at each patient destination for each delivery; and
  4. An entry indicating the date and time of the last delivery in an order.
- (d) An MTC or Marijuana Courier may not transport products other than Marijuana and Marijuana Products during times when an MTC or Marijuana Courier is performing home deliveries.

(4) Manifests.

- (a) Every home delivery shall have a manifest produced by the MTC. A manifest shall be completed in duplicate, with the original manifest remaining with the originating MTC, and a copy to be kept with the MTC or Marijuana Courier agent during the delivery. The manifest shall be signed by the Registered Qualifying Patient or Caregiver receiving the Marijuana or Marijuana Products and the MTC or Marijuana Courier agent acting on behalf of the MTC. A signed manifest shall serve as the written record of the completion of the delivery.

501.145: continued

- (b) The manifest shall, at a minimum, include:
  1. The originating MTC's name, address, and License number;
  2. The names and agent numbers of the MTC or Marijuana Courier agents performing the delivery;
  3. The Patient or caregiver's name, address, and registration number;
  4. A description of the Marijuana or Marijuana Products being transported, including the weight, form or type of product, cost and transaction number entered in the patient sales system;
  5. Signature lines for the agents who transported the Marijuana or Marijuana Products;
  6. A signature line for the person who receives the Marijuana or Marijuana Products; and
  7. The MTC or Marijuana Courier vehicle make, model, and license plate number.
- (c) The manifest shall be maintained within the vehicle during the entire transportation process, until all the deliveries are completed.
- (d) An MTC shall retain all transportation manifests for no less than one year and make them available to the Commission on request.

501.150: Edibles

- (1) Production of Edibles. Edibles shall be produced in compliance with the following:
  - (a) Any Edibles that is made to resemble a typical food or beverage product shall be packaged and labeled as required by M.G.L. c. 94G, § 4(a½)(xxiv) and (xxvi), and 935 CMR 501.105(5) and (6).
  - (b) The manufacture or sale of Edibles in the following shapes and types is prohibited:
    1. The distinct shape of a human, animal, fruit, or sporting-equipment item; or
    2. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, fruit, or sporting-equipment item including artistic, caricature, or cartoon renderings.
  - (c) Edibles that are geometric shapes and simply fruit-flavored are not considered fruit and are permissible.
- (2) Sanitary Requirements. All Edibles shall be prepared, handled, and stored in compliance with the requirements in 935 CMR 501.105(3) and (11).
- (3) Additional Labeling and Packaging Requirements for Edibles.
  - (a) In addition to the requirements set forth in M.G.L. c. 94G, § 4(a½)(xxiv) and (xxvi), and 935 CMR 501.105(5) and (6), every MTC shall ensure that the following information or statement is Affixed to every container holding an Edible:
    1. If the retail Edible MIP is perishable or time and temperature controlled, a statement that the Edible shall be refrigerated.
    2. The date on which the Edible was produced.
    3. A nutritional fact panel that shall be based on the number of THC servings within the container.
    4. Information regarding the size of each serving for the product by milligrams, the total number of servings of Marijuana in the product, and the total amount of active THC in the product by milligrams (mg). For example: "The serving size of active THC in this product is X mg, this product contains Y servings of Marijuana, and the total amount of active THC in this product is (X\*Y) mg."
    5. A warning that the impairment effects of Edibles may be delayed by two hours or more.
  - (b) Once a label with a use-by date has been Affixed to a container holding an Edible , a Licensee may not alter that date or affix a new label with a later use-by date.
  - (c) Each single serving of an Edible within a multi-serving package of Edibles shall be easily separable in order to allow an average person 21 years of age or older to physically separate, with minimal effort, individual servings of the product.



501.150: continued

(d) Each single serving of an Edible contained in a multi-serving package of Edibles shall be marked, stamped, or otherwise imprinted with the symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana consistent with 935 CMR 501.105(5)(a)8. Alternatively, a Licensee may ensure that each single serving of an Edible is individually wrapped and shall mark, stamp, or otherwise imprint each individual wrapper with the symbol or easily recognizable mark issued by the Commission that indicates the serving contains Marijuana consistent with 935 CMR 500.105(5)(a)8.

(e) Each single serving of an Edible contained in a packaged unit of multiple Edible may be marked, stamped, or otherwise imprinted with a symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana.

501.160: Testing of Marijuana and Marijuana Products

(1) No Marijuana Product, including Marijuana, may be sold or otherwise marketed for medical use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 501.000. Testing of Marijuana Products shall be performed by an Independent Testing Laboratory in compliance with a protocol(s) established in accordance with M.G.L. c. 94G, § 15 and in a form and manner determined by the Commission including, but not limited to, the Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers and Colocated Marijuana Operations. Testing of environmental media (*e.g.*, soils, solid growing media, and water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission.

(2) Marijuana and Marijuana Products shall be tested for the Cannabinoid profile and for contaminants as specified by the Commission including, but not limited to, mold, mildew, heavy metals, plant growth regulators, and the presence of Pesticides. The Commission may require additional testing. In addition to these contaminant tests, final ready-to-sell Marijuana Vaporizer Products shall be screened for heavy metals and Vitamin E Acetate (VEA) in accordance with the Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products for Marijuana Establishments, Medical Marijuana Treatment Centers and Colocated Marijuana Operations issued by the Commission.

(3) The Commission may, at its discretion, require additional testing where necessitated to safeguard public health or safety and so identified by the Commission.

(4) An MTC shall have a written policy for responding to laboratory results that indicate contaminant levels are above acceptable limits established in the protocols identified in 935 CMR 501.160(1). Such policy shall be available to Registered Qualifying Patients and Personal Caregivers.

(a) Any such policy shall include:

1. Notifying the Commission within 72 hours of any laboratory testing results indicating that the contamination cannot be remediated and disposing of the Production Batch submission of any information regarding contamination immediately upon request by the Commission; and
2. Notifying the Commission of any information regarding contamination as specified by the Commission or immediately upon request by the Commission.

(b) The notification shall be from both the MTC and the Independent Testing Laboratory, separately and directly.

(c) The notification from the MTC shall describe a proposed plan of action for both the destruction of the contaminated product and the assessment of the source of contamination.

(5) An MTC shall maintain the results of all testing for no less than one year. Testing results shall be valid for a period of one year. Marijuana and Marijuana Products with testing dates in excess of one year shall be deemed expired and may not be dispensed, sold, Transferred or otherwise conveyed until retested.

(6) The sale of seeds is not subject to these testing provisions.

501.160: continued

- (7) Clones are subject to these testing provisions, but are exempt from testing for metals.
- (8) All transportation of Marijuana and Marijuana Products to and from Independent Testing Laboratories providing Marijuana testing services shall comply with 935 CMR 501.105(13).
- (9) All storage of Marijuana and Marijuana Products at a laboratory providing Marijuana testing services shall comply with 935 CMR 501.105(11).
- (10) All excess Marijuana and Marijuana Products shall be disposed of in compliance with 935 CMR 501.105(12), either by the Independent Testing Laboratory returning excess Marijuana or Marijuana Products to the source MTC for disposal or by the Independent Testing Laboratory disposing of it directly;
- (11) No Marijuana or Marijuana Product shall be sold or otherwise marketed for adult use that has not first been tested by an Independent Testing Laboratory and deemed to comply with the standards required under 935 CMR 501.160; and
- (12) A Licensee that receives notice that Marijuana or a Marijuana Product it has submitted for testing has failed any test for contaminants shall either reanalyze the Marijuana or Marijuana Product without remediation, take steps to remediate the identified contaminants or dispose of the Marijuana or Marijuana Product.
  - (a) Reanalysis by a Second ITL. If the Licensee chooses to reanalyze the sample, a sample from the same batch shall be submitted for reanalysis at the ITL that provided the initial failed result. If the sample passes all previously failed tests at the initial ITL, a sample from the same batch previously tested shall be submitted to a second ITL other than the original ITL for a Second Confirmatory Test. To be considered passing and therefore safe for sale, the sample shall have passed the Second Confirmatory Test at a second ITL. Any Marijuana and Marijuana product that fails the Second Confirmatory Test may not be sold, transferred or otherwise dispensed to Consumers, Patients or Licensees without first being remediated. Otherwise, the MTC shall dispose of any such product.
  - (b) Remediation. If the Licensee chooses to remediate, a new test sample shall be submitted to any licensed ITL, which may include the initial ITL, for a full-panel test. Any failing Marijuana or Marijuana product may be remediated a maximum of two times. Any Marijuana or Marijuana product that fails any test after the second remediation attempt may not be sold, transferred or otherwise dispensed to Consumers, Patients or Licensees. The MTC shall dispose of any such product.
  - (c) If the Licensee chooses to dispose of the Marijuana or Marijuana Products, it shall do so in compliance with 935 CMR 501.105(12).

501.170: Municipal Requirements

- (1) An MTC and Independent Testing Laboratory and their agents shall comply with all local rules, regulations, ordinances, and bylaws.
- (2) The Commission does not mandate any involvement by municipalities or local boards of health in the regulation of MTCs, Qualifying Patients with Hardship Cultivation Registrations, or any other aspects of Marijuana for medical use. However, nothing in 935 CMR 501.000 shall be construed to prohibit lawful local oversight and regulation, including fee requirements, that does not conflict or interfere with the operation of 935 CMR 501.000.

501.200: Counties of Dukes County and Nantucket

- (1) To the extent permitted by law, MTCs operating from locations in the Counties of Dukes County and Nantucket (the "island counties") may operate in full compliance with 935 CMR 501.000.

501.200: continued

(2) If an MTC operating from locations in the island counties are prevented from operating in full compliance with 935 CMR 501.000 by operation of law, they are not required to utilize Independent Testing Laboratories until such time as a laboratory is located on the island where the MTC is located or the establishment can transport Marijuana Products to the mainland of Massachusetts.

(3) If MTCs operating from locations in the island counties are prevented from utilizing Independent Testing Laboratories by operation of law, they are required to test Marijuana Products in a manner that is not unreasonably impracticable, but also adequately protects the public health in the opinion of the Commission. Such testing may include:

(a) A modified on-Premises testing system approved by the Commission if the label on any Marijuana or Marijuana Product so tested discloses in capital letters: “WARNING: LIMITED TESTING FOR CONTAMINANTS AND PESTICIDES”;

(b) A testing facility in the island counties that does not meet the criteria for an Independent Testing Laboratory, but is approved by the Commission for testing by MTCs located in the island counties; or

(c) Such other testing system approved by the Commission.

(4) An MTC performing home delivery operations in the island counties may only perform deliveries to Residences located in the same county as the MTC which the delivery order originates from until such time as it permitted to deliver to other locations by law.

501.300: Complaints Process

(1) In a time and manner determined by the Commission, a dedicated telephone number, email address or other means shall be provided for members of the public or Qualifying Patients to notify the Commission of complaints regarding MTCs or MTC Agents.

(2) The Commission may, at its discretion, investigate or decline to investigate any complaint or refer a complaint to another law enforcement or regulatory authority.

501.301: Inspections and Compliance

(1) Pursuant to M.G.L. c. 94I and M.G.L. c. 94G, §§ 4(a)(xvii) through (xx), the Commission or a Commission Delegee may inspect an MTC and affiliated vehicles at any time without prior notice to determine the MTC's compliance with the act and 935 CMR 501.000. All areas, activities and records of an MTC and activities and records of MTC agents are subject to such inspection. Submission of an application by or issuance of a License to an MTC constitutes consent for such inspection

(2) An MTC shall allow immediate access to the facility on being presented with photo identification documenting the Commission representative's affiliation with the Commission or a Commission Delegee's affiliation with a state agency with lawful jurisdiction over the operations of an MTC.

(3) An MTC shall immediately on request make available to the Commission or a Commission Delegee all information that may be relevant to an inspection or investigation of an incident or a complaint.

(4) An MTC shall make all reasonable efforts to facilitate the inspection or investigation of an incident or a complaint, including the taking of samples, photographs, video or other evidence or recordings, and complying with demands for examination and inspection in accordance with 935 CMR 501.302.

(5) During an inspection, the Commission or a Commission Delegee may direct an MTC to test Marijuana for contaminants including, but not limited to, mold, mildew, heavy metals, plant-growth regulators, and the presence of Pesticides not approved for use on Marijuana pursuant to 935 CMR 501.120(5).

## 501.301: continued

(6) An inspection or other investigation may be made prior to the issuance of a License or the renewal of a License. Additional inspections may be made whenever the Commission or a Commission Delegee deems it necessary for the enforcement of M.G.L. c. 94I and M.G.L. c. 94G, and 935 CMR 501.000.

(7) The failure to cooperate with an inspection or otherwise comply with 935 CMR 501.301 may result in administrative or disciplinary action against the Licensee.

501.302: Compliance Examination

(1) After an MTC has been licensed, the Commission or a Commission Delegee pursuant to M.G.L. c. 94I and M.G.L. 94G, § 4(a)(xx), has the authority to demand access to its papers, books, documents, records, correspondence, electronic communications, and other tangible things to examine and inspect. Such examination and inspection may include interrogatories to parties or subpoenas to compel the production of papers, books, documents, records, correspondence, electronic communications, and other tangible things. The examination and inspection of an MTC may also include the interview of material witnesses, registered agents or Close Associates whom the Commission has determined is involved in the financing, management or operation of the MTC.

(2) Administrative Subpoenas. The Commission or a Commission Delegee may, during a preliminary investigation prior to a hearing, issue, modify, amend or rescind subpoenas. Material witnesses, registered agents, or other Persons whom the Commission has determined are involved in the financing, management or operation of an MTC may petition the Commission to modify, amend or rescind subpoenas.

(3) General Provisions. Administrative subpoenas for compliance examination and inspection shall be issued in the name of the Commission by the Commission or a Commission Delegee. Service may be made in a form and manner determined by the Commission including, but not limited to, by the consent of the parties.

(4) Enforcement of Subpoenas. On the failure of a person to comply with a *subpoena*, and not subsequently vacated or modified by the Commission or a Commission Delegee, the Commission or a Commission Delegee may apply to the Superior Court for an order to compel compliance with the *subpoena*; an order for costs and fees associated with the issuance and enforcement of the *subpoena*; or an order of contempt for any failure by a party to comply with a court order.

(5) The failure to cooperate with provisions of 935 CMR 501.302 may result in administrative or disciplinary action against the Licensee.

501.303: Unannounced Purchase for Purpose of Investigative Testing (Secret Shopper Program).

(1) Secret Shopper Program Authorized. The Commission or a Commission Delegee may at any time and without prior notice, authorize an employee or other agent to pose as a customer and purchase any Marijuana or Marijuana Products from any registered or licensed MTC. The Commission or a Commission Delegee, may authorize such purchase for any investigative purposes that are consistent with St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. c. 94I, 935 CMR 500.000: *Adult Use of Marijuana*, or 935 CMR 501.000 including, but not limited to, investigative testing for compliance with laboratory testing standards and identification check requirements. The purchasing employee or agent shall document the purchase, including the date, time and place of purchase, type and amount of Marijuana or Marijuana Products, and any other information required by the Commission.

(2) Custody and Preservation of Purchases. The Marijuana or Marijuana Products purchased as part of the program shall be securely stored during transport in a manner to prevent contamination or spoilage.

501.303: continued

(3) Contamination and Spoilage During Storage or Transport. Any contamination or spoilage of purchases under the Secret Shopper Program during storage or transport while under the control of the purchaser shall be promptly documented by the purchaser in writing and reported to the Commission. The Commission or a Commission Delegee, may authorize the disposal of the contaminated or spoiled purchase, pursuant to the regulations concerning waste disposal under 935 CMR 501.105(12).

(4) Use of Secret Shopper Investigative Results. Results of investigations conducted under Secret Shopper Program shall be promptly submitted to the Commission.

(a) All investigative results shall be retained as part of the records for the licensed MTC from which the purchase originated.

(b) The MTC may be notified of any investigative results determined to be noncompliant at a time and manner determined by the Commission.

(c) After the MTC is notified of the investigative results, such results may be used by the Commission to take action on the License of the MTC pursuant to 935 CMR 501.340, 501.350, 501.450, 501.500 or assess fines or other civil penalties pursuant to 935 CMR 501.360.

(d) Without notice to the MTC, the Commission may share such investigative results with any other law enforcement or regulatory authorities.

(e) The Commission may elect to conduct further evaluation of the investigative results at any time for verification or for other purposes reasonably related to sanitation, public health or public safety.

(5) The failure to cooperate with provisions of 935 CMR 501.303 may result in administrative or disciplinary action against the Licensee.

501.310: Deficiency Statements

After an inspection in which a violation of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. 94I, 935 CMR 500.000: *Adult Use of Marijuana*, or 935 CMR 501.000 is observed or a violation is otherwise determined to have occurred, the Commission shall issue a deficiency statement citing every violation identified, a copy of which shall be left with or sent to the MTC.

501.320: Plans of Correction

(1) An MTC shall submit to the Commission a written plan of correction for any violations cited in the deficiency statement issued pursuant to 935 CMR 501.310, within ten business days after receipt of the statement.

(2) A plan 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 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.

(3) The Commission shall review the plan of correction, and shall notify the MTC of either the acceptance or rejection of the plan or any component of the plan.

(4) An unacceptable plan shall be amended and resubmitted within five business days after receipt of such notice.

(5) The approval of a plan of correction shall not preclude the Commission from issuing an order for further corrective action fixing a reasonable time for correction of the violation, assessing an administrative fine, or taking any other administrative action authorized under the Commission's regulations.

(6) An MTC shall notify the Commission once the plan of correction has been fully implemented and completed.

501.321: Administrative Hold

- (1) Pursuant to M.G.L. c. 94I and M.G.L. c. 94G, § 4(a)(xix), the Commission or a Commission Delegee may order an Administrative Hold of Marijuana, Marijuana Products or MIPs to examine and inspect an MTC to ensure compliance with the provisions of 935 CMR 501.000, prevent the destruction of evidence, prevent the diversion of Marijuana or Marijuana Products, or as otherwise necessary to protect the public health, safety, or welfare.
- (2) An MTC subject to an Administrative Hold shall retain its inventory pending further investigation by the Commission or a Commission Delegee pursuant to the following procedure:
  - (a) If during an investigation or inspection of an MTC, the Commission has reasonable cause to believe certain Marijuana or Marijuana Products are noncompliant under 935 CMR 501.000, or otherwise constitutes a threat to the public health, safety or welfare, the Commission may issue a notice to administratively hold any Marijuana or Marijuana Product. The notice shall identify the Marijuana or Marijuana Product subject to the Administrative Hold and a concise statement stating the reasons relied on in the issuance of the Administrative Hold.
  - (b) Following the issuance of a notice of Administrative Hold, the Commission will identify and mark the Marijuana or Marijuana Product subject to the Administrative Hold in the Commission's Seed-to-sale SOR. The MTC shall continue to comply with all inventory requirements including, but not limited to, 935 CMR 501.105(8).
  - (c) The MTC shall completely and physically segregate the Marijuana or Marijuana Product subject to the Administrative Hold in a Limited Access Area, where it shall be safeguarded by the MTC.
  - (d) While the Administrative Hold is in effect, the MTC shall be prohibited from selling, transporting or otherwise Transferring or destroying the Marijuana or Marijuana Product subject to the Administrative Hold, except as otherwise authorized by the Commission.
  - (e) While the Administrative Hold is in effect, the MTC shall safeguard the Marijuana or Marijuana Product subject to the Administrative Hold and shall fully comply with all security requirements including, but not limited to, 935 CMR 501.110.
  - (f) An Administrative Hold shall not prevent an MTC from the continued possession, cultivation or harvesting of the Marijuana or Marijuana Product subject to the Administrative Hold, unless otherwise provided by an order of the Commission. All Marijuana or Marijuana Products subject to an Administrative Hold shall be put into separately tracked Production Batches.
  - (g) An Administrative Hold shall not prevent an MTC from voluntarily surrendering Marijuana or Marijuana Products subject to an Administrative Hold, except that the MTC shall comply with the waste disposal requirements in 935 CMR 501.105(12).
  - (h) At any time after the initiation of the Administrative Hold, the Commission or a Commission Delegee may modify, amend or rescind the Administrative Hold.
  - (i) The failure to cooperate with provisions of 935 CMR 501.321 may result in administrative or disciplinary action against the Licensee.

501.330: Limitation of Sales

- (1) If the Commission or a Commission Delegee determines that an MTC does not substantially comply with applicable provisions of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. c. 94I, or 935 CMR 501.000, the Commission or a Commission Delegee may order that the MTC dispose of and may not sell Marijuana or Marijuana Products, after a date specified.
- (2) The Commission or a Commission Delegee shall not make such a determination until an MTC has been notified that the MTC does not substantially comply with applicable provisions of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. c. 94I, or 935 CMR 501.000, that an order to dispose of or limit sales is contemplated, and that the MTC has a reasonable opportunity to correct the deficiencies.
- (3) An order that an MTC dispose of and may not sell Marijuana or Marijuana Products pursuant to 935 CMR 501.330(1) may be rescinded when the Commission or a Commission Delegee finds that the MTC is in substantial compliance with the applicable provisions of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, M.G.L. c. 94I, or 935 CMR 501.000.

501.335: Removal and Prohibition of Marijuana and Marijuana Products

(1) Pursuant to M.G.L. c. 94G, § 4(a½)(xxxi) and M.G.L. c. 94I, the Commission or a Commission Delegee may order the removal or prohibition of sales by more than one Licensee of categories of product types, of specific product types or of specific brands of products after notice and a determination that Marijuana, Marijuana Products, and Marijuana Accessories (for the purposes of 935 CMR 501.335, "Product"), which based on preliminary evidence, pose a substantial risk to the public health, safety or welfare including, but not limited to, that the product is especially appealing to Persons under 21 years of age.

(a) The Commission may vote to initiate a complaint about a Product and refer that complaint to the Executive Director and Enforcement staff for investigation.

(b) In consultation with the Executive Director, Enforcement staff may conduct an investigation and make a recommendation as to the Removal of Product. The recommendation shall be based on credible and reliable evidence and provide a specific description of the scope of removal and specify whether the removal or prohibition on sales applies to one of the following:

1. Category of Product Type(s). A type of Product including, but not limited to, Marijuana seeds, Marijuana Clones, Edibles, Beverages, topical products, ointments, oils, Tinctures, oral dosage forms or any other Product identified by the Commission or a Commission Delegee.

2. Specific Product Type(s). A specific type of Product within a category of Products, but not including other types of Product within the same category.

3. Specific Brand of Product(s). One or more specific Product types or category types Manufactured by a Marijuana Product Manufacturer or a specific Product type or category type Manufactured by multiple Marijuana Product Manufacturers subject to an agreement including, but not limited to, a partnership, product licensing, distribution, branding, advertising, marketing or sales agreement.

(2) After receiving a recommendation from Enforcement staff, the Executive Director may act to address the substantial risk to the public health, safety or welfare including, but not limited to:

(a) Refer the matter to a Hearing Officer with expertise to evaluate scientific evidence to conduct an informal hearing;

(b) If credible and reliable evidence has been evaluated and found to meet the standard of a substantial risk to public health, safety or welfare, if one is not yet issued, order the quarantine or Removal of Product or prohibition on sales of a Product pending consideration by a Hearing Officer; or

(c) Refer the matter to the Commission.

(3) When a matter is referred by the Executive Director, the Hearing Officer may conduct an informal hearing.

(a) If necessary and in consultation with the Executive Director, the Hearing Officer may develop a process for the purpose of identifying the Licensees and Registrants that may be impacted by a current or future order including, but not limited to, identifying those Licensees and Registrants to whom providing adequate notice and an opportunity to be heard shall be given.

(b) The Hearing Officer shall exercise discretion in admitting and weighing evidence including, but not limited to, testimony and evidence from:

1. Licensees and Registrants; and

2. Subject-matter experts.

(c) The Hearing Officer shall issue findings of fact and make a recommended decision to the Executive Director.

(d) To the extent that the Hearing Officer recommends that Products be removed or prohibited, this recommendation shall be based on credible and reliable evidence that the Product poses a substantial risk to the public health, safety and welfare.

(4) The Executive Director may refer the matter to the Commission and make a recommendation.

(5) On referral by the Executive Director, prior to issuing any order, the Commission shall deliberate on the Executive Director's recommendation at a public meeting of the Commission.

## 501.335: continued

- (a) If there is a recommendation that the Products be removed and prohibited, this recommendation shall be based on credible and reliable evidence that the Product poses a substantial risk to the public health, safety and welfare.
  - (b) An order shall require a vote by the Commission.
  - (c) The Commission or a Commission designee shall send written notice of the action taken against an identified Licensee or Registrant and the basis for that action. The notice shall include, but not be limited to, the following information:
    - 1. the Commission's statutory and regulatory authority, including its jurisdiction over the subject matter; and its authority to take action with regards to the License or registration;
    - 2. the factual basis for that action;
    - 3. the extent to which the product poses a substantial risk to the public health, safety and welfare; and
    - 4. the current restrictions on the Licensee's or Registrant's operations or sales or other use of Products, if any, including the method and timing of the Removal of Product including, but not limited to, whether the Product shall be destroyed in accordance with 935 CMR 501.105(12).
  - (d) The Commission or a Commission designee may modify, amend or rescind a notice on condition(s) just to all the parties.
- (6) On receipt of the order, the Licensee and its associated agents will immediately comply with the requirements of the order and, if requested by the Commission, post notice at public entrances to the establishment or other notice in a form and manner determined by the Commission.
- (7) The order shall be transmitted immediately to all other Licensee(s) or Registrant(s) that may reasonably be affected by the order by electronic and certified mail.
- (8) The order may be posted on the Commission's website.
- (9) It shall be a violation of 935 CMR 501.000 for Licensees to produce, sell or otherwise make available the categories of Product Types, Specific Product Types or Specific Brands of Products identified in the order.
- (10) An MTC subject to the order shall accept Registered Qualifying Patients' returns of unused and unopened product for a period of 30 days after the effective date of the order.
- (11) The failure to cooperate with provisions of this section may result in further administrative or disciplinary action against the Licensees or Registrants.

501.340: Quarantine Order

- (1) Pursuant to its authority under M.G.L. c. 94I and M.G.L. c. 94G, §§ 4(a)(xix) and 4(a½)(xxxi), a Quarantine Order may be imposed by the Commission or a Commission Delegee to immediately quarantine or otherwise restrict the sale or use of Marijuana, Marijuana Products or MIPs by a Licensee or Registrant to protect the public health, safety or welfare.
- (2) If, based on complaint(s) inspection(s), affidavit(s), or other credible evidence, the Commission or a Commission Delegee determines that a Licensee or Registrant or the Marijuana, Marijuana Products, MIPs, cultivated, produced or sold by a Licensee or Registrant pose an immediate or serious threat to the public health, safety, or welfare, the Commission or a Commission Delegee may issue an order to the Licensee that:
  - (a) Quarantines or otherwise restricts the sale or use of Marijuana, Marijuana Products, or MIPs, prepared by or in the possession of the Licensee; or
  - (b) Quarantines or otherwise restricts the sales or use of Marijuana, Marijuana Products, or MIPs to the extent necessary to avert a threat, pending final investigation results.
- (3) On receipt of the order, the Licensee and its associated agents will immediately comply with the requirements of the order and, if requested by the Commission, post notice at the public entrances to the MTC or Independent Testing Lab or other notice in a form and manner determined by the Commission or a Commission Delegee.



501.340: continued

(4) The Commission or a Commission Delegee may modify, amend or rescind the order at any time after its issuance on condition(s) just to all the parties.

(5) To the extent that the issuance of a Quarantine Order is to investigate a risk to public safety, health and welfare, a Licensee shall not have a right to a hearing, unless and until the order remains in effect beyond 21 calendar days without any further action by the Commission or a Commission Delegee.

(6) The failure to cooperate with provisions of 935 CMR 501.340 may result in administrative or disciplinary action against the Licensees or Registrants.

501.350: Cease and Desist Order and Summary Suspension Order

(1) Pursuant to its authority under M.G.L. c. 94I, and M.G.L. c. 94G, §§ 4(a) and 4(a½), a Cease and Desist or a Summary Suspension Order may be imposed by the Commission or a Commission Delegee prior to a hearing to protect the public health, safety, or welfare.

(2) If based on inspection(s), affidavit(s) or other credible evidence, the Commission or a Commission Delegee determines that a Licensee or Registrant, or the Marijuana, Marijuana Products, MIPs cultivated, produced, or sold by a Licensee or Registrant, pose an immediate or serious threat to the public health, safety, or welfare, the Commission or a Commission Delegee may:

- (a) Issue a Cease and Desist Order that requires cessation of any or all operations including, but not limited to, the cultivation, product manufacturing, Transfer, sale, delivery or transportation of Marijuana, Marijuana Products, or MIPs; or
- (b) Issue a Summary Suspension Order that requires the immediate suspension of a License and its associated registrations and cessation of all operations.

(3) Notice of Violations.

(a) For a Cease and Desist or Summary Suspension Order issued under 935 CMR 501.350(2), the Commission or a Commission Delegee shall send written notice of the action taken against a Licensee or Registrant and the basis(es) for that action, which shall include, but not be limited to, the following information:

- 1. The Commission's statutory and regulatory authority, including its jurisdiction over the subject matter and its authority to take action with regards to the License or registration;
- 2. The factual basis(es) of the action;
- 3. The immediate threat to the public health, safety, and welfare;
- 4. The alleged violation(s) of law, including the alleged noncompliance with law, regulation, guideline or other applicable requirement;
- 5. The current restriction(s), if any, on the Licensee's or Registrant's operations;
- 6. Requirements for the continued maintenance and security of any Marijuana and Marijuana Products;
- 7. The potential for further disciplinary action(s), sanction(s) or fine(s); and
- 8. The Licensee's right to a hearing, if any.

(b) The Commission or a Commission Delegee may modify, amend or rescind the order at any time after its issuance on condition(s) just to all the parties.

(4) On receipt of the order issued under 935 CMR 501.350(2), the Licensee and its associated agents will immediately comply with the requirements of the order and, if requested, post notice at public entrances to the MTC or Independent Testing Lab or other notice in a form and manner determined by the Commission or a Commission Delegee.

(5) Hearings. Pursuant to its authority under M.G.L. c. 94I, § 7, M.G.L. c. 94G, § 4(a)(xxiv) and (g), the Commission has the authority to administer the administrative hearing process and to delegate to a Hearing Officer the authority to conduct an administrative hearing.

501.350: continued

(a) Hearing Request. On written request filed with the Commission, a Licensee shall be afforded a hearing on an order issued under 935 CMR 501.350(2). The hearing request shall be submitted in a form and a manner determined by the Commission or a Commission Delegee including, but not limited to, the request shall be made no later than 21 calendar days after the effective date of the order. A request for a hearing is filed on the date the request is received by the Commission.

1. A timely request for a hearing shall specifically identify each issue and fact in dispute and state the position of the Licensee or Registrant, the pertinent facts to be adduced at the hearing, and the reasons supporting that position.

2. The failure to timely file a request for a hearing or to state the basis of the hearing request will result in dismissal of the challenge to the findings set forth in the Notice of Violations.

(b) Hearing Notice. If a hearing is requested in a timely manner under 935 CMR 501.350(5)(a), the Hearing Officer shall provide notice and a hearing promptly after that request, or as soon as is practicable, or at a time mutually agreed by the parties.

(c) Conduct of the Hearing.

1. The hearing shall be conducted pursuant to Standard Adjudicatory Rules of Practice and Procedure, which includes 801 CMR 1.01: *Formal Rules*, 801 CMR 1.02: *Informal/Fair Hearing Rules*, and 801 CMR 1.03: *Miscellaneous Provisions Applicable to All Adjudicatory Proceedings*.

2. The scope of the hearing shall be limited to whether there existed prior to, or at the time of the order(s) issued pursuant to 935 CMR 501.350(2), or an amended or a modified order, an immediate or serious threat to the public health, safety, or welfare.

3. If the Commission proves by a preponderance of the evidence that there existed an immediate or serious threat to the public health, safety, or welfare, the Hearing Officer shall affirm the order.

4. The Hearing Officer shall electronically mail a copy of the recommended decision to each Licensee or Registrant and their attorney(s) of record, and mail a copy on written request.

(6) The requirements of the order issued under 935 CMR 501.350(2) shall remain in effect until one of the following events has occurred:

(a) The Commission modifies, amends or rescinds the order;

(b) There is a Final Decision on the merits of a Commission order, including judicial review of the order, unless the order is vacated or modified by a court of competent jurisdiction or rescinded by the Commission;

(c) There is a Final Decision on the merits of a subsequently issued Order to Show Cause under 935 CMR 501.370, including judicial review of the order, unless the order is vacated or modified by a court of competent jurisdiction or rescinded by the Commission; or

(d) Until such time as is otherwise established under the procedures set forth in 935 CMR 501.500.

501.360: Fines

The Commission or a Commission Delegee may issue an order to a Licensee to show cause as to why a fine or other financial penalty against a Licensee or Registrant should not be imposed for any acts or omissions determined to be in violation of the state Marijuana laws, including 950 CMR 501.000.

(1) Notice of Fines. The Commission or a Commission Delegee shall send written notice of the action taken against a Licensee or Registrant and the basis(es) for that action, which shall include, but not be limited to, the following information:

(a) The Commission's statutory and regulatory authority, including its jurisdiction over the subject matter and its authority to issue the order with regards to the License or registration;

(b) The factual basis(es) of the order;

(c) The alleged violation(s) of law;

(d) An assessment of an administrative fine of up to \$50,000, or an order for corrective action fixing a reasonable time for correction of the violation or both; and

(e) Notice to the Licensee or Registrant that they may request a hearing in accordance with 935 CMR 501.500.

501.360: continued

- (2) An administrative fine up to \$50,000 may be assessed for each violation.
- (a) The decision to impose any fine shall identify the factors considered by the Commission or a Commission Delegee in setting the amount of the fine.
- (b) Each day during which a violation continues may constitute a separate offense, and each instance and provision of the state Marijuana laws, including M.G.L. c. 94I, and 935 CMR 501.000, that is violated may constitute a separate violation.
- (3) The Commission or a Commission Delegee, in determining the amount of sanction(s) to impose may consider greater or lesser sanction(s) depending on aggravating or mitigating circumstances including, but not limited to:
- (a) Aggravating Circumstances.
1. Duration and severity of violation;
  2. Whether the Licensee has previously been subject to an administrative action against its License including, but not limited to, a notice of deficiency;
  3. Whether the Licensee knew or had reason to know of the violation including, but not limited to, warning or issuance of a notice of deficiency; and
  4. Whether the offense:
    - a. Constitutes grounds for denial of a renewal application or suspension or revocation of licensure;
    - b. Involved multiple Persons or Entities Having Direct or Indirect Control or agents of the Licensee;
    - c. Involved any compensating features associated with a valid waiver issued pursuant to 935 CMR 501.850;
    - d. Involved a person younger than 21 years old or a Registered Qualifying Patient or Caregiver;
    - e. Involved or affected multiple Qualifying Patients;
    - f. Involved or exposed the public to risk of diversion; or
    - g. Created a risk to the public health, safety or welfare.
- (b) Mitigating Circumstances.
1. The financial impact of corrective measures, if any, which provide safeguards exceeding the minimum requirements of 935 CMR 501.000. However, financial impact shall not include any cost associated with loss of economic opportunity due to noncompliance or costs of corrective action necessary to achieve compliance with minimum requirements of 935 CMR 501.000;
  2. The Licensee's or Registrant's good faith efforts to avoid a violation;
  3. The Licensee's or Registrant's degree of cooperation in the investigation; and
  4. The Licensee's or Registrant's willingness to accept responsibility.
- (4) The fine or financial penalty shall be due and payable within 30 calendar days of the date of one of the following:
- (a) The date of the assessment; or
- (b) If a hearing is requested pursuant to 935 CMR 501.500, the date of the final agency action.
- (5) Failure to timely pay the fine or financial penalty may result in further action being taken by the Commission or a Commission Delegee including, but not limited to, suspension or revocation of a License or registration.
- (6) If remaining unpaid at the time of licensure renewal, the fine or financial penalty shall be added to the fee for renewal of the License. A License shall not be renewed without the payment of the renewal fee and if applicable, an unpaid fine or financial penalty.
- (7) All fines and financial penalties collected by or on behalf of the Commission, pursuant to 935 CMR 501.360, shall be made payable to the Commission and deposited into the Marijuana Regulation Fund.
- (8) The failure to cooperate with provisions of 935 CMR 501.360 may result in administrative or disciplinary action against the Licensees or Registrants.

501.370: Orders to Show Cause

- (1) If, after investigation, the Commission or a Commission Delegee determines that there are grounds to suspend or revoke a License or registration, it may also issue an Order to Show Cause why the Licensee or registration should not be suspended or revoked.
- (2) Notice of Violations. The Commission or a Commission Delegee shall send written notice of the action taken against a Licensee or Registrant and the basis for that action, which shall include, but not be limited to, the following information:
  - (a) the Commission's statutory and regulatory authority, including its jurisdiction over the subject matter and its authority to issue the order with regards to the License or registration;
  - (b) the factual basis(es) of the order;
  - (c) the alleged violation(s) of law, including the alleged noncompliance with law, regulation, guideline or other applicable requirement;
  - (d) the restriction(s) on the Licensee's or Registrant's operations or the sale or use of Marijuana, Marijuana Products, or MIPs, if any;
  - (e) the potential for further disciplinary action(s), sanction(s) or fine(s); and
  - (f) the right to a hearing, if any.
- (3) The Commission or a Commission Delegee may modify, amend or rescind an order issued pursuant to 935 CMR 501.370.

501.400: Medical Marijuana Treatment Center License: Grounds for Denial of Application for Licensure

Each of the following, in and of itself, constitutes full and adequate grounds for denying an applicant on an application for an MTC License and the associated individuals and entities, but not for the renewal of a License.

- (1) The applicant failed to complete the application process within the time required by the Commission.
- (2) Information provided by the applicant was deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure.
- (3) The application indicates an inability to maintain and operate an MTC in compliance with the requirements of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, and 935 CMR 501.000 including, but not limited to, 935 CMR 501.105 and 935 CMR 501.110 based on the submission of information required by 935 CMR 501.101(1) and (2).
- (4) The applicant has been determined to be unsuitable pursuant to any one or more of the factors listed in 935 CMR 501.800 and 501.801.
- (5) The applicant failed to comply with the control limitations listed in 935 CMR 501.050(1)(b) or would likely fail to comply with such limitations if a License were granted.
- (6) An applicant had its License or registration revoked or application denied in the Commonwealth or an Other Jurisdiction.
- (7) Any other ground that serves the purposes of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, or 935 CMR 501.000.

501.415: Void Medical Marijuana Treatment Center License

An MTC License is void if the MTC Ceases to Operate or transfers its location without Commission approval or adds a Person or Entity Having Direct or Indirect Control to the License without Commission approval.

501.450: Medical Marijuana Treatment Center Registration or License: Grounds for Suspension, Revocation and Denial of Renewal Applications

Each of the following, in and of itself, constitutes full and adequate grounds for suspending or revoking an MTC's License or denying a renewal application for an MTC License.

- (1) The MTC is not operational within the time projected in the License application or the time otherwise approved by the Commission.
- (2) Information provided by the MTC was deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure.
- (3) The MTC has failed to comply with any requirement of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, and 935 CMR 501.000, or any applicable law or regulation including, but not limited to, the laws and regulations of the Commonwealth relating to taxes, child support, workers' compensation, and professional and commercial insurance coverage.
- (4) The MTC has failed to submit a plan of correction as required or to implement the plan as submitted pursuant to 935 CMR 501.320.
- (5) The MTC has assigned or attempted to change ownership or assign its License to another entity without prior approval of the Commission under 935 CMR 501.104.
- (6) The Licensee failed to comply with the control limitations listed in 935 CMR 501.050(1)(b) or would likely fail to comply with such limitations, if a renewal License were granted.
- (7) There has been a lack of responsible operation of the MTC, as shown by, but not limited to, one or more of the following:
  - (a) Failure to maintain the MTC in a clean, orderly, and sanitary fashion;
  - (b) Permitting an MTC agent to use a Registration Card belonging to a different person;
  - (c) Repeated failure to verify the proper temporary or annual registration documents for a Patient or Personal Caregiver, in accordance with 935 CMR 501.015(3) and 501.020(2), prior to permitting that individual on the Premises of an MTC or making sales of Marijuana or MIPs to that individual; or
  - (d) Other incompetent or negligent operation.
- (8) The financial management of the MTC has resulted in the filing of a petition for a Court Appointee related to the financial solvency of the MTC.
- (9) A Licensee fails to satisfy the requirements of 935 CMR 501.104(3)(e) or (4), as applicable.
- (10) A Person on an MTC License has maintained a substandard level of compliance with the statutory and regulatory requirements for the operation of an MTC, healthcare facility or facility for providing Marijuana for medical purposes in an Other Jurisdiction including, but not limited to, failure to correct deficiencies, a limitation on, or a suspension, revocation, or refusal to grant or renew a registration or License to operate, or certification for Medicaid or Medicare.
- (11) The conduct or practices of the MTC demonstrate a lack of suitability as specified in 935 CMR 501.800 and 501.801.
- (12) An individual or entity on an MTC License or MTC Agent has a history of criminal conduct as evidenced by any criminal proceedings that resulted in conviction, guilty plea, plea of *nolo contendere*, or admission to sufficient facts in the Commonwealth or Other Jurisdictions.
- (13) An individual or entity listed on an MTC License has committed, permitted, aided or abetted or conspired to commit any illegal practice(s) in the operation of any MTC including, but not limited to, engaging in the diversion of Marijuana or Marijuana Products.

501.450: continued

- (14) The MTC has failed to cooperate or give information to a law enforcement official acting within his or her lawful jurisdiction related to any matter arising out of conduct at any MTC.
- (15) The conduct or practices of the MTC have been detrimental to the safety, health, or welfare of Registered Qualifying Patients, Personal Caregivers, or the public.
- (16) The MTC does not have sufficient financial resources to meet the requirements of M.G.L. c. 94I, or 935 CMR 501.000.
- (17) Any other ground that serves the purposes of St. 2016, c. 334, as amended by St. 2017, M.G.L. c. 94I, or 935 CMR 501.000.

501.500: Hearings and Appeals of Actions on Registrations or Licenses

- (1) The Commission has the authority to administer the administrative hearing process under M.G.L. c. 94I, § 7 and M.G.L. c. 94G, § 4(a)(xxiv) and (g).
- (2) A Licensee shall be afforded a hearing on any adverse action taken pursuant to:
  - (a) 935 CMR 501.360;
  - (b) 935 CMR 501.370;
  - (c) 935 CMR 501.450; or
  - (d) Any other notice of the Commission that specifies that the Licensee or Registrant has a right to challenge the findings of fact and conclusions of law set forth in the Commission's notice using the process set forth in 935 CMR 501.500.
- (3) Notice(s).
  - (a) Notice of Violation(s) includes a notice issued in accordance with 935 CMR 501.360 or 935 CMR 501.370.
  - (b) Notice of Other Action(s). The Commission or a Commission Delegee shall send written notice of the action including, but not limited to, a denial of a renewal License, taken against a Licensee and the basis(es) for that action, which shall include, but not be limited to, the following information:
    - 1. The Commission's statutory and regulatory authority, including its jurisdiction over the subject matter and its authority to take action with regards to the License or registration;
    - 2. The factual basis(es) for that action;
    - 3. The alleged violation(s) of law;
    - 4. The current restriction(s) on the Licensee's or Registrant's operations or the sale or use of Marijuana, Marijuana Products, or MIPs, if any;
    - 5. The potential for further disciplinary action(s), sanction(s) or fine(s); and
    - 6. The Licensee's right to a hearing, if any.
  - (c) The Commission or a Commission Delegee may modify, amend or rescind a notice issued under 935 CMR 500.500(3)(c).
- (4) Hearing Request. The hearing request shall be submitted in a form and a manner determined by the Commission or a Commission Delegee including, but not limited to, the request shall be made no later than 30 days after the effective date of the notice. A request for a hearing is filed on the date the request is received by the Commission.
  - (a) A timely request for a hearing shall specifically identify each issue and fact in dispute and state the position of the Licensee, the pertinent facts to be adduced at the hearing, and the reasons supporting that position.
  - (b) The failure to timely file a request for a hearing or to state the basis of the hearing request will result in dismissal of the challenge to the findings set forth in the notice of violation(s) or action(s).

501.500: continued

(c) If a timely request for a hearing is made, the Licensee may also seek to stay any action until there has been a final agency action pursuant to 935 CMR 501.500(7) or 935 CMR 501.500(12); provided however, that if the Commission issues an order or notice on the basis of information that ongoing operations pose an immediate or serious threat to the public health, safety, or welfare, and that operations without restrictions during the pendency of the administrative appeal could reasonably be expected to endanger the health, safety, or welfare of the public, there will be no stay.

(d) Nothing in 935 CMR 501.500 shall preclude the Commission or a Commission Delegee from issuing a stay.

(5) Hearing Officer. The Commission shall designate a Hearing Officer or delegate this designation to the Executive Director.

(6) Hearing Officer's Authority to Take Action in the Event of Waiver, Default or Summary Decision.

(a) Waiver. If a Licensee fails to request a hearing in a timely manner or otherwise waives their right to a hearing, the Hearing Officer may assume the truth of the allegations set forth in the notice and recommend to the Commission disciplinary action(s), sanction(s) or fine(s) or an informal disposition of the matter.

(b) Default. If a Licensee defaults, the Hearing Officer or a Commission Delegee may assume the truth of the allegations set forth in the notice and recommend to the Commission appropriate disciplinary action(s), sanction(s) or fine(s) or an informal disposition of the matter.

(c) Summary Decision. If there is no genuine issue of fact to be determined by a hearing, the Hearing Officer may assume the truth of the allegations set forth in the notice and recommend to the Commission disciplinary action(s), sanction(s) or fine(s) or an informal disposition of the matter.

(d) For actions without a hearing under 935 CMR 501.500, the Hearing Officer may conduct an evidentiary hearing on the appropriateness of disciplinary action(s), sanction(s) or fine(s).

(7) Commission's Authority to Review, Approve or Reject Informal Dispositions. At any time, the Commission or a Commission Delegee may, in its discretion, review, approve or reject an informal disposition, but only on a showing that the alleged violations have been corrected, and a submission of a written waiver of its right to judicial review.

(8) Hearing Notice. If a hearing is requested in a timely manner under 935 CMR 501.500(4), the Hearing Officer shall provide notice and a hearing within a reasonable time after that request, or as soon as is practicable, or at a time mutually agreed by the parties.

(a) The hearing notice should comply with M.G.L. c. 30A, § 11(1).

(b) Prior to the commencement of a proceeding, a Hearing Officer may conduct conference(s) and refer or require the parties to participate in settlement negotiations. If the parties reach a settlement, the Hearing Officer shall suspend the proceedings pending Commission consideration of the matter under 935 CMR 501.500(7).

(9) Conduct of the Hearing.

(a) To the extent that a Hearing Officer conducts a proceeding, it shall be conducted pursuant to M.G.L. c. 30A and the Standard Adjudicatory Rules of Practice and Procedure, which includes 801 CMR 1.01: *Formal Rules*, 801 CMR 1.02: *Informal/Fair Hearing Rules*, and/or 801 CMR 1.03: *Miscellaneous Provisions Applicable to All Adjudicatory Proceedings*.

(b) In the case of an Order to Show Cause, why a License or Registration should not be suspended or revoked, the hearing shall be conducted pursuant to M.G.L. c. 30A, §§ 10, 11 and 12.

(c) If after the commencement of the hearing, the parties reach a settlement, the Hearing Officer shall suspend the proceedings pending Commission consideration of the matter under 935 CMR 501.500(7).

501.500: continued

(10) Reopening of Hearings. At any time before the Commission's Final Decision is issued, on the motion of any party or on their own initiative, the Commission by a majority vote or the Hearing Officer may on good cause shown reopen the hearing for the purpose of receiving new evidence.

(11) Hearing Officer's Recommended Decision.

(a) Burden of proof.

1. For a notice of violation(s), the Commission or a Commission Delegee bears the burden of proving the Licensee(s)' violation(s) of law.
2. For a notice of action(s) including, but not limited to, the denial of a renewal License, the Licensee bears the burden of proving the qualifications for licensure.

(b) The Hearing Officer will make a recommended decision to the Commission.

1. The recommended decision may affirm, modify, or overturn the actions proposed in the Commission's notice of violation(s) or action(s).
2. The recommended decision shall be in writing to the Commission for its consideration, which shall include, but not be limited to, a statement of reasons, including determination of each issue of fact or law necessary to the decision.
3. The Hearing Officer may recommend disciplinary action(s), sanction(s) or fine(s), or an informal disposition of the matter and provide reasons for the recommendation, including whether the recommendation is consistent with the notice of violation(s) or action(s) and the Commission's prior disciplinary action(s), sanction(s) or fine(s).
4. The Hearing Officer shall electronically mail a copy of the recommended decision to each Licensee or their attorney(s) of record and on request, mail a copy of the recommended decision to each Licensee or their attorney(s) of record.

(c) Within 21 calendar days of the issuance of the recommended decision, the parties may submit to the Commission written objections and arguments regarding the Hearing Officer's recommended decision.

(12) Final Decision.

(a) The Commission may affirm, adopt, modify, amend, or reverse the recommended decision of the Hearing Officer or remand the matter for further consideration.

(b) The Commission's decision shall be considered the Final Decision, unless its authority to render a Final Decision is delegated.

1. The Final Decision shall be in writing. The drafting of the decision may be delegated to the General Counsel so long as the Commission votes on the substance of the Final Decision.
2. The Final Decision may incorporate by reference the Hearing Officer's recommended decision in whole or in part. The Commission shall consider the parties' written objections and arguments regarding the Hearing Officer's recommended decision under 935 CMR 501.500(11)(c), but is not required to respond to these submissions.
3. The Final Decision shall include, but not be limited to, the following:
  - a. A statement of reasons, including determination of each issue of fact or law necessary to the decision; and
  - b. Any disciplinary action(s), sanction(s) or fine(s), or an informal disposition of the matter.

(c) The vote on the Final Decision shall be supported and signed by at least three Commissioners. As part of its vote, the Commission may delegate to the General Counsel action(s) needed to finalize the decision including, but not limited to, the stamping of Commissioners' signatures.

(d) The Commission's Final Decision is a final agency action reviewable pursuant to M.G.L. c. 30A, § 14.

(e) The Commission or a Commission Delegee shall electronically mail a copy of the recommended decision to each Licensee or Registrant or their attorney(s) of record and on request, mail a copy of the recommended decision to each Licensee or Registrant or their attorney(s) of record.

(13) Appeals. Any Person aggrieved by a Final Decision may appeal that decision to the Superior Court in accordance with M.G.L. c. 30A, § 14. The filing of an appeal shall not operate as a stay of enforcement of the Commission's decision, but the Commission may in its discretion stay enforcement.



501.800: Suitability Standard for Licensure and Registration

- (1) Pursuant to M.G.L. c. 94G, §§ 4(a)(xii), (xiv), 21(a)(ii) and M.G.L. c. 94I, the Commission may make, in an exercise of its discretion, a suitability or cure determination based on a factual basis.
- (2) The Commission may also delegate suitability determinations to the Executive Director, who may appoint a Suitability Review Committee (Committee) to advise the Executive Director.
- (3) All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 501.800.
- (4) Suitability Review Process.
  - (a) Designated Enforcement staff (staff) shall conduct background checks and gather information and evidence applicable to a subject's suitability and make a recommendation as to suitability and, as appropriate, a cure. Staff may make an adverse suitability recommendation on finding information and evidence that would result in a Mandatory Disqualification, Presumptive Negative Suitability Determination or that would support a Negative Suitability Recommendation.
  - (b) Before making an adverse suitability recommendation, staff shall consult with the Executive Director or the Executive Director's delegee(s). The Executive Director may dispose of the matter or direct the Committee to institute a review of suitability or take any action consistent with M.G.L. c. 94G.
  - (c) If the Executive Director institutes a suitability review, the staff shall send the written notice of an adverse suitability recommendation that identifies the Person subject to suitability review, the particular offenses or conduct relied on and whether that the offenses or conduct results in a Mandatory Disqualification or Presumptive Negative Suitability Determination, or supports a Negative Suitability Recommendation, and reasons for that determination.
  - (d) The notice of an adverse suitability recommendation shall provide an opportunity to cure the suitability issue by removing the subject from its application. To the extent that an applicant can propose a cure, for example, by removing a subject from an application, the cure shall be done in a manner determined by the Commission.
  - (e) The notice of an adverse suitability recommendation shall provide the subject with the opportunity to request an informal proceeding before the Suitability Review Committee.
  - (f) A request for an informal proceeding shall be submitted in a form and manner determined by the Commission and no later than 14 business days following the effective date of the adverse suitability recommendation. Requests received after 14 business days may be considered at the discretion of the Executive Director or the Committee.
  - (g) On notification of an adverse suitability recommendation and receipt of an informal proceeding request, the Committee shall initiate a proceeding, make a recommendation and/or take other action(s) after consultation with the Executive Director.
  - (h) If an applicant or a subject does not make a timely request for an informal proceeding before the Committee, the Executive Director may forward the adverse suitability recommendation to the Committee for a review, make a suitability determination, or take any action consistent with M.G.L. c. 94G.
- (5) The Committee shall:
  - (a) Consider and review whether offense(s) or information resulting in a Mandatory Disqualification or a Presumptive Negative Suitability Determination under 935 CMR 501.801: *Table A*, 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C*, as applied to the subject, renders the subject unsuitable for licensure or registration;
  - (b) Consider and review whether offense(s) or information not otherwise set forth in 935 CMR 501.801: *Table A*, 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C* would result in a Negative Suitability Recommendation and renders the subject unsuitable for licensure or registration; and
  - (c) Subsequent to its review of a suitability matter, make recommendations to the Executive Director, or the Commission, or a Commission Delegee.
- (6) When reviewing an adverse suitability recommendation by staff that there is an offense resulting in a Mandatory Disqualification, the Commission shall consider credible and reliable information demonstrating that:

501.800: continued

- (a) The disqualifying event was based on erroneous information or evidence; and
  - (b) The subject can demonstrate that prior to the informal proceeding, the adverse suitability recommendation can no longer be supported because the error was corrected.
- (7) When reviewing an offense resulting in a Presumptive Negative Suitability Determination, the committee shall take into consideration the following factors:
- (a) Nature and specific circumstances of the offense or incident:
    - 1. Time since the offense or incident;
    - 2. Number of offenses or incidents;
    - 3. If criminal, sentence imposed and length, if any, of incarceration;
    - 4. If criminal, sentence imposed and length, if any, of parole or probation; and
    - 5. Relationship of offense or incident to nature of work to be performed;
  - (b) Mitigating factors:
    - 1. Age of the subject at the time of the offense or incident; and
    - 2. Whether offenses or incidents were committed in association with dependence on drugs or alcohol from which the subject has since recovered;
  - (c) Conduct since time of the offense or incident:
    - 1. If criminal, any relevant evidence of rehabilitation or lack thereof, such as information about compliance with conditions of parole or probation, including orders of no contact with victims and witnesses; and
    - 2. The subject's conduct and experience since the time of the offense including, but not limited to, professional or educational certifications obtained; and
  - (d) Any other relevant information, including information submitted by the subject to the Committee or requested by the Commission.
- (8) The Committee may make a Negative Suitability Determination in the following circumstances:
- (a) On the receipt of the staff's Negative Suitability Recommendation that there is credible and reliable information in the five years immediately preceding the application:
    - 1. The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare if a License or registration is granted or renewed; and
    - 2. The risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of an MTC.
  - (b) On review of this recommendation, the Committee shall consider whether the staff has carried its burden of demonstrating:
    - 1. The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare if a License or registration is granted or renewed; and
    - 2. The risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of an MTC.
- (9) Where an MTC Agent listed on the application for licensure in accordance with 935 CMR 501.101(1) is found to have no suitability issue under 935 CMR 501.801: *Table A*, or to have overcome any suitability issue, the Agent shall not be subject to a subsequent suitability review under 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C*.
- (a) Nothing in 935 CMR 501.800 relieves the requirement that the applicant or Licensee conduct background checks on its agents and disclose to the Commission's staff any suitability issue(s) that arise as a result of those checks.
  - (b) Any subsequent disclosure of background check information for an MTC Agent required to be listed and evaluated pursuant to 935 CMR 501.101(1), will be assessed pursuant to 935 CMR 501.801: *Table A* or on other grounds for a Negative Suitability Determination only.
  - (c) Nothing in 935 CMR 501.800 precludes the Commission from initiating a suitability review based on background information received after the Commission's initial suitability review.
- (10) The Executive Director in consultation with the Committee may determine that a subject's suitability warrants the Commission's consideration. The Executive Director may also remand a matter to staff for further investigation prior to making a determination. The Commission may consider the determination when acting on the application or renewal.

501.801: Suitability Standard for Licensure

(1) In accordance with M.G.L. c. 94I and M.G.L. c. 94G, § 5, the Commission is prohibited from licensing an MTC where an individual who is a Person Having Direct or Indirect Control has been convicted of a felony or offense in an Other Jurisdiction that would be a felony in the Commonwealth, except a prior conviction solely for a Marijuana offense or solely for a violation of M.G.L. c. 94C, § 34, unless the offense involved distribution of a controlled substance, including Marijuana, to a minor.

(2) For purposes of determining suitability based on background checks in accordance with 935 CMR 501.101(1)(b):

(a) All conditions, offenses, and violations are construed to include Massachusetts law or like or similar law(s) of Other Jurisdictions.

(b) All criminal disqualifying conditions, offenses, and violations include the crimes of attempt, accessory, conspiracy, and solicitation.

(c) Juvenile dispositions shall not be considered as a factor for determining suitability.

(d) Where applicable, all look back periods for criminal conditions, offenses, and violations included in 935 CMR 501.801: *Table A* commence on the date of disposition; provided, however, that if disposition results in incarceration in any institution, the look back period shall commence on release from incarceration.

(e) Unless otherwise specified in *Table*, a criminal condition, offense or violation include both convictions, which include guilty pleas and pleas of *nolo contendere*, and dispositions resulting in continuances without a finding or other disposition constituting an admission to sufficient facts, but shall exclude other non-conviction dispositions.

(3) Licensees and Registered Agents shall remain suitable at all times a License or registration remains in effect. An individual subject to this section shall notify the Commission in writing of any charge or conviction of an offense that would result in a presumptive negative suitability determination or mandatory disqualification under 935 CMR 501.801: *Table A*, 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C* within ten days of such individual's arrest or summons, and within ten days of the disposition on the merits of the underlying charge. Failure to make proper notification to the Commission may be grounds for disciplinary action. If the Commission lawfully finds a disqualifying event and the individual asserts that the record was sealed, the Commission may require the individual to provide proof from a court evidencing the sealing of the case.

Table A: MTC Licensees. Shall apply to applicants, Licensees and Persons or Entities Having Direct or Indirect Control in accordance with 935 CMR 501.101(1) and 935 CMR 501.103(4).

Time Period	Precipitating Issue	Result
Present (during time from start of application process through action on application or renewal).	<p><b>Open/Unresolved Criminal Proceedings:</b></p> <p>Any outstanding or unresolved criminal proceeding, the disposition of which may result in a felony conviction under the laws of the Commonwealth or Other Jurisdictions, but excluding any criminal proceeding based solely on a Marijuana-related offense or a violation of M.G.L. c. 94C, § 32E(a) or 34.</p>	Mandatory Disqualification
Present	<p><b>Outstanding or Unresolved Criminal Warrants</b></p>	Presumptive Negative Suitability Determination

501.801: continued

Time Period	Precipitating Issue	Result
Present	<p><b>Submission of Untruthful Information to the Commission Including, but Not Limited to:</b></p> <p>Submission of information in connection with a License application, waiver request or other Commission action that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure; or</p> <p>Making statements during or in connection with a Commission inspection or investigation that are deceptive, misleading, false or fraudulent, or that tend to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure.</p>	Presumptive Negative Suitability Determination
Present	<b>Open/Unresolved Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions)</b>	Presumptive Negative Suitability Determination
Present	<b>Open Professional or Occupational License Cases</b>	Presumptive Negative Suitability Determination
Indefinite	<p><b>Sex Offender Registration:</b></p> <p>Required to register as a sex offender in Massachusetts or an Other Jurisdiction.</p>	Mandatory Disqualification
Indefinite	<p><b>Felony Convictions in Massachusetts or an Other Jurisdiction Including, but Not Limited to:</b></p> <p>Felony weapons violation involving narcotics;</p> <p>Felony involving violence against a person;</p> <p>Felony involving theft or fraud;</p> <p>Felony drug, excluding conviction solely for a Marijuana-related offense or solely for a violation of M.G.L. c. 94C, § 34.</p>	Mandatory Disqualification
Indefinite	<b>Conviction or Continuance without a Finding (CWOFF) for Any Distribution of a Controlled Substance to a Minor</b>	Mandatory Disqualification
Indefinite	<b>Non-felony Weapons Violations, Including Firearms, Involving Narcotics</b>	Presumptive Negative Suitability Determination

501.801: continued

Time Period	Precipitating Issue	Result
Indefinite	<b>Firearms-related Crimes</b>	Presumptive Negative Suitability Determination
Indefinite	<p><b>Multiple Crimes of Operating under the Influence</b></p> <p>Two offenses within a ten-year period; or</p> <p>Three or more offenses within any period of time.</p>	Presumptive Negative Suitability Determination
Preceding Five Years	<p><b>Multiple Crimes</b></p> <p>During the five years immediately preceding the application for licensure that separately may not result in a negative determination of suitability but may, if taken together and tending to show a pattern of harmful behavior, result in a negative determination of suitability depending on the type and severity of the crimes</p>	Presumptive Negative Suitability Determination
Preceding Five Years	<p><b>Crimes of Domestic Violence Including, but Not Limited to:</b></p> <p>Violation of an abuse prevention restraining order under M.G.L. c. 209A;</p> <p>Violation of a harassment prevention order under M.G.L. c. 258E</p>	Presumptive Negative Suitability Determination
Preceding Five Years	<p><b>Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions)</b></p> <p>The applicant or a Licensee held a License that was revoked, a renewal application that was denied, or a similar action taken with relation to their Marijuana business in Massachusetts or Other Jurisdiction, whether by administrative action or stipulated agreement.</p>	Mandatory Disqualification
More than Five and Less than Ten Years	<p><b>Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions)</b></p> <p>The applicant or a Licensee held a License that was revoked, a renewal application that was denied, or a similar action taken with relation to their Marijuana business in Massachusetts or Other Jurisdiction, whether by administrative action or stipulated agreement.</p>	Presumptive Negative Suitability Determination

501.801: continued

Time Period	Precipitating Issue	Result
Preceding Five Years	<p>The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare; and</p> <p>the risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of an MTC.</p>	<p>May make a Negative Suitability Determination in accordance with 935 CMR 501.800(8)</p>

501.802: Suitability Standard for Registration as a Medical Marijuana Treatment Center Agent

(1) In accordance with M.G.L. c. 94G, § 4(a½)(iii), the Commission has established qualifications for licensure and minimum standards for employment that are directly and demonstrably related to the operation of an MTC and similar to qualifications for licensure and employment standards in connection with alcoholic Beverages as regulated under M.G.L. c. 138; provided, that a prior conviction solely for a Marijuana-related offense or for a violation of M.G.L. c. 94C, § 34 shall not disqualify an individual or otherwise affect eligibility for employment or licensure in connection with an MTC, unless the offense involved the distribution of a controlled substance, including Marijuana, to a minor.

(2) For purposes of determining suitability based on background checks in accordance with 935 CMR 501.030 and 501.101.

(a) All conditions, offenses, and violations are construed to include Massachusetts law or like or similar law(s) of Other Jurisdictions.

(b) All criminal disqualifying conditions, offenses, and violations include the crimes of attempt, accessory, conspiracy and solicitation.

(c) Juvenile dispositions shall not be considered as a factor for determining suitability.

(d) Where applicable, all look back periods for criminal conditions, offenses, and violations included in 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C* commence on the date of disposition; provided however, that if disposition results in incarceration in any institution, the look back period shall commence on release from incarceration.

(e) Unless otherwise specified in 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C*, a criminal condition, offense or violation shall include both convictions, which include guilty pleas and pleas of *nolo contendere*, and dispositions resulting in continuances without a finding or other disposition constituting an admission to sufficient facts, but shall exclude other non-conviction dispositions. All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 501.800. In addition to the requirements established in 935 CMR 501.800, the Suitability Review Committee shall:

1. Consider whether offense(s) or information that would result in a Presumptive Negative Suitability Determination under 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C* renders the subject unsuitable for registration, regardless of the determination of the Licensee; and

2. Consider appeals of determinations of unsuitability based on claims of erroneous information received as part of the background check during the application process in accordance with 803 CMR 2.17: *Requirement to Maintain a Secondary Dissemination Log* and 803 CMR 2.18: *Adverse Employment Decision Based on CORI or Other Types of Criminal History Information Received from a Source Other than the DCJIS*.

(3) Registered Agents shall remain suitable at all times a License or registration remains in effect. An individual subject to this section shall notify the Commission in writing of any charge or conviction of an offense that would result in a presumptive negative suitability determination or mandatory disqualification under 935 CMR 501.802: *Table B* and 935 CMR 501.803: *Table C* within ten days of such individual's arrest or summons, and within ten days of the disposition on the merits of the underlying charge. Failure to make proper notification to the Commission may be grounds for disciplinary action. If the Commission lawfully finds a disqualifying event and the individual asserts that the record was sealed, the Commission may require the individual to provide proof from a court evidencing the sealing of the case.

935 CMR: CANNABIS CONTROL COMMISSION

501.801: continued

**Table B: MTC Agents.** Shall apply solely to applicants for registration as an MTC Agent at an MTC licensed pursuant to 935 CMR 501.101.

Time Period	Precipitating Issue	Result
Present (during time from start of application process through action on application or renewal).	<p><b>Open/Unresolved Criminal Proceedings:</b></p> <p>Any outstanding or unresolved criminal proceeding, the disposition of which may result in a felony conviction under the laws of the Commonwealth or Other Jurisdictions, but excluding any criminal proceeding based solely on a Marijuana-related offense or a violation of M.G.L. c. 94C, § 32E(a) or § 34.</p>	Presumptive Negative Suitability Determination
Present	<p><b>Open Professional or Occupational License Cases</b></p>	Presumptive Negative Suitability Determination
Present	<p><b>Open/Unresolved Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions):</b></p> <p>An outstanding or unresolved violation of the regulations as included in 935 CMR 501.000 or a similar statute or regulations of Other Jurisdictions, which has either (a) remained unresolved for a period of six months or more; or (b) the nature of which would result in a determination of unsuitability for registration.</p>	Presumptive Negative Suitability Determination
Present	<p><b>Submission of Untruthful Information to the Commission Including, but Not Limited to:</b></p> <p>Submission of information in connection with an agent application, waiver request or other Commission action that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure; or</p> <p>Making statements during or in connection with a Commission inspection or investigation that are deceptive, misleading, false or fraudulent, or that tend to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure.</p>	Presumptive Negative Suitability Determination

501.801: continued

Time Period	Precipitating Issue	Result
Indefinite	<b>Sex Offense:</b> Felony conviction for a "sex offense" as defined in M.G.L. c. 6, § 178C and M.G.L. c. 127, § 133E or like offenses in Other Jurisdictions.	Mandatory Disqualification
Indefinite	<b>Felony Convictions in Massachusetts or Other Jurisdictions</b> for trafficking crimes under M.G.L. c. 94C, § 32E, or like crimes in Other Jurisdictions, except convictions for solely Marijuana-related crimes under M.G.L. c. 94C, § 32E (a), or like crimes in Other Jurisdictions.	Mandatory Disqualification
Indefinite	<b>Conviction or Continuance without a Finding (CWOFF) for Any Distribution of a Controlled Substance to a Minor</b>	Mandatory Disqualification
Indefinite	<b>Failure to Register as a Sex Offender in Any Jurisdiction</b>	Mandatory Disqualification
Indefinite	<b>(MTC Agents Engaging in Transportation or Home Delivery Operations Only) Multiple Crimes of Operating under the Influence:</b>  Two offenses within a ten-year period; or  Three or more offenses within any period of time.	Presumptive Negative Suitability Determination
Preceding Five Years	<b>Felony Convictions in Massachusetts or Other Jurisdictions</b> for crimes of violence against a person or crimes of dishonesty or fraud, "violent crime" to be defined the same way as under M.G.L. c. 140, § 121 and M.G.L. c. 127, § 133E.	Mandatory Disqualification
Preceding Five Years	The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare; and the risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of an MTC.	May make a Negative Suitability Determination in accordance with 935 CMR 501.800(8)

501.803: Suitability Standard for Registration as a Laboratory Agent

- (1) 935 CMR 501.803 shall apply to Laboratory Agents in their capacity as employees or volunteers for an Independent Testing Laboratory licensed pursuant to 935 CMR 501.029 registered with the DCJIS pursuant to 803 CMR 2.04: *iCORI Registration* and the Commission for purposes of determining suitability for registration as a Laboratory Agent with the Licensee.
- (2) In accordance with M.G.L. c. 94G, § 15(b)(5), the Commission is prohibited from issuing a registration to a Laboratory Agent who has been convicted of a felony drug offense in the Commonwealth or Other Jurisdictions that would be a felony drug offense in the Commonwealth.
- (3) For purposes of determining suitability based on background checks performed in accordance with 935 CMR 501.803:



501.803: continued

- (a) All conditions, offenses, and violations are construed to include Massachusetts law or similar law(s) of Other Jurisdictions.
- (b) All criminal disqualifying conditions, offenses, and violations include the crimes of attempt, accessory, conspiracy, and solicitation.
- (c) Juvenile dispositions shall not be considered as a factor for determining suitability.
- (d) Where applicable, all look back periods for criminal conditions, offenses, and violations included in 935 CMR 501.803: *Table C* commence on the date of disposition; provided however, that if disposition results in incarceration in any institution, the look back period shall commence on release from incarceration.
- (e) Unless otherwise specified in 935 CMR 501.803: *Table C*, a criminal condition, offense or violation shall include both convictions, which include guilty pleas and pleas of *nolo contendere*, and dispositions resulting in continuances without a finding or other disposition constituting an admission to sufficient facts, but shall exclude other non-conviction dispositions.
- (f) All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 501.800. In addition to the requirements established in 935 CMR 501.800 shall:
  1. Consider whether offense(s) or information that would result in a Presumptive Negative Suitability Determination under 935 CMR 501.803: *Table C* renders the subject unsuitable for registration, regardless of the determination of the Licensee; and
  2. Consider appeals of determinations of unsuitability based on claims of erroneous information received as part of the background check during the application process in accordance with 803 CMR 2.17: *Requirement to Maintain a Secondary Dissemination Log* and 803 CMR 2.18: *Adverse Employment Decision Based on CORI or Other Types of Criminal History Information Received from a Source Other than the DCJIS*.

**Table C:** Registration as a Laboratory Agent. Shall apply solely to applicants for registration as a Laboratory Agent in accordance with 935 CMR 501.803 at an MTC registered or licensed pursuant to 935 CMR 501.052, or 935 CMR 500.050: *Marijuana Establishments*.

Time Period	Precipitating Issue	Result
Present (during time from start of application process through action on application or renewal).	<p><b>Open/Unresolved Criminal Proceedings:</b></p> <p>any outstanding or unresolved criminal proceeding, the disposition of which may result in a felony conviction under the laws of the Commonwealth or a similar law in Other Jurisdictions.</p>	Mandatory Disqualification
Present	<p><b>Open/Unresolved Marijuana Business-related License Violations (Massachusetts or Other Jurisdictions):</b></p> <p>an outstanding or unresolved violation of the regulations as included in 935 CMR 501.000 or a similar statute or regulations in Other Jurisdictions that has either (a) remained unresolved for a period of six months or more; or (b) the nature of which would result in a determination of unsuitability for registration.</p>	Presumptive Negative Suitability Determination

501.803: continued

Time Period	Precipitating Issue	Result
Present	<p><b>Submission of False or Misleading Information to the Commission Including, but Not Limited to:</b></p> <p>Submission of information in connection with an agent application, waiver request or other Commission action that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly, or by omission or ambiguity including lack of disclosure or insufficient disclosure; or</p> <p>Making statements during or in connection with a Commission inspection or investigation that are deceptive, misleading, false or fraudulent, or that tend to deceive or create a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure.</p>	Presumptive Negative Suitability Determination
Present	<b>Open Professional or Occupational License Cases</b>	Mandatory Disqualification
Indefinite	<b>Felony Convictions in Massachusetts or Other Jurisdictions</b> for drug offenses or trafficking crimes under M.G.L. c. 94C, § 32E, or like crimes in Other Jurisdictions.	Mandatory Disqualification
Preceding Five Years	<b>Felony Convictions or CWOFF in Massachusetts or Other Jurisdictions</b> for crimes of violence against a person, "violent crime" to be defined the same way as under M.G.L. c. 140, § 121 and M.G.L. c. 127, § 133E.	Presumptive Negative Suitability Determination
Preceding Seven Years	<b>Felony Convictions or CWOFF in Massachusetts or Other Jurisdictions</b> for crimes of dishonesty or fraud.	Presumptive Negative Suitability Determination

501.803: continued

Time Period	Precipitating Issue	Result
Preceding Five Years	<p>The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare; and</p> <p>the risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of an MTC.</p>	May make a Negative Suitability Determination in accordance with 935 CMR 500.800(8)

501.820: Confidentiality

(1) All records made or received by the Commission shall be public records and shall be available for disclosure on request pursuant to 935 CMR 501.820, and 950 CMR 32.00: *Public Records Access*, except the following, which shall be exempt from disclosure to the extent permitted by law:

- (a) All records exempt from disclosure pursuant to M.G.L. c. 4, § 7, cl. 26;
- (b) All records to the extent that they contain "personal data" pursuant to M.G.L. c. 66, § 1;
- (c) All records to the extent that they contain "personal information" pursuant to M.G.L. c. 93H, § 1;
- (d) All records which contain CORI as defined by 803 CMR 2.02: *Definitions*;
- (e) All records which contain CHRI as defined by 803 CMR 7.02: *Definitions*; and
- (f) All Confidential Records as defined in 935 CMR 501.002.

(2) The Commission shall maintain the confidentiality of all medical records including, but not limited to:

- (a) All Confidential Records and information contained in the Confidential Database, including applicants for registration as a Qualifying Patient, Personal Caregiver, Institutional Caregiver, Certifying Healthcare Provider, Card Holder; or Registered Qualifying Patients, Personal Caregivers, Institutional Caregivers, Certifying Healthcare Providers, Card Holders; and
- (b) Other identifying patient information.

(3) All records protected from disclosure under 935 CMR 501.820(1) or pursuant to the laws of an Other Jurisdiction may be disclosed by the Commission:

- (a) If disclosure is required pursuant to a state or federal law;
- (b) To the individual or the individual's authorized representative, if the individual executes a written release in a form and manner determined by the Commission;
- (c) To the Commission staff for the purpose of carrying out their official duties;
- (d) To the Commission Delegee(s) as authorized by the Commission;
- (e) To other government officials and agencies acting within their lawful jurisdiction, which includes, but is not limited to:
  - 1. Law enforcement personnel for the sole purpose of verifying a cardholder's registration and certification; and
  - 2. The Board of Registration in Medicine when necessary in connection with referrals to said Board concerning violations of 935 CMR 501.000.
- (f) To a healthcare professional who has a *Bona Fide* Healthcare Professional Patient Relationship with the Qualifying Patient to facilitate dispensing of Medical-use Marijuana;
- (g) To an MTC or any state agency to facilitate dispensing of medical-use Marijuana;
- (h) To the Commission staff if required in the course of an administrative or a judicial proceeding; or
- (i) If an individual or entity obtains an order from a court of competent jurisdiction.

(4) Nothing in 935 CMR 501.820 shall prevent the Commission from acting in accordance with its authority.

501.830: Petitions for the Adoption, Amendment or Repeal of Regulations

(1) Any interested Person may file a petition with the Commission pursuant to M.G.L. c. 30A, § 4, for the adoption, amendment or repeal of any regulation. Such petition shall be submitted in written and electronic form, be signed by the petitioner or petitioner's representative, and include the following information:

- (a) The name, address, and relevant contact information for the petitioner or the petitioner's representative;
- (b) The petitioner's specific interest in the regulation;
- (c) The petitioner's request for the adoption, amendment or repeal of a regulation, including proposed regulatory language;
- (d) If the request is to amend an existing regulation, a copy of the existing regulation with changes clearly marked on paper and electronic copies; and
- (e) The reasons for the request including, but not limited to, citation to any relevant legal authority, arguments and evidence, including data, that supports the request.

(2) After receipt of a petition for submitted in accordance with 935 CMR 501.830, the Commission may consider the petition at an open meeting pursuant to M.G.L. c. 30A, § 20, and determine, in its discretion, whether to take any action on or as a result of the petition. The Commission may also delegate the review of petitions to its Executive Director.

(3) Within a reasonable time, the Commission or a Commission Delegee will notify the petitioner as to its determination, if any, concerning the petition.

(4) The submission of a petition for the adoption, amendment or repeal of any regulation pursuant to 935 CMR 501.830(1), and any action, inaction, determination or notice by the Commission pursuant to 935 CMR 501.830(2) and 935 CMR 501.830(3) with respect thereto, shall not constitute the adoption, amendment or repeal of a regulation, unless or until regulations are duly promulgated by the Commission in accordance with M.G.L. c. 30A, *State Administrative Procedure Act*, and 950 CMR 20.00: *Preparing and Filing Regulations*.

501.840: Nonconflict with Other Laws

(1) Nothing in 935 CMR 501.000 shall be construed to limit the applicability of other law as it pertains to the rights of landlords, employers, Law Enforcement Authorities, or regulatory agencies, except as otherwise provided in 935 CMR 501.000.

(2) Nothing in 935 CMR 501.000:

- (a) Allows the operation of a motor vehicle, boat, or aircraft while under the influence of Marijuana;
- (b) Requires any health insurance provider, or any government agency or authority, to reimburse any person for the expenses of the medical use of Marijuana;
- (c) Requires any healthcare professional to authorize the use of medical Marijuana for a Qualifying Patient;
- (d) Requires any accommodation of any on-site medical use of Marijuana in any place of employment, school bus or on school grounds, in any youth center, in any correctional facility, or of smoking medical Marijuana in any public place;
- (e) Supersedes Massachusetts law prohibiting the possession, cultivation, transport, distribution, or sale of Marijuana for nonmedical purposes;
- (f) Requires the violation of federal law or purports to give immunity under federal law; or
- (g) Poses an obstacle to federal enforcement of federal law.

(3) Nothing in 935 CMR 501.000 shall be construed to limit the scope of practice of a nurse practitioner pursuant to M.G.L. c. 112, § 80I.

501.850: Waivers

(1) The Commission may delegate its authority to the Executive Director to waive a regulatory requirement promulgated under M.G.L. c. 94G, § 4 and M.G.L. c. 94I, § 7. The Executive Director may determine the form and manner of the waiver process. There can be no waiver of statutory requirements.

501.850: continued

- (2) The Commission may waive applicability of one or more of the requirements imposed by 935 CMR 501.000 on the submission of written documentation and a finding that:
  - (a) Compliance would cause undue hardship to the requestor;
  - (b) If applicable, the implementation of compensating features acceptable to the Commission;
  - (c) The noncompliance with the regulatory requirement would not jeopardize the health, safety, or welfare of any Registered Qualifying Patient or the public; and
  - (d) The granting of the waiver would not constitute a waiver of any statutory requirements.
- (3) Waiver of Security Requirements. Any waiver of security requirements under 935 CMR 501.820, shall be requested under 935 CMR 501.110(2)(b).
- (4) An adverse decision on a waiver request does not entitle an applicant or Licensee to a hearing or judicial review.

501.860: Notice

- (1) The Commission shall maintain a list of individuals or entities that request notice.
- (2) Notice shall be provided, in a time and manner to be determined by the Commission, to those individuals or entities on the list in advance for:
  - (a) Meetings of the Cannabis Control Commission;
  - (b) Meetings of the Cannabis Advisory Board; and
  - (c) Other events determined by the Commission, in its discretion.
- (3) The individual or entity is responsible for ensuring that the information provided to the Commission for the purpose of receiving notice remains current.

501.900: Severability

The provisions of 935 CMR 501.000 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

935 CMR 501.000: St. 2017, c. 55; M.G.L. c. 94G and M.G.L. c. 94I.

NON-TEXT PAGE