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935 CMR: CANNABIS CONTROL COMMISSION

935 CMR 501.000: MEDICAL USE OF MARIJUANA

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501.001: Purpose

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

501.002: Definitions

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¶ 935 CMR 501.000 applies to every person who:¶
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(1) Validly registered with the Department of Public Health (Department) by or before the Program Transfer or seeks to register or registers with the Cannabis Control Commission (Commission) after the Program Transfer as a healthcare provider, registered qualifying patient, personal caregiver, institutional caregiver or for hardship cultivation;¶
(2) Is a healthcare provider who seeks to certify or certifies that an individual has a debilitating medical condition; or¶
(3) Validly registered with the Department by or before the Program Transfer or seeks to register or registers with the Commission after the Program Transfer as a Registered Marijuana Dispensary (RMD) or RMD agent, including such RMD's board members, directors, employees, executives, managers and volunteers; a caregiving institution; or an independent testing laboratory or laboratory agent.¶

501.003:

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For the purposes of 935 CMR 501.000: Medical Use of Marijuana, 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 Marijuana 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.

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

Agent Registration Card or Medical-use Agent Registration Card means an identification card formerly and validly issued by the DPH or currently and validly issued by the Commission to an 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, identification by the Commission and Law Enforcement Authorities of those individuals exempt from Massachusetts criminal and civil penalties under M.G.L. c. 94I, and 935 CMR 501.000: Medical Use of Marijuana.

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 of 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.

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.

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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 or Marijuana Product. Amounts of other Cannabinoids may be required by the Commission.

Cannabis or Marijuana means all parts of any plant of the genus Cannabis, not excepted in (a) through (c) of the definition for “Cannabis or Marijuana” in 935 CMR 501.002: Definitions 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.

Cannabis or Marijuana 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.

Cannabis or Marijuana Products means Cannabis or Marijuana and its products unless otherwise indicated. Cannabis or Marijuana Products includes products that have been Manufactured and contain Cannabis or 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 edible products, beverages, topical products, ointments, oils and Tinctures. Cannabis or Marijuana Products include MIPs defined in 935 CMR 501.002: Definitions.

Canopy means an area to be calculated in square feet and measured using clearly identifiable boundaries of all areas(s) that will contain mature plants 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

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identifiable boundary which include, but are not limited to: interior walls, shelves, Greenhouse walls, hoop house walls, garden benches, hedge rows, fencing, garden beds, or garden plots. If mature plants 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 formerly and validly by the DPH or 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 MIPs by a Licensee or Registrant to protect the public health, safety or welfare.

Ceases to Operate means a Marijuana Establishment, Medical Marijuana Treatment Center (MTC) or Independent Testing Laboratory 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: Medical Use of Marijuana, 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 formerly and validly issued by the DPH or currently and validly issued by the Commission, that confirms an MTC or Independent Testing Laboratory, individual or entity has met all applicable requirements pursuant to M.G.L. c. 94I and 935 CMR 501.000: Medical Use of Marijuana and is registered by the Commission. An MTC or Independent Testing Lab may have been issued a provisional or final Certificate of Registration. After the effective date of these regulations, new or renewal Licenses, as applicable, may be issued to MTCs and Independent Testing Labs.

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Certifying Certified Nurse Practitioner means a Massachusetts licensed certified nurse practitioner (CNP) 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.

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

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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.

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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.

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Clone means a clipping from a Cannabis or Marijuana plant which 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 management, operations or finances of an MTC or Independent Testing Lab licensed under 935 CMR 501.000: *Medical Use of Marijuana*. A person who is 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 or registration pursuant to 935 CMR 501.000: *Medical Use of Marijuana*, 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, but not any other adult-use License.

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Commercially Available Candy means any product that is Manufactured and packaged in the form of bars, drops, or pieces and that includes a sweetened mixture of chocolate, caramel, nougat, nuts, fruit, cream, honey, marshmallow or any similar combination to create a dessert-like confection.

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Commission means the Massachusetts Cannabis Control Commission 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~~, 935 CMR 501.000: *Medical Use of Marijuana*, and 935 CMR 502.000: ~~Colocated Adult-Use and Medical-Use Marijuana Operations~~.

Commission Delegee(s) means other state or local officials or agencies working in cooperation with the Commission and as ~~delegated~~ by the Commission to carry out the Commission's responsibilities and to ensure compliance with ~~the adult-use, medical-use, and colocated- operations 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: (i) the Qualifying Patients issued a Registration Card for medical use of Marijuana; (ii) the healthcare professionals registered to issue Written Certifications; (iii) the MTCs; (iv) the quantity of medical use Marijuana dispensed to a Card Holder; and (v) 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 not limited to, M.G.L. c. 4, § 7, cl. 26 and M.G.L. c. 94I, §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

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pose a risk to the public health, safety or welfare; (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 Investigatory Materials or Protected Patient Records as defined herein.

Criminal Offender Record Information (CORI) shall have the same meaning as it is defined in 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 Marijuana 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.

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 it is 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.~~

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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.

Delivery-Only Retailer means an entity that is authorized to deliver directly to Consumers, Registered Qualifying Patients or Caregivers from a licensed Marijuana Retailer and does not provide a retail location accessible to the public.

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.

Edible Marijuana-infused Products (Edible MIPs) means a Marijuana-infused Product (MIP) that is to be consumed by eating or drinking. These products, when created or sold by a Marijuana Establishment or MTC, shall not be considered a food or a drug as defined in M.G.L. c. 94G, § 1.

Electronic Certification means a document signed or executed electronically by a registered healthcare professional, 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, upon submission by a healthcare professional 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 will hold any amount of equity in an MTC.

Executive means members of the board of directors, chief executive officer, executive director, president, and any other officer of an MTC or Independent Testing Laboratory.

Executive Office of Energy and Environmental Affairs (EOEEA) means the

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Final RMD Certificate

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Massachusetts Executive Office of Energy and Environmental Affairs, unless otherwise specified.

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

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

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

Greenhouse means an Enclosed Area where Cannabis or Marijuana plants are cultivated that has been inspected by the Commission and determined to be a Greenhouse.

Hardship Cultivation Registration means a registration issued to a registered Qualifying Patient under the requirements of 935 CMR 501 027: Hardship Cultivation Registration.

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Healthcare Clinician or Provider means a Certifying Physician, Certifying certified Nurse Practitioner or Certifying physician's assistant qualified under 935 CMR 501.000: Medical Use of Marijuana, to issue Written Certifications for the medical-use of Marijuana.

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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 or 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.

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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 Canopy, plus any additional areas(s) that will contain live plants at any point in time that will be exposed to

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horticultural lighting equipment.

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.

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

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 the most current 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: Medical Use of Marijuana, and Commission protocol(s).

Individual Order means a delineated amount of Marijuana, Marijuana Products or MIPs to be delivered by an MTC or third party authorized by the Commission to perform home delivery.

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.

Known Allergen means milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, or such other allergen identified by the Commission.

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: Medical Use of Marijuana. For the purposes of testing for the medical-use program, a Laboratory agent may register under 935 CMR 501.000: Medical Use of Marijuana or 935 CMR 500.000: Adult Use of Marijuana.

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935 CMR: CANNABIS CONTROL COMMISSION

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.

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: *Medical Use of Marijuana*. 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: *Medical Use of Marijuana*. 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 with 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 Cannabis or Marijuana, MIPs, or their byproducts are cultivated, stored, weighed, packaged, Processed, or disposed, under the control of an MTC, with access limited to only those MTC Agents and Laboratory agents designated by the MTC.

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

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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-Only Retailer, Marijuana Research Facility, or any other type of licensed Marijuana-related business subject to the regulations in 935 CMR 500.000; Adult Use of Marijuana.

Marijuana Establishment Agent means a board member, director, employee, Executive, manager, or volunteer of a Marijuana Establishment, who is 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 product infused with Marijuana that is intended for use or consumption including, but not limited to, edible products, ointments, aerosols, oils, and Tinctures. These products, when created or sold by 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.

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: Application Requirements for Medical Marijuana Treatment Centers, that acquires, cultivates, possesses, Processes (including development of related products such as edible Marijuana or Marijuana Products, Tinctures, aerosols, oils, or ointments), transports, sells, distributes, delivers, dispenses, or administers Marijuana, products containing Cannabis or 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 Cannabis or Marijuana for medical use.

Medical-use Cannabis or Marijuana 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 of Marijuana.

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: Medical Use of Marijuana.

Medical Registration Card means an identification card issued formerly and validly by the DPH or currently or validly by the Commission, by the Medical Use of Marijuana

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(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;¶

Deleted: Marijuana or Cannabis means all parts of any plant of the genus Cannabis, not excepted in 935 CMR 501.003, 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

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(c) the weight of any other ingredient combined with cannabis or marijuana to prepare topical or oral administrations, food, drink or other products.¶

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Program, to a Registered Qualifying Patient, Personal Caregiver, Institutional Caregiver, MTC or Laboratory agent. The Medical 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 M.G.L. c. 94G.

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Member means a member of a non-profit entity incorporated pursuant to M.G.L. c. 180.

MTC agent, formerly an RMD agent means a board member, director, employee, Executive, manager, or volunteer of an MTC, who is 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 for medical purposes.

Mycotoxin means a secondary metabolite of a microfungus that is capable of causing death or illness in humans and other animals. For the purposes of this chapter, Mycotoxin shall include aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A.

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 plants.

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

Other Jurisdictions shall mean the United States, another state, or foreign jurisdiction, or a military, territorial or Native American tribal authority.

Owner means any Equity Holder that possesses 10% or more of equity 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.

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

Patient Registration Card means a Registration Card formerly and validly issued by the Department or a temporary or an annual Registration Card currently and validly issued by

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935 CMR: CANNABIS CONTROL COMMISSION

the Commission, to a registered Qualifying Patient. Through 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; Medical Use of Marijuana. 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.

Persons or Entities 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:

- An Owner that possess a financial interest in the form of equity of 10% or greater in an MTC;
- A Person or Entity that possess a voting interest of 10% or greater in an MTC or a right to veto significant events;
- A Close Associate;
- A Person or Entity that has rights to control, through contract or otherwise, or authority, including but not limited to:
 - to make decisions regarding operations and strategic planning, capital allocations, acquisitions and divestments;
 - to appoint more than 50% of the directors;
 - to appoint or remove Corporate-level officers;
 - to make major marketing, production, and financial decisions;
 - to execute significant or exclusive contracts; or
 - to earn 10% or more of the profits or collect more than 10% of the dividends.

Persons or Entities Having Indirect Control means any person or entity having indirect control over operations of MTC. It specifically includes any person with a controlling interest in 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.

Persons or Entities Having Direct or Indirect Control means any person or entity having direct or indirect control.

Personal Caregiver means a person, registered by the Commission, who is 21 years of age

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¶ Person means an individual or an entity.¶

¶ Personal Caregiver means a person, formerly and validly registered by the Department or currently and validly registered by the Commission, who is 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 to patients younger than 18 years old as a second caregiver.¶

¶ Personal Caregiver Registration Card means a registration card formerly and validly issued by the Department or 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

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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 to patients younger than 18 years old as a second caregiver.

Personal Caregiver Registration Card means a Registration Card formerly and validly issued by the DPH or 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: Medical Use of Marijuana. 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(w) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 321(w)), or that has been determined by the Secretary of 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(x) of such act (21 U.S.C. § 321 (x)).

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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.

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

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: Definitions.

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

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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.

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 communications related to their care provided by a medical use Marijuana Licensee or establishment or by a registered healthcare professional that are 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 Massachusetts resident 18 years of age or older who has been diagnosed by a Certifying Healthcare Provider as having a Debilitating Medical Condition, or a Massachusetts resident 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 or board-certified pediatric subspecialist, as having a Debilitating Medical Condition that is also a Life-limiting Illness, subject to 935 CMR 501.010(10).

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 was formerly and validly registered by the DPH or is currently and validly registered by the Commission.

Registrant means the holder of a Registration Card formerly and validly registered with the DPH or currently and validly with the Commission. It also means an RMD holder of

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Certificate of Registration formally and validly registered with the DPH or the Commission. After the effective date of the promulgation of these regulations, new and renewal MTC Licenses, as applicable, may be issued.

Registration Card means an identification card formerly and validly issued by the Department or 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: Medical Use of Marijuana.

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 risk to the public health, safety or welfare, including, but not limited to, the product is especially appealing to persons younger than 21 years of age.

Residence means a house, condominium or apartment, bed-and-breakfast establishment, hotel, motel or other commercial hospitality operations, and excludes, unless otherwise authorized by law dormitories, other on-campus college or university housing, federally-subsidized housing, shelters, or residential programs.

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

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 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 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 Independent Testing Laboratory must integrate with the SOR in a form and manner determined by the Commission.

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~~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.

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Shelf-stable means able to be safely stored at room temperature in a sealed container.

Summary suspension means the suspension of any License or registration issued under 935 CMR 501.000: *Medical Use of Marijuana*, 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.

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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 Marijuana or Marijuana Products through an MTC to a Registered Qualifying Patient or Caregiver.

Tincture means a Cannabis-infused alcohol or oils concentrate administered orally in small amounts using a dropper or measuring spoon.

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.

Usable Marijuana means the fresh or dried leaves and flowers of the female Marijuana plant and any mixture or preparation thereof, including Cannabis 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).

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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.

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935 CMR: CANNABIS CONTROL COMMISSION

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 or air service of the United States and who was discharged or released under conditions other than dishonorable.

Visitor means an individual, other than an MTC and 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: Medical Use of Marijuana.

Visitor Identification Badge means a badge issued by an MTC or Independent Testing Laboratory 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 must be issued in a form and manner determined by the Commission.

Written Certification means a form submitted to the Department or 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 his or her 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.

501.005: Fees

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- (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:

Medical-use ID Card Replacement	\$10
Medical-use Hardship Cultivation	\$100

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

Medical Marijuana Treatment Center (MTC):

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

Caregiving and Caregiving Institutions:

Registration of Caregiving Institutions	None
Registration of Institutional Caregivers	None

- (3) Other fees (cost per License)

<u>Change in Name Fee</u>	<u>\$1,000</u>
<u>Change in Location Fee</u>	<u>\$10,000</u>
<u>Change in Building Structure Fee</u>	<u>\$1,000</u>
<u>Change in Ownership or Control Fee</u> (involving at least one entity gaining ownership/control)	<u>\$5000 per entity, per License</u>
<u>\$500 per person</u>	
<u>Change in Ownership or Control Fee</u> (involving individuals, e.g., change of Board	<u>\$500 per person</u>

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Medical-use Management and Operations Profile

Application (Phase 2)

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<p><u>Member)</u></p> <p>Architectural <u>Review Request Fee</u></p>	<p><u>\$1,500</u></p>	<p>Deleted: ¶ Construction or renovation modification</p>
<p>(4) These fees do not include the costs associated with the Seed-to-sale <u>SOR</u>, 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: <u>Medical Use of Marijuana</u>. These fees do not include the costs associated with packaging and label approval.</p>		<p>Deleted: review</p> <p>Deleted: ¶ \$8.25 per \$100 cost of construction costs, with a minimum of \$1,500...</p> <p>Deleted: -</p> <p>Deleted: -</p> <p>Deleted: electronic tracking¶ system</p> <p>Deleted: ¶</p> <p>Deleted: These fees do not include the costs associated with packaging and label approval.¶</p>
<p>(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).</p>		<p>Deleted: _</p> <p>Deleted:</p> <p>Deleted: written certification</p> <p>Deleted: qualifying patient</p> <p>Deleted: (a)</p> <p>Deleted: (b)</p> <p>Deleted: Department</p> <p>Deleted:</p> <p>Deleted: certifying physician</p> <p>Deleted: (a)</p> <p>Deleted: (b)</p> <p>Deleted: -----Section Break (Next Page)-----</p> <p>Deleted: (d)</p> <p>Deleted:</p> <p>Deleted: Department</p> <p>Deleted: certifying physician</p> <p>Deleted: debilitating medical condition</p> <p>Deleted: qualifying patient</p> <p>Deleted:</p> <p>Deleted:</p> <p>Deleted: written certification</p> <p>Deleted: debilitating medical condition</p>
<p><u>501.006: Registration of Certifying Physicians</u></p>		
<p>(1) A physician who wishes to issue a <u>Written Certification</u> for a <u>Qualifying Patient</u> shall have at least one established place of practice in Massachusetts and shall hold:</p> <p>(a) An active full license, with no prescribing restriction, to practice medicine in Massachusetts; and</p> <p>(b) A Massachusetts Controlled Substances Registration from the <u>DPH</u>.</p>		
<p>(2) To register as a <u>Certifying Physician</u>, a physician shall submit, in a form and manner determined by the Commission, the physician's:</p> <p>(a) Full name and business address;</p> <p>(b) License number issued by the Massachusetts Board of Registration in Medicine;</p> <p>(c) Massachusetts Controlled Substances Registration number; and</p> <p>(d) Any other information required by the Commission.</p>		
<p>(3) Once registered by the <u>DPH</u> or Commission, a <u>Certifying Physician</u> will retain indefinitely a registration to certify a <u>Debilitating Medical Condition</u> for a <u>Qualifying Patient</u> unless:</p> <p>(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;</p> <p>(b) The physician's Massachusetts Controlled Substances Registration is suspended or revoked;</p> <p>(c) The physician has fraudulently issued a <u>Written Certification</u> of a <u>Debilitating Medical Condition</u>;</p>		

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- (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.

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- (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

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- (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:

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- (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.

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

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- (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.

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

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- (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;

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- (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.

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- (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.

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501.008: Registration of Certifying Physician Assistants

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- (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.

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- (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
 - (d) Any other information required by the Commission.

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- (3) Once registered by the Commission, a Certifying Physician Assistant will retain

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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.

- (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 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 t 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 must 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 must 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 must have completed a minimum of one program meeting the requirements of 263 CMR 3.05(3).

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(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: Disciplinary Proceedings for Physicians through 3.00: The Establishment of and Participation in Qualified Patient Care Assessment Programs, 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 for Nurses.
- 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 may issue a Written Certification only for a Qualifying Patient with whom the healthcare provider has a Bona Fide Healthcare Provider-Patient Relationship.

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

(6) 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.

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

(8) A certification must indicate the time period for which the certification is valid, and

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shall not be less than 15 calendar days or longer than one year.

- (9) 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.

- (10) A Qualifying Patient who is younger than 18 years old and has been diagnosed by two Massachusetts licensed Certifying Physicians, at least one of whom is a board-certified pediatrician or a board-certified pediatric subspecialist, with a debilitating Life-limiting Illness, may receive a Written Certification, provided however that the physicians may certify a Qualifying Patient who is younger than 18 years old who has a Debilitating Medical Condition that is not a Life-limiting Illness if those physicians determine that the benefits of the medical use of Marijuana outweigh the risks. This must include a discussion of the potential negative impacts on neurological development with the parent or legal guardian of the Qualifying Patient, written consent of the parent or legal guardian, and documentation of the rationale in the medical record and the Written Certification.

- (11) A Certifying Healthcare Provider, and such healthcare provider's co-worker, employee, or immediate family member, shall 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 shall not prohibit the healthcare provider from charging an appropriate fee for the clinical visit.

- (12) A Certifying Healthcare Provider shall not issue a Written Certification for himself or herself or for his or her immediate family members.

- (13) A Certifying Healthcare Provider issuing a Written Certification for their employees or co-workers shall do so in accordance with 935 CMR 501.010: Written Certification of a Debilitating Medical Condition for a Qualifying Patient, including conducting a clinical visit, completing and documenting a full assessment

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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.

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- (14) The Commission will accept Written Certifications validly issued prior to the Program Transfer for a year after the transfer. Thereafter, a Written Certification shall be issued in a form and manner determined by the Commission.

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501.015: Temporary and Annual Registration of Qualifying Patients

- (1) A Qualifying Patient must apply for a temporary or annual registration according to the procedures set out in 935 CMR 501.015: Temporary and Annual Registration of Qualifying Patients, unless otherwise provided by the Commission.

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

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(2) By or before April 1, 2019, a qualifying patient or personal caregiver

- (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:

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- (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;

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

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- (c) On submission of the requisite information, the provider shall print a packet of information for the patient, which includes a temporary Patient Registration Card, a caregiver authorization form and instructions;

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- (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;

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- (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;

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

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- (g) No more than 2.5 ounces of Marijuana may be dispensed by an MTC to a

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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 must comply with 935 CMR 501.015(5) and complete the electronic registration process for review by the Commission.

(4) To access MTCs and obtain medical-use Marijuana and MIPs, the patient must present their temporary Registration Card in addition to a government-issued identification. 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:
- The Qualifying Patient's full name, date of birth, address, telephone number, and email address if any, and a statement indicating his or her age and that his or her primary residence is in Massachusetts:
 - 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
 - If the Qualifying Patient is younger than 18 years old, that Qualifying Patient must have a designated Personal Caregiver, who shall be his or her parent or legal guardian.
 - Electronic or Written Certification(s) for the Qualifying Patient from the Qualifying Patient's Certifying Healthcare Provider(s);
 - Full name, address, and telephone number of the Qualifying Patient's Certifying Healthcare Provider(s);
 - Full name, date of birth, and address of the Qualifying Patient's Personal Caregiver(s), if any;
 - A statement of whether the Qualifying Patient will be applying for a Hardship Cultivation Registration;
 - A copy of the Qualifying Patient's Massachusetts driver's license, 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;

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- (h) Written acknowledgement of the limitations on his or her authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth;
- (i) 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
- (j) 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 must 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 must apply for a temporary or annual Registration Card according to the procedures set out in 935 CMR 501.020: Temporary and Annual Registration of Personal Caregivers, unless otherwise provided by the Commission. An individual must 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 over 21 years old, as their temporary caregiver. To

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(5) A qualifying patient who has not received written certification from a physician or a registration card from the Department prior to December 23, 2018, must apply for a temporary or annual registration according to the ...

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authorize an individual as a temporary caregiver, the patient must 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 must 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 must 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:

(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, if the patient is granted a Hardship Cultivation Registration;

(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;

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- (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 one registered Qualifying Patient at one time.
- (6) A registered Qualifying Patient may designate up to two Personal Caregivers. If the registered Qualifying Patient has been granted a Hardship Cultivation Registration, the 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 consent for such inspection of the cultivation site.
- (7) 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.
- (8) 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.

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(3) An annual registration card...egistration Card will be valid for one year from the date of issue of the temporary registration card...egistration Card unless otherwise 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(1) and (2).

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

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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:

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- (a) The name, address, telephone number of the institution, as well as telephone number and email address for the primary contact for that Caregiving Institution;

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- (b) A copy of the Caregiving Institution's current facility licensure or certification from the Commonwealth of Massachusetts;

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- (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;

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- (d) A nonrefundable registration fee, as required by the Commission;

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- (e) 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

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- (f) Any other information required by the Commission.

(e) ...An attestation by the authorized signatory of the caregiving institution...aregiving Institution that employees of the caregiving institution...aregiving Institution shall not engage in the diversion of marijuana...arijuana and that he or she understands that protections conferred by M.G.L. c. 94I, for possession of marijuana

- (2) A Caregiving Institution must 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.

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

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

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- (5) A Caregiving Institution must 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.

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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 must 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.
- (3) A Caregiving Institution must 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

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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.

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- (5) An Institutional Caregiver must apply for registration according to the procedures set out in 935 CMR 501.022: Registration of Institutional Caregivers, unless otherwise provided by the Commission.

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- (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.

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

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

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501.025: Responsibilities of Caregivers

(1) Personal Caregivers

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(a) A Personal Caregiver may:

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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 on behalf of a registered Qualifying Patient who has 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. Prepare Marijuana for consumption by a Registered Qualifying Patient; and
5. Administer Marijuana to a registered Qualifying Patient.

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(b) A Personal Caregiver may not:

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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;
 3. Unless otherwise authorized by law, cultivate Marijuana for the Personal Caregiver's own use, unless the Personal Caregiver is also a Registered Qualifying Patient who has obtained a Hardship Cultivation Registration;
 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; or
 7. 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.
- (c) A Personal Caregiver must notify the Commission within five calendar days upon the death of a Personal Caregiver's Registered Qualifying Patient.
- (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

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- 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; or
5. Receive payment or compensation above and beyond his or her regular wages.
- (c) An Institutional Caregiver must notify their employing Caregiving Institution of any changes in his or her registration information within 24 hours of the change.

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501.027: Hardship Cultivation Registration

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

(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; or

(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.

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- (2) To obtain a Hardship Cultivation Registration, a Registered Qualifying Patient shall, in a form and manner determined by the Commission, submit the following:

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(a) A nonrefundable registration fee, unless waived pursuant to 935 CMR 501.015(1)(g);

(b) Information supporting a claim that access is limited due to one or more of the circumstances listed in 935 CMR 501.027(1);

(c) An explanation including lack of feasible alternatives to mitigate the limitation claimed under 935 CMR 501.027(1);

(d) 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;

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- (e) A written explanation of how the Registered Qualifying Patient will cultivate Marijuana in accordance with the requirements of 935 CMR 501.027: Hardship Cultivation Registration;
- (f) A description of the device or system that will be used to ensure security and prevent diversion of the Marijuana plants being cultivated;
- (g) Written acknowledgment of the limitations on their authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth; and
- (h) Any other information required by the Commission.

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- (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.

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- (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) At any given location, cultivation may occur pursuant to only one Hardship Cultivation Registration, absent proof that more than one Registered Qualifying Patient resides at the location.

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- (6) A Hardship Cultivation Registration will be valid for one year from the date of issue. The Commission will accept certificates of registration validly issued prior to the Program Transfer. A 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.

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- (7) 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).

- (8) 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.

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- (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 shall not be visible from the street or other public areas.

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- (10) A Registered Qualifying Patient or their Personal Caregiver(s) cultivating Marijuana pursuant to a Hardship Cultivation Registration shall adhere to industry best practices in the cultivation of Marijuana plants and storage of finished product, and any standards specified by the Commission.
- (11) A Registered Qualifying Patient and their Personal Caregiver(s) are prohibited from selling, bartering, giving away or distributing in any manner Marijuana or Paraphernalia.
- (12) 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, 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.
- (13) 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.
- (14) 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.
- (15) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their Personal Caregiver(s) if applicable, must 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.
- (16) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their

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Personal Caregiver(s) if applicable, is prohibited from purchasing Marijuana from an MTC, provided however that such individuals may purchase seeds.

501.029: Registration 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: *Medical Use of Marijuana* 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, in a form and manner determined by the Commission, 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 Process Marijuana for medical use for testing purposes in the Commonwealth;
 - (c) A copy of the MTC agent's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Commission;
 - (d) An attestation that the individual shall not engage in the diversion of Marijuana;
 - (e) A nonrefundable application fee, as required by the Commission; and
 - (f) Any other information required by the Commission.
- (3) A Laboratory executive registered with the DCJIS pursuant to 935 CMR 501.101: *Application Requirements* must retain and make available to the Commission a Criminal Offender Record Information (CORI) report and any other background check information required by the Commission for each individual for whom the laboratory seeks an MTC agent registration, obtained within 30 calendar days prior to submission.
- (4) A laboratory must notify the Commission no more than one business day after a Laboratory agent ceases to be associated with the laboratory. The Laboratory agent's registration shall be immediately void when the agent is no longer associated with the laboratory.
- (5) A Registration Card will 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

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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, 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 501.029(1) through (3) and 501.801: *Suitability Standard for Licensure* or 501.803: *Suitability Standard for Registration as a Laboratory Agent*.

(7) After obtaining a Registration Card for a Laboratory agent, a 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 after any changes to the information that the 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 must carry their Registration Card at all times while in possession of Marijuana, including at all times while at a laboratory or while transporting Marijuana.

501.030: Registration of ~~Medical Marijuana Treatment Center Agents~~

- (1) An ~~MTC~~ shall apply for ~~MTC~~ agent registration for all board members, directors, employees, ~~Executives~~, managers, and volunteers who are associated with that ~~MTC~~.
All such individuals must:
- (a) Be 21 years of age or older; and
 - (b) Have not been convicted of a felony drug offense in the Commonwealth, or a like violation of the laws of ~~Other Jurisdictions~~;
 - (c) Be determined suitable for registration consistent with the provisions of 935 CMR 500.800: *Background Check Suitability Standard for Licensure and Registration* and 500.801: *Suitability Standard for Licensure* or 500.802: *Suitability Standard for Registration as a Marijuana Establishment Agent*.

(2) An application for registration of an ~~MTC agent~~, in a form and manner determined by the Commission, shall include:

- (a) The full name, date of birth, and address of the individual;
- (b) 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;

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- (c) A copy of the MTC agent's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Commission;
- (d) An attestation that the individual shall not engage in the diversion of Marijuana;
- (e) A nonrefundable application fee; and
- (f) Any other information required by the Commission.

(3) An MTC Executive registered with the Department of Criminal Justice Information Systems (DCJIS) pursuant to 935 CMR 501.101: Application Requirements must submit to the Commission a Criminal Offender Record Information (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.

(4) An MTC must notify the Commission no more than one business day after an MTC agent ceases to be associated with the MTC. The MTC agent's registration shall be immediately void when the agent is no longer associated with the MTC.

(5) A Registration Card will 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 destroy 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, 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 501.030(1) through (3).

(7) 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 after 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.

(8) An MTC agent must carry his or her Registration Card at all times while in possession of Marijuana, including at all times while at an MTC or while transporting Marijuana.

(9) An MTC agent affiliated with multiple MTCs must be registered as an MTC agent

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by each MTC.

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, or a Hardship Cultivation Registration:

(1) Failure to provide the information required in 935 CMR 501.000: *Medical Use of Marijuana* for a 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;

(3) Failure to meet the requirements set forth in 935 CMR 501.000: *Medical Use of Marijuana* for a Registration Card or Hardship Cultivation Registration;

(4) Revocation or suspension of a Registration Card or Hardship Cultivation Registration in the previous six months; or

(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: *Background Check Suitability Standard for Licensure and Registration*. 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

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(a) Verified financial hardship;¶

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(a) A nonrefundable registration fee, unless waived pursuant to 935 CMR 501.015(1)(g);¶

(b) Information supporting a claim that access is limited due to one or more of the circumstances listed in 935 CMR 501.035(1);

Moved up [11]: (h) Any other information required by the Commission.¶

Deleted: (1) A qualifying patient registered with the Commission pursuant 935 CMR 501.015 may apply for a hardship cultivation registration if such patient can demonstrate that his or her access to an RMD is limited by:...

Deleted: (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 RMD that will deliver marijuana to the patient's or personal caregiver's primary address; or¶

(c) Lack of an RMD within a reasonable distance of the patient's residence and lack of an RMD that will deliver marijuana to the patient's or personal caregiver's primary address.¶

¶

(2) To obtain a hardship cultivation registration, a registered qualifying patient shall, in a form and manner determined by the Commission, submit the following:

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(c) An explanation including lack of feasible alternatives to mitigate the limitation claimed under 935 CMR 501.035(1);¶

(d) 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;¶

501.035: continued¶

¶

(e) A written explanation of how the registered qualifying patient will cultivate marijuana in accordance with the requirements of 935 CMR 501.035;¶

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determination. All suitability determinations will be made in accordance with the procedures set forth in 935 CMR 500.800: *Background Check Suitability Standard for Licensure and Registration*.

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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; in the application or renewal application;
 - (b) Violation of the requirements of M.G.L. c. 94I or 935 CMR 501.000: *Medical Use of Marijuana*;
 - (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 a 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 Registration Card has been lost, stolen, or destroyed; or
 - (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 therewith.
 - (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 Other Jurisdictions; or
 - (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

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delineated in 935 CMR 501.802: *Suitability Standard for Registration as an MTC Agent* or 501.803: *Suitability Standard for Registration as a Laboratory Agent*, as applicable, that may otherwise affect the status of the suitability for registration of the Marijuana establishment 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: *General Operational Requirements for Medical Marijuana Treatment Centers*; 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 Other Jurisdictions shall be adequate grounds for the revocation of an MTC Agent Registration Card.

(4) In addition to the grounds in 935 CMR 501.032(1), the purchase of Marijuana from an MTC by a Registered Qualifying Patient with a Hardship Cultivation Registration, or his or her Personal Caregiver, shall be adequate grounds for the revocation of a Hardship Cultivation Registration.

(5) 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: *Medical Use of Marijuana* shall be sufficient to revoke a Registration Card or Hardship Cultivation Registration.

(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, 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

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Executive Director, who may appoint a Suitability Review Committee, in accordance with 935 CMR 500.801: *Background Check Suitability Standard for Licensure and Registration*. 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: *Background Check Suitability Standard for Licensure and Registration*.

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.

(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;

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- (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: *General Operational Requirements for Medical Marijuana Treatment Centers.*

(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: *Medical Use of Marijuana*; or any applicable provisions of 935 CMR 502.000: *Colocated Adult Use and Medical Use Marijuana Operations*;
- (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: *Medical Use of Marijuana.*

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Deleted: (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.¶

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.

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(3) A void Certifying Healthcare Provider registration is inactive and invalid.

501.050: Medical Marijuana Treatment Centers (MTCs)

(1) General Requirements.

- (a) An MTC shall be licensed to do business in the Commonwealth as a domestic business corporation or another domestic business entity in compliance with 935 CMR 501.000: Medical Use of Marijuana 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 with Direct or Indirect Control shall be granted, and no Licensee 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.
 1. To the extent that persons or entities seek to operate a testing facility in the Counties of Dukes County and Nantucket, the applicant may not waive statutory requirements, but can seek a waiver of regulatory requirements.
 3. The Commission shall receive notice of any such interests as part of the application pursuant to 935 CMR 501.101: Application Requirements.4. 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 must register with DCJIS on behalf of the entity as an organization user of iCORI.
- (d) An MTC applicant must demonstrate initial capital resources of \$500,000 for its first application for licensure as an MTC. An MTC applicant must 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.

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(4)

Deleted: A registered qualifying patient with a hardship cultivation registration, or his or her personal caregiver(s), may cultivate only at the location specified in the application approved by the Commission.¶

¶
(5) At any given location, cultivation may occur pursuant to only one hardship cultivation registration, absent proof that more than one registered qualifying patient resides at the location.¶

¶
(6) A hardship cultivation registration will be valid for one year from the date of issue. The Commission will accept certificates of registration validly issued prior to the Program Transfer. A certificate will remain valid until a new ...

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(10) A registered qualifying patient or his or her personal ...

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(a) Application of Intent. As necessary, the ...

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(f) All agents of the MTC must be registered pursuant to 935 CMR 501.030: Registration of Medical Marijuana Treatment Center Agents.

(g) An MTC must 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 and Transfer Marijuana to 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. The applicable 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.

(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 must demonstrate that while cultivating at the top of its production tier, it has consistently sold 85% of its product during 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.

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(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. 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. When determining whether to relegate a Licensee to a lower tier, the Commission may consider the following 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

(a) 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 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 delivery to an Institutional Caregiver at their Caregiving Institution.

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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: Medical Use of Marijuana. 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: Medical Use of Marijuana.
- (5) A Person or Entity Having Direct or Indirect Control of an MTC is prohibited from having any financial or other interest in an Independent Testing Laboratory providing testing services for any MTC.
- (6) No individual employee of a laboratory providing testing services for MTCs may receive direct or indirect financial compensation from any MTC.

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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 this section will apply to all MTC applications submitted on or after September 30, 2019. The application shall consist of three sections: Application of Intent; Background Check; and Management and Operations Profile. The applicant may complete any section of the application in any order. Once all sections of the application

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have been completed, the application may be submitted. Application materials, including attachments, may be subject to release pursuant to the Massachusetts Public Records Law, 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 500.050(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 states;
4. Documentation detailing the amounts and sources of capital resources available to the applicant from any individuals 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. The amount of capital resources available to the applicant shall comply with 935 CMR 501.050(1)(i). If any person or entity contributing initial capital would be classified as a Person or Entity Having Direct or Indirect Control, in exchange for the initial capital, they must 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 shall not be a post office box;
 - c. The primary telephone number;

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- 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 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(es) for the License;
- 7. Documentation of a property interest in the proposed address. The proposed MTC must be identified in the documentation as the entity that has or will have 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.
- 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(s);
- 9. Documentation that the applicant has conducted a community outreach meeting consistent with the Commission's *Guidance for License*

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Applicants on Community Outreach & Forms within the six months prior to the application submission date. If the MTC will be located in two locations under this License, the applicant must hold separate and distinct community outreach meetings in each municipality. Documentation must 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 (or cities or towns) at least fourteen calendar days prior to the meeting;
- b. Copy of the meeting notice filed with the city or town clerk(s);
- c. Attestation that at least one meeting was held after normal business hours;
- d. 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(es) 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(s), notwithstanding that the land of any such owner is located in another city or town;
- e. 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

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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. Information adequate to demonstrate that the location will not constitute a nuisance as defined by law; and

vi. 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(es) 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. The plan shall outline the goals, programs, and measurements the MTC will pursue once licensed;

12. The requisite non-refundable application fee pursuant to 935 CMR 501.005: Fees; and

13. Any other information required by the Commission.

(b) Background Check. Prior to an application being considered complete, each applicant for licensure must 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;

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- 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, including those individuals 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 Other Jurisdictions, 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 enforcement 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 with regard to any professional license, registration, or

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certification, including any complaint, order, stipulated agreement or settlement, or disciplinary action, by the Commonwealth, or like action in Other Jurisdictions, including, but not limited to any complaint or issuance of an order relating to the denial, suspension, or revocation of a license, registration, or certification;

e. A description and relevant dates of any administrative action, including any complaint, order or disciplinary action, by the Commonwealth, or a like action by Other Jurisdictions with regard to any professional license, registration, or certification, held by any Person or Entity Having Direct or Indirect Control, if any;

f. 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

g. 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 a certificate of good standing from the DUA cannot be obtained due to not having employees, a written statement to this effect is required;

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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;
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. Record-keeping procedures;
 - j. Maintenance of financial records; and
 - k. Diversity plans to promote equity among minorities, women, veterans, people with disabilities, and people of all gender identities and sexual orientation, in the operation of the MTC. The plan shall outline the goals, programs, and measurements the Marijuana Establishment will pursue once licensed.

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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: *General Operational Requirements for Medical Marijuana Treatment Centers* through 935 CMR 501.160: *Testing of Marijuana and Marijuana Products*, as applicable;

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11. Disclosure of the proposed hours of operation, and the names and contact information for individuals that will be the emergency contacts for the Marijuana Establishment;

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 for home delivery of Marijuana and Marijuana Products to patients and caregivers must 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 of the date of these regulations and as subsequently amended;

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 Marijuana Establishment 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.

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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 September 30, 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: *Medical Marijuana Treatment Centers*, 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. This requirement 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;

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;

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(b) Action on Application of Intent. The Commission shall notify each applicant that submitted an application in a timely manner that satisfies the criteria in 935 CMR 501.100(2)(a) that it may proceed to the ...

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(c) Management and Operations Profile.

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2. The name, address, date of birth, and résumés 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;

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3. List of all Persons or Entities Having Direct or Indirect Control over the management or policies of the MTC;

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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);

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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;

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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;

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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, record-keeping procedures, plans for patient education, and any plans for patient or Personal Caregiver home-delivery;

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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: Medical Marijuana Treatment Centers;

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10. A detailed description of all intended training(s) for MTC agents;

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11. Evidence that the applicant is responsible and suitable to maintain an MTC. Information including, but not limited to, the following factors

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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 is in compliance 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. Any criminal action under the laws of the Commonwealth, or an Other Jurisdiction, whether for a felony or misdemeanor, against any of the Executives of the applicant, or of the members of the entity, if any, including, but not limited to, action against any healthcare facility or facility for providing Marijuana for medical purposes in which those individuals either owned shares of stock or served as executives, and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;
- f. Any civil or administrative action under the laws of the Commonwealth, another state, the United States, or Other Jurisdictions relating to any Executive's (or members of the entity, if any) profession or occupation or fraudulent practices including, but not limited to:
 - i. Fraudulent billing practices;
 - ii. Past or pending legal or enforcement 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;

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- 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
- v. ~~Prescribing~~ for or distributing controlled substances or legend drugs by any ~~Executive~~, including of the members of the entity, if any, except for therapeutic or other proper medical or scientific purpose.
- g. 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:~~

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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.

501.102: Action on Applications

(1) Action on Each Application Completed Pursuant to 935 CMR 501.101(1).
The Commission shall grant Licenses with the goal of ensuring that the needs of the Commonwealth are met with regard to access, quality, and community safety.

(a) License applications shall be evaluated based on the Applicant's:

1. Demonstrated compliance with the laws and regulations of the Commonwealth;

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5. An analysis of the projected patient population and projected need in the service area of the proposed RMD;¶
6. A statement of whether the applicant would consider a location other than the county or physical address provided pursuant to 935 CMR 501.100(2)(d)1.;...

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2. Suitability for licensure based on the provisions of 935 CMR 501.101(1), 935 CMR 501.800: *Background Check Suitability Standard for Licensure and Registration* and 935 CMR 501.801: *Suitability Standard for Licensure*; 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; or

2. 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: *Action on Applications* by the Commission will result in evaluation of the application as submitted. Nothing in 935 CMR 501.100: *Application for Licensing of Medical Marijuana Treatment Centers (MTCs)* 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 (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.

(e) The applicant shall keep current all information required by 935 CMR 501.000: *Medical Use of Marijuana* 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.

(2) Action on Completed Applications Completed Pursuant to 935 CMR 501.101(1)

(a) The Commission shall review applications from applicants in the order they were submitted as determined by the Commission's electronic licensing system.

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(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 must be invited to the Management and Operations Profile phase within six (6) months of the promulgation of these regulations. 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.

(b) Once the Application of Intent and Management and Operations Profile have been submitted, respectively, and deemed complete, the applicant will be invited by

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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: Licensure and Renewal shall apply to all applicants that are granted a provisional License under 935 CMR 501.101: Application Requirements.

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 shall 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

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3. A selection committee established

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5. The Commission shall grant registrations with the goal of ensuring that the needs of the Commonwealth are met with regard to access, quality, and community safety.¶

6. The Commission may request additional information from an applicant.¶

7. Nothing in 935 CMR 501.000 is intended to confer a property or other right or interest entitling an applicant to a hearing before an application may be denied.¶

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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 must 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: Medical Use of Marijuana, 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: Medical Use of Marijuana.

(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: Application Requirements and will require Commission approval.

(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: Medical Use of Marijuana that is not available at the time of submission must 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.

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- (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: Medical Use of Marijuana at the address(es) identified on the final License issued by the Commission.
- (3) The MTC must 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 against that License.
- (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 (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. If a Licensee did not previously submit the plans required under 935 CMR 501.101(1), they shall do so upon the first License renewal following the promulgation of these regulations.
- (c) An MTC engaged in indoor cultivation must include a report of the MTC's energy and water usage over the 12-month period preceding the date of the application.

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- (d) To the extent updates are required to the information provided for initial licensure, the MTC must 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) The MTC shall submit as a component of the renewal application document of any cost to a city or town imposed by the operation of a Marijuana Establishment or MTC. 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.
- (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 45 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 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 (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.

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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. 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 a 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.

(2) The MTC shall keep current all information required by 935 CMR 501.000: Medical Use of Marijuana 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

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the Commission within five business days after such change or addition.

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501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (1) 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. Operating procedures shall include, but need not be limited to the following:
- (a) Security measures in compliance with 935 CMR 501.110: *Security Requirements for Medical Marijuana Treatment Centers.*
- (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 officials upon request, and updated pursuant to 935 CMR 501.104(2).
- (d) Storage and waste disposal of Marijuana in compliance with 935 CMR 501.105(11) and 935 CMR 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: *Testing of Marijuana and Marijuana Products.*
- (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 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 officials and to the Commission;

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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 an Other Jurisdiction.
- (n) A list of all board members and Executives of an MTC, and members, if any, of the entity, must 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) A description of the MTC's patient education activities in accordance with 935 CMR 501.140(6).
- (2) MTC Agent Training. MTCs shall ensure that all MTC agents complete training prior to performing job functions. Training shall be tailored to the roles and responsibilities of the job function of each MTC agent, and at a minimum must include training on confidentiality, privacy, security and other topics as specified by the Commission. Agents responsible for tracking and entering product into the Seed-to-sale SOR must receive training in a form and manner determined by the Commission. At a minimum, staff shall receive eight hours of on-going training annually.
- (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;
 4. Prepared and handled on food-grade stainless steel tables with no contact with MTC agents' bare hands; and

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5. Packaged in a secure area.

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(b) All MTCs, including those that develop 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

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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.

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c. Hand-washing facilities shall be adequate and convenient and shall be furnished with running water at a suitable temperature.

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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;

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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);

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6. Floors, walls, and ceilings shall be constructed in such a manner that they may be adequately kept clean and in good repair;

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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;

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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

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labeled instructions. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable;

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10. All toxic items shall be identified, held, and stored in a manner that protects against contamination of Marijuana and MIPs. Toxic items shall 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;

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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 must 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).

(c) All MTCs shall comply with sanitary requirements during the development or Processing of Edible MIPs. All Edible MIPs shall be prepared, handled, and stored in compliance with the sanitation requirements in 105 CMR 590.000: *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

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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;
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.

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(4) Marketing and Advertising Requirements.

(a) Permitted Practices

1. An MTC may develop a business name and logo to be used in labeling, signage, and other materials; provided, however, that use of medical symbols, images of Marijuana, or related Paraphernalia, images that are appealing to persons younger than 21 years of age, and colloquial references to Cannabis and Marijuana are prohibited from use in this business name and logo;
2. Sponsorship of a charitable, sporting or similar event, except that advertising, marketing, and branding at or in connection with such an event is prohibited unless at least 85% of the audience is reasonably expected to be either 21 years of age or older or individuals with a debilitating condition, as determined by reliable, current audience composition data;
3. 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: *Security Requirements for Medical 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 patient for inspection, provided the patient may not consume or otherwise use the sample unless otherwise authorized herein.
4. 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 patients and may post the same catalogue or printed list on its website and in the retail store.
5. An MTC may engage in reasonable marketing, advertising and branding 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 marketing, advertising and branding created for viewing by the public shall include the statement "Please Consume Responsibly," in a

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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:

- 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.”
- d. “For use only by adults 21 years of age or older. Keep out of the reach of children.”
- e. “Marijuana should not be used by women who are pregnant or breastfeeding.”

6. All marketing, advertising and branding produced by or on behalf of an MTC shall include the following warning, including capitalization, in accordance with M.G.L. c. 94G, § 4(a½)(xxvi):

- a. This product has not been analyzed or approved by the Food and Drug Administration (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. There may be health risks associated with consumption of this product. Marijuana can impair concentration, coordination, and judgment. The impairment effects of edible Marijuana may be delayed by two hours or more. In case of accidental ingestion, contact poison control hotline 1-800-222-1222 or 9-1-1. This product may be illegal outside of MA.

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(b) Prohibited Practices.

1. Advertising, marketing, and branding 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, marketing and branding 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, marketing, and branding that utilizes statements, designs,

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- representations, pictures or illustrations that portray anyone younger than 21 years old.
4. Advertising, marketing, and branding including, but not limited to, mascots, cartoons, brand sponsorships and celebrity endorsements, that is deemed to appeal to a person younger than 21 years old.
 5. Advertising, marketing, and branding, 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;
 6. Advertising, marketing, and branding through certain identified promotional items as determined by the Commission including, but not limited to, gifts, giveaways, coupons, or “free” or “donated” Marijuana, except that the foregoing shall not apply to financial hardship programs approved pursuant to 935 CMR 501.050(1)(h);
 7. Advertising, marketing, and branding by a Licensee 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;
 8. Advertising on any billboards or any other public signage which fails to comply with all state and local ordinances and requirements;
 9. Installation of any illuminated neon 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;
 10. The use of vehicles equipped with radio or loudspeakers for the advertising of Marijuana;
 11. The use of radio or loudspeaker equipment in any Marijuana Establishment for the purpose of attracting attention to the sale of Marijuana;
 12. Advertising, marketing, and branding at, or in connection with, a charitable, sporting or similar event, unless at least 85% of the audience is reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data;
 13. Operation of any website of an MTC that fails to verify that the entrant is 21 years of age or older;
 14. The use of unsolicited pop-up advertisements on the internet or text message;

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15. Any advertising of an improper or objectionable nature including, but not limited to, the use of recipe books or pamphlets for Marijuana Products which contain obscene or suggestive statements;
 16. Advertising, marketing or branding of Marijuana Products, on clothing, cups, drink holders, apparel accessories, electronic equipment or accessories, sporting equipment, novelty items and similar portable promotional items;
 17. Advertising, marketing or branding 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 or company cars;
 18. Advertising, marketing, branding, signs or other printed matter advertising any brand or kind of Marijuana Products that are displayed on the exterior or interior of any licensed Premises where Marijuana Products are not regularly and usually kept for sale;
 19. Advertising or marketing of the price of Marijuana Products, except as permitted above pursuant to 935 CMR 501.105(4)(a);
 20. Display of Marijuana Products so as to be clearly visible to a person from the exterior of an MTC;
 21. 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;
 22. Advertising, marketing or branding including any statement, design, representation, picture, or illustration that encourages or represents the recreational use of Marijuana; and
 23. An MTC shall not display on the exterior of the facility advertisements for Marijuana or any brand name, and may only identify the building by the registered name.
- (c) The Commission shall maintain and make available a list of all MTCs, their dispensing location, and their contact information.
- (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 1/16 inch in size on each package of

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Marijuana that it makes available for retail sale, containing at a minimum the following information:

1. The name and registration number 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 quantity of Usable Marijuana contained within the package;
3. The date that the MTC packaged the contents and a statement of which Licensee performed the packaging;
4. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
5. The full Cannabinoid profile of the Marijuana contained within the package, including THC and other Cannabinoid level;
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:
 - a. 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 Product:



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



(b) Labeling of Edible Marijuana Products. Prior to edible Marijuana Products being sold or Transferred, the MTC shall place a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size on each edible Marijuana Product that it prepares for retail sale or wholesale containing at a minimum the following information:

1. The name and registration number of the product manufacturer that produced the Marijuana Product, together with the 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. Net weight or volume in US customary and metric units;
5. The quantity of Usable Marijuana contained within the product as measured in ounces;
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 (Δ^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 serving size of the Marijuana Product in milligrams;
9. The number of serving sizes within the Marijuana Product;
10. The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving;
11. The date of creation and the recommended "use by" or expiration date which shall

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not be altered or changed;

12. A batch number, sequential serial number and bar codes when used, to identify the batch associated with manufacturing and Processing;

13. Directions for use of the Marijuana Product;

14. 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;

15. A warning if nuts or other Known Allergens are contained in the product;

16. This statement, including capitalization:

- a. 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;

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



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

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(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 $\frac{1}{16}$ inch in size on each Marijuana concentrate container that it prepares for retail sale or wholesale, containing at a minimum the following information:

1. The name and registration number of the product manufacturer that produced the Marijuana Product, together with the product manufacturer's business telephone number, e-mail address, and website information, if any;
2. The name of the Marijuana Product;
3. Product identity including the word "concentrate" or "extract" as applicable;
4. Net weight of volume expressed in US customary units and metric units;
5. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
6. A list of ingredients, including the full *Cannabinoid* profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol (Δ 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;
7. A statement of the serving size and number of servings per container or amount suggested for use;
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 of testing in accordance with M.G.L. c. 94G, § 15;

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12. A warning if nuts or other Known Allergens are contained in the product;

13. This statement, including capitalization:

- a. 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.;

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



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



(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 1/16 inch in size on each container of Marijuana infused product that it prepares for retail sale or wholesale, containing at a minimum the following information:

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;

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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 (Δ 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. Net weight or volume as expressed in US customary units or metric units;
6. The date of product creation;
7. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
8. Directions for use of the Marijuana Product;
9. 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;
10. A warning if nuts or other Known Allergens are contained in the product;
11. This statement, including capitalization:
 - a. 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.;
12. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product:



13. The following symbol or other easily recognizable mark issued by the

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Commission that indicates that the product is harmful to children:



- (e) 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) 935 CMR 501.105(5)(a) shall 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 for Patients.
- (g) 935 CMR 501.105(5)(b) shall apply to edible Marijuana Products produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13) and shall be in addition to any regulation regarding the appearance of edible Marijuana Products under 935 CMR 501.150.
- (h) 935 CMR 501.105(5)(c) shall apply to Marijuana concentrates and extracts produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13).
- (i) 935 CMR 501.105(5)(d) shall apply to Marijuana-infused Tinctures and topicals produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13).
- (6) Packaging of Marijuana and Marijuana Products.
 - (a) Tamper and Child-resistant Packaging. MTCs engaged in product manufacturing operations shall ensure that all Marijuana Products that are provided for sale to patients shall be sold in tamper and child-resistant packaging. To be in compliance 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. Resealable for any Marijuana Product intended for more than a single use or containing multiple servings; and

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- c. Certified by a qualified third-party tamper and child-resistant packaging testing firm that the packaging is in compliance with the most recent poison prevention packaging regulations of the US Consumer Product Safety Commission as included at 16 CFR 1700.
 - 2. That where compliance with the requirements of tamper and child-resistant packaging is deemed to be unreasonably impracticable, Marijuana Products shall be placed in an exit package that is:
 - a. Capable of being resealed and made tamper and child-resistant resistant again after it has been opened;
 - b. Not be able to be opened easily with scissors or knives if appealing to children;
 - c. Includes the following statement, including capitalization, in at least ten-point Times New Roman, Helvetica or Arial font: KEEP OUT OF REACH OF CHILDREN; and
 - d. Is certified by a qualified third-party tamper and child-resistant packaging testing firm that the packaging is in compliance with the most recent poison prevention packaging regulations of the US Consumer Product Safety Commission as included at 16 CFR 1700.
- (b) Limits on Packaging Design. Packaging for Marijuana Products sold or displayed for Registered Qualifying Patients, including any label or imprint Affixed to any packaging containing Marijuana Products or any exit packages, shall 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.
- (c) Packaging of Multiple Servings.
 - 1. Packaging for Marijuana Products sold or displayed for patients in multiple servings shall include the following statement on the exterior of the package in a

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- 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 patients in multiple servings shall allow a Registered Qualifying Patient to easily perform the division into single servings.
- a. Edible Marijuana Products 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 is able to 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 Marijuana Product 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.
- (7) Packaging and Labeling Pre-approval. Prior to a Marijuana Product being sold at an MTC, a Licensee or License applicant may submit an application, in a form and manner determined by the Commission, for packaging and label approval to the Commission. The Commission may charge a fee for packaging and labeling pre-approval. The packaging and labeling pre-approval process shall in no way substitute for compliance with 935 CMR 501.105(5) through (6).
- (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)(k)(2) and (3). Such transfers cannot violate provisions protecting patient supply under 935 CMR 502.140(9). An MTC must limit its transfer of inventory of seeds, plants, and Usable Marijuana to reflect the projected needs of registered Qualifying Patients.
- (b) Seed-to-sale Electronic Tracking shall be maintained as specified by the Commission 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.

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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 must 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 must limit its inventory of seeds, plants, and Usable Marijuana to reflect the projected needs of registered Qualifying Patients.

(j) An MTC may acquire Marijuana from or distribute Marijuana to another MTC or Marijuana Establishment in accordance with 935 CMR 502.105(8)(b) and subject to the following:

1. A documented emergency occurs such as loss of crop, vandalism, or theft, or other circumstance as approved by the Commission; or
2. The distribution and acquisition of Marijuana, except MIPs, to and from all other MTCs does not exceed, cumulatively, 45% of the MTC's total annual

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inventory of Marijuana as measured by weight; except that such requirement shall not apply to CMOs; and

3. The distribution and acquisition of MIPs to and from all other MTCs does not exceed, cumulatively, 45% of the MTC's total annual inventory of MIPs as measured by its dry weight equivalent to Marijuana; except that such requirement shall not apply to CMOs;

(k) Any distribution and acquisition of Marijuana and MIPs must 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 502.140(9).

(9) Record Keeping. Records of an MTC must 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: Medical Use of Marijuana, in addition to the following:

(a) Operating procedures as required by 935 CMR 501.105(1);

(b) Inventory records as required by 935 CMR 501.105(8);

(c) Seed-to-sale tracking records for all Marijuana and MIPs as required by 501.105(8)(d);

(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: Registration of Independent Testing Laboratory Agents and 935 CMR 501.030: Registration of Medical Marijuana Treatment Center Agents, as applicable;

b. Documentation of verification of references;

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- 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; and
- g. 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; and
- 5. All background reports obtained in accordance with M.G.L. c. 6, § 172, 935 CMR 501.029: Registration of Independent Testing Laboratory Agents, 935 CMR 501.030: Registration of Medical Marijuana Treatment Center Agents, 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 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 must be kept for at least two years at the expense of the MTC and in a form and location acceptable to the Commission.

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Deleted: for the production and distribution of marijuana, which shall include, but not be limited to:

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(10) Liability Insurance Coverage or Maintenance of Escrow.

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(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.

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(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) must 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: *Medical Use of Marijuana*.

(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: *Operational Requirements for Medical Marijuana Treatment Centers* and 935 CMR 501.110: *Security Requirements for Medical Marijuana Treatment Centers*.

(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: *Security Requirements for Medical Marijuana Treatment Centers*.

(12) Waste Disposal.

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(a) All recyclables and waste, including organic waste composed of or containing

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finished Marijuana and MIPs, shall be stored, secured, and managed in accordance with applicable state and local statutes, ordinances, and regulations.

(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 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: *Definitions* 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 is in compliance with the requirements of 310 CMR 16.00: *Site Assignment Regulations for Solid Waste Facilities*.

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.

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(d) No fewer than two MTC Agents must 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 must 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 enforcement action and may be extended by an order of the Commission.

(13) Transportation Between MTCs.

(a) General Requirements.

1. A licensed MTC shall, as an element of its License, be licensed to transport its Marijuana Products to other licensed establishments, except as otherwise provided herein.
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(8) 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 tracking program. 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 must 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 must re-weigh, re-inventory, and account for, on video, all Marijuana Products transported.

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9. When videotaping the weighing, inventorying, and accounting of Marijuana Products before transportation or after receipt, the video must show each product being weighed, the weight, and the manifest.
10. Marijuana Products must be packaged in sealed, labeled, and tamper and child-resistant packaging prior to and during transportation.
11. In the case of an emergency stop during the transportation of Marijuana Products, a log must be maintained describing the reason for the stop, the duration, the location, and any activities of personnel exiting the vehicle.
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 must 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).
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 shall not significantly obscure the picture.

(b) Reporting Requirements.

1. MTC agents must 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.

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1. A vehicle used for transporting Marijuana Products must 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 must not be visible from outside the vehicle.

3. Any vehicle used to transport Marijuana Products shall not bear any markings indicating that the vehicle is being used to transport Marijuana Products, and any such vehicle shall not indicate the name of the MTC.

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 must be transported in a secure, locked storage compartment that is a part of the vehicle transporting the Marijuana Products.
2. The storage compartment must 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

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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.
- 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 must 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 must have an MTC agent assigned to monitoring the GPS unit and secure form of communication, who must 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

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- 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 must, 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 re-weighed and re-inventoried;
 - k. The name of the MTC agent at the destination MTC who re-weighed 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.

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(g) Requirements for Agents.

1. Each employee or agent transporting or otherwise handling Marijuana Products for an MTC must 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.
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 officials 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.

(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 M.G.L. c. 94G, c. 94I, and 935 CMR 501.000: Medical Use of Marijuana;
2. Representatives of other state agencies of the Commonwealth; and
3. Emergency responders while responding to an emergency.

(b) 935 CMR 501.000: Medical Use of Marijuana shall 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 must 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;

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(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 the destruction of Cannabis goods necessitated by a violation of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94I, or 935 CMR 501.000: *Medical Use of Marijuana* or the cessation of operation of the MTC.

(b) All bonds required under 935 CMR 501.000: *Medical Use of Marijuana* must 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) 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) must be replenished within ten business days of any expenditure required under 935 CMR 501.105: *General Operational Requirements for Medical Marijuana Treatment Centers* except if the MTC has ceased operations. Documentation of the replenishment must 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.

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(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

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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).

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(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

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- (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)(h). 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 must

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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.

(j) An MTC may not sell Marijuana to a registered Qualifying Patient with a Hardship Cultivation Registration or to his or her Personal Caregiver(s), provided however that the MTC may sell seeds to such individuals or gift seeds pursuant to 935 CMR 501.050(h).

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 must include, but are not limited to, the following:

(a) Allow only registered Qualifying Patients, Personal Caregivers, MTC agents and, subject to the requirements of 935 CMR 501.110(4)(e), outside vendors, contractors, and Visitors, access to the MTC;

(b) Prevent 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: *Medical Use of Marijuana*;

(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: *General Operational Requirements for Medical Marijuana Treatment Centers*;

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- (d) Securing all entrances to the MTC to prevent unauthorized access;
- (e) Establishing Limited Access Areas which 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

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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)(3). Inside the MTC, all Marijuana shall be stored in a locked, access-controlled space in a Limited Access Area during non-business hours.

(2) Alternative Security Provisions.

(a) Notwithstanding the requirements specified in 935 CMR 501.110(1) and (4)-(6), 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(6)(b) shall be considered to be adequate substitutes.

(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 Marijuana Establishment 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 shall not be determinative. If no response is received from the chief law enforcement officer or a delegatee within 30 days of submitting the request to the chief law enforcement officer, the Commission shall proceed with a determination.

(3) Buffer Zone.

(a) The property where the proposed MTC is to be located, at the time the License application is received by the Commission, is not located within 500 feet of a pre-existing public or private school providing education in kindergarten or any of grades one through 12, unless a city or town adopts an ordinance or bylaw that reduces the distance requirement. The distance under 935 CMR 501.110(3) shall be measured in a straight line from the nearest point of the property line in question to the nearest

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point of the property line where the MTC is or will be located.

(4) Limited Access Areas.

- (a) All Limited Access Areas must be identified by the posting of a sign that shall be a minimum of 12" x 12" and which states: "Do Not Enter - Limited Access Area - Access Limited to Authorized Personnel Only" in lettering no smaller than 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. Said diagram shall also show all Propagation, Vegetation, Flowering, Processing, production, storage, disposal, and retail sales areas.
- (c) 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 colocated-operations 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) All outside vendors, contractors, and Visitors must obtain a Visitor Identification Badge prior to entering a Limited Access Area, and shall be escorted at all times by an MTC agent authorized to enter the Limited Access Area. The Visitor Identification Badge must be visibly displayed at all times while the Visitor is in any Limited Access Area. All Visitors must be logged in and out, and that log shall be available for inspection by the 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;

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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 shall 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 shall not significantly obscure the picture;
 8. The ability to remain operational during a power outage for a minimum of 48 hours; 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 shall 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.

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(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: *Medical Use of Marijuana*, and Commission Delegee(s).

(e) A current list of authorized employees and service personnel that have access to the surveillance room must be available to the Commission upon request. If on-site, surveillance rooms shall remain locked and shall not be used for any other function.

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(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.

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(g) Trees, bushes and other foliage outside of the Marijuana Establishment 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.

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

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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 its delegee. If an MTC receives notice that the motion detection sensor is not working correctly, it must take prompt action to make corrections and document those actions. Recordings shall 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 shall not significantly obscure the picture;

8. The ability to remain operational during a power outage; 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 shall 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

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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 must be available to the Commission on request. If the surveillance room is on-site of the MTC, it shall remain locked and shall 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)(15)(c).

(7) Cash Handling and Transportation Requirements.

(a) An MTC 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,

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§ 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(8)(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") 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

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- payment for deliveries of Marijuana or Marijuana Products.
4. A means of secure communication between each vehicle and the MTC'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.
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 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 may delegate monitoring of the GPS to the Third-Party Technology Platform Provider with which the MTC has a contract, provided that the MTC Licensee shall be responsible for ensuring that monitoring occurs as required under these regulations 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 shall 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 agents that must

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be completed within a reasonable period of time and at the expense of the MTC.

Trainings shall include, but may not be limited to, training on:

1. Safely conducting deliveries;
2. Safe cash handling practices;
3. Strategies for de-escalating potentially dangerous situations;
4. Collecting and communicating information to assist in investigations;
5. Procedures for checking identification;
6. Indications of impairment;
7. Notification to Qualifying Patients of use of mandatory recording devices; and
8. Such other areas of training determined by the Commission to be included in a training program.

(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.

(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: *Medical Use of Marijuana* or the Act;
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) This regulation shall 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.

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(i) Firearms are strictly prohibited from MTC vehicles and from MTC agents performing home deliveries.

(9) Incident Reporting.

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(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:

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; or
9. 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(10)(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(10)(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

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jurisdiction upon request.

- (10) Security Audits. An MTC, must, 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 must 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 must also submit a plan to mitigate those concerns within ten business days of submitting the audit.

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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: General Operational Requirements for Marijuana Treatment Centers, MTCs shall comply with additional operational requirements for the cultivation, acquisition, and distribution of Marijuana required under 935 CMR 501.120: Additional Operational Requirements for the Cultivation, Acquisition, and Distribution of Marijuana.
- (2) 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.
- (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 under an entity.
- (4) All phases of the cultivation of Marijuana shall take place in designated, locked, Limited Access Areas that are monitored by a surveillance camera system in accordance with 935 CMR 501.110(5)(a)(4)-(9) and that is not visible from a public place without the use of binoculars, aircraft or other optical aids.
- (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: Testing of Marijuana and Marijuana Products.
- (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

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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(4), 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* in effect of the date of these regulations and as subsequently amended.

(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): *Final License* and as a condition of renewal under 935 CMR 501.103(4): *Expiration and Renewal of Licensure*. 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): *Expiration and Renewal of Licensure* must include a report of the MTC cultivation operations' energy and water usage over the 12-month period preceding the date of application.

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

(a) The building envelope for all facilities, except Greenhouses, must 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.

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- (b) Lighting used for MTC cultivation operations must meet one of the following compliance paths:
 - 1. Horticulture Lighting Power Density must not exceed 36 watts per square foot, except for Tier 1 and Tier 2 which must not exceed 50 watts per square foot; or
 - 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 percent above the minimum Horticultural QPL threshold rounded up to the nearest 0.1 $\mu\text{mol/J}$ (micromoles per joule).
- (c) Heating Ventilation and Air Conditioning (HVAC) and dehumidification systems must 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 must 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 must be established and documented to protect workers and Qualifying Patients (e.g., eye protection near operating Horticultural Lighting Equipment).
- (e) The requirements of 935 CMR 501.120(11) shall not be required if an indoor MTC cultivation operation is generating 80% or more of the total annual onsite energy use for all fuels (expressed on a MWh basis) from an onsite clean or renewable generating source, as defined by M.G.L. c. 25A § 11F, and/or alternative energy generating source, as defined by M.G.L. c. 25A § 11F ½. Additionally, the Licensee must document that renewable energy credits or alternative energy credits representing the portion of the Licensee’s energy usage not generated onsite has been purchased and retired on an annual basis.
- (f) To demonstrate compliance with 935 CMR 501.120(11), an MTC applicant seeking to engage in cultivation operations must submit 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) but prior to final licensure. To the extent updates are required to the information provided for initial licensure, the MTC must 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 co-located Marijuana Establishment and MTC with a final Certificate of Licensure

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shall have until January 1, 2020 to comply with 935 CMR 501.120(22), except that any additions to or renovations to a facility must comply with 935 CMR 501.120(11). An MTC without a final Certificate of Licensure before January 1, 2021, shall demonstrate compliance with 935 CMR 501.120(11) at time of application.

(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).
2. Horticulture Lighting Square Footage (HLSF) means Canopy, plus any additional areas(s) that will contain live plants at any point in time that will be exposed to horticultural lighting equipment.
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.

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: *General Operational Requirements for Medical Marijuana Treatment Centers*, MTCs shall comply with additional operational requirements required under 935 CMR 501.130: *Additional Operational Requirements for Handling and Testing Marijuana and for Production of MIPs*.

(2) Production of Edible MIPs shall take place in compliance with the following:

(a) All Edible MIPs 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 MIP that is made to resemble a typical food or beverage product must be packaged in an opaque package and labeled as required by 935 CMR 501.105(5)(c).

(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

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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: *Testing of Marijuana and Marijuana Products*, 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.

(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;

(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 is segregated from other Marijuana and destroyed. This procedure shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, must be in compliance 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; and

(f) Policies and procedures to ensure that all Edible MIPs 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*.

(6) Notwithstanding a stricter municipal or state regulation, an MTC shall identify the method of extraction (e.g., Butane, Propane, CO2) 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

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Deleted: (o) A policy for the immediate dismissal of any RMD agent who has:¶

1. Diverted marijuana, which shall be reported to law enforcement officials and to the Commission; or¶

2. Engaged in unsafe practices with regard to operation of the RMD, which shall be reported to the Commission; and¶

(p) A list of all board members and executives of an RMD, and members, if any, of the entity, must be made available upon request by any individual. This requirement may be fulfilled by placing this information on the RMD's website.¶

(q) Policy and procedure for the handling of cash on RMD premises including, but not limited to, storage, collection frequency, and transport to financial institution(s).¶

501.105: continued¶

¶

(2) Cultivation, Acquisition, and Distribution Requirements.¶

(a) The following requirements pertain to cultivation of marijuana for medical use:¶

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permit to keep, store, handle or otherwise use flammable and combustible at each place of operation within the facility.

- (7) Except for a registered Qualifying Patient or Personal Caregiver, who are not subject to 935 CMR 501.105: General Operational Requirements for Medical Marijuana Treatment Centers, 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: General Operational Requirements for Medical Marijuana Treatment Centers, MTCs engaged in patient sales shall comply with additional operational requirements for MTCs under 935 CMR 501.140: Additional Operational Requirements for Patient Sales.

(2) Verification of Patient and Caregiver Certification

(a) Upon entry into an MTC by a Registered Qualifying Patient or Personal Caregiver, an MTC agent shall immediately inspect the patient's or caregiver's temporary or annual Registration Card and proof of identification.

1. The identification must contain a name, photograph, and date of birth, and shall be limited to one of the following:

- A driver's license;
- A government-issued identification card;
- A military identification card; or
- 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 which 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.

(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

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Moved up [40]: All contact surfaces, including ...

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60 day supply in each 60 day period as defined in 935 CMR 501.002: *Definitions* (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.

(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 may 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 must notify the patient's Certifying Healthcare Provider within 24 hours.
- (c) An MTC shall 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 (POS) system approved by the Commission.
- (b) A retailer is prohibited from utilizing software or other methods to manipulate or alter sales data.
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

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- Moved up [49]:** Conduct a comprehensive annual ...
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- Moved up [54]:** Operating procedures as required by ...
- Deleted:** (b) Inventory records as required by 935 ...
- Moved up [55]:** The following personnel records:¶ ...
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- Moved up [56]:** Job descriptions for each employee ...
- Deleted:** 2. A personnel record for each RMD agent ...
- Moved up [57]:** Documentation of verification of ...
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- Moved up [59]:** Documentation of all required ...
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- Moved up [60]:** Documentation of periodic ...
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- Moved up [62]:** Business records, which shall ...
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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: *General Operational Requirements for Medical Marijuana Treatment Centers.*

(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 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 must 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 501.000: *Medical Use of Marijuana*;

(6) Patient Education.

(a) An MTC shall provide educational materials about Marijuana to registered Qualifying Patients and their Personal Caregivers.

1. An MTC must have an adequate supply of up-to-date educational material

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available for distribution.

2. Educational materials must 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 must 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 must also be explained;

6. A discussion of tolerance, dependence, and withdrawal;

7. Facts regarding substance abuse signs and symptoms, as well as referral information for substance abuse treatment programs;

8. A statement that registered Qualifying Patients may not distribute Marijuana to any other individual, and that they must 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

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(12) Marketing and Advertising Requirements.¶

(a) An RMD may develop a logo to be used in labeling, signage, and other materials use of medical symbols, images of marijuana, related paraphernalia, and colloquial references to cannabis and marijuana are prohibited from use in this logo.¶

(b) RMD external signage shall not be illuminated except for a period of 30 minutes before sundown until closing, and shall comply with local requirements regarding signage, ...

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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: Medical Use of Marijuana. The product must be deemed to comply with the standards required under 935 CMR 501.160: Testing of Marijuana and Marijuana Products.

501.145: Home Delivery

(1) General Requirements.

(a) An MTC or a Delivery-Only Retailer acting on behalf of an MTC must obtain Commission approval prior to engaging in the delivery of Marijuana and Marijuana Products directly to Registered Qualified Patients and Caregivers. An MTC shall comply with 935 CMR 501.110(8) and adhere 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.

(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 performing the delivery. An MTC cannot pick up Marijuana or Marijuana Products from another MTC to fulfill a Individual Order.

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

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

2. The Commission shall be notified in writing within five days of any substantial modification to an agreement between an MTC and a Third-Party

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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 of an ongoing basis of any new or additional or assigned agreements between an MTC 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.

(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 must be completed before 9:00 p.m. local time or the time determined by municipal bylaw or ordinance, whichever occurs first, and deliveries Marijuana shall 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 vehicle at any one time. MTCs 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).

(2) Orders. All orders for deliveries made by MTCs 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) MTCs 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 500.145(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 dormitories, other on-campus college or university housing, federally-subsidized housing, shelters

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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 shall not be allowed to be delivered by or on behalf of an MTC.

(g) For home delivery, each order must 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 to ensure that any undelivered product is returned to the MTC's physical location and stored in accordance with 935 CMR 501.105(11).

(3) Vehicle and Transport Requirements for Home Delivery.

(a) Vehicles used for home delivery by an MTC shall be owned or leased by the MTC and shall be properly registered as commercial vehicles, inspected and insured in the Commonwealth of Massachusetts.

(b) Vehicles and transportation operations of an MTC shall comply with 935 CMR 501.105(13) and 935 CMR 501.110(7).

(c) The MTC shall maintain a separate log for each vehicle in use for home deliveries. For each delivery, the MTC 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

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4. An entry indicating the date and time of the last delivery in an order.

(d) MTCs shall not transport products other than Marijuana and Marijuana Products during times when MTCs are 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 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 agent acting on behalf of the MTC. A signed manifest shall serve as the written record of the completion of the delivery.

(b) The manifest must, at a minimum, include:

1. The originating MTC's name, address, and license number;
2. The names and MTC agent numbers of the MTC 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 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.

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501.150: Edible Marijuana Products

(1) Production of Edible Marijuana Products. Production of edibles shall take place in compliance with the following:

(a) Any edible Marijuana Product that is made to resemble a typical food or beverage product must be packaged and labeled as required by M.G.L. c. 94G, § 4(a½)(xxvi) and 935 CMR 500.105(5) and (6).

(b) The manufacture or sale of edibles in the following shapes and types is prohibited:

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1. The distinct shape of a human, animal, or fruit; or
2. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

(c) Edible Marijuana Products that are geometric shapes and simply fruit-flavored are not considered fruit and are permissible.

(2) Sanitary Requirements. All edible Marijuana Products shall be prepared, handled, and stored in compliance with the requirements in 935 CMR 500.105(3) and (11).

(3) Additional Labeling and Packaging Requirements for Edible Marijuana Products.

(a) In addition to the requirements set forth in M.G.L. c. 94G, § 4(a½)(xxvi) and 935 CMR 500.105(5) and (6), every MTC must ensure that the following information or statement is Affixed to every container holding an edible Marijuana Product:

1. If the retail edible Marijuana Product is perishable or time and temperature controlled, a statement that the edible Marijuana Product must be refrigerated.
2. The date on which the edible Marijuana Product was produced.
3. A nutritional fact panel that must 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 (mgs). For example: "The serving size of active THC in this product is X mg(s), this product contains Y servings of Marijuana, and the total amount of active THC in this product is (X*Y) mg(s)."
5. A warning that the impairment effects of edible Marijuana 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 Marijuana Product, a Licensee shall not alter that date or affix a new label with a later use-by date.

(c) An MTC must ensure that each single serving of an edible Marijuana Product is physically demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC.

(d) Each serving of an edible Marijuana Product within a multi-serving package of edible Marijuana Products must 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.

(e) Each single serving of an edible Marijuana Product contained in a packaged unit of

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multiple edible Marijuana Product may be marked, stamped, or otherwise imprinted with a symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product.

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: *Medical Use of Marijuana*. 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 Medical Marijuana Products and Marijuana-infused Products*. 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.
- (3) 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 must be from both the MTC and the Independent Testing Laboratory, separately and directly.
 - (c) The notification from the MTC must describe a proposed plan of action for both the destruction of the contaminated product and the assessment of the source of contamination.
- (4) 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.

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- sold, Transferred or otherwise conveyed until retested.
- (5) The sale of seeds is not subject to these testing provisions.
- (6) Clones are subject to these testing provisions, but are exempt from testing for metals.
- (7) 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).
- (8) All storage of Marijuana and Marijuana Products at a laboratory providing Marijuana testing services shall comply with 935 CMR 501.105(11).
- (9) All excess Marijuana and Marijuana Products must 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;
- (10) 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
- (11) Marijuana and Marijuana Products submitted for retesting prior to remediation must be submitted to an Independent Testing Laboratory other than the laboratory which provided the initial failed result. Marijuana and Marijuana Products submitted for retesting after documented remediation may be submitted to the same Independent Testing Laboratory that produced the initial failed testing result prior to remediation.

501.170: Municipal Requirements

- (1) An MTC and Independent Testing Laboratory and their agents shall comply with all local rules, regulations, ordinances, and by-laws.
- (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: *Medical Use of Marijuana* 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: *Medical Use of Marijuana*.

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: *Medical Use of Marijuana*.
- (2) If an MTC operating from locations in the island counties are prevented from operating in

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full compliance with 935 CMR 501.000: *Medical Use of Marijuana* 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.

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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)-(xx), the Commission or its delegatee 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: *Medical Use of Marijuana*. 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

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- Commission or 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 its 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: *Compliance Examination*.
- (5) During an inspection, the Commission or its 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).
- (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 its delegee deems it necessary for the enforcement of M.G.L. c. 94I and M.G.L. c. 94G and 935 CMR 501.000: *Medical Use of Marijuana*.
- (7) The failure to cooperate with an inspection or otherwise comply with this section may result in administrative or disciplinary action against the Licensee.

501.302: Compliance Examination

- (1) After an MTC has been licensed, the Commission 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 its 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 its 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

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not subsequently vacated or modified by the Commission or its delegee, the Commission or its 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 this section 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 its 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 licensed MTC. The Commission or its 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. 94I, or 935 CMR 501.000: *Medical Use of Marijuana*, 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.
- (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 its 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: *Quarantine Order*, 501.350: *Cease and Desist Order and Summary Suspension Order*, 501.450: *Medical Marijuana Treatment Center Registration or License: Grounds for Suspension, Revocation, or Denial of Renewal Applications*, or 501.500: *Hearings and Appeals of Actions on Registrations or Licenses* or assess fines or other

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- civil penalties pursuant to 935 CMR 501.360: Fines.
- (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 this section 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. 94I, or 935 CMR 501.000: Medical Use of Marijuana 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: Deficiency Statements, within ten business days after receipt of the statement.
- (2) Every 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 with 935 CMR 501.000: Medical Use of Marijuana 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 for compliance with the requirements of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, and 935 CMR 501.000: Medical Use of Marijuana and shall notify the MTC of either the acceptance or rejection of the plan.
- (4) An unacceptable plan must be amended and resubmitted within five business days after receipt of such notice.

501.321 Administrative Hold

- (1) Pursuant to M.G.L. c. 94I and M.G.L. c. 94G, § 4(a)(xix), the Commission or its delegates 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: Medical Use of Marijuana, 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.

Moved (insertion) [87]

Moved (insertion) [88]

Moved up [85]: Incident Reporting.¶

Deleted: (d) An RMD and independent testing laboratory shall ensure that marijuana is:¶

1. Transported in a secure, locked storage compartment that is part of the vehicle transporting the marijuana;¶

2. Not visible from outside the vehicle; and¶

3. Transported in a vehicle that bears no markings that indicate that the vehicle is being used to transport marijuana nor indicates the name of the RMD or independent testing laboratory.¶

(e) Any vehicle transporting marijuana shall travel directly from origination to destination and shall not make any stops except in the case of delivery pursuant to 935 CMR 501.110(5)(k). In case of an emergency stop, a detailed log must be maintained describing the reason for the event, the duration, the location, and any activities of personnel exiting the vehicle.¶

(f) An RMD shall ensure that all delivery times and routes are randomized.¶

(g) An RMD shall staff all transport vehicles with a minimum of two dispensary or laboratory agents. At least one dispensary or laboratory agent shall remain with the vehicle at all times that the vehicle contains marijuana.¶

(h) Each dispensary or laboratory agent shall have access to a secure form of communication with personnel at the sending site at all times that the vehicle contains marijuana.¶

(i) Each dispensary or laboratory agent shall carry his or her Commission-issued registration card at all times when transporting marijuana and shall produce it to the Commission's authorized representative or law enforcement official upon request.¶

(j) An RMD or independent testing laboratory shall ...

Deleted: (a) An RMD shall immediately notify appropriate law enforcement authorities and the Commission within 24 hours after discovering the following:¶

1. Discrepancies identified during inventory, diversion, theft, loss, and any criminal action involving the RMD or an RMD agent;¶

2. Any suspicious act involving the sale, cultivation...

Moved up [86]: must, 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 must be submitted, in a form and manner determined by the Commission, no later than 30 calendar days after the audit is conducted.

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- (2) An MTC subject to an Administrative Hold shall retain its inventory pending further investigation by the Commission or its 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 constitutes evidence of non-compliance with 935 CMR 501.000: *Medical Use of Marijuana*, 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 Products. The notice shall identify the Marijuana or Marijuana Products 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 Products 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 Products 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 Products subject to the Administrative Hold, except as otherwise authorized by the Commission.
 - (e) While the Administrative Hold is in effect, the MTC must safeguard the Marijuana or Marijuana Products subject to the Administrative Hold and must fully comply with all security requirements including, but not limited to, 935 CMR 501.110: *Security Requirements for Marijuana Treatment Centers*.
 - (f) An Administrative Hold shall not prevent an MTC from the continued possession, cultivation or harvesting of the Marijuana or Marijuana Products subject to the Administrative Hold unless otherwise provided by an order of the Commission. All Marijuana or Marijuana Products subject to an Administrative Hold must 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 may modify, amend or rescind the Administrative Hold.
 - (i) The failure to cooperate with provisions of this section may result in administrative or disciplinary action against the Licensee.

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501.330: Limitation of Sales

- (1) If the Commission or its 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. 94I, or 935 CMR 501.000: *Medical Use of Marijuana*, the Commission or its delegee may order that the MTC shall not sell Marijuana or Marijuana Products, after a date specified.
- (2) The Commission or its 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. 94I, and 935 CMR 501.000: *Medical Use of Marijuana*, that an order to limit sales is contemplated, and that the MTC has a reasonable opportunity to correct the deficiencies.
- (3) An order that an MTC shall not sell Marijuana or Marijuana Products pursuant to 935 CMR 501.330(1) may be rescinded when the Commission or its delegee finds that the MTC is in substantial compliance with the applicable provisions of 935 CMR 501.000: *Medical Use of Marijuana*.

501.335: Removal and Prohibition of Marijuana and Marijuana Products

- (1) Pursuant to M.G.L. c. 94G, § 4(a ½)(xxxi) and G.L. c. 94I, the Commission or its delegee may order the removal of or prohibition of sales by more than one Licensee of categories of product types, specific product types or specific brands of products after notice and a determination that Marijuana, Marijuana Products, and Marijuana Accessories (for the purposes of this section, “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) A majority of the voting Commissioners 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 a 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, Marijuana edibles, beverages, topical products, ointments, oils, Tinctures, oral dosage forms or any other product

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identified by the Commission or its 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 the expertise to evaluate scientific evidence to conduct an informal hearing;
- (b) If credible and reliable evidence has been evaluated and found to meeting the standard of a substantial risk to the public health safety or welfare, if one not yet issued, order the quarantine or Removal of Product or prohibition on sales 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 purposes 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:
 - a. Licensees and Registrants; and
 - b. subject-matter experts.

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- (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.
 - (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 majority vote of the voting Commissioners.
 - (c) The Commission or its 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 must be destroyed in accordance with 935 CMR 500.105(12).
 - (d) The Commission or its designee may modify, amend or rescind a notice on condition(s) just to all the parties.

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- (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) In consultation with the Executive Director, the order may be posted on the Commission's website.
- (9) It shall be a violation of these regulations 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 Patient's 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 (a)(2)(xxviii), a Quarantine Order may be imposed by the Commission or its 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 its 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 its 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

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- public entrances to the MTC or Independent Testing Lab or other notice in a form and manner determined by the Commission or its delegee.
- (4) The Commission or its 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 its delegee.
- (6) The failure to cooperate with provisions of this section 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 (a½), a Cease and Desist or a Summary Suspension Order may be imposed by the Commission or its 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 its 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 its 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 its 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;

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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 its 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 501.450(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 its delegee.
- (5) Hearings. 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. M.G.L. c. 94I, § 7, M.G.L. c. 94G, § 4(a)(xxiv) and (g).
 - (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 its 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 must 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 Administrative 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.

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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: *Orders to Show Cause*, 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: *Hearings and Appeals of Actions on Registrations or Licenses*.

501.360: Fines

The Commission or its 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: *Medical Use of Marijuana*.

- (1) Notice of Fines. The Commission or its 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: *Hearings and Appeals of Actions on Registrations or Licenses*.
- (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 its delegee in setting the amount of the fine.
 - (b) Each day during which a violation continues may constitute a separate offense, and

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- each instance and provision of the state Marijuana laws, including M.G.L. c. 94I, and 935 CMR 501.000: *Medical Use of Marijuana* that is violated may constitute a separate violation.
- (3) The Commission or its 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: *Waivers*;
 - d. Involved a person younger than 21 years of age 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: *Medical Use of Marijuana*. However, financial impact shall not include any cost associated with loss of economic opportunity due to non-compliance or costs of corrective action necessary to achieve compliance with minimum requirements of 935 CMR 501.000: *Medical Use of Marijuana*;
 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: *Hearings and Appeals of Actions on Registrations or Licenses*, 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 its delegee including, but not limited to, suspension or revocation

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- 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 this section, shall be made payable to the Commission and deposited into the Marijuana Regulation Fund.
- (8) The failure to cooperate with provisions of this section 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 its delegatee 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 its delegatee 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);
- (f) the right to a hearing, if any.
- (3) The Commission or its delegatee may modify, amend or rescind an order issued pursuant to 935 CMR 501.370: Orders to Show Cause, on condition(s) to all the parties.

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.

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- (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 tended to deceive or create a misleading impression, whether directly, or by omission or ambiguity.
- (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, 935 CMR 501.000: *Medical Use of Marijuana*, including, but not limited to, 935 CMR 501.105: *General Operational Requirements for Medical Marijuana Treatment Centers* and 935 CMR 501.110: *Security Requirements for Medical Marijuana Treatment Centers* 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: *Background Check Suitability Standard for Licensure and Registration* and 935 CMR 501.801: *Suitability Standard for Licensure*.
- (5) The applicant failed to comply with the control limitations listed in 935 CMR 501.050(1)(b)-(d) 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: *Medical Use of Marijuana*.

501.415: ^vVoid 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.

Moved (insertion) [90]

Moved (insertion) [91]

Deleted: If the audit identifies concerns related to the RMD's security system, the RMD must also submit a plan to mitigate those concerns within ten business days of submitting the audit.¶

¶
501.200: Confidentiality¶

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

¶
(2) Information held by the Commission about applicants for registration as a qualifying patient, personal caregiver, or RMD agent, and registered qualifying patients, personal caregivers, and RMD agents may be released by the Commission to:¶
(a) The data subject or the data subject's

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- (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, or 935 CMR 501.000: *Medical Use of Marijuana*, 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: *Plans of Correction*.
- (5) The MTC has assigned or attempted to change ownership or assign its License to another entity without prior approval of the Commission.
- (6) The Licensee failed to comply with the control limitations listed in 935 CMR 501.050(1)(b)-(d) 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 935 CMR 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 bankruptcy or receivership related to the financial solvency of the MTC.
- (9) An individual or entity 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.
- (10) The conduct or practices of the MTC demonstrate a lack of suitability as specified in 935 CMR 501.800: *Background Check Suitability Standard for Licensure and Registration* and 935 CMR 501.801: *Suitability Standard for Licensure*.
- (11) 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.
- (12) 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.

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Products.

- (13) 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.
- (14) 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.
- (15) The MTC does not have sufficient financial resources to meet the requirements of M.G.L. c. 94I or 935 CMR 501.000: *Medical Use of Marijuana*.
- (16) 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: *Medical Use of Marijuana*.

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: *Fines*;
 - (b) 935 CMR 501.370: *Order to Show Cause*;
 - (c) 935 CMR 501.450: *Medical Marijuana Treatment Center Registration or License: Grounds for Suspension, Revocation, and Denial of Renewal Applications*; 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: *Hearings and Appeals of Actions on Registrations and Licenses*.
- (3) Notice(s)
 - (a) Notice of Violation(s) includes a notice issued in accordance with 935 CMR 501.360: *Fines* or 935 CMR 501.370: *Order to Show Cause*.
 - (b) Notice of Other Action(s). The Commission or its delegatee 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;

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- 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 its delegee may modify, amend or rescind a notice on condition(s) to all the parties.
- (4) Hearing Request. The hearing request shall be submitted in a form and a manner determined by the Commission or its 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 must 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).
 - (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 this section shall preclude the Commission or its 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 other 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

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- 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 (a) through (c), 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 its 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 Administrative 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, § 13.
- (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): *Commission's Authority to Review, Approve or Reject Informal Dispositions*.
- (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) Recommended Decision.
- (a) Burden of proof.

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1. For a notice of violation(s), the Commission or its 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

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- 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 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 its 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: Background Check Suitability Standard for Licensure and Registration

- (1) Pursuant to M.G.L. c. 94G, § 4(a)(xii), (xiv), and § 21(a)(ii) and M.G.L. c. 94I, the Commission may make, in an exercise of its discretion, a suitability determination.
- (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: *Background Check Suitability Standard for Licensure and Registration*.
- (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. 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.

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- (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 or entity 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 removes a subject from an application, the removal must 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 must 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:

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- (a) consider and review whether offense(s) or information resulting in a Mandatory Disqualification or a Presumptive Negative Suitability Determination under Tables A-E, in 935 CMR 501.801: *Suitability Standard for Licensure* through 500.803: *Suitability Standard for Registration as a Laboratory Agent*, 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 Tables A-E 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 their delegee(s).
- (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:
- (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

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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 a Marijuana Establishment.

(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 a Marijuana Establishment.

(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 Table A, or to have overcome any suitability issue, the agent shall not be subject to a subsequent suitability review under Tables B-E.

(a) Nothing in this subsection relieves the requirement that the applicant or

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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 a Marijuana establishment agent required to be listed and evaluated pursuant to 935 CMR 501.101(1), will be assessed pursuant to Table A or on other grounds for a Negative Suitability Determination only.

(c) Nothing in subsection 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. 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 Other Jurisdictions 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):

(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 Table A commence on the date of disposition; provided,

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however, that if disposition results in incarceration in any institution, the look back period shall commence on release from incarceration.

(e) Unless otherwise specified, a criminal condition, offense or violation referenced in Table A 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.

(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 Tables A-E 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.

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Table A: MTC Licensees. Shall apply solely to Persons or Entities Having Direct or Indirect Control in accordance with 935 CMR 501.100(2).

<u>Time Period</u>	<u>Precipitating Issue</u>	<u>Result</u>
<u>Present (during time from start of application process through action on application or renewal)</u>	<u>Open/Unresolved Criminal Proceedings:</u> <u>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, § 34.</u>	<u>Mandatory Disqualification</u>
<u>Present</u>	<u>Outstanding or Unresolved Criminal Warrants</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Present</u>	<u>Submission of untruthful information to the Commission including, but not limited to:</u> <u>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; or</u> <u>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.</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Present</u>	<u>Open/Unresolved Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions)</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Present</u>	<u>Open Professional or Occupational License Cases</u>	<u>Presumptive Negative Suitability Determination</u>

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<u>Indefinite</u>	<u>Sex Offender Registration:</u> <u>Required to register as a sex offender in Massachusetts or Other Jurisdiction.</u>	<u>Mandatory Disqualification</u>
<u>Indefinite</u>	<u>Felony Convictions in Massachusetts or an Other Jurisdiction Including, but not Limited to:</u> <u>Felony weapons violation involving narcotics;</u> <u>Felony involving violence against a person;</u> <u>Felony involving theft or fraud;</u> <u>Felony drug, excluding conviction solely for a Marijuana-related offense or solely for a violation of M.G.L. c. 94C, § 34.</u>	<u>Mandatory Disqualification</u>
<u>Indefinite</u>	<u>Conviction or Continuance Without a Finding (CWO) for any Distribution of a Controlled Substance to a Minor</u>	<u>Mandatory Disqualification</u>
<u>Indefinite</u>	<u>Non-Felony Weapons Violations, Including Firearms, Involving Narcotics</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Indefinite</u>	<u>Firearms-Related Crimes</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Indefinite</u>	<u>Multiple Crimes of Operating Under the Influence</u> <u>Two offenses within a ten-year period; or</u> <u>Three or more offenses within any period of time.</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Preceding Five Years</u>	<u>Multiple Crimes</u> <u>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</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Preceding Five Years</u>	<u>Crimes of Domestic Violence including, but not limited to:</u>	<u>Presumptive Negative</u>

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	<u>Violation of an abuse prevention restraining order under M.G.L. c. 209A</u> <u>Violation of a harassment prevention order under M.G.L. c. 258E</u>	<u>Suitability Determination</u>
<u>Preceding Five Years</u>	<u>Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions)</u> <u>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.</u>	<u>Mandatory Disqualification</u>
<u>More Than Five and less than Ten Years</u>	<u>Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions)</u> <u>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.</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Preceding Five Years</u>	<u>The applicant's or Licensee's prior actions posed or would likely pose a risk to the public health, safety, or welfare; and</u> <u>the risk posed by the applicant's or Licensee's actions relates or would likely relate to the operation of a Marijuana Establishment.</u> -	<u>May make a Negative Suitability Determination in accordance with 935 CMR 501.800(8)</u>

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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 501.101(1)(b) and (2)(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 Tables B-D 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 Tables B-D, 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 501.800: *Background Check Suitability Standard for Licensure and Registration*. In addition to the requirements established in 935 CMR 501.800: *Background Check Suitability Standard for Licensure and Registration*, the Suitability Review Committee shall:
 1. Consider whether offense(s) or information that would result in a Presumptive Negative Suitability Determination under Table B-D 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 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 Tables B-D 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

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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.

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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: *Application Requirements for Medical Marijuana Treatment Centers.*

<u>Time Period</u>	<u>Precipitating Issue</u>	<u>Result</u>
<u>Present (during time from start of application process through action on application or renewal.)</u>	<u>Open/Unresolved Criminal Proceedings:</u> <u>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.</u>	<u>Presumptive</u> <u>Negative</u> <u>Suitability</u> <u>Determination</u>
<u>Present</u>	<u>Open Professional or Occupational License Cases</u>	<u>Presumptive</u> <u>Negative</u> <u>Suitability</u> <u>Determination</u>
<u>Present</u>	<u>Open/Unresolved Marijuana License or Registration Violations (Massachusetts or Other Jurisdictions):</u> <u>An outstanding or unresolved violation of the regulations as included in 935 CMR 501.000: <i>Medical Use of Marijuana</i> 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.</u>	<u>Presumptive</u> <u>Negative</u> <u>Suitability</u> <u>Determination</u>
<u>Present</u>	<u>Submission of untruthful information to the Commission including, but not limited to:</u> <u>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; or</u> <u>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.</u>	<u>Presumptive</u> <u>Negative</u> <u>Suitability</u> <u>Determination</u>
<u>Indefinite</u>	<u>Sex Offense:</u> <u>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.</u>	<u>Mandatory</u> <u>Disqualification</u>

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<u>Indefinite</u>	<u>Felony Convictions in Massachusetts or Other Jurisdictions for trafficking crimes under M.G.L. c. 94C, § 32E, or like crimes in Other Jurisdictions, except convictions for solely Marijuana-related crimes under § 32E (a), or like crimes in Other Jurisdictions.</u>	<u>Mandatory Disqualification</u>
<u>Indefinite</u>	<u>Conviction or Continuance Without a Finding (CWOFF) for Any Distribution of a Controlled Substance to a Minor</u>	<u>Mandatory Disqualification</u>
<u>Indefinite</u>	<u>Failure to Register as a Sex Offender in Any Jurisdiction</u>	<u>Mandatory Disqualification</u>
<u>Preceding Five Years</u>	<u>Crimes of Domestic Violence including, but not limited to:</u> <u>Violation of an abuse prevention restraining order under M.G.L. c. 209A</u> <u>Violation of a harassment prevention order under M.G.L. c. 258E</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Indefinite</u>	<u>(MTC agents engaging in transportation or home delivery operations only)</u> <u>Multiple Crimes of Operating Under the Influence</u> <u>Two offenses within a ten-year period; or</u> <u>Three or more offenses within any period of time.</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Preceding Five Years</u>	<u>Felony Convictions in Massachusetts or Other Jurisdictions 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.</u>	<u>Mandatory Disqualification</u>
<u>Preceding Seven Years</u>	<u>CWOFF for Crimes of Violence, Fraud</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Preceding Five Years</u>	<u>The applicant’s or Licensee’s prior actions posed or would likely pose a risk to the public health, safety, or welfare.</u>	<u>May make a Negative Suitability Determination in accordance with 935 CMR 501.800(8)</u>

501.803: Suitability Standard for Registration as a Laboratory Agent

(1) 935 CMR 501.803: Suitability Standard for Registration as a Laboratory Agent shall apply to laboratory agents in their capacity as employees or volunteers for an Independent Testing Laboratory licensed pursuant to 935 CMR 501.032: Registration of Independent Testing Laboratory Agents and shall be used by the Independent Testing Laboratory Executive 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 in 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: *Suitability Standard for Registration as a Laboratory Agent*:
- (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 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 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: *Background Check Suitability Standard for Licensure and Registration*. In addition to the requirements established in 935 CMR 501.800: *Background Check Suitability Standard for Licensure and Registration*, the Suitability Review Committee shall:
1. Consider whether offense(s) or information that would result in a Presumptive Negative Suitability Determination under 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: *Suitability Standard for Registration as a Laboratory Agent* at an MTC registered pursuant to 935 CMR 501.052: *Independent Testing Laboratories* or 935 CMR 500.050: *Marijuana Establishments*.

Time Period	Precipitating Issue	Result
<u>Present (during time from start of application process through action on application or renewal.)</u>	<u>Open/Unresolved Criminal Proceedings:</u> <u>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.</u>	<u>Mandatory Disqualification</u>
<u>Present</u>	<u>Open/Unresolved Marijuana Business-Related License Violations (Massachusetts or Other Jurisdictions):</u> <u>an outstanding or unresolved violation of the regulations as included in 935 CMR 501.000: <i>Medical Use of Marijuana</i> 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.</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Present</u>	<u>Submission of false or misleading information to the Commission including, but not limited to:</u> <u>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; or</u> <u>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.</u>	<u>Presumptive Negative Suitability Determination</u>
<u>Present</u>	<u>Open Professional or Occupational License Cases</u>	<u>Mandatory Disqualification</u>
<u>Indefinite</u>	<u>Felony Convictions in Massachusetts or Other Jurisdictions for drug offenses or trafficking crimes under M.G.L. c. 94C, § 32E, or like crimes in Other Jurisdictions.</u>	<u>Mandatory Disqualification</u>
<u>Preceding Five Years</u>	<u>Felony Convictions or CWOFF in Massachusetts or Other Jurisdictions</u> 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.	<u>Presumptive Negative Suitability Determination</u>

<u>Preceding Seven Years</u>	<u>Felony Convictions or CWO of in Massachusetts or Other Jurisdictions</u> for crimes of dishonesty or fraud.	<u>Presumptive Negative Suitability Determination</u>
<u>Preceding Five Years</u>	<u>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 a Marijuana Establishment.</u>	<u>May make a Negative Suitability Determination in accordance with 935 CMR 500.800(8)</u>

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 this section 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: *Definitions*.
- (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 other state or federal laws 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;

2. The Board of Registration in Medicine when necessary in connection with referrals to said Board concerning violations of 935 CMR 501.000: *Medical Use of Marijuana*; and

(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 to facilitate dispensing of medical use Marijuana; and

(h) To the Commission staff if required in the course of an administrative or a judicial proceeding;

(I) If an individual or entity obtains an order from a court of competent jurisdiction.

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Deleted: 6. Other government officials and agencies acting within their lawful jurisdiction.¶¶ (3) Applications, supporting information, and other information regarding an RMD are not confidential, provided however, that the following is confidential and exempt from the provisions of M.G.L. c. 66:¶ 501.200: continued¶¶ (a) Information that identifies a specific registered qualifying patient, personal caregiver, or registered RMD agent; and¶ (b) Information held by the Commission about RMD physical layout, as well as policies, procedures, practices, and plans pertaining to security.¶ (4) Information held by an RMD about registered qualifying patients, personal caregivers, and RMD agents is confidential and shall not be disclosed without the written consent of the individual to whom the information applies, or as required under law or pursuant to an order from a court of competent jurisdiction, provided however, the Commission may access this information to carry out official duties.¶¶ 501.300: *Inspection of Registered Marijuana Dispensaries*¶ (1) The Commission agents or designee(s) may inspect an RMD and affiliated vehicles at any time without prior notice in order to determine the RMD’s compliance with M.G.L. c. 94I, and 935 CMR 501.000. All areas of an RMD, all RMD agents and activities, and all records are subject to such inspection. Acceptance of a certificate of registration by an RMD constitutes consent for such inspection.¶ (2) An RMD shall immediately upon request make available to the Commission agents or designees all information that may be relevant to a Commission inspection, or an investigation of any incident or complaint.¶ (3) An RMD shall make all reasonable efforts to facilitate the Commission agent’s or designee’s inspection, or investigation of any incident or complaint, and to facilitate the Commission agent’s or designee’s interviews of RMD agents.¶ (4) An inspection or other investigation may be made prior to the issuance of a certificate of registration or renewal of registration. Additional inspections may be made whenever the Commission deems it necessary for the enforcement of M.G.L. c. 94I, and 935 CMR 501.000.¶ (5) During an inspection, the Commission agents or designees may direct an RMD to test marijuana for contaminants as specified by the Commission including, but not limited to, mold, mildew, heavy metals, and the presence of pesticides not approved for use on marijuana by the Massachusetts Department of Agricultural Resources. ¶¶ 501.305: *Deficiency Statements*¶ After an inspection in which a violation of 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 ...

(4) Nothing in this provision 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 this section, 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 its delegatee 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) 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, *The Administrative Procedure Act*, and 950 CMR 20.00: *Preparing and Filing Regulations*, and the regulatory process requirements of the Secretary of the Commonwealth.

501.840: Non-conflict with Other Laws

- (1) Nothing in 935 CMR 501.000: *Medical Use of Marijuana* 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.
- (2) Nothing in 935 CMR 501.000: *Medical Use of Marijuana*:
- (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; or
 - (f) Requires the violation of federal law or purports to give immunity under federal law;
 - (g) Poses an obstacle to federal enforcement of federal law.
- (3) Nothing in 935 CMR 501.000: *Medical Use of Marijuana* 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. 94I, § 7 and M.G.L. c. 94G, § 4. The Executive Director may determine the form and manner of the waiver process. There can

Moved up [87]: The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.¶

Moved up [89]: ¶
Each of the following, in and of itself, constitutes full and adequate grounds for denying

Moved up [25]: 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 therewith.¶
¶
(

Deleted: (3) The Commission shall review the Plan of Correction for compliance with the requirements of 935 CMR 501.000 and shall notify the RMD of either the acceptance or rejection of the plan.

Moved up [88]: An unacceptable plan must be amended and resubmitted within five business days after receipt of such notice.¶

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501.400: Registered Marijuana Dispensary: Grounds for Denial of Initial Application for Registration¶

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Dispensaries¶

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be no waiver of statutory requirements.

- (2) The Commission may waive applicability of one or more of the requirements imposed by 935 CMR 501.000: *Medical Use of Marijuana* 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 this section, 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: *Medical Use of Marijuana* 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. 94I, and M.G.L. c. 94G.

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