935 CMR 501.000: MEDICAL USE OF MARIJUANA

Section

501.001: Purpose

The purpose of 935 CMR 501.000 is to implement *Sections 64 through 71, and 82 of St. 2017, c. 55, An Act to Ensure Safe Access to Marijuana,* and M.G.L. c. 94I.

501.002: Scope

935 CMR 501.000 applies to every person who:

(A) 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;

501.002: continued

(B) Is a healthcare provider who seeks to certify or certifies that an individual has a debilitating medical condition; or

(C) 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: Definitions

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

Act *St. 2017, c. 55, An Act to Ensure Safe Access to Marijuana*.

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

Agent Registration Card or Medical-Use Agent Registration Card means an identification card formerly and validly issued by the Department or currently and validly issued by the Commission to a RMD 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 the act, M.G.L. c. 94I, and 935 CMR 501.000.

Bona Fide Healthcare Provider-Patient Relationship means a relationship between a certifying healthcare provider, acting in the usual course of his or her 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.

Card Holder means a registered qualifying patient, personal caregiver, independent laboratory agent, or RMD agent of an RMD who was formerly and validly issued and possesses a valid registration card by the Department or is currently and validly issued and possesses a valid registration card by the Commission.

Caregiver means a personal caregiver or institutional caregiver.

Caregiving Institution means a hospice program, long term care facility, or hospital duly licensed or certified by the Department or Commission providing care to a registered qualifying patient on the premises of the facility or through a hospice program.

Certificate of Registration means the certificate formerly and validly issued by the Department or currently or validly issued by the Commission that confirms that an RMD, caregiving institution or independent testing laboratory has met all applicable requirements pursuant to M.G.L. c. 94I, and 935 CMR 501.000, and was formerly and validly registered by the Department or is currently and validly registered by the Commission. An RMD may be eligible for a provisional or final certificate of registration.

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 his or her professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks for a qualifying patient.

Certifying Healthcare Provider means a certifying CNP or a certifying physician.

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

Colocated Marijuana Operations (CMO) means an entity operating under both an RMD registration pursuant to 935 CMR 501.000: *Medical Use of Marijuana* and under at least one Marijuana Establishment license pursuant to 935 CMR 500.000: *Adult Use of Marijuana* on the same premise. Colocated marijuana operations pertain to cultivation, product manufacturing, and retail, but not any other adult-use license.

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.

Commission means the Massachusetts Cannabis Control Commission established by M.G.L. c. 10, § 76, or its designee. The Commission has authority to implement the state marijuana laws, which include, but are not limited to, the adult-use marijuana laws, St. 2016, c. 334 as amended by St. 2017, c. 55, M.G.L. c. 94G, and 935 CMR 500.000: *Adult Use of Marijuana*; the medical-use marijuana laws, the

act, M.G.L. c. 94I, and 935 CMR 501.000; and the collocated-operations laws, 935 CMR 502.000: *Colocated Adult-Use And Medical-Use Marijuana Operations*.

Commission designee(s) means other state or local officials or agencies working in cooperation with the Commission and as designated by the Commission to carry out the Commission's responsibilities and to ensure compliance with the act, M.G.L. c. 94I, and with 935 CMR 501.000.

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.

501.003: continued

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 means the Massachusetts Department of Public Health.

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

Edible Marijuana-Infused Products (Edible MIPs) means a Marijuana-infused Product (MIP) that is to be consumed by eating or drinking.

Enclosed, Locked Area means a closet, room, greenhouse, or other indoor or outdoor area equipped with locks or other security devices, accessible only to RMD agents, registered qualifying patients, or caregivers.

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

Final RMD Certificate of Registration means a certificate formerly and validly issued by the Department or currently and validly issued by the Commission that confirms that an RMD has passed all inspection(s) required by the Department or Commission and may commence cultivation of medical-use marijuana, but not adult-use marijuana unless the RMD is also licensed in accordance with 935 CMR 500.000: *Adult Use of Marijuana*.

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

Hardship Cultivation Registration means a registration issued to a registered qualifying patient under the requirements of 935 CMR 501.035.

Healthcare Provider means a certifying physician or certifying CNP qualified under 935 CMR 501.000, to issue written certifications for the medical use of marijuana. A certifying healthcare provider must have a bona fide healthcare provider-patient relationship.

Holdup Alarm means a silent alarm signal generated by the manual activation of a

device intended to signal a robbery in progress.

Visitor Identification Badge means a badge issued by an RMD or the Commission to be used at all times while on the premises of an RMD or Independent Testing Laboratory. These identification badges must be issued in a form and manner determined by the Commission.

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

Independent Testing Laboratories means laboratories qualified to test marijuana in compliance with M.G.L. 94I, and 935 CMR 501.000.

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 Department or Commission.

Laboratory Agent means an employee of an independent testing laboratory who transports or tests medical-use marijuana or marijuana products, but not adult-use marijuana or marijuana products unless the agent is also registered in accordance with 935 CMR 500.000: *Adult Use of Marijuana*.

501.003: continued

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.

Limited Access Area means a building, room, or other indoor or outdoor area on the registered premises of an RMD where marijuana, MIPs, or marijuana by-products are cultivated, stored, weighed, packaged, processed, or disposed, under control of an RMD, with access limited to only to RMD agents and persons that are essential to operations in these areas designated by the RMD, representatives of the Commission in the course of responsibilities authorized by the act, M.G.L. c. 94I, and 935 CMR 501.000, Commission designee(s), and law enforcement authorities acting within their lawful jurisdiction, unless otherwise authorized by the Commission.

Marijuana or Cannabis means all parts of any plant of the genus Cannabis, not excepted in 935 CMR 501.0034, 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.

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

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 RMD, shall not be considered a food or a drug as defined in M.G.L. c. 94, § 1.

Registered Marijuana Dispensary (RMD), a.k.a. Medical Marijuana Treatment Center, means an entity formerly and validly registered under 105 CMR 725 or currently and validly registered under 935 CMR 501.100, that acquires, cultivates, possesses, processes (including development of related products such as edible

MIPs, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to registered qualifying patients or their personal caregivers. Unless otherwise specified, RMD refers to the site(s) of dispensing, cultivation, and preparation of marijuana.

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

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

Person means an individual or an entity.

Patient 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, RMD agent or laboratory agent. The medical registration card allows access into Commission-supported databases. The medical 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.*

Personal Caregiver means a person, formerly and validly registered by the Department or currently and validly registered by the Commission, who is at least 21 years old, who has agreed to assist with a registered qualifying patient's medical use of marijuana and is not the registered qualifying patient's certifying 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.

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

Production Area means any limited access area within the RMD where marijuana is handled or produced in preparation for sale.

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

Provisional RMD Certificate of Registration means a certificate formerly and validly issued by the Department or currently and validly issued by the Commission confirming that an RMD has completed the application process.

501.003: continued

Qualifying Patient0means a Massachusetts resident 18 years of age or older who has been diagnosed by a Massachusetts licensed 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(J).

Registered Qualifying Patient0means a qualifying patient who was formerly and validly issued a registration card by the Department or is currently and validly issued a registration card by the Commission.

Registrant means the holder of a registration card or a certificate of registration, or a certifying healthcare provider registered with the Department or Commission.

RMD Agent means a board member, director, employee, executive, manager, or volunteer of an RMD, who is 21 years of age or older. Employee includes a consultant or contractor who provides on-site services to an RMD related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of marijuana.

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 an RMD or an Independent Testing Laboratory. This system shall capture everything that happens to an individual marijuana plant, from seed and cultivation, through growth, harvest and manufacture of MIPs, including transportation, if any, to final sale of finished products. This 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 RMD or Independent Testing Laboratory must integrate with the SOR in a form and manner determined by the Commission.

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

Usable Marijuana means the fresh or dried leaves and flowers of the female marijuana plant and any mixture or preparation thereof, including MIPs, but does not include the seedlings, seeds, stalks, roots of the plant, or marijuana rendered unusable in accordance with 935 CMR 501.105(J)(3)(c).

Vegetation means the sporophytic state of the marijuana plant, which is a form of asexual reproduction in plants during which plants do not produce resin or flowers

and are bulking up to a desired production size for flowering.

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

Visitor means an individual, other than a RMD agent, authorized by the RMD to be on the premises of an RMD for a purpose related to RMD operations and consistent with the objectives of M.G.L. c. 94I, and 935 CMR 501.000: *Medical Use of Marijuana*.

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

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(I).

501.004: Medical-Use Fees

Each qualifying patient is subject to the following nonrefundable fees. If the fee poses a verified financial hardship, the qualifying patient may request a waiver of the fee in a form and manner determined by the Commission.

Patients:	**Fee**
Patient Registration, annual	$50
Medical-Use ID Card Replacement	$10
Medical-Use Hardship Cultivation	$100

Each of the entities identified below is subject to the following nonrefundable fees.

Registered Marijuana Dispensaries (RMD):

RMD agent Registration, annual	$500
Medical-Use Application of Intent (Phase 1)	$1,500
Medical-Use Management and Operations Profile Application (Phase 2)	$30,000
RMD Registration, annual (and renewal of registration)	$50,000

Independent Testing Laboratories:

Medical-Use Application of Intent (Phase 1)	None.
Medical-Use Management and Operations Profile Application (Phase 2)	None.
RMD Registration, annual (and renewal of registration)	None.
Registration of Medical-Use Independent Testing Laboratory Agents	None.

Caregiving and Caregiving Institutions:

Registration of Caregiving Institutions	None.
Registration of Institutional Caregivers	None.

Other Operation Fees:

Location change	$10,000
Name change	$100
Construction or renovation modification	?
Architectural review	$8.25 per $100 cost of construction costs, with a minimum of $1,500

These fees do not include the costs associated with the seed-to-sale electronic tracking system, which includes a monthly program fee and fees for plant and package tags.

These fees do not include the costs associated with criminal background checks as required under 935 CMR 501.000.

These fees do not include the costs associated with packaging and label approval.

501.005: Registration of Certifying Physicians

(A) A physician who wishes to issue a written certification for a qualifying patient shall have at least one established place of practice in Massachusetts and shall hold:

(1) An active full license, with no prescribing restriction, to practice medicine in Massachusetts; and

(2) A Massachusetts Controlled Substances Registration from the Department or Commission.

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

(1) Full name and business address;

(2) License number issued by the Massachusetts Board of Registration in Medicine;

(3) Massachusetts Controlled Substances Registration number; and

(4) Any other information required by the Commission.

(C) Once registered by the Department or Commission, a certifying physician will retain indefinitely a registration to certify a debilitating medical condition for

a qualifying patient unless:

(1) The physician's license to practice medicine in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts;

(2) The physician's Massachusetts Controlled Substances Registration is suspended or revoked;

(3) The physician has fraudulently issued a written certification of a debilitating medical condition;

(4) The physician has certified a qualifying patient for a debilitating medical condition on or after July 1, 2014, without appropriate completion of continuing professional development credits pursuant to 935 CMR 501.010(A); or

(5) The physician surrenders his or her registration.

(D) 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.

501.006: Registration of Certifying Certified Nurse Practitioners

(A) 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:

(1) An active full license, with no prescribing restriction, to practice nursing in Massachusetts;

(2) A board authorization by the Massachusetts Board of Registration in Nursing to practice as a CNP; and

(3) A Massachusetts Controlled Substances Registration from the Department or Commission.

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

(1) Full name and business address;

(2) License number issued by the Massachusetts Board of Registration in Nursing;

(3) Board Authorization by the Massachusetts Board of Registration in Nursing;

(4) Massachusetts Controlled Substances Registration number;

(5) 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

(6) Any other information required by the Commission.

(C) Once registered by the Department or Commission, a certifying CNP will retain indefinitely a registration to certify a debilitating medical condition for a

qualifying patient unless:

(1) 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;

(2) The CNP's Board Authorization to practice as an advanced practice nurse in Massachusetts is suspended, revoked or restricted with regard to prescribing;

501.006: continued

(3) The CNP's Massachusetts Controlled Substances Registration is suspended or revoked;
(4) The CNP has fraudulently issued a written certification of a debilitating medical condition;
(5) 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(A); or
(6) The CNP surrenders his or her registration.

(D) After registering, a certifying CNP is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any changes to the CNP's information including, but not limited to, changes to his or her supervising physician.

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

(A) A certifying physician issuing a written certification on or after July 1, 2014, must have completed a minimum of 2.0 Category 1 continuing professional development credits as defined in 243 CMR 2.06(6)(a)1: *Category 1*. A certifying CNP issuing a written certification on or after July 1, 2014, must have completed a minimum of one program meeting the requirements of 244 CMR 5.00: *Continuing Education* and 6.00: *Approval of Nursing Education Programs and the General Conduct Thereof*. Such programs must explain 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.

(B) A certifying physician issuing a written certification shall comply with generally accepted standards of medical practice, including regulations of the Board of Registration in Medicine at 243 CMR 1.00 through 3.00. A certifying CNP issuing a written certification shall comply with generally accepted standards of nursing practice, including regulations of the Board of Registration in Nursing at 244 CMR 9.00: *Standards of Conduct*

(C) 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.

(D) 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.

(E) 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.

(F) 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.

(G) 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.

(H) A certification must indicate the time period for which the certification is valid, and shall not be less than 15 calendar days or longer than one year.

(I) A certifying healthcare provider may determine and certify that a qualifying patient requires an amount of marijuana other than ten ounces as a 60-day supply and shall document the amount and the rationale in the medical record and in the written certification. For that qualifying patient, that amount of marijuana constitutes a 60-day supply.

(J) A 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.

(K) A certifying healthcare provider, and such healthcare provider's co-worker, employee, or immediate family member, shall not:

(1) Have ever directly or indirectly accepted or solicited from, or offered to an RMD, a board member or executive of an RMD, any RMD personnel, or any other individual associated with an RMD, or a personal caregiver, anything of value;

(2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular personal caregiver or RMD;

(3) Examine or counsel a patient, or issue a written certification, at an RMD;

(4) Have a direct or indirect financial interest in an RMD; or

(5) 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.

(L) A certifying healthcare provider shall not issue a written certification for himself or herself or for his or her immediate family members.

(M) A certifying healthcare provider issuing a written certification for his or her employees or co-workers shall do so in accordance with 935 CMR 501.010, including conducting a clinical visit, completing and documenting a full assessment of the patient's medical history and current medical condition, explaining the potential benefits and risks of marijuana use, and maintaining a role in the ongoing care and treatment of the patient.

(N) 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.

501.015: Registration of Qualifying Patients

(A) To obtain a registration card, a qualifying patient shall submit, in a form and manner determined by the Commission, the following:

(1) The qualifying patient's full name, date of birth, address, telephone number, and email address if any, and a statement indicating his or her age and that his or her primary residence is in Massachusetts:

(a) If the qualifying patient is younger than 18 years old, an attestation from a parent or legal guardian granting permission for the child to register with the Commission; and

(b) If the qualifying patient is younger than18 years old, that qualifying patient must have a designated personal caregiver, who shall be his or her parent or legal guardian.

(2) Written certification(s) for the qualifying patient from the qualifying patient's certifying healthcare provider(s);

(3) Full name, address, and telephone number of the qualifying patient's certifying healthcare provider(s);

(4) Full name, date of birth, and address of the qualifying patient's personal caregiver(s), if any;

(5) A statement of whether the qualifying patient will be applying for a hardship cultivation registration;

(6) 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;

501.015: continued

(7) A non-refundable registration fee. If the fee poses a verified financial hardship, the qualifying patient may request a waiver of the fee in a form and manner determined by the Commission;
(8) Written acknowledgement of the limitations on his or her authorization to cultivate, possess, and use marijuana for medical purposes in the Commonwealth;
(9) An attestation that the registered qualifying patient will not engage in the diversion of marijuana and 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
(10) Any other information required by the Commission.

(B) A registration card will be valid for one year from the date of issue, and may be renewed, in a form and manner determined by the Commission, which includes, but is not limited to, meeting the requirements in 935 CMR 501.015(A) and (B). 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 will destroy any previously issued registration card(s) in a responsible manner.

(C) A qualifying patient who has not received written certification from a physician or a registration card from the Department prior to the effective date of 935 CMR 501.000, must apply for a registration according to the procedures set out in 935 CMR 501.015, unless otherwise provided by the Commission.

(D) After obtaining a registration card, a qualifying patient is responsible for notifying the Commission, in a form an 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.

(E) A registered qualifying patient must carry his or her registration card at all times while in possession of medical-use marijuana.

501.020: Registration of Personal Caregivers

(A) To obtain a registration card for a personal caregiver, a registered qualifying patient shall submit, in a form and manner determined by the Commission, the following:

(1) The personal caregiver's full name, date of birth, address, telephone number, and email address if any, and a statement that the individual is 21 years of age or older;
(2) 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;
(3) A copy of the personal caregiver's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Commission;
(4) 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;
(5) 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;
(6) An attestation by the personal caregiver that he or she will 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
(7) Any other information required by the Commission.

(B) An individual must be granted a registration card by the Commission prior to serving as a personal caregiver for any registered qualifying patient.

501.020: continued

(C) A registration card will be valid for one year from the date of issue, and may be renewed, in a form and manner determined by the Commission, which includes, but is not limited to, meeting the requirements in 935 CMR 501.020(A) and (B). 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 will destroy any previously issued registration card(s) in a responsible manner.

(D) A personal caregiver who has not received a registration card from the Department prior to the effective date of 935 CMR 501.000, must apply for a registration card according to the procedures set out in 935 CMR 501.020, unless otherwise provided by the Commission.

(E) 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.

(F) 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.

(G) 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(A) for registration of personal caregivers.

(H) 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 his or her registration card has been lost or stolen.

(I) A personal caregiver must carry his or her registration card at all times while in possession of marijuana.

501.021: Registration of Caregiving Institutions

(A) Prior to facilitating the medical use of marijuana to a registered qualifying marijuana 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:

(1) The name, address, telephone number of the institution, as well as telephone number and email address for the primary contact for that caregiving institution;

(2) A copy of the caregiving institution's current facility licensure or certification from the Commonwealth of Massachusetts;

(3) 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;

(4) A non-refundable registration fee, as required by the Commission;

(5) An attestation by the authorized signatory of the caregiving institution that employees of the caregiving institution will 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

(6) Any other information required by the Commission.

(B) 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 will destroy any previously issued certificate in a responsible manner.

501.021: continued

(C) An employee of the caregiving institution may serve as a caregiver for more than one registered qualifying patient at one time.

(D) An employee of the caregiving institution may not cultivate marijuana for a registered qualifying patient under the care of the caregiving institution.

(E) 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.

(E) A certificate of registration for a caregiving institution will remain valid unless and until the caregiving institution's current facility licensure or certification from the Commonwealth of Massachusetts is no longer active, or is suspended, revoked, or restricted.

501.022: Registration of Institutional Caregivers

(A) 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.

(B) 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:

(1) The full name, date of birth, and address of the individual;
(2) 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;
(3) Written acknowledgment by the individual of the prohibition against cultivation in his or her role as an institutional caregiver;
(4) A copy of the institutional caregiver's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Commission;
(5) An attestation that the individual will not engage in the diversion of marijuana;
(6) A non-refundable application fee, as required by the Commission; and
(7) Any other information required by the Commission.

(C) 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.

(D) A registration card will be valid for one year from the date of issue, and may be renewed, in a form and manner determined by the Commission, on an annual basis by meeting the requirements in 935 CMR 501.022(A) and (B).

(E) 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 will destroy any previously issued registration card(s) in a responsible manner.

(F) An institutional caregiver who has not received a registration card from the Department prior to the effective date of 935 CMR 501.000, must apply for registration according to the procedures set out in 935 CMR 501.022, unless otherwise provided by the Commission.

(G) 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.

(H) An institutional caregiver must carry his or her registration card at all times while in possession of marijuana.

(I) An institutional caregiver affiliated with multiple caregiving institutions must be registered as an institutional caregiver by each caregiving institution.

501.025: Responsibilities of Caregivers

(A) Personal Caregivers.

(1) A personal caregiver may:

(a) Transport a registered qualifying patient to and from an RMD;

(b) Obtain and transport marijuana from an RMD on behalf of a registered qualifying patient;

(c) 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;

(d) Prepare marijuana for consumption by a registered qualifying patient; and

(e) Administer marijuana to a registered qualifying patient.

(2) A personal caregiver may not:

(a) Consume, by any means, marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;

(b) Sell or otherwise divert marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;

(c) 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;

(d) Cultivate marijuana for purposes of selling or providing marijuana to anyone other than the registered qualifying patient;

(e) 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;

(f) 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

(g) 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 his or her regular wages.

(3) A personal caregiver must notify the Commission within five calendar days upon the death of a personal caregiver's registered qualifying patient.

(B) Institutional Caregivers.

(1) An institutional caregiver may:

(a) Receive marijuana delivered to the caregiving institution for a registered qualifying patient;

(b) Prepare marijuana for consumption by a registered qualifying patient; and

(c) Administer marijuana to a registered qualifying patient or facilitate consumption of marijuana for medical use by the qualifying patient.

(2) An institutional caregiver may not:

(a) Consume, by any means, marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;

(b) Sell, provide, or otherwise divert marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;

(c) Cultivate marijuana for a registered qualifying patient; or

(d) 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.

(e) Receive payment or compensation above and beyond his or her regular wages.

(3) An institutional caregiver must notify his or her employing caregiving institution of any changes in his or her registration information within 24 hours of the change.

501.030: Registration of RMD agents

(A) An RMD shall apply for RMD agent registration for all board members, directors, employees, executives, managers, and volunteers who are associated with that RMD. All such individuals must:

(1) Be 21 years of age or older; and

501.030: continued

(2) Have not been convicted of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority.

(B) An application for registration of a RMD agent, in a form and manner determined by the Commission, shall include:

(1) The full name, date of birth, and address of the individual;

(2) Written acknowledgment by the individual of the limitations on his or her authorization to cultivate, harvest, prepare, package, possess, transport, and dispense marijuana for medical purposes in the Commonwealth;

(3) A copy of the RMD agent's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Commission;

(4) An attestation that the individual will not engage in the diversion of marijuana;

(5) A non-refundable application fee; and

(6) Any other information required by the Commission.

(C) An RMD executive registered with the Commission of Criminal Justice Information Systems pursuant to 935 CMR 501.100(A)(7) 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 RMD seeks a RMD agent registration, obtained within 30-calendar days prior to submission.

(D) An RMD must notify the Commission no more than one business day after a RMD agent ceases to be associated with the RMD. The RMD agent's registration shall be immediately void when he or she is no longer associated with the RMD.

(E) 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 will destroy any previously issued registration card(s) in a responsible manner.

(F) 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(A) through (C).

(G) After obtaining a registration card for a RMD agent, an RMD 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 RMD was previously required to submit to the Commission, or after discovery that a registration card has been lost or stolen.

(H) A RMD agent must carry his or her registration card at all times while in possession of marijuana, including at all times while at an RMD or while transporting marijuana.

(I) A RMD agent affiliated with multiple RMDs must be registered as a RMD agent by each RMD.

501.031: Registration of Independent Testing Laboratories

(A) To obtain a certificate of registration as an independent testing laboratory, the institution shall submit, in a form and manner determined by the Commission, the following:

(1) The name of the institution, address, telephone number, as well as telephone number and email address for the primary contact for that independent testing laboratory;

(2) Documentation that it meets the requirements of an independent testing laboratory pursuant to 935 CMR 501.000;

(3) Written acknowledgement by the authorized signatory of the independent testing laboratory of the limitations on the institution's authorization to possess and transport marijuana for medical purposes in the Commonwealth;

(4) A non-refundable registration fee, as required by the Commission;

(5) An attestation by the authorized signatory of the independent testing laboratory that employees of the laboratory will 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

(6) Any other information required by the Commission.

501.031: continued

(B) A laboratory must be granted a certificate of registration by the Commission prior to serving as an independent testing laboratory for an RMD. The Commission will accept certificates 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 will destroy any previously issued certificate in a responsible manner.

(C) An independent testing laboratory may not cultivate marijuana.

(D) 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 501.000.

501.032: Registration of Independent Testing Laboratory Agents

(A) An independent testing laboratory providing testing services for an RMD in compliance with 935 CMR 501.000, 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.

(B) An application for registration of a laboratory agent, in a form and manner determined by the Commission, shall include:

(1) The full name, date of birth, and address of the individual;

(2) Written acknowledgment by the individual of the limitations on his or her authorization possess, transport, and process marijuana for medical use for testing purposes in the Commonwealth;

(3) A copy of the RMD agent's driver's license, government-issued identification card, or other verifiable identity document acceptable to the Commission;

(4) An attestation that the individual will not engage in the diversion of marijuana;

(5) A non-refundable application fee, as required by the Commission; and

(6) Any other information required by the Commission.

(C) A laboratory executive registered with the Department of Criminal Justice Information Systems pursuant to 935 CMR 501.100(A)(7) 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 a RMD agent registration, obtained within 30-calendar days prior to submission.

(D) 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 he or she is no longer associated with the laboratory.

(E) 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 will be destroyed any previously issued registration card(s) in a responsible manner.

(F) A registration card may be renewed, in a form and manner determined by the Commission, on an annual basis, which includes, but it not limited to meeting the requirements in 935 CMR 501.030 (A) through (C).

(G) 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.

(H) A laboratory agent must carry his or her registration card at all times while in possession of marijuana, including at all times while at a laboratory or while transporting marijuana.

501.035: Hardship Cultivation Registration

(A) 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:

(1) Verified financial hardship; or

(2) Physical incapacity to access reasonable transportation, as demonstrated by an inability to use public transportation or drive oneself, lack of a personal caregiver with a reliable source of transportation, and lack of an RMD that will deliver marijuana to the patient's or personal caregiver's primary address; or

501.035: continued

(3) 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.

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

(1) A non-refundable registration fee, unless waived pursuant to 935 CMR 501.015(A)(7);

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

(3) An explanation including lack of feasible alternatives to mitigate the limitation claimed under 935 CMR 501.035(A);

(4) 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;

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

(6) A description of the device or system that will be used to ensure security and prevent diversion of the marijuana plants being cultivated;

(7) Written acknowledgment of the limitations on his or her authorization to cultivate, possess, and use marijuana for medical purposes in the Commonwealth; and

(8) Any other information required by the Commission.

(C) 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.

(D) 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.

(E) 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.

(F) 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 will destroy any previously issued certificate in a responsible manner.

(G) 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 501.035(B).

(H) A hardship cultivation registration shall allow the registered qualifying patient or his or her 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, or as further specified by the Commission.

(I) Cultivation and storage of marijuana shall be in an enclosed, locked area accessible only to the registered qualifying patient or his or her personal caregiver(s), subject to 935 CMR 501.650. Marijuana shall not be visible from the street or other public areas.

(J) A registered qualifying patient or his or her 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.

(K) A registered qualifying patient and his or her personal caregiver(s) is prohibited from selling, bartering, giving away or distributing in any manner marijuana or paraphernalia.

(L) The Commission may inspect the cultivation site of a registered qualifying patient with a hardship cultivation registration, or the cultivation site of his or her personal caregiver(s), at any time. Acceptance of a hardship cultivation registration by a registered qualifying patient constitutes consent for such inspection of the cultivation site.

501.035: continued

(M) 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 he or she or his or her personal caregiver(s) was previously required to submit to the Commission.

(N) A registered qualifying patient with a hardship cultivation registration, or his or her personal caregiver(s) if applicable, must have the registration available at the site of cultivation. Such registration must be made available upon request of the Commission or other government agency acting within their lawful authority.

(O) A registered qualifying patient with a hardship cultivation registration, or his or her personal caregiver(s) if applicable, is prohibited from purchasing marijuana from an RMD, provided however that such individuals may purchase seeds.

501.100: Registration of Registered Marijuana Dispensaries

(A) General Requirements.

(1) An RMD is required to maintain an entity in good standing with the Secretary of the Commonwealth.

(2) No executive, member, or any entity owned or controlled by such executive or member, may directly or indirectly control more than three RMDs.

(3) An RMD must make vaporizers available for sale to registered qualifying patients.

(4) Under a medical-use registration alone, an RMD may not operate more than two locations in Massachusetts at which marijuana is cultivated, MIPs are prepared, and marijuana is dispensed. Each of these activities may occur at only one such location, which may be either the RMD's principal place of business or one Commission-approved alternate location in Massachusetts, but not both.

(5) All RMD agents of the RMD must be registered pursuant to 935 CMR 501.030.

(6) An RMD must have a program to provide reduced cost or free marijuana to patients with documented verified financial hardship.

(7) At least one executive of the entity seeking registration as an RMD must register with the Massachusetts Department of Criminal Justice Information Services (DCJIS) on behalf of the entity as an organization user of iCORI.

(B) Application Requirements.

(1) Application of Intent. As necessary, the Commission shall announce publicly, in a form or manner determined by the Commission, the opportunity

for entities that seek authority to apply for a certificate of registration. Every applicant responding to the announcement shall file, with respect to each application, a response in a form and manner specified by the Commission, and must at a minimum provide:

(a) Documentation that it is an entity in good standing as specified in 935 CMR 501.100(A)(1), as well as a list of all executives of the proposed RMD, and a list of all members, if any, of the entity;

(b) Documentation that it has at least $500,000 in its control and available, as evidenced by bank statements, lines of credit, or the equivalent, to ensure that the applicant has sufficient resources to operate. 935 CMR 501.100(B)(1)(b) 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;

(c) 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 non-refundable application fee as specified in the Notice;
(d) The requisite non-refundable application fee; and
(e) Any other information required by the Commission.

(2) 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(B)(1) that it may proceed to the Management and Operations Profile. At the time of such notice by the Commission, an applicant must notify the chief administrative officer, or equivalent, and chief of police, or equivalent, of the proposed city or town in which an RMD would be sited, if applicable, and the sheriff of the applicable county, of the intent to submit a Management and Operations Profile.

(3) Management and Operations Profile. Within 45 days after receipt of an invitation to submit an application pursuant to 935 CMR 501.100(B)(2), each applicant that proceeds to the Management and Operations Profile shall submit, with respect to each application, a response in a form and manner specified by the Commission, which includes:
(a) A non-refundable application fee;
(b) Detailed information regarding entity, including the legal name, a copy of the articles of organization and bylaws;
(c) 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 including, but not limited to, CORI reports obtained from the DCJIS within 30-calendar days prior to submission to the Commission, pursuant to the RMD's registration with DCJIS under M.G.L. c. 6, § 172;
(d) The name, address, and date of birth of all RMD agents that the RMD intends to employ, to the extent that they are known;
(e) A list of all persons or entities having direct or indirect authority over the management or policies of the RMD, including the members of the entity, if any, and a list of all persons or entities contributing 5% or more of the initial capital to operate an RMD, including capital that is in the form of land or buildings;
(f) A description of the RMD's plan to obtain a liability insurance policy or otherwise meet the requirements of 935 CMR 501.105(Q);
(g) A detailed summary of the business plan for the RMD;
(h) An operational plan for the cultivation of marijuana, including a detailed summary of policies and procedures for cultivation;
(i) If the RMD intends to produce MIPs, a description of the types and

forms of MIPs that the RMD intends to produce, and the methods of production;

(j) A detailed summary of operating policies and procedures for the RMD, 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;

(k) A detailed summary of the RMD'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 501.100(A)(6);

(l) A detailed description of all intended training(s) for RMD agents;

(m) Evidence that the applicant is responsible and suitable to maintain an RMD. Information including, but not limited to, the following factors shall be considered in determining the responsibility and suitability of the applicant to maintain an RMD:

1. Demonstrated experience running a business;
2. History of providing healthcare services or services providing marijuana for medical purposes, including provision of services in other states;
3. History of response to correction orders issued under the laws or regulations of the Commonwealth or other states;
4. 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;

5. Any criminal action under the laws of the Commonwealth, or another state, the United States, or a military, territorial, or Indian tribal authority, 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;

6. Any civil or administrative action under the laws of the Commonwealth, another state, the United States, or a military, territorial, or Indian tribal authority relating to any executive's (or members of the entity, if any) profession or occupation or fraudulent practices, including but not limited to:

a. fraudulent billing practices;

b. 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;

c. past or pending denial, suspension, or revocation of a license or registration, or the denial of a renewal of a license or registration, for any type of business or profession, by any federal, state, or local government, or any foreign jurisdiction, including denial, suspension, revocation, or refusal to renew certification for Medicaid or Medicare;

d. past discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or a like action or complaint by another state, the United States or a military, territorial, or Indian tribal authority with regard to any professional license or registration of an executive of the applicant, as well as by any member of the entity, if any; or

e. 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.

7. Any attempt to obtain a registration, license, or approval to operate in any state by fraud, misrepresentation, or the submission of false information; and

8. Any other information required by the Commission.

(n) Any other information required by the Commission.

(4) Siting Profile.

(a) The county, city, or town in which the proposed RMD would be sited, and if known, the physical address of the proposed RMD. If marijuana will be cultivated or MIPs will be prepared at any location other than the dispensing location of the proposed RMD, the physical address of the one additional location where marijuana will be cultivated or MIPs will be prepared, if known;

(b) If the applicant has identified the physical address of the proposed RMD pursuant to 935 CMR 501.100(B)(4)(a), the applicant shall provide evidence of interest in the subject property, and the additional cultivation location, if any. Interest may be demonstrated by one of the following:

1. Clear legal title to the proposed site;
2. An option to purchase the proposed site;
3. A lease;
4. A legally enforceable agreement to give such title under 935 CMR 501.100 (B)(4)(b)1. or 2., or such lease under 935 CMR 501.100 (B)(4)(b)3., in the event the Commission determines that the applicant qualifies for registration as a RMD; or
5. Binding permission to use the premises.

(c) If available at the time of submission, pursuant to 935 CMR 501.100(B)(4)(a), a description of plans to ensure that the RMD is or will be compliant with local codes, ordinances, and bylaws for the physical address of the RMD and for the physical address of the additional location, if any, including any demonstration of support or non-opposition furnished by the local municipality;

(d) A proposed timeline for achieving operation of the RMD and evidence that the RMD will be ready to operate within the proposed timeline after notification by the Commission that the applicant qualifies for registration;

(e) An analysis of the projected patient population and projected need in the service area of the proposed RMD;

(f) A statement of whether the applicant would consider a location other than the county or physical address provided pursuant to 935 CMR 501.100(B)(4)(a); and

(g) Any other information required by the Commission.

(5) 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.

(6) Action on Application Submissions.

(a) The Commission shall not consider an application that is submitted after the due date specified.

(b) The Commission may conduct a site visit to the proposed location, if applicable, of the RMD, to determine the appropriateness of the site(s).

(c) A selection committee established by the Commission shall evaluate applications for the purpose of granting registrations. Decisions will be based on the thoroughness and quality of the applicants' responses to the required criteria, and the applicants' ability to meet the overall health needs of registered qualifying patients and the safety of the public.

(d) For purposes of evaluation, the Commission may take into account desired geographical distribution of RMDs (*i.e.*, convenience for and proximity to Massachusetts residents, and avoidance of clustering of RMDs in one area), local support for the RMD application, likelihood of successful siting of the RMD in the proposed location, the presence of a home-delivery system, and other mechanisms to ensure appropriate patient access, as well as other factors as described in the application form.

(e) The 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.

(f) The Commission may request additional information from an applicant.

(g) 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.

(C) RMD Certificate of Registration.

(1) Upon selection by the Commission, an applicant shall submit the required registration fee and subsequently be issued a provisional certificate of registration to develop an RMD, in the name of the entity. Such provisional certificates of registration shall be subject to reasonable conditions specified by the Commission, if any.

(a) Inspections:

1. The Commission shall review architectural plans for the building or renovation of an RMD. Construction or renovation related to such

plans shall not begin until the Commission has granted approval. Submission of such plans shall be accompanied by a requisite fee and shall occur in a manner and form established by the Commission including, but not limited to, a detailed floor plan of the premises of the proposed RMD that identifies the square footage available and describes the functional areas of the RMD, including areas for any preparation of MIPs, and, if applicable, such information for the single allowable off-premises location in Massachusetts where marijuana will be cultivated or MIPs will be prepared; and a description of plans to ensure that the RMD will be compliant with requirements of the Americans with Disabilities Act (ADA) Accessibility Guidelines;

2. An RMD shall construct its dispensary, processing and cultivation facilities in accordance with 935 CMR 501.000, conditions set forth by the Commission in its provisional certificate of registration and architectural review, and any applicable state and local laws, regulations, permits or licenses;

3. The Commission may conduct inspections of the dispensary, processing and cultivation facilities, as well as review all written materials required in accordance with 935 CMR 501.000.

(b) Final Certificate of Registration: Upon completion of all inspections required by the Commission, an RMD is eligible for a final certificate of registration. All information described in 935 CMR 501.100(B)(3) and (4) that is not available at the time of submission, must be provided to and approved by the Commission, before an RMD may receive a final certificate of registration. Such final certificates of registration shall be subject to reasonable conditions specified by the Commission, if any.

(2) No person shall operate an RMD without a final certificate of registration issued by the Commission.

(3) A provisional or final certificate of registration may not be assigned or transferred without prior Commission approval.
(4) A provisional or final certificate of registration shall be immediately null and void if the RMD ceases to operate, or if, without the permission of the Commission, it relocates.
(5) Acceptance of a provisional or final certificate of registration constitutes an agreement by the RMD 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 registration.
(6) The RMD shall post the final certificate of registration in a conspicuous location on the premises at each Commission-approved location.
(7) The RMD shall conduct all activities authorized by 935 CMR 501.000 at the address(es) identified on the final certificate of registration issued by the Commission. Under a medical-use registration alone, except for the two permitted locations, no operations are permitted at any other locations, except surveillance activities in accordance with 935 CMR 501.110(D).

(D) The RMD must be operational within the time indicated in 935 CMR 501.100(B)(4)(d) or as otherwise amended through the application process, and approved by the Commission through the issuance of a final certificate of registration.

(E) Expiration and Renewal of Registration. The RMD's certificate of registration, as applicable, shall expire one year after the date of issuance of the provisional certificate of registration and annually thereafter, and may be renewed as follows unless an action has been taken based upon the grounds set forth in 935 CMR 501.405:
(1) No later than 60 calendar days prior to the expiration date, an RMD shall submit a completed renewal application to the Commission in a form and manner determined by the Commission, as well as the required fee; and
(2) The RMD shall update as needed, and ensure the accuracy of, all information that it submitted on its initial application for a certificate of registration.

(F) Notification to the Commission and Commission Approval of Changes.
(1) Prior to changing location(s), the RMD shall submit a request for such change to the Commission and shall pay the appropriate fee. No such change shall be permitted until approved by the Commission.
(2) Prior to any modification, remodeling, expansion, reduction, or other physical, non-cosmetic alteration of the RMD, the RMD shall submit an application for such change to the Commission and shall pay the appropriate

fee. No such change shall be permitted until approved by the Commission.
(3) Prior to changing its name, the RMD shall notify the Commission and shall pay the appropriate fee. No such change shall be permitted until approved by the Commission.
(4) The RMD shall keep current all information required by 935 CMR 501.000 or otherwise required by the Commission. The RMD shall report any changes in or additions to the content of the information contained in any document to the Commission within five business days after such change or addition.

501.105: Operational Requirements for Registered Marijuana Dispensaries

(A) Every RMD shall have and follow a set of detailed written operating procedures. If the RMD has a second 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:

(1) Security measures in compliance with 935 CMR 501.110;
(2) Employee security policies, including personal safety and crime prevention techniques;
(3) A description of the RMD's:
(a) 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 501.100(F)(4); and
(b) Price list for marijuana, MIPs, and any other available products, and alternate price lists for patients with documented verified financial hardship as required by 935 CMR 501.100(A)(6);
(4) Storage of marijuana in compliance with 935 CMR 501.105(D);
(5) Description of the various strains of marijuana to be cultivated and dispensed, and the form(s) in which marijuana will be dispensed;

(6) Procedures to ensure accurate recordkeeping, including inventory protocols and procedures for integrating a secondary electronic system with the Seed-to-Sale SOR;

(7) Plans for quality control, including product testing for contaminants in compliance with 935 CMR 501.105(C)(2);

(8) A staffing plan and staffing records in compliance with 935 CMR 501.105(I)(4)(c);

(9) Emergency procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

(10) Alcohol, smoke, and drug-free workplace policies;

(11) A plan describing how confidential information will be maintained in accordance with 935 CMR 501.200;

(12) A description of the RMD's patient education activities in accordance with 935 CMR 501.105(K);

(13) The standards and procedures by which the RMD determines the price it charges for marijuana, and a record of the prices charged, including the RMD'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 501.100(A)(6);

(14) 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 RMD 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;

(d) Policies and procedures for patient or personal caregiver home-delivery; and

(e) Policies and procedures for the transfer, acquisition, or sale of marijuana between RMDs, and if applicable, Marijuana Establishments and CMOs.

(15) A policy for the immediate dismissal of any RMD agent who has:

(a) Diverted marijuana, which shall be reported to law enforcement officials and to the Commission; or

(b) Engaged in unsafe practices with regard to operation of the RMD, which shall be reported to the Commission; and

(16) 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.

(17) 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).

(B) Cultivation, Acquisition, and Distribution Requirements.

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

(a) Unless otherwise authorized by the Commission, only an RMD is permitted to cultivate medical-use marijuana, except for a registered qualifying patient granted a hardship cultivation registration or that patient's personal caregiver;

(b) Unless otherwise authorized by the Commission, a cultivation location of an RMD may cultivate marijuana for only that RMD, and up to two additional RMDs under an entity;

(c) 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(D)(1)(d) through (i);

(d) An RMD may label marijuana and MIPS with the word "organic" only if all cultivation is consistent with U.S. Department of Agriculture organic requirements at 7 CFR Part 205;

(d) Soil for cultivation shall meet the *U.S. Agency for Toxic Substances and Disease Registry's Environmental Media Evaluation Guidelines* for residential soil levels; and

(f) The cultivation process shall use best practices to limit contamination, including but not limited to mold, fungus, bacterial diseases, rot, pests, mildew, and any other contaminant identified as posing potential harm.
(g) Application of pesticides shall be performed in compliance with M.G.L. c. 132B and the regulations promulgated at 333 CMR 2.00 through 333 CMR 14.00. Any testing results indicating noncompliance shall be immediately reported to the Commission, who may refer any such result to the Massachusetts Department of Agricultural Resources.

(2) An RMD may acquire marijuana from or distribute marijuana to another RMD when:
(a) A documented emergency occurs such as loss of crop, vandalism, or theft, or other circumstance as approved by the Commission; or
(b)
(c) The distribution and acquisition of marijuana, except MIP's, to and from all other RMDs does not exceed, cumulatively, 45% of the RMD's total annual inventory of marijuana as measured by weight; this does not apply to CMOs; The distribution and acquisition of MIPs to and from all other RMDs does not exceed, cumulatively, 45% of the RMD's total annual inventory of MIPs as measured by its dry weight equivalent to marijuana; this does not apply to CMOs; and
(d) By or before April 1, 2019, 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 RMD registration.

(C) Requirements for Handling and Testing Marijuana and for Production of MIPs.
(1) Except for a registered qualifying patient or personal caregiver, who are not subject to 935 CMR 501.105, only a registered RMD is permitted to produce MIPs. Unless otherwise authorized by the Commission, an MIP production facility of an RMD may produce MIPs for only that RMD, and up to two additional RMDs under an entity.
(2) The RMD is responsible for having all marijuana cultivated by the RMD tested in accordance with the following:
(a) Marijuana 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;
(b) The RMD shall maintain the results of all testing for no less than one year;
(c) The RMD must follow established policies and procedures for

responding to results indicating contamination as well as:

1. notification within 72 hours by the RMD and the independent testing laboratory separately and directly to the Commission on a form prescribed by the Commission of any results indicating contamination that cannot be remediated; and
2. submission of any information regarding contamination immediately upon request by the Commission.

Such policy shall be available to registered qualifying patients and personal caregivers. Any notifications indicating contamination that cannot be remediated shall include a proposed plan for destruction of contaminated product and assessment of the source of contamination;

(d) All testing must be conducted by an independent laboratory that is:

1. *Accredited to International Organization for Standardization (ISO) 17025* by a third-party accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement; or
2. Certified, registered, or accredited by an organization approved by the Commission.

(e) The RMD shall arrange for testing to be conducted in accordance with the frequency required by the Commission;

(f) An RMD must have a contractual arrangement with a laboratory for the purposes of testing marijuana;

(g) An executive of an RMD, or a member, if any, of the entity, is prohibited from having any financial or other interest in a laboratory providing testing services for any RMD;

(h) No individual employee of a laboratory providing testing services for RMDs may receive direct financial compensation from any RMD;

(i) All transportation of marijuana to and from laboratories providing marijuana testing services shall comply with 935 CMR 501.110(E);

(j) All storage of marijuana at a laboratory providing marijuana testing services shall comply with 935 CMR 501.105(D); and

(k) All excess marijuana must be returned to the source RMD and be disposed of pursuant to 935 CMR 501.105(J).

(3) 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.

(a) Such items shall be accessible only to the minimum number of specifically authorized RMD agents essential for efficient operation.

(b) Such items shall be returned to a secure location immediately after completion of the process or at the end of the scheduled business day.

(c) If a manufacturing process cannot be completed at the end of a working day, the processing area or tanks, vessels, bins, or bulk containers containing marijuana shall be securely locked inside an area or building that affords adequate security.

(4) An RMD shall process marijuana in a safe and sanitary manner. An RMD shall process the leaves and flowers of the female marijuana plant only, which shall be:

(a) Well cured and free of seeds and stems;

(b) Free of dirt, sand, debris, and other foreign matter;

(c) Free of contamination by mold, rot, other fungus, and bacterial diseases;

(d) Prepared and handled on food-grade stainless steel tables with no contact with RMD agents' bare hands; and

(e) Packaged in a secure area.

(5) 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 935 CMR 501.000: *Good Manufacturing Practices for Food*, and with the requirements for food handlers specified in 935 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(E)(3).

(6) All RMDs, including those that develop or process non-edible MIPs, shall comply with the following sanitary requirements:

(a) Any RMD 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 935 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*;

(b) Any RMD agent working in direct contact with preparation of marijuana or non-edible MIPs shall conform to sanitary practices while on duty, including:

1. Maintaining adequate personal cleanliness; and
2. Washing hands thoroughly in an adequate hand-washing area

before starting work, and at any other time when hands may have become soiled or contaminated.

(c) Hand-washing facilities shall be adequate and convenient and shall be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the RMD in production areas and where good sanitary practices require employees to wash and/or sanitize their hands, and shall provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices;

(d) There shall be sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations;

(e) Litter and waste shall be properly removed, disposed of so as to minimize the development of odor, and minimize the potential for the waste attracting and harboring pests. The operating systems for waste disposal shall be maintained in an adequate manner pursuant to 935 CMR 501.105(J);

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

(g) There shall be adequate safety lighting in all processing and storage areas, as well as areas where equipment or utensils are cleaned;

(h) Buildings, fixtures, and other physical facilities shall be maintained in a sanitary condition;

(i) All contact surfaces, including utensils and equipment, shall be maintained in a clean and sanitary condition. Such surfaces shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the U.S. Environmental Protection Agency (EPA), in accordance with labeled instructions. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable;

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

(D) RMD Storage Requirements.

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

(2) An RMD 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.

(3) RMD storage areas shall be maintained in a clean and orderly condition.

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

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

(E) Packaging and Labeling.

(1) Marijuana shall be packaged in plain, opaque, tamper-proof, and child-proof containers without depictions of the product, cartoons, or images other than the RMD's logo. Edible MIPs shall not bear a reasonable resemblance to

any product available for consumption as a commercially available candy.

(2) Labeling of Marijuana (Excluding MIPs). The RMD shall place a legible, firmly affixed label on which the wording is no less than $^{1}/_{16}$ inch in size on each package of marijuana that it prepares for dispensing, containing at a minimum the following information:

(a) The registered qualifying patient's name;

(b) The name and registration number of the RMD that produced the marijuana, together with the RMD's telephone number and mailing address, and website information, if any;

(c) The quantity of usable marijuana contained within the package;

(d) The date that the RMD packaged the contents;

(e) A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;

(f) The cannabinoid profile of the marijuana contained within the package, including THC level;

(g) A statement that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with 935 CMR 501.105(C)(2); and

(h) This statement, including capitalization: "This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. Do not drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN."

(3) Labeling of MIPs. The RMD shall place a legible, firmly affixed label on which the wording is no less than 1/8 inch in size on each MIP that it prepares for dispensing, containing at a minimum the following information:

(a) The registered qualifying patient's name;

(b) The name and registration number of the RMD that produced the MIP, together with the RMD's telephone number and mailing address, and website information, if any;

(c) The name of the product;

(d) The quantity of usable marijuana contained within the product as measured in ounces;

(e) A list of ingredients, including the cannabinoid profile of the marijuana contained within the product, including the THC level;

(f) The date of product creation and the recommended "use by" or expiration date;

(g) A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;

(h) Directions for use of the product if relevant;

(i) A statement that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with 935 CMR 501.105(C)(2);

(j) A warning if nuts or other known allergens are contained in the product; and

(k) This statement, including capitalization: "This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. Do not drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN."

(F) Dispensing Marijuana.

(1) Registered qualifying patients and personal caregivers shall be identified as follows:

(a) An RMD shall refuse to sell marijuana to any registered qualifying patient or personal caregiver who is unable to produce a registration card and valid proof of identification, or who does not have a valid certification in the Commission-supported interoperable database. The identification must contain a name, photograph, and date of birth, and shall be limited to one of the following:

1. A driver's license;
2. A government-issued identification card;
3. A military identification card; or
4. A passport.

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

(2) An RMD may dispense only to a registered qualifying patient who has a current valid certification, or to his or her personal caregiver. Pursuant to 935 CMR 501.010(H), a certifying healthcare provider shall have defined the calendar daylength of valid certification of a qualifying patient.

(a) For a registered qualifying patient certified for 60 days or longer, the amount of marijuana dispensed, including marijuana contained in MIPs, shall be no more than a 60-day supply in each 60-day period as defined in 935 CMR 501.003 (*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(I), 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.

(3) An RMD 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.

(4) An RMD may refuse to dispense to a registered qualifying patient or personal caregiver if in the opinion of the RMD agent, the patient or the public would be placed at risk. In any instance of denial, an RMD must notify the patient's certifying healthcare provider within 24 hours.

501.105: continued

(G) Inventory.

(1) An RMD must limit its inventory of seeds, plants, and usable marijuana to reflect the projected needs of registered qualifying patients.

(2) Real-Time Inventory or Seed-to-Sale Electronic Tracking shall be maintained as specified by the Commission and in 935 CMR 501.105(G)(3) and (4), including, at a minimum, an inventory of marijuana plants; marijuana plant seeds and clones in any phase of development such as propagation, vegetation, and flowering; marijuana ready for dispensing; all MIPs; and all damaged, defective, expired, or contaminated marijuana and MIPs awaiting disposal.

(3) An RMD shall:

(a) Establish inventory controls and procedures for the conduct of inventory reviews, and comprehensive inventories of marijuana and MIPs in the process of cultivation, and finished, stored marijuana;

(b) Conduct a monthly inventory of marijuana in the process of cultivation and finished, stored marijuana;

(c) Conduct a comprehensive annual inventory at least once every year after the date of the previous comprehensive inventory; and

(d) Promptly transcribe inventories if taken by use of an oral recording device.

(4) The record of each inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the names, signatures, and titles of the individuals who conducted the inventory.

(5) An RMD shall tag and track all marijuana seeds, clones, plants, and MIPs, and other products, using a seed-to-sale methodology in a form and manner to be approved by the Commission.

(6) After Program Transfer, an RMD shall enter all its inventory into the Seed-to-Sale SOR in a form and a manner determined by the Commission.

(a) By April 1, 2019, and thereafter, an RMD must do the following:
1. Attach plant tags to all marijuana clones and plants; and
2. attach package tags to all MIPs and any remaining inventory, including

seeds, into the Seed-to-Sale SOR.

(b) The failure to enter inventory into the Seed-to-Sale SOR may result in the suspension or revocation of an RMD registration.

(c) The use of the Seed-to-Sale SOR does not preclude an RMD from using a secondary electronic tracking system so long as it complies with 935 CMR 501.105(G).

1. The RMD 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.

(7) Subject to an RMD entering all of its inventory into the Seed-to-Sale SOR designated by the Commission in accordance with 935 CMR 501.105(G)(6), the requirements of 935 CMR 501.105(G)(3) and (4), shall be deemed waived.

(H) RMD agent Training. RMDs shall ensure that all RMD agents complete training prior to performing job functions. Training shall be tailored to the roles and responsibilities of the job function of each RMD agent, and at a minimum must include training on confidentiality, 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.

(I) Record Keeping. Records of an RMD must be available for inspection by the Commission, upon request. Written records that are required and are subject to inspection include, but are not necessarily limited to, all records required in any section of 935 CMR 501.000, in addition to the following:

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

(2) Inventory records as required by 935 CMR 501.105(G);

(3) Seed-to-sale tracking records for all marijuana and MIPs as required by 501.105(G)(5);

(4) The following personnel records:

(a) Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;

(b) A personnel record for each RMD agent. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with the RMD and shall include, at a minimum, the following:

1. All materials submitted to the Commission pursuant to 935 CMR 501.030(B);

2. Documentation of verification of references;

3. The job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision;

4. 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;

5. A copy of the application that the RMD submitted to the Commission on behalf of any prospective RMD agent;

6. Documentation of periodic performance evaluations; and

7. A record of any disciplinary action taken.

(c) A staffing plan that will demonstrate accessible business hours and safe cultivation conditions;

(d) Personnel policies and procedures; and

(e) All CORI reports obtained in accordance with 935 CMR 501.030(C), M.G.L. c. 6, § 172 and 803 CMR 2.00: *Criminal Offender Record Information (CORI)*;

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

(a) Assets and liabilities;

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

(6) Waste disposal records as required under 935 CMR 501.105(J)(5); and
(7) Following closure of an RMD, all records must be kept for at least two years at the expense of the RMD and in a form and location acceptable to the Commission.

(J) Waste Disposal.
(1) All waste, including waste composed of or containing finished marijuana and MIPs, shall be stored, secured, and managed in accordance with applicable state and local statutes, ordinances, and regulations.
(2) Liquid waste containing marijuana or by-products of marijuana processing shall be disposed 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 §§ 26-53; 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 Tanks and Containers*.

(3) Solid waste generated at an RMD shall be disposed of as follows:
(a) Incineration in a commercial or municipal waste combustor in Massachusetts holding a valid permit issued by the Commission of Environmental Protection (DEP). No fewer than two RMD agents must witness and document destruction; or
(b) Disposal in a landfill holding a valid permit issued by the DEP or by the appropriate state agency in the state in which the facility is located. No fewer than two RMD agents must witness and document disposal in the landfill; or

(c) Grinding and incorporating the medical marijuana waste with solid wastes such that the resulting mixture renders the medical marijuana waste unusable. Once such medical marijuana waste has been rendered unusable, it may be:

1. Disposed of in a solid waste management facility that holds a valid permit issued by the DEP or by the appropriate state agency in the state in which the facility is located; or

2. If the material mixed with the medical marijuana waste is organic material as defined in 310 CMR 16.02: *Definitions*, the mixture may be composted at an operation that is in compliance with the requirements of 310 CMR 16.00: *Site Assignment Regulations for Solid Waste Facilities*.

(4) An RMD must accept at no charge unused, excess, or contaminated marijuana or MIPs from a registered qualifying patient or personal caregiver, and shall destroy it as provided in 935 CMR 501.105(J) and maintain a written record of such disposal, which shall include the name of the supplying registered qualifying patient or personal caregiver if applicable.

(5) When marijuana or MIPs are disposed of, the RMD must create and maintain an electronic record of the date, the type and quantity disposed of, the manner of disposal, and two RMD Agents present during the disposal, with their signatures. RMDs shall keep disposal 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.

1.

2. On April 1, 2019 and thereafter, the disposal of marijuana, MIPs, and marijuana products must be recorded and tracked in the Seed-to-Sale SOR.

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

(1) A warning that marijuana has not been analyzed or approved by 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;

501.105: continued

(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 RMD from which they purchased the product, for disposal; and
(9) Any other information required by the Commission.

(L) Marketing and Advertising Requirements.
(1) An RMD maydevelop a logo to be used in labeling, signage, and other materials use of medical symbols, images of marijuana, related paraphernalia, and colloquial references to cannabis and marijuana are prohibited from use in this logo.
(2) 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, provided however that the Commission may further specify minimum signage requirements. Neon signage or any illuminated external signage which fails to comply with all local ordinances and requirements is prohibited.
(3) An RMD shall not display on the exterior of the facility advertisements for marijuana or any brand name, and may only identify the building by the registered name.
(4) An RMD shall not utilize graphics related to marijuana or paraphernalia on the exterior of the RMD or the building in which the RMD is located.
(5) An RMD shall not advertise the price of marijuana, except that it shall provide a catalogue or a printed list of the prices and strains of marijuana available at the RMD to registered qualifying patients and personal caregivers upon request. A catalogue or a printed list of the prices, strains of marijuana and MIPs available at the RMD may also be posted on an RMD's website.
(6) Marijuana, MIPs, and associated products shall not be displayed or clearly visible from the exterior of an RMD.
(7) An RMD shall not produce any items for sale or promotional gifts, such as T-shirts or novelty items, bearing a symbol of or references to marijuana or

MIPs, including the logo of the RMD.

(8) All advertising materials and materials produced by an RMD and disseminated pursuant to 935 CMR 501.105(K) or (L) are prohibited from including:

(a) Any statement, design, representation, picture, or illustration that encourages or represents the use of marijuana for any purpose other than to treat a debilitating medical condition or related symptoms;

(b) Any statement, design, representation, picture, or illustration that encourages or represents the recreational use of marijuana;

(c) advertising, marketing, and branding that asserts that its products are safe, or represent that its products have curative or therapeutic effects, other than labeling required pursuant to M.G.L. c. 94G, § 4(a½)(xxvi), unless supported by substantial evidence or substantial clinical data with reasonable scientific rigor as determined by the Commission;

(d) Any statement, design, representation, picture, or illustration portraying anyone younger than 21 years old.

(9) Inside the RMD, all marijuana shall be kept in a limited access area inaccessible to any persons other than RMD agents, except for displays allowable under 935 CMR 501.105(L)(10). Inside the RMD, all marijuana shall be stored in a locked, access-controlled space in a limited access area during non-business hours.

(10) A RMD may display, in secure, locked cases, samples of each product offered for sale. These display cases may be transparent.

(11) A RMD is prohibited from engaging in any advertising, marketing, and branding, including statements by a registrant, that makes any false or misleading statements concerning other registrants or licensees and the conduct and products of such other registrants or licensees.

(12) An RMD is prohibited from using unsolicited pop-up advertisements on the internet.

(13) An RMD is prohibited from engaging in 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

(14) The Commission shall maintain and make available a list of all RMDs, their dispensing location, and their contact information.

501.105: continued

(M) 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.

(N) Prohibitions.

(1) Unless otherwise authorized by the Commission, an RMD 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 RMD as specified in 935 CMR 501.105(B)(2), or to a laboratory as specified in 935 CMR 501.105(C)(2).

(2) Unless otherwise authorized by the Commission, an RMD may not acquire marijuana or marijuana plants except through the cultivation of marijuana by that RMD or another RMD as specified in 935 CMR 501.105(B)(2), provided however that an RMD may acquire marijuana seeds, cuttings or genetic plant material.

(a) Cuttings or genetic plant material may only be acquired within 90 days of receiving a final certificate of registration, or such other time period approved by the Commission and otherwise as authorized under 935 CMR 501.105(B)(2).

(3) Unless authorized by the Commission, an RMD is prohibited from acquiring, possessing, cultivating, delivering, transferring, transporting, supplying, or dispensing marijuana for any purpose except to assist registered qualifying patients.

(4) An RMD may not give away any marijuana except as required pursuant to 935 CMR 501.100(A)(6). An RMD may not provide any samples of marijuana.

(5) An RMD may not receive orders for marijuana in any manner other than from a registered qualifying patient or personal caregiver in-person at the RMD, except in the cases of delivery, in which an order may be received by telephone or through a password-protected, internet-based platform.

(6) An RMD may not fill orders for marijuana in any manner other than to a registered qualifying patient or personal caregiver in-person at the RMD, except in the case of delivery, in which an order may be delivered only to the primary 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 possess a registration card and valid photo identification as required pursuant to 935 CMR 501.105(F)(2). An RMD is prohibited from delivering adult-use marijuana.

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

(8) Consumption of marijuana on the premises or grounds of any RMD is

prohibited, provided however that an RMD may administer medical-use marijuana for the purposes of teaching use of vaporizers, or demonstration of use of other products as necessary. An RMD is prohibited from administering adult-use marijuana.

(9) An RMD may not adulterate marijuana, including with psychoactive additives or other illicit substances.

(10) An RMD 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 RMD may sell seeds to such individuals.

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

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

(a) Immediately discontinue cultivation and production of marijuana;

(b) Weigh and inventory all unused marijuana in all stages of cultivation and all MIPs in any stage of production, and create and maintain a written record of all such items;

(c) Dispose of the unused marijuana in accordance with 935 CMR 501.105(J) after approval by the Commission. Such disposal shall be in the public interest, and the Commission shall not be held liable in any way for any financial or other loss; and

(d) Maintain all records as required by 935 CMR 501.105(I)(7).

(2) If the RMD does not comply with the requirements of 935 CMR 501.105(O)(1), the Commission shall have the authority to, at the RMD's expense, secure the RMD, and after a period of 30-calendar days, seize and destroy the inventory and equipment and contract for the storage of RMD records.

501.105: continued

(P) Access to the Commission, Emergency Responders, and Law Enforcement.
(1) The following individuals shall have access to an RMD or RMD transportation vehicle:
(a) Representatives of the Commission as authorized by M.G.L. c. 94I, and935 CMR 501.000;
(b) Commission designee(s); and
(c) Emergency responders while responding to an emergency.
(2) 935 CMR 501.000 shall not be construed to prohibit access to authorized law enforcement personnel or local public health, inspectional services, acting within their lawful jurisdiction.

(Q) Liability Insurance Coverage or Maintenance of Escrow.
(1) An RMD 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(Q)(2). The deductible for each policy shall be no higher than $5,000 per occurrence.
(2) An RMD that documents an inability to obtain minimum liability insurance coverage as required by 935 CMR 501.105(Q)(1) may place in escrow a sum of no less than $250,000, to be expended for coverage of liabilities.
(3) The escrow account required pursuant to 935 CMR 501.105(Q)(2) must be replenished within ten business days of any expenditure.
(4) Reports documenting compliance with 935 CMR 501.105(Q) shall be made in a manner and form determined by the Commission pursuant to 935 CMR 501.105(M).

501.110: Security Requirements for Registered Marijuana Dispensaries

(A) General Requirements. An RMD shall implement sufficient security measures to deter and prevent unauthorized entrance into areas containing marijuana and theft of marijuana at the RMD. Security measures to protect the premises, registered qualifying patients, personal caregivers, and RMD agents of the RMD must include, but are not limited to the following. The RMD must:
(1) Allow only registered qualifying patients, personal caregivers, RMD agents, persons authorized by 935 CMR 501.105(P), and, subject to the requirements of 935 CMR 501.110(C)(4), outside vendors, contractors, and visitors, access to the RMD;
(2) Prevent individuals from remaining on the premises of the RMD if they are

not engaging in activity expressly or by necessary implication permitted by M.G.L. c. 94I, and and 935 CMR 501.000;
(3) Dispose of marijuana in accordance with 935 CMR 501.105(J), in excess of the quantity required for normal, efficient operation as established in 935 CMR 501.105(G)(1);
(4) Establish limited access areas accessible only to specifically authorized personnel, which shall include only the minimum number of employees essential for efficient operation;
(5) Store all finished marijuana in a secure, locked safe or vault and in such a manner as to prevent diversion, theft, and loss;
(6) Keep all safes, vaults, and any other equipment or areas used for the production, cultivation, harvesting, processing, or storage of marijuana and MIPs securely locked and protected from entry, except for the actual time required to remove or replace marijuana;
(7) Keep all locks and security equipment in good working order;
(8) Prohibit keys, if applicable, from being left in the locks, or stored or placed in a location accessible to persons other than specifically authorized personnel;
(9) Prohibit accessibility of security measures, such as combination numbers, passwords, or electronic or biometric security systems, to persons other than specifically authorized personnel;
(10) Ensure that the outside perimeter of the RMD is sufficiently lit to facilitate surveillance;
(11) Ensure that trees, bushes, and other foliage outside of the RMD do not allow for an individual or individuals to conceal themselves from sight;
(12) Develop emergency policies and procedures for securing all product following any instance of diversion, theft, or loss of marijuana, and conduct an assessment to determine whether additional safeguards are necessary; and
(13) Develop sufficient additional safeguards as required by the Commission for RMDs that present special security concerns.

501.110: continued

(14) An RMD shall comply with all local requirements regarding siting, provided however that if no local requirements exist, an RMD shall not be sited within a radius of 500 feet of a school, daycare center, or any facility in which children commonly congregate. The 500-foot distance under this section is measured in a straight line from the nearest point of the facility in question to the nearest point of the proposed RMD.

(B) Alternate Security Provisions. If an RMD has provided other safeguards that can be regarded as an adequate substitute for a security requirement specified in 935 CMR 501.110, such added protection may be considered by the Commission in evaluating overall required security measures.

(C) Limited Access Areas.

(1) All limited access areas must be identified by the posting of a sign that shall be a minimum of 12" X 12" and which states: "Do Not Enter - Limited Access Area - Access Limited to Authorized Personnel Only" in lettering no smaller than one inch in height.

(2) All limited access areas shall be clearly described by the filing of a diagram of the registered premises, in the form and manner determined by the 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.

(3) Access to limited access areas shall be limited to persons that are essential to operations in these areas and specifically permitted by the RMD, representatives of the Commission acting in accordance with their authority under the adult-use, medical-use and collocated-operations laws; Commission designee(s); and law enforcement authorities and emergency responders acting within their lawful jurisdiction.

(4) A RMD agent shall visibly display an identification badge issued by the RMD or the Commission at all times while at the RMD or transporting marijuana.

(5) All outside vendors, contractors, and visitors must obtain a visitor identification badge prior to entering a limited access area, and shall be escorted at all times by a RMD 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 RMD upon exit.

(D) Security and Alarm Systems.

(1) An RMD shall have an adequate security system to prevent and detect diversion, theft, or loss of marijuana or unauthorized intrusion, utilizing

commercial grade equipment, which shall, at a minimum, include:

(a) A perimeter alarm on all entry and exit points and perimeter windows;

(b) A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to designated employees of the RMD within five minutes after the failure, either by telephone, email, or text message;

(c) A duress alarm, panic alarm, or holdup alarm connected to local public safety or law enforcement authorities;

(d) Video cameras in all areas that may contain marijuana, at all points of entry and exit, and in any parking lot, which shall be appropriate for the normal lighting conditions of the area under surveillance. The cameras shall be directed at all safes, vaults, sales areas, and areas where marijuana is cultivated, harvested, processed, prepared, stored, handled, or dispensed. Cameras shall be angled to allow for the capture of clear and certain identification of any individual entering or exiting the RMD or area;

(e) 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 RMD is aware of a pending criminal, civil, or administrative investigation, or legal proceeding for which the recording may contain relevant information;

(f) The ability to immediately produce a clear, color, still photo (live or recorded);

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

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

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

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

(3) In addition to the requirements listed in 935 CMR 501.110(D)(1) and (2), the RMD 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.

(4) Access to surveillance areas shall be limited to persons that are essential to surveillance operations, law enforcement authorities acting within their lawful jurisdiction, security system service personnel, representatives of the Commission as authorized by M.G.L. c. 94I, and 935 CMR 501.000, and Commission designee(s).

(5) 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.

(6) 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.

(E) Registered Marijuana Dispensary Transportation of Marijuana and MIPs.

(1) Unless otherwise authorized by the Commission, only a RMD agent may transport marijuana or MIPs on behalf of an RMD, between RMDs, RMD sites, or to registered qualifying patients or personal caregivers. Unless otherwise authorized by the Commission, only a RMD agent or laboratory agent may transport marijuana or MIPs between an independent testing laboratory and RMDs.

(2) An RMD and independent testing laboratory shall:

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

(b) Re-weigh, re-inventory, and account for on video all marijuana transported, within eight hours after arrival at the destination RMD or independent testing laboratory except in the case of transport from a RMD

for delivery pursuant to 935 CMR 501.110(E)(11);

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

(d) Complete a shipping manifest in a form and manner determined by the Commission, for retention by the origination location, and carry a copy of said manifest with the products being transported; and

(e) Securely transmit a copy of the manifest to the destination prior to transport except in the case of home delivery pursuant to 935 CMR 501.110(E)(11).

(3) An RMD and independent testing laboratory shall retain all shipping manifests for no less than one year and make them available to the Commission upon request.

(4) An RMD and independent testing laboratory shall ensure that marijuana is:

(a) Transported in a secure, locked storage compartment that is part of the vehicle transporting the marijuana;

(b) Not visible from outside the vehicle; and

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

(5) 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(E)(11). 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.

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

(7) 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.

(8) 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.

(9) 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.

(10) An RMD or independent testing laboratory shall report to the Commission and local law enforcement any vehicle accidents, diversions, losses, or other reportable incidents pursuant to 935 CMR 501.110(F), that occur during transport, within 24 hours.

(11) Delivery of marijuana to the primary residence of a registered qualifying patient or a personal caregiver or to the caregiving institution of a registered qualifying patient shall be conducted in accordance with 935 CMR 501.105(F) and 935 CMR 501.110(E).

(12) Each vehicle used for transport of marijuana shall have a global positioning system 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 MIPs;

(c) monitored by the RMD or independent laboratory during transport of MIPs; and

(d) inspected by the Commission prior to initial transportation of MIPs, and after any alteration to the locked storage compartment.

(F) Incident Reporting.

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

(a) Discrepancies identified during inventory, diversion, theft, loss, and any criminal action involving the RMD or a RMD agent;

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

(c) Unauthorized destruction of marijuana;

(d) Any loss or unauthorized alteration of records related to marijuana, registered qualifying patients, personal caregivers, or RMD agents;

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

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

(g) Any other breach of security.

(2) An RMD shall, within ten calendar days, provide written notice to the

Commission of any incident described in 935 CMR 501.110(F)(1), 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.

(3) All documentation related to an incident that is reportable pursuant to 935 CMR 501.110(F)(1) shall be maintained by an RMD for no less than one year and made available to the Commission and to law enforcement authorities acting within their lawful jurisdiction upon request.

(G) An RMD 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 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

(A) 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.

(B) 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:

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

(2) Commission staff for the purpose of carrying out their official duties;

(3) Commission designee(s);

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

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

501.200: continued

(6) The Board of Registration in Medicine when necessary in connection with referrals to said Board concerning violations of 935 CMR 501.000; and
(7) Other government officials and agencies acting within their lawful jurisdiction.

(C) 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:
(1) Information that identifies a specific registered qualifying patient, personal caregiver, or registered RMD agent; and
(2) Information held by the Commission about RMD physical layout, as well as policies, procedures, practices, and plans pertaining to security;

(D) 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

(A) 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.
(B) 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.

(C) 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.

(D) 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.

(E) 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.

(E) 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, plant-growth regulators, 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 identified, a copy of which shall be left with or sent to the RMD.

501.310: Plan of Correction

(A) An RMD shall submit to the Commission a written Plan of Correction for any violations cited in the Deficiency Statement issued pursuant to 935 CMR 501.305 within ten business days after receipt of the Deficiency Statement.

(B) Every Plan of Correction shall state, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance with 935 CMR
501.000 will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.

501.310: continued

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

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

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

(A) Information provided by the applicant was misleading, incorrect, false, or fraudulent.

(B) The application received a low evaluation, indicating the inability to maintain and operate an RMD in compliance with the requirements of M.G.L. c. 94I, and 935 CMR 501.000.

(C) The application received a lower evaluation than other applications.

(D) The applicant has been determined to be either not responsible or suitable pursuant to any one or more of the factors listed in 935 CMR 501.100(B)(3)(n).

(E) The application does not serve the needs of the Commonwealth with regard to location, access, quality, and community safety.

(F) Any other ground that serves the purposes of M.G.L. c. 94I or935 CMR 501.000

501.405: Registered Marijuana Dispensary Registration: Grounds for Denial of Renewal Applications and Revocation

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

(A) The RMD is not operational within the time indicated pursuant to 935 CMR 501.100(D).

(B) Information provided by the RMD was materially inaccurate, incomplete, or fraudulent.

(C) The RMD has failed to comply with any requirement of M.G.L. c. 94I or

935 CMR
501.000 or any applicable law or regulation, including laws and regulations of the Commonwealth relating to taxes, child support, workers compensation, and professional and commercial insurance coverage.

(D) The RMD has failed to submit a Plan of Correction as required or to implement a Plan of Correction as submitted pursuant to 935 CMR 501.310.

(E) The RMD has assigned or attempted to assign its certificate of registration to another entity.

(F) There has been a lack of responsible operation of the RMD, as shown by, but not limited to, one or more of the following:

(1) Incompetent or negligent operation;
(2) Failure to maintain the RMD in a clean, orderly, and sanitary fashion; or
(3) Permitting an individual to use a registration card belonging to a different individual.

(G) The RMD does not have sufficient financial resources to meet the requirements of M.G.L. c. 94I or 935 CMR 501.000.

(H) The financial management of the RMD has resulted in the filing of a petition for bankruptcy or receivership related to the financial solvency of the RMD.

501.405: continued

(I) An executive of an RMD, or a member, if any, of the entity, has maintained a substandard level of compliance with the statutory and regulatory requirements for the operation of a healthcare facility or facility for providing marijuana for medical purposes in another jurisdiction including, but not limited to, failure to correct deficiencies, a limitation upon or a suspension, revocation, or refusal to grant or renew a registration or license to operate, or certification for Medicaid or Medicare.

(J) A RMD agent of an RMD has a history of criminal conduct as evidenced by any criminal proceedings against such individual or against healthcare facilities or marijuana facilities in which such individual either owned shares of stock or served as a corporate officer, and which resulted in conviction, guilty plea, plea of *nolo contendere*, or admission to sufficient facts.

(K) An executive of an RMD, or a member, if any, of the entity, has committed, permitted, aided, or abetted any illegal practices in the operation of any RMD.

(L) The RMD 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 RMD.

(M) The conduct or practices of the RMD have been detrimental to the safety, health, or welfare of registered qualified patients, personal caregivers, or the public.

(N) The conduct and/or practices of the RMD demonstrate a lack of responsibility or suitability as specified in 935 CMR 501.100(B)(3)(u).

(O) Any other ground that serves the purposes of M.G.L. c. 94I or 935 CMR 501.000.

501.410: Void Registered Marijuana Dispensary Registration

An RMD registration is void if the RMD transfers its location without Commission approval or ceases to operate.

501.415: Registered Marijuana Dispensary Registration: Limitation of Sales by Registered Marijuana Dispensaries

(A) If the Commission determines that an RMD does not substantially comply with applicable provisions of M.G.L. c. 94I or 935 CMR 501.000, the Commission may order that the RMD shall not sell marijuana, after a date specified, to registered

qualifying patients or their personal caregivers.

(B) The Commission shall not make such a determination until an RMD has been notified that the RMD does not substantially comply with applicable provisions of M.G.L. c. 94I or 935 CMR 501.000, that an order to limit sales is contemplated, and that the RMD has a reasonable opportunity to correct the deficiencies.

(C) An order that an RMD shall not sell marijuana pursuant to 935 CMR 501.415(A) may be rescinded when the Commission finds that the RMD is in substantial compliance with the applicable provisions of 935 CMR 501.000.

501.420: Denial of a Registration Card or Hardship Cultivation Registration

Each of the following, in and of itself, constitutes full and adequate grounds for denial of a registration card for a registered qualifying patient, personal caregiver, or RMD agent, or a hardship cultivation registration:

(A) Failure to provide the information required in 935 CMR 501.000 for a registration card or hardship cultivation registration;

(B) Provision of misleading, incorrect, false, or fraudulent information on the application;

501.420: continued

(C) Failure to meet the requirements set forth in 935 CMR 501.000 for a registration card or hardship cultivation registration;

(D) Revocation or suspension of a registration card or hardship cultivation registration in the previous six months;

(E) Failure to pay all applicable fees; or

(F) Any other ground that serves the purposes of M.G.L. c. 94I or935 CMR 501.000.

501.425: Revocation of a Registration Card or Hardship Cultivation Registration

(A) Each of the following, in and of itself, constitutes full and adequate grounds for revocation of a registration card issued to a registered qualifying patient, personal caregiver, institutional caregiver, RMD agent, laboratory agent or a hardship cultivation registration:

(1) Submission of misleading, incorrect, false, or fraudulent information in the application or renewal application;
(2) Violation of the requirements of M.G.L. c. 94I or 935 CMR 501.000;
(3) Fraudulent use of a registration card;
(4) Selling, distributing, or giving marijuana to any unauthorized person;
(5) Tampering, falsifying, altering, modifying, duplicating, or allowing another person to use, tamper, falsify, alter, modify, or duplicate a registration card or hardship cultivation registration;
(6) Failure to notify the Commission within five business days after becoming aware that the registration card has been lost, stolen, or destroyed; or
(7) 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.

(B) In addition to the grounds in 935 CMR 501.425(A), each of the following, in and of itself, shall be adequate grounds for the revocation of a registration card issued to a registered qualifying patient:

(1) The qualifying patient is no longer a resident of the Commonwealth;
(2) The qualifying patient, taking into account the amounts of marijuana or MIPs obtained by his or her personal caregiver if applicable, seeks to obtain or obtains more of such amounts than is allowable under 935 CMR 501.105(F)(2); or
(3) The qualifying patient has used marijuana in a manner that puts others at risk of their health, safety, or welfare, or has failed to take reasonable precautions to avoid putting others at such risk.

(C) In addition to the grounds in 935 CMR 501.425(A), a conviction of a felony drug offense in the Commonwealth, or a like violation of the laws of another state, the United States or a military, territorial, or Indian tribal authority shall be adequate grounds for the revocation of a RMD agent's registration card.

(D) In addition to the grounds in 935 CMR 501.425(A), the purchase of marijuana from an RMD 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.

(E) In addition to the applicable grounds in 935 CMR 501.425(A) through (C), any other ground that serves the purposes of M.G.L. c. 94I or 935 CMR 501.000 shall be sufficient to revoke a registration card or hardship cultivation registration.

501.430: Revocation of a Certifying Healthcare Provider Registration

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

501.430: continued

(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; or any applicable provisions of 935 CMR 501.000;

(C) The certifying healthcare provider issued a written certification on or after July 1, 2014, without completion of continuing professional development credits pursuant to 935 CMR 501.010(A); or

(D) Any other ground that serves the purposes of M.G.L. c. 94I or935 CMR 501.000.

501.435: Void Certifying Physician Registration

(A) When a certifying healthcare provider's license to practice medicine or nursing, as applicable, in Massachusetts is no longer active, or is 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.

(B) When a certifying healthcare provider surrenders his or her registration, the registration is void.

(C) A void certifying healthcare provider registration is inactive and invalid.

501.440: Void Registration Cards

(A) A registration card validly issued prior to the Program Transfer shall be void on the issuance of a new registration card.

(B) A registration card issued to a RMD agent shall be void when the agent has ceased to be associated with the RMD that applied for and received the RMD agent's registration card.

(C) A registration card that has been issued to a qualifying patient, including a hardship cultivation registration, shall be void when:
(1) The card has not been surrendered upon the issuance of a new registration card based on new information;
(2) The qualifying patient is no longer a resident of Massachusetts; or

(3) The patient is deceased.

(D) A registration card issued to a personal caregiver is void:
(1) 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;
(2) When the sole registered qualifying patient for whom the personal caregiver serves as such is no longer registered with the Commission; or
(3) Five days after the death of the registered qualifying patient to allow for appropriate disposal of marijuana pursuant to 935 CMR 501.105(J)(4).

(E) A void registration card is inactive and invalid.

501.445: Summary Cease and Desist Order and Quarantine Order

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

(A) If, based upon inspection, affidavits, or other evidence, the Commission determines that an RMD or the products prepared by an RMD pose an immediate or serious threat to the public health, safety, or welfare, the Commission may:

501.445: continued

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

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

501.450: Summary Suspension Order

The Commission may summarily suspend any registration card or certificate of registration issued pursuant to 935 CMR 501.000, pending further proceedings for denial of renewal or revocation of a registration, whenever the Commission finds that the continued registration poses an imminent danger to the public health, safety, or welfare.

501.500: Administrative Review: Non-selection of a Registered Marijuana Dispensary's Application for Initial Registration

(A) The Commission shall provide written notice of non-selection to an applicant.

(B) Applicants may request copies of the evaluation scores and any documentation supporting the evaluation process for all applications.

(D) The written notice of non-selection becomes final agency action ten business days after issuance, subject to judicial review in Superior Court in an action for certiorari relief under
M.G.L. c. 249, § 4, unless the applicant submits a request pursuant to 935 CMR 501.500(B).

(E) If an applicant submits a request pursuant to 935 CMR 501.500(B), the written notice of non-selection becomes final upon provision of the requested written documentation.

(F) No entity whose application has been denied pursuant to 935 CMR 501.400 may make another application for at least one year after the date of denial.

501.505: Hearings

(A) Upon written request filed with the Commission no later than 28-calendar days after the effective date of a summary cease and desist order or quarantine order issued pursuant to 935 CMR 501.445, a registrant shall be afforded a hearing. At the hearing, the Commission must prove by a preponderance of the evidence that there existed immediately prior to, or at the time of the order, an immediate or serious threat to the public health, safety, or welfare.

(B) Upon written request filed with the Commission no later than 14-calendar days after the effective date of a summary suspension order issued pursuant to 935 CMR 501.450., a registrant shall be afforded a hearing. At the hearing, the Commission must prove by a preponderance of the evidence that there existed immediately prior to, or at the time of the suspension, an imminent danger to the public health, safety, or welfare.

(C) With the exception of the provisions for cease and desist orders and quarantine orders pursuant to 935 CMR 501.445, and summary suspension orders pursuant to 935 CMR 501.450, the Commission shall provide written notice, and shall provide a hearing if a hearing is requested in writing within 21-calendar days, or as soon as is practicable, after the effective date stated in the notice, prior to:

(1) Denying a renewal application for a registration card;
(2) Revoking a registration card for a registered qualifying patient, personal caregiver, or RMD agent;
(3) Denying a renewal application for or revoking a hardship cultivation registration;
(4) Denying a renewal application of an RMD;
(5) Revoking the registration certificate of an RMD;
(6) Limiting sales of marijuana by an RMD; or

501.505: continued

(7) Revoking a certifying physician registration.

(D) The written notice shall provide the registrant with a statement of the grounds for the action and of the right to request a hearing and the time-period for such request.

(E) If a request for a hearing is made, the hearing shall be conducted and a tentative decision issued by the Commission or its delegated decision maker, , in accordance M.G.L. c. 30A and 801 CMR 1.02: *Informal/Fair Hearing Rules*.

(F) At the hearing, the Commission must prove the basis for the action by a preponderance of the evidence. If, at the hearing, the decision maker, i.e., the Commission, a Hearing Officer, Magistrate or Presiding Officer, finds any single ground for revocation, suspension, limitation of sales of marijuana, denial of any application, or refusal to renew any application, the decision maker shall render a decision affirming the action initiated by the Commission. The decision maker shall forward a recommended decision to the Commission for its consideration.

(G) A final decision by the Commission, after a hearing, is a final agency action subject to judicial review in Superior Court pursuant to M.G.L. c. 30A.

(H) If a hearing pursuant to 935 CMR 501.505 is not requested within the required time, the right to a hearing is waived.

501.510: Effect of Denial of Renewal or Revocation of Registered Marijuana Dispensary Registration, Revocation of RMD Agent Registration, and Surrender of a Registration

(A) An RMD that has had its application for renewal registration denied or its registration revoked is disqualified from future registration as an RMD. The Commission may consider this action in any proceedings under 935 CMR 500.000: *Adult Use of Marijuana,* or 502.000: *Colocated Adult-Use and Medical-Use Marijuana Operations*.

(B) A RMD agent whose registration card has been revoked is disqualified from serving as a RMD agent or from having any financial interest in an RMD. The Commission may consider this action in any proceedings under 935 CMR 500.000: *Adult Use of Marijuana,* or 502.000: *Colocated Adult-Use and Medical-Use Marijuana Operations.*

(C) The surrender of a certificate of registration or a registration card shall not prevent the Commission from revoking, or imposing other penalties with respect

to, such certificate of registration or registration card.

501.600: Municipal Requirements

(A) An RMD and other registered persons shall comply with all local rules, regulations, ordinances, and bylaws.

(B) The Commission does not mandate any involvement by municipalities or local boards of health in the regulation of RMDs, qualifying patients with hardship cultivation registrations, or any other aspects of marijuana for medical use. However, nothing in 935 CMR 501.000 shall be construed to prohibit lawful local oversight and regulation, including fee requirements, that does not conflict or interfere with the operation of 935 CMR 501.000.

501.650: Non-conflict with Other Law

(A) Nothing in 935 CMR 501.000 shall be construed to limit the applicability of other law as it pertains to the rights of landlords, employers, law enforcement authorities, or regulatory agencies.

(B) Nothing in 935 CMR 501.000:

(1) Allows the operation of a motor vehicle, boat, or aircraft while under the influence of marijuana;

(2) Requires any health insurance provider, or any government agency or authority, to reimburse any person for the expenses of the medical use of marijuana;

(3) Requires any healthcare professional to authorize the use of medical marijuana for a patient;

501.650: continued

(4) 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;
(5) Supersedes Massachusetts law prohibiting the possession, cultivation, transport, distribution, or sale of marijuana for nonmedical purposes; or
(6) Requires the violation of federal law or purports to give immunity under federal law;
(7) Poses an obstacle to federal enforcement of federal law.

(C) Nothing in 935 CMR 501.000 shall be construed to limit the scope of practice of a nurse practitioner pursuant to M.G.L. c. 112, § 80I.

501.700: Waivers

The Commission may waive the applicability of one or more of the requirements imposed by 935 CMR 501.000 upon finding that:

(A) If applicable, compliance would prevent licensed operations in accordance with 935 CMR 500:000: *Adult Use of Marijuana*, and 935 CMR 502:000: *Colocated Adult-Use and Medical-Use Marijuana Operations*;

(B) Compliance would cause undue hardship to the requestor;

(C) If applicable, the requestor's non-compliance does not jeopardize the health or safety of any patient or the public;

(D) If applicable, the requestor has instituted compensating features that are acceptable to the Commission;

(E) The Commission may delegate its authority to the Executive Director to waive administrative regulatory requirements under either 935 CMR 500.000 or 935 CMR 501.000. The Executive Director may determine the process or manner of the waiver process, including whether a registrant, licensee or applicant is required to request a waiver in writing.

(F) There can be no waiver of statutory requirements. A waiver of the regulatory requirements cannot pose a risk to the public health, safety or welfare.

501.800: Severability

The provisions of 935 CMR 501.000 are severable. If a court of competent

jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY

935 CMR 501.000: St. 2017, c. 55, An Act to Ensure Safe Access to Marijuana, and M.G.L. c. 94I.

NON-TEXT PAGE