

# **Public Meeting Packet-**

# **Proposed Draft Regulations**

July 20, 2020

Microsoft Teams Live



# Public Meeting Packet - Proposed Draft Regulations

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July 16, 2020

In accordance with Sections 18-25 of Chapter 30A of the Massachusetts General Laws and the Governor's Order suspending certain provisions of the Open Meeting Law, M.G.L Ch. 30A §20, notice is hereby given of a meeting of the Cannabis Control Commission. The meeting will take place as noted below.

## CANNABIS CONTROL COMMISSION

July 20, 2020 10:00AM

Remote Participation via Microsoft Teams Live\*

## PUBLIC MEETING AGENDA

- 1) Call to Order
- 2) Chairman's Comments and Updates
- 3) Commission Discussion and Votes a. Draft Regulations
- 4) Next Meeting Date
- 5) Adjournment

\*Closed captions available





## Memorandum

**To:** Chairman Hoffman, Commissioner Flanagan, Commissioner McBride,

Commissioner Title

Cc: Shawn Collins, ED; Erika Scibelli, COS; Alisa Stack, COO; Christine Baily, GC

From: Pauline Nguyen, DGC

**Date:** July 13, 2020

**Subject:** 7/20 Commission Meeting Materials: Draft Regulations

## Attached please find the following four documents:

1. Attachment A – *Draft Regulations* – *Recommendations and Provisions*: This document contains all proposed regulatory changes, except some amendments to defined terms, which are in Attachment B, and changes to the colocated regulations, 502.000, which are presented in Attachments C and D.

The draft regulations are organized by topic. For each topic, at the top you will find a summary of the recommended regulatory changes, followed by the relevant sections of the regulations with the redlined changes. Due to the length of this document, I have marked each Topic for easy navigation if you open this in Word (go to View > Navigation Pane (check the box)).

- 2. Attachment B *Definitions Draft Regs*: This document contains the entire 500.002 and 501.002 definitions sections for adult- and medical-use regulations. Most of the changes are already reflected in Attachment A above.
- 3. Attachment C *Colocated Regs Draft Regs*: It is being recommended to merge 502.000 into the adult- and medical-use regulations. This document contains the regulatory language that would be added to 500.000 and 501.000. There were very few substantive changes made to the CMO regulations most were either moved or eliminated because they were already accounted for in the adult-use and medical-use regulations.





4. Attachment D – *Colocated Regs - Trace-through Chart*: This chart provides a quick glance of each section or subsection of the CMO regulations showing (1) whether/where any provision needs to be inserted into the adult-use or medical-use regulations and (2) an explanation for each.

Please note that these and any subsequent changes by you will be incorporated into the full set of adult-use and medical-use regulations for filing with the Secretary's Office and posting for public comment. Legal will ensure that formatting and global changes resulting from these changes, and proofreading edits, will be made to the filed version.





# **DRAFT REGULATIONS**

July 20, 2020

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## **Topic: Greenhouse Definition**

Recommendation: Update the definition of 'greenhouse' to align with the building code.

## 500.002: Definitions

Greenhouse means a structure or thermally isolated Enclosed Area of a building that maintains a specialized sunlit environment used for and essential to the cultivation, protection or maintenance of plants an Enclosed Area where Cannabis or Marijuana plants are cultivated that has been inspected by the Commission and determined to be a Greenhouse.

Commented [A1]: Enclosed Area means an indoor or outdoor area equipped with locks or other security devices, which is accessible only to Consumers, Marijuana Establishment Agents, Registered Qualifying Patients, or Caregivers.



## **Topic: Fingerprint Checks**

Recommendations: Amend adult-use regulations to be consistent with Commission's practice and with FBI/DCJIS requirements. These changes provide applicants who are subject to the fingerprint-based check requirement with additional notice.

### 500.029: Registration and Conduct of Laboratory Agents

[...]

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

[...]

- (c) <u>W</u>written acknowledgment <u>signed</u> by the <u>individual applicant</u> of the limitations on his or her authorization to possess, <u>test. transportTransfer</u>, <u>and or Process Marijuana or Marijuana for Products testing purposes</u> in the Commonwealth;
- (f) Written acknowledgment signed by the applicant of any limitations on his or her authorization to possess, test or transport Marijuana Products in the Commonwealth;
- (fg) Authorization to obtain a full set of fingerprints, in accordance with M.G.L. c. 94G, § 21, submitted in a form and manner as determined by the Commission; and
- (gh) Background information including, as applicable: [...]
- (4) The Commission shall conduct fingerprint-based checks of state and national criminal history databases, as authorized by <u>G.L. c. 94G, §§ 15 and 21</u> and Public Law 92-544, to determine the suitability of Laboratory Agents. <u>As part of these checks, fingerprints are used to check the national criminal history records of the Federal Bureau of Investigation (FBI).</u> The Independent Testing Laboratory shall pay a nonrefundable fee to in a form and manner determined by the Commission for the purpose of administering the fingerprint-based background check.

## **500.101: Application Requirements**



- (1) New Applicants. [...]
- [...]
- (b) Background Check. Prior to an application being considered complete, each applicant for licensure must submit the following information:
  - 1. The list of individuals and entities in 935 CMR 500.101(1)(a)1.;
  - 2. Information for each individual identified in 935 CMR 500.101(1)(a)1. which shall include:
    - a. the individual's full legal name and any aliases;
    - b. the individual's address;
    - c. the individual's date of birth;
    - d. a photocopy of the individual's driver's license or other government-issued identification card:
    - e. a CORI Acknowledgment Form, pursuant to 803 CMR 2.09: Requirements for Requestors to Request CORI, provided by the Commission, signed by the individual and notarized;
    - f. authorization to obtain a full set of fingerprints, in accordance with M.G.L. c. 94G,  $\S$  21 and Public Law 92-544, submitted in a form and manner as determined by the Commission; and
    - g. any other authorization or disclosure deemed necessary by the Commission, for the purposes of conducting a background check.



## **Topic: Equity Ownership Threshold for SEP Participants to Receive License**related Benefits

### Recommendation:

- Require 51% or more equity ownership by SEPs for fee waivers and discounts;
- Allow fee waivers and discounts to apply to microbusinesses and OSD-certified minorityowned, veteran-owned, and women-owned businesses, who are also deemed to be small businesses by the Commission, to access the same fee waivers and discounts.

### 500.002: Definitions

Small Business means, for the purposes of 935 CMR 500.005(1)(b), an applicant or Licensee that (i) currently employs a combined total of 50 or fewer full-time equivalent employees in all locations or employees work less than a combined total of 2,600 hours per quarter; and (ii) has gross revenues of \$15 million or less, as reported to the Massachusetts Department of Revenue the year prior to the date of the Licensee's initial or renewal application or as otherwise demonstrated in a form and manner determined by the Commission.

## 500.005: Fees

- (1) Marijuana Establishment Application and License Fees.
  - (a) Each applicant for licensure as a Marijuana Establishment shall pay to the Commission a nonrefundable application fee, annual license fee, and a monthly Seed-to-sale licensing fee. These fees do not include the costs associated with the Seed-to-sale licensing 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 500.030 or 935 CMR 500.101(1)(b)
  - (b) Waiver of Fees.
    - Application fees are waived for <u>Microbusinesses</u>, <u>businesses</u> controlled by and <u>with majority ownership comprised of Social Equity Program</u> Participants and/<u>or Economic Empowerment Priority Applicants, and Massachusetts Minority Business Enterprises (MBE), Women Business
      </u>

Commented [A2]: Based on criteria the Commonwealth uses for eligibility to be a member of the Operational Services Division's (OSD) Small Business Purchasing Program (SBPP). See <a href="https://www.mass.gov/how-to/register-for-the-small-business-purchasing-program-sbpp">https://www.mass.gov/how-to/register-for-the-small-business-purchasing-program-sbpp</a>



Enterprises (WBE), and Veteran Business Enterprises (VBE) with valid certification from the Massachusetts Operational Services Division's Supplier Diversity Office and which are considered to be Small Businesses as defined by the Commission. This does not include the costs associated with background checks.

- 2. For Annual License Fees, <u>businesses controlled by and with majority ownership comprised of Social Equity Program Participants and/or Economic Empowerment Priority Applicants, and Massachusetts Minority Business Enterprises (MBE), Women Business Enterprises (WBE), and Veteran Business Enterprises (VBE) with valid certification from the Massachusetts Operational Services Division's Supplier Diversity Office and which are considered to be Small Businesses as defined by the Commission receive a 50% reduction in the fee associated with an application.</u>
- 3. Seed-to-sale SOR monthly program fees are waived for Economic Empowerment Priority Applicants, Social Equity Program Participants, Craft Marijuana Cooperatives, and-Microbusinesses, businesses controlled by and with majority ownership comprised of Economic Empowerment Priority Applicants and/or Social Equity Program Participants, and Massachusetts Minority Business Enterprises (MBE), Women Business Enterprises (WBE), and Veteran Business Enterprises (VBE) with valid certification from the Massachusetts Operational Services Division's Supplier Diversity Office and which are considered to be Small Businesses as defined by the Commission. This waiver does not include other costs associated with the Seed-to-sale licensing system, specifically the fees for plant and package tags.
- All other applicants are responsible for the payment of fees in accordance with 935 CMR 500.005(a) and may not waive their obligation pursuant to 935 CMR 500.850, Waivers.

[...]



## **Topic: Social Equity Program**

<u>Recommendation</u>: Create regulatory flexibility for the Commission to add new groups via vote; and expand SEP eligibility to individuals associated with an EEA, who meet one of the equity ownership criteria for EEA status.

### 500.105: General Operational Requirements for Marijuana Establishments

### (17) Social Equity Program.

- (a) There shall be a Social Equity Program established by the Commission to provide training and technical assistance to eligible applicants and Licensees, which may include, but shall not be limited to:
  - 1. Management, recruitment and employee trainings;
  - 2. Accounting and sales forecasting;
  - 3. Tax prediction and compliance;
  - 4. Legal compliance;
  - 5. Business plan creation and operational development;
  - 6. Marijuana industry best practices; and
  - 7. Assistance with identifying or raising funds or capital.
- (b) Eligibility for the Social Equity Program shall be met if applicants or Licensees satisfy one or more of the following criteria:
  - 1. Income does not exceed 400% of Area Median Income and Residency in an Area of Disproportionate Impact, as defined by the Commission, for at least five of the preceding ten years, as established by:
    - a. A Massachusetts driver's record or Massachusetts ID card record;
    - b. A signed lease agreement that includes the subject's name;
    - c. Residential property deed that includes the subject's name;
    - d. School records;
    - e. Housing authority records;
    - f. Banking records;



- g. Utility bills, which identifies energy and water use; or
- h. Dated notices or correspondence from a local or state government entity that includes the subject's name.
- 2. Residency in Massachusetts for at least the preceding 12 months and a conviction or continuance without a finding for an M.G.L. c. 94C offense under M.G.L. c. 94C or an equivalent conviction in Other Jurisdictions; or
- 3. Residency in Massachusetts for at least the preceding 12 months and proof that the individual was either married to or the child of an individual convicted or continuance without a finding for a M.G.L. c. 94C offense or an equivalent conviction in Other Jurisdictions.
- 4. Any individual listed as an owner on the original certification of an Economic Empowerment Priority Applicant who satisfies one or more the following criteria:
  - a. Lived for five of the preceding ten years in an Area of Disproportionate Impact, as determined by the Commission
  - Experience in one or more previous positions where the primary population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision or empowerment to disproportionately impacted individuals or communities;
  - c. Black, African American, Hispanic or Latino descent; or
  - d. Other significant articulable demonstration of past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact.
- 5. The Commission may, in consideration of new information and data, broaden the categories of eligibility for the Social Equity Program by a vote of the Commission.



## **Topic: Diversity Plans**

<u>Recommendation</u>: Replace "minorities" referenced in the diversity plans requirements with "people of color, particularly, Black, African American, Latinx, and Indigenous people."

## 500.100: Application Requirements

- (1) New Applicants. [...]
  - (a) Application of Intent. [...]
  - (b) <u>Background Check</u>. [...]
  - (c) <u>Management and Operations Profile</u>. [...]
    - 8. A detailed summary of operating policies and procedures for the Marijuana Establishment which shall include, but not be limited to, provisions for:

[...]

- k. diversity plans to promote equity among minorities people of color, particularly Black, African American, Latinx, and Indigenous people, women, Veterans, people persons with disabilities, and LGBTQ+ people of all gender identities and sexual orientation, in the operation of the Marijuana Establishment. The plan shall outline the goals, programs, and measurements the Marijuana Establishment will pursue once licensed.
- (2) Social Consumption Pilot Program Application Process.

[...]

(j) Management and Operations Profile.

[...]



6. A diversity plan to promote equity among minorities people of color, particularly Black, African American, Latinx, and Indigenous people, women, Veterans, people persons with disabilities, and LGBTQ+ people of all gender identities and sexual orientation, in the operation of the Marijuana Establishment. The plan shall outline the goals, programs, and measurements the Marijuana Establishment will pursue once licensed.



## **Topic: Delivery Licenses and Delivery Endorsements**

<u>Recommendation</u>: Give the Commission flexibility to choose to expand Delivery licenses and Delivery endorsements to cooperatives and OSD Supplier Diversity Office-certified women-, minority-, veteranowned businesses during the exclusivity period.

## 500.050: Marijuana Establishments

[...]

## (10) Delivery-only Licensee.

- (a) A Delivery-only Licensee may deliver Marijuana or Marijuana Products directly to Consumers from a Marijuana Retailer or MTC with which the Delivery-only Licensee has a Delivery Agreement. A Delivery-only Licensee shall not have a retail location accessible to the public.
- (b) A Delivery-only Licensees shall be limited on an exclusive basis to businesses controlled by and with majority ownership comprised of Economic Empowerment Priority Applicants or Social Equity Program Participants for a period of 24 months from the date the first Delivery-only Licensee receives a notice to commence operations, provided, however, that the Commission may vote to decide to extend that period following a determination that the goal of the exclusivity period to promote and encourage full participation in the regulated Marijuana industry by people from communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law has not beenmet; and the Commission may vote to expand eligibility for a Delivery-only License during the exclusivity period pursuant to 935 CMR 500.050(10)(b)4.
  - 1. The Commission shall develop criteria for evaluating whether the goals of the exclusivity period are met, which shall include, but not be limited to:
    - a. Overall rates of participation in the regulated marijuana industry by people from communities that have previously been disproportionately harmed by marijuana prohibition and enforcement of the law;
    - b. Overall rates of participation in the regulated Marijuana industry by people of color;
    - c. Licenses granted to businesses with majority ownership comprised of



Economic Empowerment Priority Applicants and Social Equity Program Participants;

- d. Number of registered agents who are Social Equity Program Participants;
- e. Number of Delivery-only Licensees in operation and business performance relative to other Marijuana Establishments;
- f. Financial feasibility of continued participation in the regulated Marijuana industry by communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law if exclusivity period ends; and
- g. Any other information the Commission determines relevant.
- 2. The Commission shall collect and report on data measuring the criteria throughout the exclusivity period. The Commission shall begin evaluating whether the goals of the exclusivity period have been met at least eight months before the end of the 24-month period to provide adequate time to consider whether an extension of the 24-month period is necessary prior to the conclusion of that time period.
- 3. The licenses shall generally be available to applicants after the 24-month period unless the Commissioners affirmatively votes to extend the period of exclusivity by a period of 12 months after the first 24-month period. Any subsequent extension of the exclusivity period would require the Commission affirmatively to find that the goals and objectives of the exclusivity period as set forth in 935 CMR 500.050(10)(b)1. have not been met.
- 4. If data collected by the Commission demonstrates progress toward the goals and objectives of the exclusivity period as set forth in 935 CMR 500.050(10)(b)1. and that demand for consumer delivery is likely to exceed the supply that could be provided by businesses that meet the exclusivity requirements during the exclusivity period, the Commission may vote during the exclusivity period to allow the following additional businesses to own Delivery licenses:
  - Worker-owned cooperatives organized to operate consistently with the Seven Cooperative Principles established by the International Cooperative Alliance in 1995; or
  - a-b.Massachusetts Minority Business Enterprises (MBE), Women Business Enterprises (WBE), and Veteran Business Enterprises (VBE) with valid certification from the Massachusetts Operational Services Division's Supplier Diversity Office.
- (c) No person or entity other than those disclosed in the application shall be a Person or Entity Having Direct or Indirect Control in a Delivery—only License.



## **Topic: Economic Empowerment Applicants**

### Recommendations:

- 1. Require Economic Empowerment Priority Applicants (EEAs) to continue to meet 3 of the 6 criteria, at least one of which must be a majority-equity-ownership criterion, to maintain EEA status [500.002].
- Require EEAs to report to the Commission all changes of ownership and control (while still only seeking approval in compliance with 935 CMR 500.104) [500.104].
- Require EEAs to certify to the Commission as part of a renewal application that the requisite ownership and control has been maintained by the requisite class of people identified on the EEAs certification. [500.103].

## 500.002: Definitions

Economic Empowerment Priority Applicant means an applicant who <u>was certified by the Commission as such in 2018</u>, <u>demonstrated</u> and continues to <u>meet demonstrate</u> three or more of the following <u>six</u> criteria, <u>at least one of which must be a majority-equity-ownership criterion:</u>

## 1. Majority-Equity-Ownership Criteria:

- a. A majority of ownership belongs to people who have lived for five of the preceding ten years in an Area of Disproportionate Impact, as determined by the Commission.
- b. A majority of ownership has held one or more previous positions where the primary population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision or empowerment to disproportionately impacted individuals or communities.
- <u>a.c. A</u> majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent.

#### 2. Additional Criteria:

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



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

## 500.103: Licensure and Renewal

[...]

(4) Expiration and Renewal of Licensure. [...]

(j) All Economic Empowerment Priority Applicants must submit, as part of its renewal application, an attestation in a form and manner determined by the Commission, executed by the individuals who, through ownership, qualify an applicant or licensee as an Economic Empowerment Priority Applicant certifying that:

- 1. Such individuals have had control and ownership since licensure, or the most recent renewal; and
- 2. The licensee acknowledges that it may only avail itself of the benefits of Economic Empowerment Priority Applicant status so long as such individuals continue to have control and ownership or otherwise satisfy the criteria of Economic Empowerment Priority Applicant status as provided 935 CMR 500.0002.

## 500.104: Notification and Approval of Changes

- (1) Prior to making the following changes, the Marijuana Establishment shall submit a request for such change to the Commission and pay the appropriate fee. No such change shall be permitted until approved by the Commission. Failure to obtain approval of such changes may result in a license being suspended, revoked, or deemed void.
  - (a) <u>Location Change</u>. [...]
  - (b) Ownership or Control Change.
    - 1. <u>Ownership Change</u>. Prior to any change in ownership, where an Equity Holder acquires or increases its ownership to 10% or more of the equity or contributes 10% or more of the initial capital to operate the Marijuana Establishment, including capital that is in the form of land or buildings, the Marijuana Establishment shall submit a request for such change to the Commission.
    - 2. <u>Control Change</u>. Prior to any change in control, where a new Person or Entity Having Direct or Indirect Control should be added to the license, the Marijuana Establishment shall submit a request for such change to the Commission prior to effectuating such a change. An individual, corporation, or entity shall be determined to be in a position to control the decision-making of a Marijuana Establishment if the



individual, corporation, or entity falls within the definition of Person or Entity Having Direct or Indirect Control.

## 3. Priority Applicants Change in Ownership or Control.

a. Economic Empowerment Priority Applicants must notify the Commission of any change in ownership or control, regardless of whether such change would require the applicant to seek approval pursuant to 935 CMR 500.104(1)(b)1. and 2..

a.—b. When an Economic Empowerment Applicant implicates the approval process established in 935 CMR 500.104(1)(b)(1)-(2), the applicant shall seek. Where a certified Economic Empowerment Priority Applicant seeks approval by the Commission of a change in ownership or control, approval by the Commission of a change in ownership or control, and must undergo the approval process provided therein prior to making a change in ownership or control.

- In order to maintain its status as an Economic Empowerment Priority Applicant, the Economic Priority Applicant in its submission must demonstrate that it continues to qualify as an Economic Empowerment Priority Applicant, as defined in 935 CMR 500.002.
- On receipt of notice and a request for approval under 935 CMR 500.104, the Commission shall review anew the applicant's eligibility for economic empowerment certification status.
- If the qualifications are no longer are met subsequent to the approved change, the applicant will no longer be certified as an Economic Empowerment Priority Applicant and will no longer receive any benefits stemming from that designation.
- The applicant may still seek approval of a change of ownership or control.



## **Topic: Persons or Entities with Direct Control**

Recommendations: Update the definition of Persons or Entities with Direct Control by

- 1. changing subsection (d)(2) to encompass the equivalent of a Director in a business entity such as a Limited Liability Company, which has Managers in lieu of a Board of Directors.
- changing subsection (d)(5) to set a bright line dollar amount with respect to what the Commission considers "significant contracts;" and
- 3. explicitly including persons or entities appointed as a receiver as having direct control.

## 500.002: Definitions

<u>Persons or Entities Having Direct Control</u> means any person or entity having direct control over the operations of a Marijuana Establishment, which satisfies one or more of the following criteria:

- (a) An Owner that possesses a financial interest in the form of equity of 10% or greater in a Marijuana Establishment;
- (b) A Person or Entity that possesses a voting interest of 10% or greater in a Marijuana Establishment or a right to veto significant events;
- (c) A Close Associate;
- (d) A Person or Entity that has the right to control or authority, through contract or otherwise including, but not limited to:
  - $1. \ \ to make decisions regarding operations and strategic planning, capital allocations, acquisitions and divestments;$
  - 2. to appoint more than 50% of the directors or their equivalent;
  - 3. to appoint or remove Corporate-level officers or their equivalent;
  - 4. to make major marketing, production, and financial decisions;
  - 5. to execute significant (in aggregate of \$10,000 or greater) or exclusive contracts; or
  - 6. to earn 10% or more of the profits or collect more than 10% of the dividends.
- (e) A Person or Entity appointed as a receiver.

## 501.002: Definitions

<u>Persons or Entities Having Direct Control</u> means any person or entity having direct control over the operations of a MTC, which satisfies one or more of the following criteria:



- (a) An Owner that possesses a financial interest in the form of equity of 10% or greater in a MTC;
- (b) A Person or Entity that possesses a voting interest of 10% or greater in a MTC or a right to veto significant events;
- (c) A Close Associate;
- (d) A Person or Entity that has the right to control or authority, through contract or otherwise including, but not limited to:
  - 1. to make decisions regarding operations and strategic planning, capital allocations, acquisitions and divestments;
  - 2. to appoint more than 50% of the directors or their equivalent;
  - 3. to appoint or remove Corporate-level officers or their equivalent;
  - 4. to make major marketing, production, and financial decisions;
  - 5. to execute significant (in aggregate of \$10,000 or greater) or exclusive contracts; or
- 6. to earn 10% or more of the profits or collect more than 10% of the dividends. (f) A Person or Entity appointed as a receiver.



## **Topic: Notification and Approval of Changes**

<u>Recommendation</u>: Delegate to the Executive Director certain authority to approve certain applicant/licensee changes and adding a new subsection to spell out the types of changes the Executive Director is authorized to approve.

### 500.104 - Notification and Approval of Changes

- (1) Prior to making the following changes, the Marijuana Establishment shall submit a request for such change to the Commission and pay the appropriate fee. No such change shall be permitted until approved by the Commission or in certain cases, the Commission has delegated authority to approve changes to the Executive Director. Failure to obtain approval of such changes may result in a license being suspended, revoked, or deemed void.
  - (a) <u>Location Change</u>. Prior to changing its location, a Marijuana Establishment shall submit a request for such change to the Commission.
  - (b) Ownership or Control Change.
    - 1. Ownership Change. Prior to any change in ownership, where an Equity Holder acquires or increases its ownership to 10% or more of the equity or contributes 10% or more of the initial capital to operate the Marijuana Establishment, including capital that is in the form of land or buildings, the Marijuana Establishment shall submit a request for such change to the Commission.
    - 2. <u>Control Change</u>. Prior to any change in control, where a new Person or Entity Having Direct or Indirect Control should be added to the license, the Marijuana Establishment shall submit a request for such change to the Commission prior to effectuating such a change. An individual, corporation, or entity shall be determined to be in a position to control the decision-making of a Marijuana Establishment if the individual, corporation, or entity falls within the definition of Person or Entity Having Direct or Indirect Control.
    - 3. <u>Priority Applicants Change in Ownership or Control</u>. Where a certified Economic Empowerment Priority Applicant seeks approval by the Commission of a change in ownership or control, the applicant must undergo the approval process provided by 935 CMR 500.104 prior to making a change in ownership or control.



- a. In order to maintain its status as an Economic Empowerment Priority Applicant, the Economic Priority Applicant in its submission must demonstrate that it continues to qualify as an Economic Empowerment Priority Applicant, as defined in 935 CMR 500.002.
- b. On receipt of notice and a request for approval under 935 CMR 500.104, the Commission shall review anew the applicant's eligibility for economic empowerment certification status.
- c. If the qualifications are no longer are met subsequent to the approved change, the applicant will no longer be certified as an Economic Empowerment Priority Applicant and will no longer receive any benefits stemming from that designation.
- d. The applicant may still seek approval of a change of ownership or control.
- (c) <u>Structural Change</u>. Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of the Marijuana Establishment, the establishment shall submit a request for such change to the Commission.
- (d) Name Change. Prior to changing its name, the Marijuana Establishment shall submit a request for such change to the Commission. Name change requests, and prior approval, shall apply to an establishment proposing a new or amending a current doing-business-as name.

  (e) Receiverships. Notification and approval of receiverships provisions are detailed in 935 CMR 500.XXX.
- (2) The Executive Director of the Commission may approve, provided the Executive Director gives the Commission timely notice of his decision:
  - (a) a Location Change;
  - (b) a Name Change;
  - (c) any new equity owner, provided that the equity acquired is below 10%;
  - (d) any new Executive or Director, provided that the equity acquired is below 10%;
  - (e) a reorganization, provided that the ownership and their equity does not change; and
  - (f) Receiverships, as detailed in 935 CMR 500.XXX.
- (3) The Marijuana Establishment shall keep current all information required by 935 CMR 500.000 or otherwise required by the Commission. The Marijuana Establishment 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.



### 501.104 - Notification and Approval of Changes

- (1) Prior to making the following changes, the MTC shall submit a request for such change to the Commission and pay the appropriate fee. No such change shall be permitted until approved by the Commission or in certain cases, the Commission has delegated authority to approve changes to the Executive Director. Failure to obtain approval of such changes may result in a license being suspended, revoked, or deemed void.
  - (a) <u>Location Change</u>. Prior to changing its location, the MTC shall submit a request for such change to the Commission.
  - (b) Ownership or Control Change.
    - 1. <u>Ownership Change</u>. Prior to any change in ownership, where an Equity Holder acquires or increases its ownership to 10% or more of the equity or contributes 10% or more of the initial capital to operate the MTC, including capital that is in the form of land or buildings, the MTC shall submit a request for such change to the Commission.
    - 2. <u>Control Change</u>. Prior to any change in control, where a new Person or Entity Having Direct or Indirect Control should be added to the License, the MTC shall submit a request for such change to the Commission prior to effectuating such a change. An individual, corporation, or entity shall be determined to be in a position to control the decision-making of an MTC if the individual, corporation, or entity falls within the definition of Person or Entity Having Direct or Indirect Control.
  - (c) <u>Structural Change</u>. Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of the MTC, the establishment shall submit a request for such change to the Commission.
  - (d) <u>Name Change</u>. Prior to changing its name, the MTC shall submit a request for such change to the Commission. Name change requests, and prior approval, shall apply to an establishment proposing a new or amending a current doing-business-as name.
  - (e) Receiverships. Notification and approval of receiverships provisions are detailed in 935 CMR 501.XXX.
- (2) The Executive Director of the Commission may approve, provided the Executive Director gives the Commission timely notice of his decision:
  - (a) a Location Change;
  - (b) a Name Change;
  - (c) any new equity owner, provided that the equity acquired is below 10%;



(d) any new Executive or Director, provided that the equity acquired is below 10%; (e) a reorganization, provided that the ownership and their equity does not change; and (f) Receiverships, as detailed in 935 CMR 50X.XXX.

(23) The MTC shall keep current all information required by 935 CMR 501.000 or otherwise required by the Commission. The MTC shall report any changes in or additions to the content of the information contained in any document to the Commission within five business days after such change or addition.



## **Topic: Receivership**

Recommendation: Establish a process for circumstances where Marijuana Establishments (MEs) and Medical Marijuana Treatment Centers (MTCs) are placed under the control of a receiver by a Massachusetts court or otherwise designated, including requiring notice and (pre)approval by the Commission.

## [NEW SECTION] 500.XXX: Receiverships

### (1) Service and notice.

(a) Any person who files any receivership or trustee action involving any Marijuana Establishment Licensee must serve the Commission with original notice of the action and otherwise comply with requirements for service established under federal and state law, which include, but are not limited to, Mass. R. Civ. P. 4 (d)(3), as amended, 370 Mass. 918 (1976).

1. Service to the Commission is accomplished by delivery of the original notice of action to the Cannabis Control Commission at:

<u>Union Station</u>
2 Washington Square
Worcester, MA 01604.

## Mailed notice must be addressed to:

<u>Cannabis Control Commission, ATTN: Executive Director, General Counsel, and Licensing – Receiverships.</u>

(b) Only if the Commission receives original notice of the action and the receiver is selected in accordance with the Commission's requirements will the Commission treat the licensee as compliant with this section.



- (2) The role of a receiver when a licensee is placed in receivership. If a marijuana licensee is placed under receivership, the receiver:
  - (a) Upon compliance with the requirements set forth below, the receiver may operate the licensee's business during the receivership period;
  - (b) The receiver assumes all licensee reporting responsibilities under this chapter including, but not limited to, full responsibility for maintaining records and entries into the seed-to-sale tracking software maintained by the Commission; and
  - (c) The receiver is required to comply with all applicable laws under St. 2017, c. 55, An Act to Ensure Safe Access to Marijuana, M.G.L. c. 94G, 94I, and regulations of the Commission setting forth the responsibilities of Marijuana Establishment Licensees, including, but not limited to, the general operational requirements for Marijuana Establishments required under 935 CMR 500.105, security requirements under 935 CMR 500.110, and any other applicable additional operational requirements.
  - (d) Failure to abide by the requirements set forth in M.G.L. c. 94G, 94I, and the regulations of the Commission as specified in this subsection may result in enforcement action against the license under M.G.L. c. 94G, 94I, and the regulations of the Commission and may result in the receiver being disqualified to act as a receiver by the Commission.
- (3) Who may serve as a receiver. Any person who is appointed as a receiver under M.G.L. c. 155, 156, or 156D and meets the following additional requirements may serve as a receiver:
  - (a) Is currently in active status on the preapproved receiver list maintained by the Commission; or
  - (b) Is approved by the Commission under the requirements in subsection (5) of this section to serve as a receiver of a marijuana licensee.
- (4) Qualifying for the Commission's preapproved receiver list.
  - (a) The following requirements must be met to qualify for the Commission's preapproved receiver list:
    - 1. Submit a complete receiver application with the Commission;
    - 2. Be an individual who is a Massachusetts resident for at least six months, or a foreign or domestic business entity authorized to conduct business in the



Commonwealth pursuant to M.G.L. c. 156D prior to the application for preapproval as a receiver and maintain residency or status throughout the term of the receivership; 3. Submit to and pass a criminal background check in accordance with 935 CMR 500.030, 500.101, and 500.105;

- 4. Provide any financial disclosures requested by the Commission; and
- 5. Disclose any interests the person or entity has in any marijuana licensee(s).

  (b) Review and qualification requirements in this subsection only apply to persons or entities actively participating in the management of the receivership and do not apply to spouses of those persons or persons involved in a business entity or fellow members of a business entity that are not actively involved in the management of the receivership.

  (c) A receiver placed on the preapproved receiver list maintained by the Commission must annually update all information and disclosures required under this subsection to remain eligible to act as a receiver and be on the preapproved receiver list. Annual updates must be made one calendar year after the date the receiver is approved.
- (5) Appointing a receiver who is not preapproved by the Commission.
  - (a) Within two days of filing of any action to appoint a receiver, a proposed receiver must:
    - 1. Submit a complete application with the Commission to serve as receiver for the licensee;
    - 2. Be an individual who is a Massachusetts resident for six months, or a foreign or domestic business entity authorized to conduct business in the Commonwealth pursuant to M.G.L. 156D prior to appointment as a receiver and maintain residency or status throughout the term of the receivership;
    - 3. Submit to and pass a criminal background check in accordance with this 935 CMR 500.029, 500.030, 500.101, and 500.105.
    - 4. Provide any financial disclosures requested by the Commission; and
    - 5. Disclose any interest the proposed receiver has in any marijuana licensee(s).
  - (b) Review and qualification requirements in this subsection only apply to persons or entities actively participating in the management of the receivership and do not apply to spouses of those persons or persons involved in a business entity or fellow members of a business entity that are not actively involved in the management of the receivership.



- (c) If the proposed receiver is denied approval by the Commission at any time, a substitute receiver may be proposed for Commission approval. The substitute receiver must provide all information required by this subsection.
- (d) If the proposed receiver is not approved by the Commission at the time the receiver is appointed by the court, the receiver or Licensee will not be considered compliant with this section, and may be subject to penalty under M.G.L. c. 94G, 94I, or as provided in this chapter and may result in the receiver being disqualified to act as a receiver by the Commission.
- (6) Limitations on a person's ability to serve as a receiver.
  - (a) As operators and controllers of licensed marijuana establishments, receivers are subject to the same limits as licensees or any other person. Those limits include, but are not limited to:
    - 1. No person serving as a receiver of a licensed marijuana producer or licensed marijuana processor shall have a financial interest in, or simultaneously serve as a receiver for, a licensed marijuana retailer; and
    - 2. No person shall serve as a receiver for, or be a true party of interest in, more than three licenses of a particular class at the same time.
  - (b) If the Commission determines that a receiver is violating or has violated the restrictions in this subsection, the receiver may be disqualified to act as a receiver by the Commission.
- (7) Delegation of Authority. The authority to preapprove or approve receivers is delegated to the Executive Director. The Executive Director may determine the form and manner of this process.

## [NEW SECTION] 501.XXX: Receiverships

#### (1) Service and notice.

(a) Any person who files any receivership or trustee action involving any MTC Licensee must serve the Commission with original notice of the action and otherwise comply with requirements for service established under federal and state law, which include, but are not limited to, Mass. R. Civ. P. 4 (d)(3), as amended, 370 Mass. 918 (1976).



1. Service to the Commission is accomplished by delivery of the original notice of action to the Cannabis Control Commission at:

<u>Union Station</u>
2 Washington Square
Worcester, MA 01604.

#### Mailed notice must be addressed to:

<u>Cannabis Control Commission</u>
ATTN: Executive Director, General Counsel, Licensing – Receiverships.

(b) Only if the Commission receives original notice of the action and the receiver is selected in accordance with the Commission's requirements will the Commission treat the licensee as compliant with this section.

- (2) The role of a receiver when a licensee is placed in receivership. If a marijuana licensee is placed under receivership, the receiver:
  - (a) Upon compliance with the requirements set forth below, the receiver may operate the licensee's business during the receivership period;
  - (b) The receiver assumes all licensee reporting responsibilities under this chapter including, but not limited to, full responsibility for maintaining records and entries into the seed-to-sale tracking software maintained by the Commission; and
  - (c) The receiver is required to comply with all applicable laws under St. 2017, c. 55, *An Act to Ensure Safe Access to Marijuana*, M.G.L. c. 94G, 94I, and regulations of the Commission setting forth the responsibilities of MTC Licensees, including, but not limited to, the general operational requirements for Marijuana Establishments required under 935 CMR 501.105, security requirements under 935 CMR 501.110, and any other applicable additional operational requirements.
  - (d) Failure to abide by the requirements set forth in M.G.L. c. 94G, 94I, and the regulations of the Commission as specified in this subsection may result in enforcement action against the license under M.G.L. c. 94G, 94I, and the regulations of the Commission and may result in the receiver being disqualified to act as a receiver by the Commission.



- (3) Who may serve as a receiver. Any person who is appointed as a receiver under M.G.L. c. 155, 156, or 156D and meets the following additional requirements may serve as a receiver:
  - (a) Is currently in active status on the preapproved receiver list maintained by the Commission; or
  - (b) Is approved by the Commission under the requirements in subsection (5) of this section to serve as a receiver of a marijuana licensee.
- (4) Qualifying for the Commission's preapproved receiver list.
  - (a) The following requirements must be met to qualify for the Commission's preapproved receiver list:
    - 1. Submit a complete receiver application with the Commission;
    - 2. Be an individual who is a Massachusetts resident for at least six months, or a foreign or domestic business entity authorized to conduct business in the Commonwealth pursuant to M.G.L. 156D prior to the application for preapproval as a receiver and maintain residency or status throughout the term of the receivership;

      3. Submit to and pass a criminal background check in accordance with 935 CMR
    - 3. Submit to and pass a criminal background check in accordance with 935 CMR 501.029, 501.030, 501.101, and 501.105;
    - 4. Provide any financial disclosures requested by the Commission; and
    - 5. Disclose any interests the person or entity has in any marijuana licensee(s).
  - (b) Review and qualification requirements in this subsection only apply to persons or entities actively participating in the management of the receivership and do not apply to spouses of those persons or persons involved in a business entity or fellow members of a business entity that are not actively involved in the management of the receivership.

    (c) A receiver placed on the preapproved receiver list maintained by the Commission must annually update all information and disclosures required under this subsection to remain eligible to act as a receiver and be on the preapproved receiver list. Annual updates must be made one calendar year after the date the receiver is approved.
- (5) Appointing a receiver who is not preapproved by the Commission.(a) Within two days of filing of any action to appoint a receiver, a proposed receiver must:



- 1. Submit a complete application with the Commission to serve as receiver for the licensee;
- 2. Be an individual who is a Massachusetts resident for six months, or a foreign or domestic business entity authorized to conduct business in the Commonwealth pursuant to M.G.L. c. 156D prior to appointment as a receiver and maintain residency or status throughout the term of the receivership;
- 3. Submit to and pass a criminal background check in accordance with this 935 CMR 501.030, 501.101, and 501.105.
- 4. Provide any financial disclosures requested by the Commission; and
- (b) Review and qualification requirements in this subsection only apply to persons or entities actively participating in the management of the receivership and do not apply to spouses of those persons or persons involved in a business entity or fellow members of a

5. Disclose any interest the proposed receiver has in any marijuana licensee(s).

- business entity that are not actively involved in the management of the receiverships (c) If the proposed receiver is denied approval by the Commission at any time, a substitute receiver may be proposed for Commission approval. The substitute receiver must provide all information required by this subsection.
- (d) If the proposed receiver is not approved by the Commission at the time the receiver is appointed by the court, the receiver or Licensee will not be considered compliant with this section, and may be subject to penalty under M.G.L. c. 94G, 94I, or as provided in this chapter and may result in the receiver being disqualified to act as a receiver by the Commission.

#### (6) Limitations on a person's ability to serve as a receiver.

- (a) As operators and controllers of licensed marijuana establishments, receivers are subject to the same limits as licensees or any other person. Those limits include, but are not limited to:
  - 1. No person serving as a receiver of a licensed marijuana producer or licensed marijuana processor shall have a financial interest in, or simultaneously serve as a receiver for, a licensed marijuana retailer; and
  - 2. No person shall serve as a receiver for, or be a true party of interest in, more than three licenses of a particular class at the same time.



(b) If the Commission determines that a receiver is violating or has violated the restrictions in this subsection, the receiver may be disqualified to act as a receiver by the Commission.

(7) Delegation of Authority. The authority to preapprove or approve receivers is delegated to the Executive Director. The Executive Director may determine the form and manner of this process.



# Topic: Craft Marijuana Cooperatives

<u>Recommendation</u>: Open up the restriction on farmer involvement by allowing a craft marijuana cooperative to rent land from a farmer who has filed a Schedule F tax form within the past 5 years instead of having the farmer be a member of the cooperative.

#### 500.050: Marijuana Establishments

- (3) Craft Marijuana Cooperative.
  - (a) A Craft Marijuana Cooperative may be organized as a limited liability company, limited liability partnership, or a cooperative corporation under the laws of the Commonwealth.
  - (b) The Members or shareholders of the cooperative must be residents of the Commonwealth for the 12 months immediately preceding the filing of an application for a license.
  - (c) The Craft Marijuana Cooperative shall have:
    - 1. One Member that has of the Craft Marijuana Cooperative shall have filed a Schedule F (Form 1040), Profit or Loss from Farming, within the five years prior to application for licensure; or
    - 2. An agreement to lease land wholly owned by a person or entity that has filed a Schedule F (Form 1040), Profit or Loss from Farming, within the five years prior to application for licensure-
  - (d) Where the agreement to lease land in 935 CMR 500.050(3)(c)2. renders the individual or entity filing a Schedule F (Form 1040) a Person or Entity Having Direct or Indirect Control, the Craft Marijuana Cooperative shall report the individual or entity and submit the agreement, as required by 935 CMR 500.101(1)(a)(1).
  - (ed) The Craft Marijuana Cooperative must operate consistently with the Seven Cooperative Principles established by the International Cooperative Alliance in 1995.
  - (fe) The cooperative license authorizes it to cultivate, obtain, Manufacture, Process, package, brand and Transfer Marijuana Products and to deliver Marijuana to Marijuana Establishments, but not to Consumers



- (gf) The Craft Marijuana Cooperative is limited to one license, under which it may cultivate Marijuana, subject to the limitations of 935 CMR 500.050. The cooperative's total locations are limited to cultivating 100,000 square feet of Canopy. A cooperative is not limited in the number of cultivation locations it may operate, provided that for each location over six locations, additional application and licensing fees shall apply pursuant to 935 CMR 500.0505(3)(d). The cooperative may also conduct activities authorized for Marijuana Product Manufacturers at up to three locations.
- (hg) For the Seed-to-sale SOR, a cooperative that designates a system administrator will pay one licensing program fee on a monthly basis for Seed-to-sale tracking software.
- (ih) Members of a cooperative shall not be a Person or Entity Having Direct or Indirect Control in any other Marijuana Establishment. Such restriction shall not be construed to prohibit a Craft Marijuana Cooperative for applying for a Marijuana Retailer, Marijuana Existing Licensee Transporter, Marijuana Research or Marijuana Social Consumption Establishment License.



# Topic: Marijuana Research Facility License and Research Permit

- Establishes process for applying to conduct research using regulated sources of Marijuana or Marijuana Products cultivated, produced or sold by licensed MEs or MTCs in Massachusetts.
- 2. Add \$1000 fee for Research Permit to the fee schedule in 500.005.
- 3. Establishes what is allowed for research.
- 4. Establishes Research Permit as requirement to conduct research and establishes what is necessary to apply for and receive a Research Permit.

#### 500.002: Definitions

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

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

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

Marijuana Research Facility-means the Premises at which a Marijuana Research Facility Licensee is approved to conduct research an entity licensed to engage in research projects by the Commission.

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

Research Permit means a certificate indicating Commission approval to conduct a specified research project over a specified and finite period of time. To the extent that a Research Licensee is subject to



other IRB, institutional, industry, or professional standards, they shall demonstrate compliance with those standards.

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

## 500.005: Fees

- (1) <u>Marijuana Establishment Application and License Fees</u>.
- [...]
  - (d) Application and Annual License Fee Schedule.

License Types	Application Fees (Indoor/Outdoor)	Annual License Fee (Indoor/Outdoor)
Marijuana Cultivator		
(Indoor or Outdoor)		
Tier 1: up to 5,000 square feet Tier 2:	\$200 (I)/\$100 (O)	\$1,250 (I)/\$625 (O)
5,001 to 10,000 sq. ft.	\$400 (I)/\$200 (O)	\$2,500 (I)/\$1,250 (O)
Tier 3: 10,001 to 20,000 sq. ft.	\$600 (I)/\$300 (O)	\$5,000 (I)/\$2,500 (O)
Tier 4: 20,001 to 30,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$20,000 (I)/\$10,000 (O)
Tier 5: 30,001 to 40,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$22,500 (I)/\$11,250 (O)
Tier 6: 40,001 to 50,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$25,000 (I)/\$12,500 (O)
Tier 7: 50,001 to 60,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$30,000 (I)/\$15,000 (O)
Tier 8: 60,001 to 70,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$35,000 (I)/\$17,500 (O)
Tier 9: 70,001 to 80,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$40,000 (I)/\$20,000 (O)
Tier 10: 80,001 to 90,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$45,000 (I)/\$22,500 (O)
Tier 11: 90,0001 to 100,000 sq. ft.	\$2,000 (I)/\$1,500 (O)	\$50,000 (I)/\$25,000 (O)



Craft Marijuana Cooperative	Total fees for its Canopy.	Total fees for its
	If more than six locations,	Canopy.
	add	If more than six locations,
	\$200 (I)/\$100(O)	add
	per additional location.	\$1,250(I)/\$625(O)
		per additional location.
Marijuana Product Manufacturing	\$1,500	\$10,000
Marijuana Microbusiness	\$1,000	50% of
		all applicable license fees
Independent Testing Laboratory	\$1,500	\$10,000
Marijuana Retailer (brick-and-	\$1,500	\$10,000
mortar)		
Social Consumption Establishment	\$1,500	\$10,000
Marijuana Transporter:	\$1,500	\$5,000
Third-party Transporter		
Marijuana Transporter: Existing	\$1,000	\$5,000
Licensee Transporter		
Marijuana Delivery-only Licensee	\$1,500	\$10,000
Marijuana Establishment with a	\$500	\$5,000
Delivery Endorsement		
Marijuana Research Facility	\$300	\$1,000
Marijuana Research Permit	\$1,000	

# 500.050: Marijuana Establishments

[...]

(11) <u>Marijuana Research Facility Licensee</u>.



- (a) A Marijuana Research Facility <u>Licensee</u> may eultivate, purchase or otherwise acquire Marijuana for the purpose of conducting research regarding Marijuana Products conduct research after receiving approval from the Commission. A license to operate a Marijuana Research Facility shall be separate from receipt of a Research Permit to conduct a specific research project at the Marijuana Research Facility.
- (b) A <u>Marijuana Research Facility Licensee</u> may be an academic institution, nonprofit corporation or domestic corporation or entity authorized to do business in the Commonwealth, including a <u>licensed Marijuana Establishment or MTC</u>.
- (c) Any research involving humans must be authorized by an Institutional Review Board. Unless otherwise authorized by law, any Marijuana Research Facility Licensee that is not licensed pursuant to 935 CMR 500.050 or 935 CMR 501.050 to engage in the cultivation, production or retail sale of Marijuana or Marijuana Products shall acquire all Marijuana or Marijuana Products used in research from a Marijuana Establishment or MTC licensed to engage in such activity.
- (d) A Marijuana Research Facility may be colocated with another Marijuana Establishment or MTC license provided that the Marijuana Research Facility and the colocated licensed Marijuana Establishment or MTC are:
  - 1. Commonly owned; and
  - 2. Clearly physically separated.
- (ed) A Marijuana Research Facility Licensee may not Transfer Marijuana or Marijuana Products to another Marijuana Establishment, other than for testing, or sell to a Consumer, Registered Qualifying Patient or Caregiver Marijuana or Marijuana Products that has been cultivated acquired for a research project under its Marijuana Research Facility Llicense.

(e) All research regarding Marijuana must be conducted by individuals 21 years of age or older.

[NEW SECTION] 500.XXX Operational Requirements for Marijuana Research Facility Licensees and Research Permits.



(1) In addition to the security requirements provided in 935 CMR 500.110, Marijuana Research Facility Licensees shall comply with the operational requirements required under 935 CMR 500.XXX.

## (2) General Requirements

- (a) For each research project to be conducted on the Premises, a Marijuana Research Facility Licensee shall have a valid Research Permit issued by the Commission pursuant to 500.XXX(4) prior to beginning a research project. The Research Permit shall be renewed at least annually, or sooner depending on the nature and duration of the approved research project.
- (b) All individuals engaging in research at the Marijuana Research Facility shall be registered with the Commission as Marijuana Establishment Agents under 935 CMR 500,030.
- (c) A Marijuana Research Facility Licensee may submit an application for a Research Permit to conduct research in areas including, but not limited to, the following:
  - Chemical potency and composition levels of Marijuana and Marijuana Products;
  - ii. Clinical investigations of Marijuana Products, including dosage forms;
  - <u>iii.</u> Efficacy and safety of administering Marijuana or Marijuana Products as a component of medical treatment under the supervision of a Certifying Healthcare Provider;
  - iv. Genomic research on Marijuana;
  - v. Horticultural research on Marijuana;
  - vi. Agricultural research on Marijuana; and
  - vii. Other research topics upon the approval of the Commission, provided
     however that research conducted under the Marijuana Research Facility
     License shall not be a substitute for processes for drug approval established
     by the U.S. Food and Drug Administration (FDA) pursuant to 21 CFR 312.
- (d) Marijuana or Marijuana Products used in research conducted under a Marijuana Research Facility License shall be cultivated by, produced by or acquired from a licensed MTC or Marijuana Establishment authorized to cultivate, produce or sell Marijuana or Marijuana Products, which includes a Marijuana Cultivator, Marijuana Product Manufacturer, Marijuana Retailer, a Microbusiness or a Craft Marijuana Cooperative. A Marijuana Research Facility Licensee not authorized to cultivate its



- own Marijuana may enter into an agreement with a licensed MTC or Marijuana Cultivator, Microbusiness or Craft Marijuana Cooperative to grow Marijuana specifically for research.
- (e) Any Marijuana or Marijuana Product cultivated, produced or acquired for use in a Commission-approved research project shall be entered by the Marijuana Establishment providing it to the Marijuana Research Facility into the Seed-to-Sale SOR in a form and manner to be determined by the Commission.
- (f) All Marijuana or Marijuana Products used in research and consumed by human or animal subjects must comply with the following
  - i. Be adequately described in the Informed Consent Form.
  - ii. Tested in accordance with 935 CMR 500.160 prior to consumption by human or animal subjects.
- (g) Any research project where human research subjects are participants shall include one or more licensed physicians in good standing to monitor the participants.
- (h) For any research project other than a survey-only research project, human participants in research conducted by a Marijuana Research Facility Licensee where consumption of Marijuana or Marijuana Products is a component of the research project design shall reside in the Commonwealth.
- (i) Any research project where animal research subjects are participants shall include one or more licensed veterinary doctors in good standing to monitor the participants.
- (j) For any research project other than a survey-only research project, research conducted pursuant to a license granted by the Commission shall be conducted solely within the boundaries of the Commonwealth.
- (k) A Marijuana Research Facility shall supply the Commission with copies of all final reports, findings or documentation regarding the outcomes of approved research projects receiving a Research Permit. Any records received by the Commission may be subject to release pursuant to the Public Records Law, M.G.L. c. 66, § 10 and M.G.L. c. 4, § 7, cl. 26, or other compulsory legal process, or at the Commission's discretion.
- (3) Marijuana Research Facility Activities and Premises.



- (a) A Marijuana Research Facility Licensee may conduct research at one or more than one Marijuana Research Facility so long as the facility is approved by the Commission.
- (b) A Marijuana Research Facility may be colocated with another Marijuana Establishment provided that the Marijuana Research Facility and other, colocated Marijuana Establishment(s) are commonly owned and physically separated. Physical separation shall include, but may not be limited to, separation by a permanent wall with a secure, locked entrance.
- (c) A Marijuana Research Facility shall only possess for research the amount of Marijuana or Marijuana Products approved by the Commission to be used in each research project receiving a Research Permit.
- (d) A Marijuana Research Facility with more than one Research Permit shall physically separate all Marijuana or Marijuana Products used in the Licensee's approved research projects according to Research Permit and in such a way that it is objectively clear what Marijuana or Marijuana Products are being used for each approved project.
- (e) One or more Marijuana Research Facility Licensees may enter into agreements to conduct research jointly on an identified research project, provided that research activities authorized under the Research Permit shall be conducted at one identified, licensed Marijuana Research Facility's Premises. The Marijuana Research Facility Licensees shall disclose to the Commission all contracts or agreements entered into with other Marijuana Research Facility Licensees in furtherance of a research project.
- (f) A Marijuana Research Facility shall not permit the consumption of Marijuana or Marijuana Products on its licensed Premises, unless consumption of Marijuana is part of an approved research project holding a valid Research Permit and the Marijuana Research Facility is not co-located with another Marijuana Establishment.

#### (4) Research Permits

(a) To qualify for a Research Permit to conduct human- or animal-based research, the research project shall have an Institutional Review Board ("IRB") which shall approve the proposed research project.



- (b) Applicants for a Research Permit to conduct research at a Marijuana Research
  Facility shall submit for each project the following information to the Commission in
  a form and manner determined by the Commission:
  - The name and curriculum vitae (CV) of each investigator, including the Principal Investigator who leads the research project and each subinvestigator;
  - ii. The name of each licensed physician in good standing that will lead the project as Principal Investigator, be a sub-investigator, or monitor the participation by human subjects, if any, in the research project;
  - iii. The name of each licensed veterinary doctor in good standing that will lead the project as Principal Investigator, be a sub-investigator, or monitor the participation by animal subjects, if any, in the research project;
  - iv. The IRB Institution, if applicable;
  - v. A publication-ready summary of the research project to be conducted;
  - vi. A detailed research protocol, including safety protocols;
  - vii. Articulated goals of the research project;
  - viii. Start and end dates of the research project;
  - ix. A description of the project funding or resources, an attestation that the project is adequately funded or resourced, and the sources of funding or resources;
  - x. Information about the human subject participants, if any, which shall include but not be limited to:
    - 1. The number of participants;
    - 2. The number of Registered Qualifying Patients, if any;
    - 3. Demographic information about the participants;
    - 4. The ages of the participants; and
    - Any cohort deemed "vulnerable" and applicable safety precautions (e.g. pregnant/breastfeeding women, minors, disable veterans, etc.).
    - A copy of the Informed Consent Form or Waiver of Consent, if applicable; and
    - Documentation that the process of obtaining Informed Consent complied with the Research Licensee's other IRB, institutional, industry, or professional standards.



- xi. The quantity of Marijuana or Marijuana Products anticipated to be needed over the duration of the research project;
- xii. The Independent Testing Laboratory where the Marijuana or Marijuana Products will be tested;
- xiii. The name and license number of the licensed Marijuana Research Facility or facilities where the research project will take place, provided that if a license has not yet been granted to the Marijuana Research Facility, the Research Permit applicant will still identify the facility and provide its application number;
- xiv. The disposal protocol for Marijuana or Marijuana Products that are unused;
- xv. Disclosures of any actual or apparent conflicts of interest between any Marijuana Research Facility Licensee or Agent and any member of the IRB required by 935 CMR 500.XXX(4)(b)iv.
- xvi. Application Fee
- (c) The information required in 935 CMR 500.XXX(4)(b) to qualify for a Research Permit may, but is not required to, be submitted with an application for licensure as a Marijuana Research Facility.
- (d) Prior to receiving a Research Permit for a research project that includes human or animal participants as subjects, the applicant shall submit evidence of approval of the project by the identified IRB. Evidence of IRB approval or exemption may be submitted separately from the information required in 935 CMR 500.XXX(4)(b), but must be submitted to receive a Research Permit.
- (e) Materials submitted in support of an application for a permit that are received by the Commission may be subject to release pursuant to the Public Records Law, M.G.L. c. 66, § 10 and M.G.L. c. 4, § 7, cl. 26, or other compulsory legal process, or at the Commission's discretion.

## (5) Research Permit Approval.

- (a) When evaluating an application for a Research Permit to conduct a research project at a licensed Marijuana Research Facility the Commission or its delegee(s) shall consider:
  - i. Whether the research project is allowed under 935 CMR 500.XXX (2)(c):
  - ii. The adequacy of safety protocols detailed in 935 CMR 500.XXX(3)(b)(vii);



- iii. The research project design;
- iv. Whether the research project is adequately funded or resourced and the sources of the funding or resources;
- Whether the amount of Marijuana or Marijuana Products anticipated to for growth or use during the duration of the research project is consistent with the proposed research project's scope, goals, aims and the protocols for tracking the amount used;
- vi. Disclosures of agreements between licensed Marijuana Research Facilities and the nature of those agreements; and
- vii. Whether a required IRB is affiliated with an accredited academic institution, licensed healthcare institution or other licensed research institution and, if not, may require additional information regarding the sufficiency of the IRB as it relates to the proposed research project.
- (b) Prior to issuing a Research Permit, the Commission or its delegee shall consider whether sufficient evidence of approval of the research project by the identified IRB has been provided.
- (c) Research Permits shall not require a vote of the Commission prior to issuance.
- (d) As set forth in 935 CMR 500.840: *Non-conflict with Other Laws*, the issuance of a Research Permit shall not give immunity under federal law or poses an obstacle to federal enforcement of federal law.

## (6) Denial of Research Permits.

- (a) The Commission or its delegee may deny an application for a Research Permit for any of the following reasons, provided that a written denial including the reason for the denial shall be issued to the applicant(s):
  - i. No IRB approval;
  - ii. Failure to provide adequate information regarding the IRB;
  - iii. Proposed research poses a danger to public health or safety;
  - iv. Proposed research lacks scientific value or validity;
  - v. The applicant for the Research Permit is not qualified to do the research;
  - vi. The Research Permit applicant's protocols or funding or other resources are insufficient to perform the research; or



- vii. Proposed research is otherwise in consistent with the Commission's governing laws.
- (b) The applicant shall not be entitled to an administrative hearing under 935 CMR 500.500 for the denial of a research permit.

#### (7) Inspections and Audits.

- (a) The Commission or its delegee may at its discretion inspect a Marijuana Research Facility.
- (b) The Commission or its delegee may at its discretion require an audit of a research project granted a Research Permit. Reasons for an audit shall include, but are not limited to:
  - The Commission has reasonable grounds to believe that the Marijuana
     Research Facility is in violation of one or more of the requirements set forth in these regulations or present a danger to the public health, safety or welfare;
  - ii. The Commission has reasonable grounds to believe that the activities of the Marijuana Research Facility Licensee or a Marijuana Establishment Agent present a danger to the public health, safety or welfare; or
  - iii. The Commission has reasonable grounds to believe that the Marijuana
    Research Facility Licensee has been or is engaged in research activities that
    have not been approved or permitted by the Commission.



# **Topic: Independent Testing Laboratories—Modifying ISO Certification**

Recommendation: Allow ITL applicants to submit their ISO certification prior to final licensure.

## 500.050: Marijuana Establishments

- (7) Independent Testing Laboratory.
  - (d) Prior to final licensure, aAn Independent Testing Laboratory shall be:
    - 1. Accredited to the most current 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
    - Certified, registered, or accredited by an organization approved by the Commission.

[...]

## **500.101: Application Requirements**

- (3) Additional Specific Requirements.
  - (a) Additional Requirements for Cultivators. [...]
  - (b) Additional Requirements for Craft Marijuana Cooperatives. [...]
  - (c) Additional Requirements for Marijuana Product Manufacturers. [...]
  - (d) Additional Requirements for Microbusinesses. [...]
  - (e) Additional Requirements for Retailers. [...]
  - (f) Additional Requirements for Independent Testing Laboratories. In addition to the requirements set forth in 935 CMR 500.101(c), applicants for a license to operate an Independent Testing Laboratory may provide, as part of the Management and Operations Profile packet, documentation demonstrating accreditation that complies with 935 CMR 500.050(7)(a). If unable to demonstrate accreditation prior to provisional licensure, the applicant shall demonstrate accreditation prior to final licensure.



## 500.103: Licensure and Renewal

- (1) <u>Provisional License</u>. On selection by the Commission, an applicant shall submit the required license fee and subsequently be issued a provisional license to develop a Marijuana Establishment, in the name of the entity. Such provisional license shall be subject to reasonable conditions specified by the Commission, if any.
  - (a) The Commission shall review architectural plans for the building or renovation of a Marijuana Establishment. Construction or renovation related to such plans shall not begin until the Commission has granted approval. Submission of such plans shall occur in a manner and form established by the Commission including, but not limited to, a detailed floor plan of the Premises of the proposed Marijuana Establishment that identifies the square footage available and describes the functional areas of the Marijuana Establishment, including areas for any preparation of Marijuana Products, and, if applicable, such information for the single allowable off-Premises location in Massachusetts where Marijuana will be cultivated or Marijuana Products will be prepared; and a description of plans to ensure that the Marijuana Establishment will be compliant with requirements of the Americans with Disabilities Act (ADA) Accessibility Guidelines.
  - (b) To demonstrate compliance with 935 CMR 500.120(11), a Marijuana Cultivator applicant must also submit an energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation. For a Microbusiness or Craft Marijuana Cooperative with a cultivation location sized as Tier 1 or Tier 2, compliance with any of the requirements of 935 CMR 500.120(11) may be demonstrated through an energy compliance letter prepared by one or more of the following energy professionals:
    - 1. A Certified Energy Auditor certified by the Association of Energy Engineers;
    - $2. \quad A \ Certified \ Energy \ Manager \ certified \ by \ the \ Association \ of \ Energy \ Engineers;$
    - 3. A Massachusetts Licensed Professional Engineer; or
    - 4. A Massachusetts Licensed Registered Architect.
  - (c) A Marijuana Establishment shall construct its facilities in accordance with 935 CMR 500.000, conditions set forth by the Commission in its provisional license and



- architectural review, and any applicable state and local laws, regulations, permits or licenses.
- (d) The Commission may conduct inspections of the facilities, as well as review all written materials required in accordance with 935 CMR 500.000.
- (e) The applicable license fee shall be paid within 90 days from the date the applicant was approved for a provisional license by the Commission. Failure to pay the applicable license fee within the required time frame shall result in the license approval expiring. If this occurs, a new license application will need to be completed pursuant to 935 CMR 500.101 and will require Commission approval.
- (f) To the extent updates are required to the information provided for initial licensure, the Marijuana Cultivator must submit an updated energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with a renewal application submitted under 935 CMR 500.103(4).
- (g) Prior to the issuance of a final license, an Independent Testing Laboratory shall demonstrate compliance with 935 CMR 500.050(7)(a) and provide to the Commission documentation relating to its accreditation.



# **Topic: ME/MTC Agent Registration**

#### Recommendations:

- After considering a 'free Agent model' where the Agent registration runs with the individual rather than the licensee, group recommends no change to the current Agent registration model (Agent registration attaches to the license)
- 2. The first renewal for an Agent occurs after 12 months, and subsequent registration renewals occur every 3 years instead of every year.
- 3. Increase application and renewal fee for ME and laboratory Agents from \$100 to \$115.
- 4. No change to the regulations to address Agents having to carry multiple badges until a technical solution for a single badge is developed or implemented and financial implications of the solution is evaluated. Making changes in the regulations would be too premature as the viability of a technical solution and the financial implications still need to be assessed.
- Amend the MTC Agent registration section of the medical use of marijuana regulations to make it consistent with the requirements under the adult-use section, including matching up paragraph and subparagraph letters and numbers.

# 500.005: Fees

[...]

#### (2) Registration Card Holder Fees.

- (a) An applicant for a Registration Card as a Marijuana Establishment Agent, a Laboratory Agent, or any other position designated as an agent by the Commission shall pay a nonrefundable application fee of \$11500 with any such application.
- (b) An applicant for a renewal of a Registration Card as a Marijuana Establishment Agent, a Laboratory Agent, or any other position designated as an agent by the Commission shall pay a fee of \$11500.

[...]



#### 500.030: Registration of Marijuana Establishment Agents

[...]

(5) An agent Registration Card shall be valid for one year from the date of issue and may be renewed thereafter on an tri-annual basis on a determination by the Commission that the applicant for renewal continues to be suitable for registration.

[...]

(8) A Marijuana Establishment Agent affiliated with multiple Marijuana Establishments shall be registered as a Marijuana Establishment Agent by each Marijuana Establishment and shall be issued an agent Registration Card for each establishment-

[Proposed language to replace (8) above if new card program implemented]

(8) A Marijuana Establishment Agent affiliated with multiple Marijuana Establishments shall be registered as a Marijuana Establishment Agent by each Marijuana Establishment and shall be issued an agent Registration Card by the Commission with a unique identifier indicating all agent registrations that are capable of being validated by Commission recordkeeping software.

## 501.030: Registration of Medical Marijuana Treatment Center Agents

- (1) An MTC shall apply for MTC agent registration for all its board members, directors, employees, Executives, managers, and volunteers who are associated with that MTC. The Commission shall issue an agent Registration Card to each individual determined to be suitable for registration. All such individuals shall:
  - (a) Be 21 years of age or older;



- (b) Have not been convicted of an offense in the Commonwealth involving the distribution of controlled substances to minors, or a like violation of the laws of other jurisdictions; and
- (c) Be determined suitable for registration consistent with the provisions of 935 CMR 500.800: Background Check Suitability Standard for Licensure and Registration and 935 CMR 500.801: Suitability Standard for Licensure or 935 CMR 500.802: Suitability Standard for Registration as a Marijuana Establishment Agent.
- (2) An application for registration of an MTC agent shall include:
  - (a) The full name, date of birth and address of the individual;
  - (b) All aliases used previously or currently in use by the individual, including maiden name, if any;
  - (b)(c) a copy of the applicant's driver's license, government-issued identification card, liquor purchase identification card issued pursuant to M.G.L. c. 138, § 34B, or other verifiable identity document acceptable to the Commission;
  - (e)(d) an attestation that the individual will not engage in the diversion of Marijuana or Marijuana Products;
  - (d)(e) Written acknowledgment by the individual of the limitations on their authorization to cultivate, harvest, prepare, package, possess, transport, and dispense marijuana for medical purposes in the Commonwealth;
  - (f) A copy of the applicant's driver's license, government issued identification card, or other verifiable identity document acceptable to the Commission background information including, as applicable:
    - 1. a description and the relevant dates of any criminal action under the laws of the Commonwealth, or an Other Jurisdiction, whether for a felony or misdemeanor and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;
    - 2. a description and the relevant dates of any civil or administrative action under the laws of the Commonwealth, or an Other Jurisdiction, relating to any professional or occupational or fraudulent practices;

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- 3.a description and relevant dates of any past or pending denial, suspension, or revocation of a license or registration, or the denial of a renewal of a license or registration, for any type of business or profession, by any federal, state, or local government, or any foreign jurisdiction;
- 4. a description and relevant dates of any past discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or an Other Jurisdiction, with regard to any professional license or registration held by the applicant; and
- (e) An attestation that the individual will not engage in the diversion of marijuana or marijuana products;
- (f)(g) A nonrefundable application fee paid by the MTC with which the MTC Agent will be associated; and
- (g)(h) Any other information required by the Commission
- (3) An MTC Executive registered with DCJIS pursuant to 803 CMR 2.04: *iCORI Registration*, shall submit to the Commission a CORI report and any other background check information required by the Commission for each individual for whom the MTC seeks an MTC agent registration, obtained within 30 calendar days prior to submission.
  - (a) The CORI report obtained by the MTC shall provide information authorized under Required Access Level 2 pursuant to 803 CMR 2.05(3)(a)2.
  - (b) The MTC's collection, storage, dissemination and usage of any CORI report or background check information obtained for MTC Agent registrations shall comply with 803 CMR 2.00: Criminal Offender Record Information (CORI).
- (4) An MTC shall notify the Commission no more than one business day after an MTC agent ceases to be associated with the MTC. The registration shall be immediately void when the agent is no longer associated with the MTC.
- (5) An agent Registration Card shall be valid for one year from the date of issue and may be renewed thereafter on a tri-annual basis on a determination by the Commission that the applicant for renewal continues to be suitable for registration. The Commission will accept Registration

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

(6) A Registration Card may be renewed, in a form and manner determined by the Commission, on an annual basis, which includes, but is not limited to, meeting the requirements in 935 CMR 501.030(1) through (3).

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

(87) An MTC agent shall always carry a Registration Card associated with the appropriate Marijuana Establishment while in possession of Marijuana or Marijuana Products, including at all times while at an MTC or while transporting Marijuana or Marijuana Products.

[Proposed language to replace (7) above if new card program implemented]

(7) An MTC Agent affiliated with multiple MTCs shall be registered as an MTC Agent by each MTC and shall be issued an agent Registration Card by the Commission with unique identifier indicating all the individual agent's registrations that are capable of being validated by Commission recordkeeping software.

(9) An MTC agent affiliated with multiple MTCs shall be registered as an MTC agent by each MTC.



# **Topic: Leadership Rating Programs**

#### Recommendations:

- Social Justice Leadership award Clarify existing criterion for a Social Justice Leadership
  Award that contribution to the Social Equity Training and Technical Assistance Fund (or
  similar fund) can be prospective, upon establishment of the fund by the Legislature; adding
  additional criteria, two of which the licensee must satisfy to get the award.
- Energy and Environmental Leadership award Replace current criteria with criterion that the licensee has met the energy and environmental goals in one or more subcategories in compliance with the criteria published in the new Energy & Environment Compiled Guidance.
- 3. Consider adding new category or integrating into employment leader award: employment of veterans no change; Group 1 felt that this would "open up a can of worms" with respect to a whole host of various categories to include for this award.
- 4. Add Leadership Award program to medical Adopt the same Leadership Rating Program in the adult-use regulations (Social Justice Leader; Local Employment Leader; Energy and Environmental Leader; and Compliance Leader), and add new Leader type, "MTC Leader."
- Change criterion under Compliance Leader Rating from 'having no deficiency statements issued' to 'having no unresolved deficiency statements.' This is to reflect the reality that many applicants and licensees receive written deficiency for routine matters that are promptly resolved.
- Incorporate recommendations that the Local Employment Leader rating include supporting other local businesses.

# 500.040: Leadership Rating Program for Marijuana Establishments and Marijuana-related Businesses

- (1) <u>Leadership Rating Categories</u>. In a time and manner to be determined by the Commission, Licensees will be eligible to earn leadership ratings in the following categories:
  - (a) Social Justice Leader;
  - (b) Local Employment Leader;
  - (c) Energy and Environmental Leader; and



#### (d) Compliance Leader.

#### (2) Leadership Rating Application.

- (a) Marijuana Establishments annually submit information, in a time and manner determined by the Commission, demonstrating their eligibility for the applicable leadership rating.
- (b) All information submitted is subject to verification and audit by the Commission prior to the award of a leadership rating.
- (c) Award of a leadership rating in one year does not entitle the applicant to a leadership rating for any other year.

#### (3) Leadership Rating Criteria.

- (a) <u>Social Justice Leader</u>. In the year preceding the date of application for a leadership rating, a <u>Licensee satisfies at least two of the following</u>:
  - 1. Upon the Legislature's establishment of a dedicated Social Equity or Technical Assistance Fund (Fund) or a similar fund, Oone percent of the Marijuana Establishment's gross revenue is donated to the Social Equity Training and Technical Assistance Fund; and
  - 2. The Licensee has conducted 50 hours of educational seminars targeted to residents of Areas of Disproportionate Impact in one or more of the following: Marijuana cultivation, Marijuana Product manufacturing, Marijuana retailing, or Marijuana business training. A Social Justice Leader may use a logo or symbol created by the Commission to indicate its leadership status:
  - 3. The Licensee can demonstrate that a majority of employees are people with a conviction or continuance without a finding for a M.G.L. c. 94C offense under M.G.L. c. 94C or an equivalent conviction in Other Jurisdictions;
  - 4. Sixty-six percent (66%) or more of the Licensees employees are Black, African-American, Latinx, Hispanic, Native American, Asian, Veterans, LGBTQ+, and/or women;
  - 5. The Licensee has developed, and can demonstrate execution of, a Diversity Plan or Positive Impact Plan recognized as exemplary by the Commission, in its sole discretion.
  - 6. The Licensee can demonstrate that at least one percent of its gross revenue or a minimum of 20 hours of each staff member's paid time is contributed to local community development initiatives in a year.



- (b) <u>Local Employment Leader</u>. In the year preceding the date of application for a leadership rating:
  - 1. 51% or more of the Licensee's employees have been a Massachusetts Resident for 12 months or more, as determined by the Commission; and
  - 2. 51% or more of the Licensee's Executives have been a Massachusetts Resident for 12 months or more, as determined by the Commission.
- 3. 3. 51% or more of ancillary business service expenditures purchased by the Licensee have been from businesses with its primary place of businesses within Massachusetts.
- (c) Energy and Environmental Leader. In the year preceding the date of application for a leadership rating, 1. The the Licensee has met or exceeded its the energy and environmental impact goals in one or more subcategories in compliance with criteria published as Appendix B in the Energy & Environment Compiled Guidance: for its registration period;
  - 1. Energy
  - 2. Recycling & Waste Disposal
  - 3. Transportation
  - 4. Delivery
  - 5. Water Usage
  - 6. Soil Sampling
  - 3. The Licensee has consistently documented and complied with best management practices for energy use, waste disposal and environmental impact;
  - 4. The Licensee has documented that renewable energy credits representing 100% of the Licensee's energy usage have been retired; and
  - 5. The Licensee has labeled all their products as being produced using 100% renewable energy.
- (d) <u>Compliance Leader</u>. In the year preceding the date of application for a leadership rating:
  - 1. All Licensee employees have completed all required trainings for their positions within 90 days of hire;
  - 2. The Licensee has not unresolved been issued a written deficiency



#### statements;

- 3. The Licensee has not been the subject of a Cease and Desist Order or a Quarantine Order:
- 4. The Licensee has not had its license suspended; and
- 5. The Licensee has met all timelines required by the Commission.
- (e) Leadership ratings will be taken into consideration by the Commission in assessing fines pursuant to 935 CMR 500.360 and disciplinary action pursuant to 935 CMR 500.450.

#### 501.040: Leadership Rating Program for Medical Marijuana Treatment Centers

- (1) Leadership Rating Categories. In a time and manner to be determined by the Commission, Licensees will be eligible to earn leadership ratings in the following categories:
  - (a) Social Justice Leader;
  - (b) Local Employment Leader;
  - (c) Energy and Environmental Leader;
  - (d) Compliance Leader; and
  - (e) Medical Treatment Center Leader.

## (2) Leadership Rating Application.

- (a) MTCs annually submit information, in a time and manner determined by the Commission, demonstrating their eligibility for the applicable leadership rating.
- (b) All information submitted is subject to verification and audit by the Commission prior to the award of a leadership rating.
- (c) Award of a leadership rating in one year does not entitle the applicant to a leadership rating for any other year.

## (3) Leadership Rating Criteria.

- (a) Social Justice Leader. In the year preceding the date of application for a leadership rating a licensee satisfies at least two of the following:
  - 1. Upon the Legislature's establishment of a dedicated Social Equity or Technical Assistance Fund (Fund) or a similar fund, one percent of the MTC's gross revenue is donated to the Fund. This requirement will not go into effect until



#### such a Fund is created; and

- 2. The Licensee has conducted 50 hours of educational seminars targeted to residents of Areas of Disproportionate Impact in one or more of the following: Marijuana cultivation, Marijuana Product manufacturing, Marijuana retailing, or Marijuana business training. A Social Justice Leader may use a logo or symbol created by the Commission to indicate its leadership status.
- The Licensee can demonstrate that a majority of employees are people with a conviction or continuance without a finding for a M.G.L. c. 94C offense under M.G.L. c. 94C or an equivalent conviction in Other Jurisdictions;
- Sixty-six percent (66%) or more of the Licensees employees are Black, African-American, Latinx, Hispanic, Native American, Asian, Veterans, LGBTQ+, and/or women;
- The Licensee has developed, and can demonstrate execution of, a Diversity Plan
  or Positive Impact Plan recognized as exemplary by the Commission, in its sole
  discretion.
- 6. The Licensee can demonstrate that at least one percent of its gross revenue or a minimum of 20 hours of each staff member's paid time is contributed to local community development initiatives in a year.
- (b) Local Employment Leader. In the year preceding the date of application for a leadership rating:
  - 1. 51% or more of the Licensee's employees have been a Massachusetts Resident for 12 months or more, as determined by the Commission; and
  - 4-2.51% or more of the Licensee's Executives have been a Massachusetts Resident for 12 months or more, as determined by the Commission.
  - 3. 51% or more of ancillary business service expenditures purchased by the Licensee have been from businesses with its primary place of businesses within Massachusetts.
- (d) Energy and Environmental Leader. In the year preceding the date of application for a leadership rating, the licensee has met the energy and environmental goals in one or more subcategories in compliance with criteria published as Appendix B in the Energy & Environment Compiled Guidance:
  - 1. Energy
  - 2. Recycling & Waste Disposal
  - 3. Transportation
  - 4. Water Usage
  - 5. Soil Sampling



- (f) Compliance Leader. In the year preceding the date of application for a leadership rating:
  - All Licensee employees have completed all required trainings for their positions within 90 days of hire;
  - 2. The Licensee has no unresolved written deficiency statements;
  - The Licensee has not been the subject of a Cease and Desist Order or a Quarantine Order;
  - 4. The Licensee has not had its license suspended; and
  - 5. The Licensee has met all timelines required by the Commission.
- (g) Medical Marijuana Treatment Center Leader. In the year preceding the date of application for a leadership rating:
  - 1. The MTC has met or exceeded their goals outlined in their submitted verified financial hardship program according to 935 CMR 501.050(1)(h).
  - Demonstrated a consistent availability of Marijuana-infused Products in serving sizes above 5mg of THC and greater than 100mg of THC per package.
  - Maintained a consistent patient supply as per 935 CMR 502.140(9) and reserved
     <u>a quantity and variety of Marijuana and Marijuana Products beyond what is</u>
     required.
  - Demonstrated accessibility in multiple forms including foreign languages, developmental disabilities, patients with mental and/or physical disabilities, homebound patients, pediatric patients, and patients on hospice.
  - Conducted community outreach to Qualifying Patient communities to educate those communities on the benefits of registering with the medical program.
  - 6. Has no disciplinary actions related to treatment of Qualifying Patients.
  - Offers meaningful pediatric patient programs or specializes in collaboratively working with families/patients that need specialized Marijuana and Marijuana Products.
- (h) Leadership ratings will be taken into consideration by the Commission in assessing fines pursuant to 935 CMR 501.360 and disciplinary action pursuant to 935 CMR 501.450.



# **Topic: Priority Review and Expedited Review**

<u>Recommendation</u>: Codify in the expedited review policy and the interpretation of MTC priority status as proposed by Commissioner Doyle in the following motion:

move that the Commission request the Executive Director implement any changes necessary to ensure that priority RMD status is limited to those who qualified in April, 2018, be limited to the locations and activities for which the applicants have RMD licensure, and require that RMD licensure must be maintained to be eligible for priority treatment for that location.

This motion was made at the October 10, 2019 Commission meeting and voted on 4-1 by the Commission.

#### 500.002: Definitions

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

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

MTC Priority Applicant means a previously Medical Marijuana Treatment Center (MTC) (previously, Registered Marijuana Dispensary (RMD)) certified by the Commission as an MTC Priority Applicant in 2018 upon that demonstratinged that it had at least a provisional Certification of Registration prior to April 1, 2018, it had received a Final Certificate of Registration and is selling Marijuana or Marijuana infused Products as of the date of application; it had received a Final Certificate of Registration, but is not selling Marijuana or Marijuana infused Products as of the date of application; or it had received a Provisional Certificate of Registration, but not a Final Certificate of Registration. This applicant has priority for the purposes of the review of its license application.





#### **500.101: Application Requirements**

- (4) MTC Priority Applicants: An MTC Priority Applicant shall be granted priority review of its application for a Marijuana Establishment license that is colocated with and for the same type of licensed activity (Marijuana Cultivator, Product Manufacturer or Retailer) as the MTC (formerly, RMD) license which was the basis for its priority review status certified by the Commission.
  - (a) The MTC license, for which priority review status was certified by the Commission, must be active at the time the Marijuana Establishment application is submitted in order to receive priority review for that application.
  - (b) An MTC Priority Applicant shall be eligible for priority review of only its application for a Marijuana Establishment license that is:
    - a. Colocated with the MTC whose Certificate of Registration was the basis for its priority review status previously certified by the Commission in 2018; and
    - b. For the same type of licensed activity (Marijuana Cultivator, Product Manufacturer or Retailer) for which the MTC received a provisional Certificate of Registration or final Certificate of Registration that formed the basis of its priority review status certified by the Commission in 2018.
- (5) Expedited Applicants: Following the review of applications submitted by priority applicants, applications submitted by Expedited Applicants shall be reviewed.
  - (a) The following applicants are eligible to be considered Expedited Applicants:
    - Social Equity Participants;
    - 2. Marijuana Microbusiness applicants;
    - 3. Marijuana Craft Marijuana Cooperative applicants;
    - Independent Testing Laboratory applicants;
    - 5. Outdoor Marijuana Cultivator applicants; or
    - Minority-owned businesses, women-owned businesses, and veteran-owned businesses.



#### (b) Eligibility Criteria

- Applicants for Marijuana Microbusinesses, Craft Marijuana Cooperatives, Independent
   Testing Laboratories, and Outdoor Marijuana Cultivators are only eligible for expedited
   review for those specific applications only and no other type of license application.
- 2. A Social Equity Participant must possess 10% or more of equity in a proposed ME for the application to receive expedited review.
- 3. A minority-owned business, woman-owned business, and/or veteran-owned business shall:
  - a. disclose this designation in their license application and either be certified as that specific type of business with the Supplier Diversity Office or submit documentation in a time and manner determined by the Commission to demonstrate that they have signed up for the Supplier Diversity Office's required business class.
  - Receive certification as minority-owned business, women-owned business, and/or veteran-owned business by the Supplier Diversity Office prior to obtaining a final license.



## Topic: Social Consumption/Delivery – Application Requirements

<u>Recommendation</u>: Clarify and expressly state that the two-part application, the pre-certification and the provisional license applications, applies to both Social Consumption and Delivery-Only while also separating additional requirements pertinent to the respective licenses.

#### 500.050: Marijuana Establishments

- (6) Social Consumption Establishment Pilot Program.
  - (a) Under the Social Consumption Establishment Pilot Program, Social Consumption Establishments may apply for licensure.
  - (b) Municipal Participation for Social Consumption Pilot Program.
    - The Commission may select no more than 12 Massachusetts municipalities for participation in the pilot program.
    - The Commission shall establish criteria for selecting participating municipalities. The Commission may take into consideration factors including, but not limited to, the geographic location, socioeconomic characteristics, and population size of municipal applicants.
    - An interested municipality shall submit an application for participation in a form and manner determined by the Commission.
    - The application for participation shall be signed by the municipality's contracting authority.
    - 5. The Commission shall make the Pre-certification Application identified in 935 CMR 500.101(2)(c) available for Social Consumption licenses upon the Commission's selectiong at of least six municipalities for participation in the Social Consumption Pilot Program.

(b)(c) Social Consumption Establishment licenses shall be limited on an exclusive basis to businesses controlled by and with majority ownership comprised of Economic Empowerment Priority Applicants or Social Equity Program Participants; Microbusinesses; and Craft Marijuana Cooperatives, for a period of 24 months from the date the first Social Consumption Establishment receives a notice to commence operations, provided, however, that the Commission may, by vote, decide to extend

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that period following a determination that the goal of the exclusivity period to promote and encourage full participation in the regulated Marijuana industry by people from communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law, by farmers, and by businesses of all sizes, has not been met.

- 1. The Commission shall develop criteria for evaluating whether the goals of the exclusivity period are met which shall include, but not be limited to:
  - a. Overall rates of participation in the regulated Marijuana industry by people from communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law, by farmers, and by businesses of all sizes;
  - b. Overall rates of participation in the regulated Marijuana industry by people of color;
  - c. Licenses granted to businesses with majority ownership comprised of Economic Empowerment Priority Applicants and Social Equity Program Participants; Microbusinesses; and Craft Marijuana Cooperatives;
  - d. Number of registered agents who are Social Equity Program Participants;
     e. Number of Social Consumption Establishments in operation and
  - e. Number of Social Consumption Establishments in operation and business performance relative to other Marijuana Establishments;
  - f. Financial feasibility of continued participation in the regulated Marijuana industry by people from communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law, by farmers, and by businesses of all sizes if exclusivity period ends; and
  - g. any other information the Commission determines relevant.
- 2. The Commission shall collect and report on data measuring the criteria throughout the exclusivity period. The Commission shall begin evaluating whether the goals of the exclusivity period have been met at least eight months before the end of the 24-month period to provide adequate time to consider whether an extension of the 24-month period is necessary prior to the conclusion of that time period.
- 3. The licenses may be made available to any qualifying applicants after the 24-month period, unless the Commission affirmatively votes to extend the period of exclusivity by
- a period of 12 months after the first 24-month period. Any subsequent extension of the exclusivity period would require the Commission affirmatively to find that the goals and objectives of the exclusivity period as set forth in 935 CMR



500.050(10)(b)1. have not been met.

(e)(d) No person or entity other than those disclosed in the application shall be a Person or Entity Having Direct or Indirect Control in a Social Consumption Establishment license.

## 500.101: Application Requirements

[...]

(2) Delivery-Only and Social Consumption Pilot Program Application Process.

(a) Municipal Participation for Social Consumption Pilot Program.

1. The Commission may select no more than 12 Massachusetts municipalities for participation in the pilot program.

2. The Commission shall establish criteria for selecting participating municipalities. The Commission may take into consideration factors including, but not limited to, the geographic location, socioeconomic characteristics, and population size of municipal applicants.

3. An interested municipality shall submit an application for participation in a form and manner determined by the Commission.

The application for participation shall be signed by the municipality's contracting authority.

4. The Commission shall make the Pre-certification Application available for Social Consumption licenses on the Commission selecting at least six municipalities for participation in the Social Consumption Pilot Program.

(a) Delivery-Only and Social Consumption Establishment Applicants. An applicant for a Social Consumption Establishment license—shall file, in a form and manner specified by the Commission, an application for licensure. An application for licensure shall consist of two component parts: a Pre-certification Application and a Provisional License Application. Until the Commission determines that both component parts have been fully submitted, the application shall not be deemed complete. After an applicant receives a Provisional License, the applicant shall comply with the requirements of 935 CMR 500.103: Licensure and Renewal.

(b) Pre-certification Application. The Pre-certification Application shall consist of

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three sections: Application of Intent, Background Check and Management and Operations Profile.

- 1. The Commission shall make the Pre-certification Application available for Social Consumption licenses on the Commission selecting at least six municipalities for participation in the Social Consumption Pilot Program pursuant to 935 CMR 500.101(2)(a).
- 2. The applicant may <u>complete</u> submit any section of the application in any order. Once all sections of the application have been completed, the application may be submitted.
- 3. The Commission may determine an applicant to be pre-certified upon finding the applicant has submitted responsive documentation demonstrating a propensity to successfully operate <u>under</u> a <u>Delivery-Only license or Social Consumption Establishment license</u>.
- 4. On approval of the Pre-certification Application, the applicant shall be given a dated notice of such approval along with a copy of the Pre-certification Application to the extent permitted by law.
- 5. Application materials, including attachments, may be subject to release pursuant to the Public Records Law, M.G.L. c. 66, § 10 and M.G.L. c. 4, § 7, cl. 26.
- (c) <u>Application of Intent</u>. An applicant for pre-certification under this section shall submit the following as part of the Application of Intent:
  - 1. Documentation that the Marijuana Establishment is an entity registered to do business in Massachusetts and a list of all Persons or Entities Having Direct or Indirect Control;
  - 2. A disclosure of an interest of each individual named in the application in any Marijuana Establishment for licensure in Massachusetts;
  - 3. Documentation disclosing whether any individual named in the application have past or present business interests in Other Jurisdictions;
  - 4. The requisite nonrefundable application fee pursuant to 935 CMR 500.005; and
  - 5. Any other information required by the Commission.
- (d) <u>Background Check</u>. Each applicant for pre-certification must submit the following information:
  - 1. The list of individuals and entities in 935 CMR 500.101(1)(a)1;
  - 2. <u>Relevant Background Check Information</u>. All Persons and Entities Having Direct or Indirect Control listed in the Pre-certification Application shall provide information detailing involvement in any of the following criminal, civil, or administrative matters:

**Commented [A7]:** Moved this section to 500.050(6): Social Consumption Establishment Pilot program



- a. a description and the relevant dates of any criminal action under the laws of the Commonwealth, or Other Jurisdictions, whether for a felony or misdemeanor including, but not limited to, action against any health care facility or facility for providing Marijuana for medical- or adult-use purposes, in which those individuals either owned shares of stock or served as board member, Executive, officer, director or member, and which resulted in conviction, or guilty plea, or plea of *nolo contendere*, or admission of sufficient facts;
- a description and the relevant dates of any civil action under the laws of the Commonwealth, or Other Jurisdictions including, but not limited to, a complaint relating to any professional or occupational or fraudulent practices;
- c. a description and relevant dates of any past or pending legal or enforcement actions in the Commonwealth or any Other Jurisdiction against an entity whom the applicant served as a Person or Entity Having Direct or Indirect Control, related to the cultivation, Processing, distribution, or sale of Marijuana for medical- or adult-use purposes;
- d. a description and the relevant dates of any administrative action with regard to any professional license, registration, or certification, including any complaint, order, stipulated agreement or settlement, or disciplinary action, by the Commonwealth, or like action in an Other Jurisdiction including, but not limited to, any complaint or issuance of an order relating to the denial, suspension, or revocation of a license, registration, or certification or the surrender of a license;
- a description and relevant dates of any administrative action, including any complaint, order or disciplinary action, by the Commonwealth, or a like action by Other Jurisdictions with regard to any professional license, registration, or certification, held by any Person or Entity Having Direct or Indirect Control, if any;
- f. a description and relevant dates of actions against a license to prescribe or distribute controlled substances or legend drugs held by any Person or Entity Having Direct or Indirect Control that is part of the applicant's application, if any; and
  - g. any other information required by the Commission.
- (e) <u>Management and Operations Profile</u>. Each applicant shall submit, with respect to each application, a response in a form and manner specified by the Commission, which



## includes:

- 1. A description of the Marijuana Establishment's plan to obtain a liability insurance policy or otherwise meet the requirements of 935 CMR 500.105(10);
- 2. A detailed summary of the business plan for the Marijuana Establishment;
- 3. A detailed summary of operating policies and procedures for the Marijuana Establishment which shall include, but not be limited to, provisions for:
  - a. security, including specific plans for securing entrances and that all Marijuana and Marijuana Products are kept out of plain sight and not visible from a public place;
  - b. prevention of diversion;
  - e. prevention of a Consumer from bringing Marijuana or Marijuana Products, Marijuana Accessories onto the Premises that have not been obtained from the Social Consumption Establishment, including policies for ensuring Marijuana Accessories brought on site, if permitted, do not contain Marijuana or Marijuana Products not obtained from the Social Consumption Establishment:
  - d.c. storage of Marijuana; including, but not limited to, disposal procedures for unsold and unconsumed Marijuana Products;
  - e.d. transportation of Marijuana;
  - f.e. inventory procedures;
  - g.f. procedures for quality control and testing of product for potential contaminants;
  - h.g. personnel policies;
  - i.h.dispensing procedures;
  - j-i. procedures to ensure that Consumers are not overserved;
  - k. procedures to educate Consumers about risk of impairment and penalties for operating under the influence;
  - procedural and operational plans to ensure the Marijuana Establishment
    makes a diligent effort to assist customers who may be impaired in finding
    means of transportation and that explain how the plans are adequately tailored
    to the region in which the establishment is located.
  - m.j. recordkeeping procedures;
  - n.k. maintenance of financial records; and
  - o. if vaporization or other non smoking forms of consumption involving heat are permitted indoors, procedures and building plans or schematic to

**Commented [A8]:** Moved below to additional requirements for Social Consumption Applicants

**Commented [A9]:** Moved below to additional requirements for Social Consumption Applicants

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## ensure that:

- i. the area(s) in which consumption involving heat takes place are isolated from the other areas, separated by walls and a secure door, with access only from the Social Consumption Establishment;
- ii. employees have access to a smoke free, vapor free area where they may monitor the consumption area from a smoke free, vapor free area;
  iii. a ventilation system directs air from the consumption area to the outside of the building through a filtration system sufficient to remove vapor, consistent with all applicable building codes and ordinances, and adequate to eliminate odor at the property line;
- procedures to ensure no sales occur within the consumption area;
- employees shall monitor the consumption from a smoke free, vaporfree area including, but not limited to, an employee monitoring the exit of the Marijuana Establishment;
- r. procedures to ensure that smoking as defined by M.G.L. c. 270, § 22 is prohibited indoors;
- s-1. sanitary practices in compliance with 105 CMR 590.000: State Sanitary Code Chapter X − Minimum Sanitation Standards for Food Establishments: 
  ⇒and
- tim. a detailed description of qualifications and intended training(s) for Marijuana Establishment Agents who will be employees;
- 4. The Management and Operation Profile submitted in accordance with 935 CMR 500.101(1)(c) shall demonstrate compliance with the operational requirements set forth by incorporation in 935 CMR 500.050(2)(b), as applicable;
- 5. Disclosure of the proposed hours of operation, and the names and contact information for individuals that will be the emergency contacts for the Marijuana Establishment; and
- 6. Any other information required by the Commission.
- (f) Provisional License Application. [...]
- (g) <u>Application of Intent</u>. An applicant for licensure under this section shall submit the following as part of the Application of Intent:

[...]

9. Documentation that the applicant has conducted a community outreach

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meeting consistent with the Commission's *Guidance for License Applicants on Community Outreach* within the six months prior to the application. Documentation must include:

- a. Copy of a notice of the time, place and subject matter of the meeting, including the proposed address of the Marijuana Establishment, that was published in a newspaper of general circulation in the city or town at least <a href="14seven">14seven</a> calendar days prior to the meeting;
- b. Copy of the meeting notice filed with the city or townclerk;
- c. Attestation that notice of the time, place and subject matter of the meeting, including the proposed address of the Marijuana Establishment, was mailed at least seven calendar days prior to the community outreach meeting to abutters of the proposed address of the Marijuana Establishment, and residents within 300 feet of the property line of the petitioner as they appear on the most recent applicable tax list, notwithstanding that the land of any such Owner is located in another city ortown;
- d. Information presented at the community outreach meeting, which shall include, but not be limited to:
  - i. The type(s) of marijuana establishment to be located at the proposed address;
  - ii. Information adequate to demonstrate that the location will be maintained securely;
  - iii. Steps to be taken by the marijuana establishment to prevent diversion to minors;
  - iv. A plan by the marijuana establishment to positively impact the community;
  - v. Information adequate to demonstrate that the location will not constitute a nuisance as defined by law; and
  - vi. An attestation that community members were permitted to ask questions and receive answers from representatives of the marijuana establishment.
- e. Documentation in the form of a single-page certification signed by the contracting authorities for the municipality and applicant evidencing that the applicant for licensure and host municipality in which the establishment is located executed a host community agreement. In addition to this requirement, the host community must state that they have and accepted the Social Consumption Establishment applicant's plans to:



- i. mitigate noise;
- ii. mitigate odor; and
- iii. comply with outdoor smoking laws, ordinances, or bylaws.
- f. A description of plans to ensure that the marijuana establishment is or will be compliant with local codes, ordinances, and bylaws for the physical address of the marijuana establishment, which shall include, but not be limited to, the identification of any local licensing requirements for social consumption of the adult use of marijuana;
- g. A plan by the marijuana establishment to positively impact areas of disproportionate impact, as defined by the commission, for the purposes established in M.G.L. c. 94G,  $\S$  4(a½)(iv). The plan shall outline the goals, programs, and measurements the marijuana establishment will pursue once licensed; and
- h. Any other information required by the Commission.
- (h) Background Check. [...]
- (i) Management and Operations Profile. [...]

## (3) Additional Specific Requirements.

- (a) Additional Requirements for Cultivators. [...]
- (b) Additional Requirements for Craft Marijuana Cooperatives. [...]
- (c) Additional Requirements for Marijuana Product Manufacturers. [...]
- (d) Additional Requirements for Microbusinesses. [...]
- (e) Additional Requirements for Retailers. [...]
- (f) Additional Requirements for Independent Testing Laboratories. [...]
- (g) Additional Requirements for Delivery-Only Applicants. In addition to the requirements set forth in 935 CMR 500.101(2), applicants to operate under a Delivery-Only license shall also provide the following:
  - As part of the Pre-Certification application, a delivery plan that demonstrates compliance with 935 CMR 500.145.
  - As part of the Provisional License application, information and documentation regarding any agreements with Marijuana Retailers and/or Third-Party Technology Platforms pursuant to 935 CMR 500.145(1)(d) and (e).
- (h) Additional Requirements for Social Consumption Establishment Applicants. In addition to the requirements set forth in 935 CMR 500.101(2), applicants for a



license to operate a Social Consumption Establishment shall also provide the following summaries of policies and procedures as part of their Pre-Certification application:

- prevention of a Consumer from bringing Marijuana or Marijuana Products, Marijuana Accessories onto the Premises that have not been obtained from the Social Consumption Establishment, including policies for ensuring Marijuana Accessories brought on-site, if permitted, do not contain Marijuana or Marijuana Products not obtained from the Social Consumption Establishment;
- 2. disposal procedures for unsold and unconsumed Marijuana Products;
- procedures to educate Consumers about risk of impairment and penalties for operating under the influence;
- 4. procedural and operational plans to ensure the Marijuana Establishment makes a diligent effort to assist customers who may be impaired in finding means of transportation and that explain how the plans are adequately tailored to the region in which the establishment is located;
- 5. if vaporization or other non-smoking forms of consumption involving heat are permitted indoors, procedures and building plans or schematic to ensure that:
  - the area(s) in which consumption involving heat takes place are isolated from the other areas, separated by walls and a secure door, with access only from the Social Consumption Establishment;
  - iii. employees have access to a smoke-free, vapor-free area where they may monitor the consumption area from a smoke-free, vapor-free area;
  - iii.a ventilation system directs air from the consumption area to the outside of the building through a filtration system sufficient to remove vapor, consistent with all applicable building codes and ordinances, and adequate to eliminate odor at the property line;
- 6. procedures to ensure no sales occur within the consumption area;
- employees shall monitor the consumption from a smoke-free, vapor-free area including, but not limited to, an employee monitoring the exit of the Marijuana Establishment;
- procedures to ensure that smoking as defined by M.G.L. c. 270, § 22 is prohibited indoors;

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# **Topic: Delivery**

## Recommendations:

- Allow the delivery of Marijuana Accessories (for consumption) and ME branded goods (such as tshirts, etc.). Note: we discussed and decided as a group not to allow the delivery of food items with Marijuana and Marijuana Products.
- Allow Delivery Licensees and Endorsement holders to directly sell Marijuana Accessories and branded merchandise. In other words, those items do not need to be procured from a Marijuana Retailer; the Delivery-Only Licensee or Endorsement holder may sell direct to consumers.
- 3. Change 'Delivery-only Licensee' to 'Delivery Licensee;' remove prohibition against having a retail location; and deem a Delivery license to be a Marijuana Retailer license.
- 4. Clarify in the general requirements for a Marijuana Retailer that a Marijuana Retailer must have a Delivery license in order to deliver Marijuana or Marijuana Products.
- 5. Allow a Delivery Licensee to be an Owner of or have a controlling interest in a Cultivation, Product Manufacturing, Social Consumption Establishment, Research, Retail or Transportation license

## 500.002: Definitions

<u>Delivery only Licensee</u> means an entity that is authorized to deliver <u>Marijuana or Marijuana Products</u> directly to Consumers from a Marijuana Retailer or Registered Qualifying Patients or Caregivers from an MTC-and that does not provide a retail location accessible to the public. The Delivery License shall be considered a Marijuana Retailer license in accordance with the provisions of G.L. c. 94G, § 1 and 935 CMR 500.000.

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

## 500.050: Marijuana Establishments

Commented [A14]: Cannabis or Marijuana Accessories means equipment, products, devices or materials of any kind that are intended or designed for use in planting, Propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, Processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, ingesting, inhaling or otherwise introducing Cannabis or Marijuana into the human body.



[...]

## (8) Marijuana Retailer.

- (a) General Requirements.
  - 1. A Marijuana Retailer may purchase, transport, sell or otherwise Transfer Marijuana or Marijuana Products to Marijuana Establishments and sell to Consumers. A Marijuana Retailer cannot deliver Marijuana or Marijuana Products to Consumers or unless the Marijuana Retailer also has been issued a Delivery License, nor may a Marijuana Retailer allow on-site social consumption by Consumers on the Premises of the Marijuana Establishment.

## (10) <u>Delivery-only Licensee</u>.

- (a) A Delivery-only Licensee may deliver Marijuana or Marijuana Products directly to Consumers from a Marijuana Retailer or MTC with which the Delivery-Only Licensee has a Delivery Agreement. A Delivery only Licensee shall not have a retail location accessible to the public. A Delivery Licensee may be an Owner of or have a controlling interest in a Cultivation, Product Manufacturing, Social Consumption Establishment, Research, Retail or Transportation license.
- (b) A Delivery-only Licensees shall be limited on an exclusive basis to businesses controlled by and with majority ownership comprised of Economic Empowerment Priority Applicants or Social Equity Program Participants for a period of 24 months from the date the first Delivery-only Licensee receives a notice to commence operations, provided, however, that the Commission may vote to decide to extend that period following a determination that the goal of the exclusivity period to promote and encourage full participation in the regulated Marijuana industry by people from communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law has not been met.
  - 1. The Commission shall develop criteria for evaluating whether the goals of the exclusivity period are met, which shall include, but not be limited to:



- a. Overall rates of participation in the regulated marijuana industry by people from communities that have previously been disproportionately harmed by marijuana prohibition and enforcement of the law;
- b. Overall rates of participation in the regulated Marijuana industry by people of color;
- c. Licenses granted to businesses with majority ownership comprised of Economic Empowerment Priority Applicants and Social Equity Program Participants;
- d. Number of registered agents who are Social Equity Program Participants;
- e. Number of Delivery-only Licensees in operation and business performance relative to other Marijuana Establishments;
- f. Financial feasibility of continued participation in the regulated Marijuana industry by communities that have previously been disproportionately harmed by Marijuana prohibition and enforcement of the law if exclusivity period ends; and
- g. Any other information the Commission determines relevant.
- 2. The Commission shall collect and report on data measuring the criteria throughout the exclusivity period. The Commission shall begin evaluating whether the goals of the exclusivity period have been met at least eight months before the end of the 24-month period to provide adequate time to consider whether an extension of the 24-month period is necessary prior to the conclusion of that time period.
- 3. The licenses shall generally be available to applicants after the 24-month period unless the Commissioners affirmatively votes to extend the period of exclusivity by a period of 12 months after the first 24-month period. Any subsequent extension of the exclusivity period would require the Commission affirmatively to find that the goals and objectives of the exclusivity period as set forth in 935 CMR 500.050(10)(b)1. have not been met.
- (c) No person or entity other than those disclosed in the application shall be a Person or Entity Having Direct or Indirect Control in a Delivery only License.



# 500.145: Additional Operational Requirements for Delivery of Marijuana, and Marijuana Products, Marijuana Accessories, and Marijuana Establishment Branded Goods to Consumers

## (1) General Requirements.

- (a) For purposes of section 935 CMR 500.145, "Delivery Items" means Marijuana, Marijuana Products, Marijuana Accessories, and Marijuana Establishment Branded Goods."
- (a)(b) Pursuant to 935 CMR 500.105(4), aA Delivery only License or Delivery Endorsement is a necessary prerequisite for the delivery of <u>Delivery Items Marijuana and Marijuana Products</u> directly to Consumers. Applications for a Delivery—only License or Delivery Endorsement shall be in a form and manner to be determined by the Commission.
- (b)(c) Prior to commencing operations, Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsements shall comply with all operational requirements imposed by:
  - 1. 935 CMR 500.105;
  - 2. 935 CMR 500.110(8); and
  - 3. 935 CMR 500.145.
- (e)(d) \_\_\_\_All individuals delivering Marijuana and Marijuana Products for a Deliveryonly\_Licensee or a Marijuana Establishment with a Delivery Endorsement directly to
  Consumers shall be employees of the Delivery-only Licensee or a Marijuana
  Establishment with a Delivery Endorsement and shall hold a valid Marijuana
  Establishment Agent registration.
- (d)(e) All Marijuana and Marijuana Products delivered by a Delivery only Licensee shall be obtained from a licensed Marijuana Retailer. Delivery only Licensees may deliver Marijuana Establishment Branded Goods carrying the Delivery Licensee's brand or that of a licensed Marijuana Retailer. Delivery Licensees may deliver Marijuana Accessories from a licensed Marijuana Retailer, or source and deliver their own Marijuana Accessories. Delivery Licensees shall not source electronic vape devices, hardware or batteries utilized in products that vaporize concentrates and oils, other than from a licensed Marijuana Retailer.
  - Delivery only Licensees shall only obtain Marijuana or Marijuana Products for delivery from a licensed Marijuana Retailer with which the Delivery-only Licensee has a Delivery Agreement.
  - All agreements between a Delivery—only Licensee and a Marijuana Retailer shall be disclosed under the requirements of licensure in 935 CMR 500.101 and



- subject to limitations on control over Licenses under 935 CMR 500.050(1)(a).
- The Commission shall be notified in writing of any substantial modification to a Delivery Agreement.
- (e)(f) A Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement and Marijuana Retailer may use a Third-party Technology Platform Provider to facilitate the ordering of Marijuana or Marijuana Productsorders by Consumers.
  - All agreements between a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement and a Third-party Technology Platform Provider shall be available for inspection as part of the requirements for licensure in 935 CMR 500.101 and shall be subject to the control limitations under 935 CMR 500.050(1)(a).
  - The Commission shall be notified in writing within five days of any substantial modification to an agreement between a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement and a Third-party Technology Platform Provider.
  - Any Third-party Technology Platform shall comply with privacy and consumer protection standards established by the Commission.
  - 4. The Commission shall be notified in writing of an ongoing basis of any new or additional or assigned agreements between a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement and a Third-party Technology Platform Provider within five days.
- (f)(g) The maximum retail value of Marijuana or Marijuana Products allowed in a Delivery only Licensee or a Marijuana Establishment with a Delivery Endorsement's vehicle at any one time shall be \$10,000. For purposes of this provision, "maximum retail value" shall mean the aggregate value of Marijuana and Marijuana Products as priced on the day of the order for delivery.
- (g)(h) All Marijuana and Marijuana Product deliveries shall be tracked using the Seedto-sale SOR as designated by the Commission.
- (i) Records of sales of Marijuana Accessories and Marijuana Establishment Branded Goods shall be maintained by the Delivery Licensee or Marijuana Establishment with a Delivery Endorsement, but shall not be tracked in the Seed-to-sale SOR.
- (j) For non-Marijuana or non-Marijuana Product sales, a Delivery Licensee or Marijuana Establishment with a Delivery Endorsement shall comply with Massachusetts tax laws, and DOR rules and regulations including, but not limited to, 830 CMR 62C.25.1: Record Retention and DOR Directive 16-1 regarding recordkeeping requirements.



- (h)(k) Deliveries of Marijuana or Marijuana Products by a Delivery only Licensee or a Marijuana Establishment with a Delivery Endorsement shall be geographically limited to:
  - The municipality identified as the Marijuana Establishment License's place of business;
  - 2. Any municipality which allows for retail within its borders whether or not one is operational; or
  - Any municipality which after receiving notice from the Commission, has notified the Commission that delivery may operate within its borders.
- (i)(1) Limitations on the time for delivery shall comply with all municipal bylaws and ordinances, provided however, that all deliveries of Marijuana or Marijuana Products must be completed before 9:00 P.M. local time or the time determined by municipal bylaw or ordinance, whichever occurs first, and deliveries of Marijuana or Marijuana Products shall not occur between the hours of 9:00 P.M. and 8:00 A.M., unless otherwise explicitly authorized by municipal bylaw or ordinance.
- (j)(m) Every effort shall be made to minimize the amount of cash carried in a Delivery-only Retail vehicle at any one time. Marijuana Retailers utilizing a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement for Consumer transactions shall use best efforts to implement platforms for the electronic payment of funds. Where cash is carried by a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement vehicle, cash shall be stored in a locked compartment.
- (n) Delivery-only Retail Licensees and Marijuana Establishments with a Delivery Endorsement shall comply with the requirements of 935 CMR 500.110(7) for purposes of cash transport to financial institutions.
- (o) In addition to complying with 935 CMR 500.105-(4), a Delivery Licensee shall include on any website it operates or that operates on its behalf the license number issued by the Commission.
- (k)(p) In addition to complying with 935 CMR 500.105—(4), a Marijuana Establishment with a Delivery Endorsement shall include on any website it operates or that operates on its behalf the endorsement number issued by the Commission.
- (2) Orders. All orders for deliveries made by Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsements shall comply with the following requirements:
  - (a) All Marijuana and Marijuana Products delivered by a Delivery-only Licensee shall be obtained from a licensed Marijuana Retailer with which the Deliveryy-only Licensee



has a Delivery Agreement. Delivery Licensees and Marijuana Establishments with a Delivery Endorsement may deliver Marijuana Accessories and Marijuana Establishment Branded Goods provided directly from the Delivery Licensee.

- (b) Orders for home delivery shall be received by a Marijuana Retailer and transmitted to a Delivery—only Licensee for delivery to a Residence.
- (c) Only Marijuana Products that are Shelf-stable may be delivered. Products that are perishable or time and temperature controlled to prevent deterioration shall not be allowed to be delivered by a Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsement.
- (d) Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsements shall deliver Marijuana or Marijuana Products only to the Residence address provided. A Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsements shall be prohibited from delivering to college or university dormitories; and federal public housing identified at <a href="https://resources.hud.gov/">https://resources.hud.gov/</a>.
- (e) Delivery-only Licensees shall only deliver Delivery Items Marijuana or Marijuana Products for which a specific order has been received by a licensed Marijuana Retailer with which the Delivery-only Licensee has a Delivery Agreement. Delivery-only Licensees are prohibited from delivering Delivery Items Marijuana or Marijuana Products without a specific order destined for an identified Residence. An order may be generated directly through a Marijuana Retailer or through a Third-party Technology Platform identified to the Commission under 935 CMR 500.145(1)(e).
- (f) Marijuana Establishments with a Delivery Endorsement shall only deliver <u>Delivery Items Marijuana or Marijuana Products</u> for which a specific order has been received. Marijuana Establishments with a Delivery Endorsement are prohibited from delivering <u>Delivery Items Marijuana or Marijuana Products</u> without a specific order destined for an identified Residence. An order may be generated directly through a Marijuana Establishments with a Delivery Endorsement or through a Third-party Technology Platform identified to the Commission under 935 CMR 500.145(1)(e).
- (g) Delivery—only Licensees or a Marijuana Establishments with a Delivery Endorsements are prohibited from delivery of more Marijuana or Marijuana Products to an individual Consumer than the individual possession amounts authorized by M.G.L. c. 94G, § 7(a)(1). An Individual Order shall not exceed one ounce of Marijuana or its dry-weight equivalent. The Individual Order shall only be delivered to the individual Consumer identified on the order after verification of the individual's identity consistent with the requirements of 935 CMR 500.140(2)(d) and 935 CMR 500.145(3). Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsements shall only deliver one Individual Order, per Consumer, during each



delivery.

- (h) A Deliveryy only Licensee or a Marijuana Establishment with a Delivery Endorsement shall not deliver to the same Consumer at the same Residence more than once each calendar day and only during authorized delivery hours.
- For home delivery, each order must be packaged and labeled in accordance with 935 CMR 500.105(5) and (6) originating the order prior to transportation by the Deliveryonly Licensee or a Marijuana Establishment with a Delivery Endorsement to the Consumer.
- (j) Any Marijuana or Marijuana Product Delivery Item that is undeliverable or is refused by the Consumer shall be transported back to the originating Marijuana Establishment that provided the product once all other deliveries included on a delivery manifest have been made. Delivery-only Licensees or Marijuana Establishments with a Delivery Endorsement are prohibited from maintaining custody overnight of Marijuana or Marijuana Products intended for delivery overnight. It shall be the responsibility of the Delivery-only Licensee or Marijuana Establishment with a Delivery Endorsement to ensure that any undelivered product is returned to the appropriate Marijuana Retailer and not retained by the Delivery-only Licensee or Marijuana Establishment with a Delivery Endorsement.

## (3) Consumer Age Verification.

- (a) A Marijuana Retailer shall require any Consumer making a purchase for delivery by a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall require any Consumer making a purchase for delivery to have the <u>valid</u> government-issued <u>photo</u>-identification a Consumer intends to use to verify her or his age at the time of delivery examined and authenticated by the Marijuana Retailer prior to the first Individual Order.
- (b) Pre-verification of the Consumer's identification shall be performed <u>prior to the initial</u> <u>delivery</u>, by using one of the following Pre-verification methods:
  - Jin-person at the Marijuana Retailer's physical location or through a Commission approved electronic means and shall include examination of the Consumer's valid, unexpired government-issued photo-identification that bears a date of birth in accordance with 935 CMR 500.140(2)(d). A Delivery-only Licensee or Marijuana Establishment with a Delivery Endorsement is prohibited from performing a delivery to any Consumer who has not established an account for delivery through Pre-verification of the Consumer's government-issued identification by the Marijuana Retailer; or-



- 2. Pre verification of the Consumer's identification shall be performed by a Marijuana Establishment with a Delivery Endorsement tThrough a Commission approved electronic means and shall include examination of the Consumer's valid, unexpired government- issued photo-identification that bears a date of birth. A Marijuana Establishment with a Delivery Endorsement is prohibited from performing a delivery to any Consumer who has not established an account for delivery through Pre-verification of the Consumer's government-issued identification.
- (c) A Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsement shall not deliver <u>Delivery Items Marijuana or Marijuana Products</u> to any Person other than the Consumer who ordered the <u>Delivery Items Marijuana or Marijuana Products</u>.
- (d) A Delivery-only-Licensee or a Marijuana Establishment with a Delivery Endorsement shall verify the age and identity of the Consumer at the time at which the <u>Delivery Items Marijuana or Marijuana Products</u> are delivered to the Consumer at a Residence to ensure that Marijuana and Marijuana Products are not delivered to individuals younger than 21 years old. Prior to relinquishing custody of the Marijuana or Marijuana Products to the Consumer, the Marijuana Establishment Agent conducting the delivery shall verify that the <u>government-issued</u> identification of the Consumer receiving the Marijuana or Marijuana Products matches the pre-verified <u>government-issued</u> identification of the Consumer who placed the order for delivery by:
  - Viewing the valid government-issued photo-identification as provided for Preverification under 935 CMR 500.145(3)(a);
  - 2. Viewing proof of order generated at the time of order; and
  - Receiving the signature of the Consumer who ordered the Marijuana or Marijuana Products on the manifest for the Marijuana or Marijuana Products Delivery Items and verifying that the signature matches the governmentissued photo-identification presented.

## (4) Vehicle and Transport Requirements for Home Delivery.

- (a) Vehicles used for home delivery by a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall be owned or leased by the Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement, shall be properly registered as commercial vehicles, and inspected and insured in the Commonwealth of Massachusetts.
- (b) Vehicles used for home delivery by a Delivery-only Licensee or a Marijuana



Establishment with a Delivery Endorsement may be parked overnight at the address identified as the Licensee's place of business or another location, provided that keeping the vehicle at the identified location complies with all general and special bylaws of the municipality.

- (c) Vehicles used for delivery by a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall carry liability insurance in an amount not less than \$1,000,000 combined single limit.
- (d) Vehicles used for delivery by a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement vehicles shall have no external markings, words or symbols that indicate the vehicle is being used for home delivery of Marijuana or Marijuana Products Delivery Items.
- (e) A Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsements transporting Marijuana and Marijuana Products for home delivery shall ensure that all vehicles used for deliveries are staffed with a minimum of two Marijuana Establishment Agents. At least one Marijuana Establishment Agent shall remain with the vehicle at all times that the vehicle contains Marijuana or Marijuana Products.
- (f) Marijuana and Marijuana Products Delivery Items must not be visible from outside the vehicle.
- (g) A Delivery only Licensee or a Marijuana Establishment with a Delivery Endorsement shall transport Marijuana and Marijuana Products in a secure, locked storage compartment that is a part of the vehicle and complies with the requirements of 935 CMR 500.110(8).
- (h) A Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall maintain, in each vehicle used for deliveries of Marijuana and Marijuana Products, a secure, locked storage compartment for the purpose of transporting and securing cash used as payment. This compartment shall be separate from compartments required under 935 CMR 500.145(4)(h) for the transport of Marijuana and Marijuana Products.
- (i) In the case of an emergency stop during the transportation of <u>Delivery Items Marijuana or Marijuana Products</u>, a log must be maintained describing the reason for the stop, the duration, the location, and any activities of personnel exiting the vehicle. The Marijuana Establishment Agents in the vehicle shall provide notice of the location of the stop and employ best efforts to remain in contact with the Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsement.
- (j) The Marijuana Establishment Agents transporting Delivery Items Marijuana or



Marijuana Products for home delivery shall contact the Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement fixed location when arriving at and leaving any delivery, and regularly throughout the trip, at least every 30 minutes.

- (k) The Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall maintain a separate log for each vehicle in use for home deliveries. For each delivery, the Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall record:
  - 1. The location of the originating Marijuana Establishment and date and time the vehicle leaves the location;
  - The mileage of the transporting vehicle at departure from the Marijuana Establishment mileage on arrival at each Consumer destination, and mileage on return to the Marijuana Establishment;
  - 3. The date and time of departure from the Marijuana Establishment and arrival at each Consumer destination for each delivery; and
  - 4. An entry indicating the date and time of the last delivery in an order.
- A Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsement shall ensure that all delivery routes remain within the Commonwealth of Massachusetts at all times.
- (m) A Delivery only Licensee or a Marijuana Establishment with a Delivery Endorsement shall make every effort to randomize its delivery routes.
- (n) A Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsements shall not transport products other than Delivery Items Marijuana and Marijuana Products during times when the Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsements are performing home deliveries.
- (o) Firearms are strictly prohibited from Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement vehicles and from Marijuana Establishment Agents performing home deliveries.

## (5) Manifests.

(a) Every home delivery shall have a manifest produced by the originating Marijuana Establishment and provided to the Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement. A manifest shall be completed in duplicate, with the original manifest remaining with the originating Marijuana Retailer, and a copy to be kept with the Delivery-only Licensee or a Marijuana Establishment with a Delivery



Endorsement during the delivery. The manifest shall be signed by the Consumer receiving the Marijuana or Marijuana Products and the Marijuana Establishment Agent acting on behalf of the Delivery only Licensee or a Marijuana Establishment with a Delivery Endorsement. A signed manifest shall serve as the written record of the completion of the delivery. A manifest does not need to include Marijuana Accessories or Marijuana Establishment Branded Goods; however the Delivery Licensee or Marijuana Establishment with a Delivery Endorsement shall maintain a record of the sale of all Delivery Goods.

- (b) The manifest must, at a minimum, include:
  - 1. The originating Marijuana Retailer name, address, and License number;
  - 2. The name and License number of the Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement performing the home delivery;
  - The names and Marijuana Establishment Agent numbers of the Marijuana Establishment Agents performing the delivery;
  - 4. The Consumer's name and address;
  - A description of the Marijuana or Marijuana Products being transported, including the weight and form or type of product;
  - 6. Signature lines for the agents who transported the Marijuana or Marijuana Products;
  - 7. A signature line for Consumer who receives the Marijuana or Marijuana Products; and
  - 8. The Delivery—only Licensee or a Marijuana Establishment with a Delivery Endorsement vehicle make, model, and license plate number.
- (c) The manifest shall be maintained within the vehicle during the entire transportation process, until all the deliveries are completed.
- (d) A Marijuana Establishment shall retain all transportation manifests for no less than one year and make them available to the Commission on request.



## **Topic: Responsible Vendor Training**

## Recommendations:

- In addition to current program for MEs, establish RVT Program for MTCs.
- Clarify training requirements: 8 annual hours required training for Marijuana Establishment Agents, four of which must be RVT Program courses.
- Establish Basic and Advance Core Curriculums.
- Include Delivery-specific RVT requirements (formerly listed in 500.110(8)(d)).
- Clarify that the RVT Program is mandatory and subject to enforcement.
- Incorporate the criteria for teaching on-line, non-real-time courses (current criteria for a waiver).
- Establish definitions of Responsible Vendor Trainer, Basic Core Curriculum, and Advanced Core Curriculum.
- Modify the definition of Responsible Vendor Training to remove duplicative portions covered in the regulations and clarify mandatory nature.
- Clarify that training related to written policies and procedures developed by Social Consumption Establishments under 500.141(2) can be training delivered by the ME rather than having to be taught by a Responsible Vendor Trainer.

## 500.002: Definitions

Advanced Core Curriculum means the advanced training curriculum taught by a Responsible Vendor Trainer that may be taken by Marijuana Establishment Agents after completing the Basic Core Curriculum under 935 CMR 500.105(2)(b).

Basic Core Curriculum means the foundational training curriculum required of all Marijuana Establishment Agents taught by a Responsible Vendor Trainer under 935 CMR 500.105(2)(b).

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



Responsible Vendor Training (RVT) Program means a mandatory program operated by an education provider accredited by the Commission to provide that provides training courses taught by a Responsible Vendor Trainer for Marijuana Establishment Agents in order to satisfy the minimum training of three hours\_of-required training to Marijuana Establishment Agentsunder 935 CMR 500.105(2). The program shall be mandatory and the topics covered shall include, but not be limited to: an understanding of different products and methods of consumption including Edibles; potency; effects; secondhand absorption time; procedures to ensure that Consumers are not overserved; procedures for mitigating the risk of an impaired Consumer and ensuring the safety of patrons and the general public in the event of impairment.

## 501.002: Definitions

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

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

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

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

## 500.105: General Operational Requirements for Marijuana Establishments

- (2) Marijuana Establishment Agent Training.
  - (a) Marijuana Establishments shall ensure that all Marijuana Establishment Agents complete minimum training requirements prior to performing job functions.

1. At a minimum, Marijuana Establishment Agents shall receive a total of eight



hours of training annually. The eight-hour total tale requirement shall be tailored to the roles and responsibilities of the job function of each Marijuana Establishment Agent, and at a.

- A minimum of four hours of training must include abe from Responsible Vendor Training Program courses established under 935 CMR 500.105(2)(b). Any additional RVT hours over the four-hour RVT requirement may count toward the eight-hour total training requirement.
- 3. Non-RVT training may be conducted in-house by the Marijuana Establishment or by a third-party vendor engaged by the Marijuana Establishment. Basic on-the-job training Marijuana Establishments provide in the ordinary course of business may be counted toward the eight-hour total training requirement.
- 4.4. Agents responsible for tracking and entering product into the Seed-tosale 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.
- 5. Marijuana Establishments must maintain records of compliance with all training requirements noted above. Such records must be maintained for four years and Marijuana Establishments must make such records available for inspection on request.

## (b) Responsible Vendor Training.

- On or after July 1, 2019, all. All current Owners, managers and employees of a
  Marijuana Establishment Agents that are involved in the handling and sale of
  Marijuana for adult use at the time of licensure or renewal of licensure, as
  applicable, shall have attended and successfully completed a Responsible
  Vendor Training Program to be designated a "Responsible Vendor."-
- 2. Once a Licensee is designated a "Responsible Vendor", all new employees involved in the handling and sale of Marijuana for adult use shall successfully complete a Responsible Vendor Training Program within 90 days of hire.
- 3. After initial successful completion of a Responsible Vendor Training Program, each Owner, manager, and employee involved in the handling and sale of Marijuana for adult use shall successfully complete the program once every year thereafter to maintain designation as a "Responsible Vendor".
  - a. Marijuana Establishment Agents must first take the Basic Core Curriculum.



- b. On completing the Basic Core Curriculum, a Marijuana Establishment Agent is eligible to take the Advanced Core Curriculum.
- a-c. Exception for Administrative Eemployees. Marijuana Establishment Agents who serve as administrative employees and do not handle or sell Marijuana are exempt from the four-hour RVT requirement but may take the "a Responsible Vendor" program Training Program course on a voluntary basis as part of fulfilling the eight-hour total training requirement.
- 2. Once a Marijuana Establishments must maintain records of Establishment is designated a Responsible Vendor—Training Program compliance, all Marijuana Establishment Agents employed by the Marijuana Establishment that are involved in the handling and sale of Marijuana for four years and make them available to inspection adult use shall successfully complete the Basic Core Curriculum within 90 days of hire.
- 4-3. After successful completion of the Basic Core Curriculum, each Marijuana Establishment Agent involved in the handling and sale of Marijuana for adult use shall fulfill the four-hour RVT requirement every year thereafter for the Marijuana Establishment to maintain designation as a Responsible Vendor. Failure to maintain Responsible Vendor status is grounds for action by the Commission and any other applicable licensing authority on request during normal business hours.

  5-4.Responsible Vendor Trainer Certification Training Program Standards.
  - (a) No owner, manager or employee of a Responsible Vendor program shall have an interest in Trainer may be a licensed Person Or Entity Having Direct Or Indirect Ownership or Control of a Marijuana Establishment.
  - (b) Program providersResponsible Vendor Trainers shall submit their programsprogram materials to the Commission prior to offering courses, every two years for approval as a following for Commission certification of the Responsible Vendor program.
  - (b) Trainer and Responsible Vendor Training Program curriculum, and on request. The program shall include process for certification will be in a form and manner determined by the Commission.
  - (c) Responsible Vendor Training Program courses must consist of at least two hours of instruction time.
  - (d) The program Except as provided in 935 CMR 500.105(2)(b)(4)(e), Responsible Vendor Training Program courses shall be taught in a real-time, interactive, virtual or in-person classroom setting wherein which the instructor is able to verify the identification of each individual attending the



program and certify completion of the program by the individual identified.

(e) The Responsible Vendor Training Program courses may be presented in a virtual format that is not taught in a real-time, provided that the Responsible Vendor Trainer, as part of its application for certification, can demonstrate means:

- 1. To verify the identification of each trainee participating in the program provider course and certify completion by the individual.
- 2. To track trainees' time needed to complete the course training;
- 3. To allow for the trainees to ask questions of the Responsible Vendor Trainer, for example, by email, virtual discussion board, or group/class discussion; and
- To evaluate each trainee's proficiency with course material.
- (f) Responsible Vendor Trainers shall seek certification for each Basic Core Curriculum and Advanced Core Curriculum. Applications for Advanced Core Curriculum certification will be open on or before July 1, 2022.
- (e)(g) Responsible Vendor Trainers must maintain its training records at its principal place of business during the applicable year and for the following threefor four years.
- (f)(h) The program provider shall Responsible Vendor Trainers must make the records available for inspection by the Commission and any other applicable licensing authority on request during normal business hours.
- (g)(i) The programResponsible Vendor Trainers shall provide to the appropriate Marijuana Establishment and Marijuana Establishment Agent written documentation of attendance and successful evaluation of proficiency, such as passage of a test on the knowledge of the required curriculum for each attendee.
- (h)(j) Attendees Trainees who can speak and write English fluently must successfully passdemonstrate proficiency, such as passing a written test with a score of 70% or better.
- (i)(k) Attendees Marijuana Establishment Agents who cannot speak or write English may be offered a verbal evaluation or test, provided that the same questions are given as are on the written test and the results of the verbal test are documented with a passing score of 70% orbetter.
- (j)(l) Program providers Responsible Vendor Trainers shall solicit effectiveness evaluations from individuals Marijuana Establishment Agents



who have completed their program-(s).

- 6-5. <u>Certification Training Class</u> Basic Core Curriculum. The Basic Core Curriculum must cover the following subject matter:
  - (a) Discussion concerning Marijuana's effect on the human body. Training shall include, including:
    - 1. Scientifically based evidence on the physical and mental health effects based on the type of Marijuana Product;
    - 2. The amount of time to feel impairment;
    - 3. Visible signs of impairment; and
    - 4. Recognizing the signs of impairment.
  - (b) Diversion prevention and prevention of sales to minors, including best practices.
  - (c) Compliance with all tracking requirements.
  - (d) Acceptable forms of identification. Training shall include:
    - 1. How to check identification;
    - 2. Spotting false and confiscating fraudulent identification;
    - 3. Patient registration cards formerly and validly issued by the DPH or currently and validly issued by the Commission;
    - 4. Provisions for confiscating fraudulent identifications; and
    - 5.4. Common mistakes made in <u>identification</u> verification.
    - 5. Prohibited purchases and practices, including purchases by persons under the age of twenty-one in violation of G.L. c. 94G, § 13.
  - (e) Other key state laws and rules affecting Owners, managers, and employees Marijuana Establishment Agents, which shall include:
    - 1. Local and state licensing and enforcement;
    - 2. Incident and notification requirements;
    - 3. Administrative and criminal liability;
    - 4. License sanctions:
    - 5. Waste disposal;
    - 6. Health and safety standards;
    - 7. Patrons prohibited from bringing marijuana onto licensed premises;
    - 8. Permitted hours of sale;
    - 9.1. Conduct of establishment Marijuana Establishment Agents;
    - 10.2. Permitting inspections by state and local licensing and enforcement authorities;



- 3. Local and state licensing and enforcement, including registration and license sanctions;
- 4. Incident and notification requirements;
- 5. Administrative, civil, and criminal liability;
- 6. Health and safety standards, including waste disposal;
- 7. Patrons prohibited from bringing marijuana and marijuana products onto licensed premises;
- 8. Permitted hours of sale;
- 11.9.Licensee responsibilities for activities occurring within licensed premises;

Maintenance of records; including confidentiality and privacy; and

- 12. Privacy issues; and
- 13. Prohibited purchases and practices.
- (f) Such other areas of training determined by the Commission to be included in a Responsible Vendor Training Program.
- 6. Advanced Core Curriculum.
  - (a) Each Advanced Core Curriculum class shall be approved by the Commission prior to being offered. The curriculum shall build on the knowledge, skills, and practices covered in the Basic Core Curriculum.
  - (b) An Advanced Core Curriculum class must include standard and best practices in one or more of the following areas
    - 1. Cultivation;
    - 2. Product Manufacturing;
    - 3. Retail;
    - 4. Transportation
    - Social Consumption;
    - 6. Laboratory Science;
    - 7. Energy and Environmental Best Practices;
    - 8. Social Justice and Economically Reparative Practices;
    - 9. Implicit Bias and Diversity Training;
    - 10. Worker Safety;
    - 11. Food Safety and Sanitation;
    - 12. Confidentiality and Privacy;
    - 13. In dept coverage of any topic(s) taught in the Basic Core Curriculum; or



- 14. Such other topic as the Commission may approve in its sole discretion.
- 7. Delivery Core Curriculum. In addition to the Basic Core Curriculum, all
  Marijuana Establishment Agents acting as delivery employees of a Delivery-only
  Licensee or a Marijuana Establishment with a Delivery Endorsement must have
  attended and successfully completed Delivery Core Curriculum prior to making a
  delivery, which must, to the extent not covered in Basic Core Training, include,
  without limitation, training on:
  - (a) Safely conducting deliveries;
  - (b) Safe cash handling practices;
  - (c) Strategies for de-escalating potentially dangerous situations;
  - (d) Collecting and communicating information to assist in investigations;
  - (e) Procedures for checking identification;
  - (f) Indications of impairment;
  - (g) Notification to Consumers of use of mandatory recording devices; and
  - (f)(h) Such other areas of training determined by the Commission to be included in a Responsible Vendor Training Program.

[...]

## (9) Recordkeeping. [...]

- (d) The following personnel records:
  - Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;
  - A personnel record for each marijuana establishment agent. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with the marijuana establishment and shall include, at a minimum, the following:
    - a. All materials submitted to the commission pursuant to 935 CMR 500.030(2);
    - b. Documentation of verification of references;
    - The job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision;



- d. Documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time, and place he or she received said training and the topics discussed, including the name and title of presenters;
- e. Documentation of periodic performance evaluations;
- f. A record of any disciplinary action taken; and
- g. Notice of completed responsible vendor Responsible Vendor Training Program and eight hourin-house related duty training for Marijuana Establishment Agents required under 935 CMR 500.105(2).

## 500.110: Security Requirements for Marijuana Establishments

(8) <u>Security Requirements for Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement Operations.</u>

[...]

- (d) All Marijuana Establishment Agents acting as delivery employees of a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement shall-must have attended and successfully completed Responsible Vendor Training <u>Basic Core</u> <u>Curriculum and Delivery Core Curriculum courses</u> in accordance with 935 CMR 500.105(2)(b) prior to making a delivery, which shall include, but may not be limited to, training on:
  - 1. Safely conducting deliveries;
  - 2. Safe cash handling practices;
  - 3. Strategies for de escalating potentially dangerous situations;
  - 4. Collecting and communicating information to assist in investigations;
  - 5. Procedures for checking identification;
  - 6. Indications of impairment;
  - 7. Notification to Consumers of use of mandatory recording devices; and
  - 8. Such other areas of training determined by the Commission to be included in a Responsible Vendor Training Program.



## 500.141: Additional Operational Requirements for Social Consumption Establishments

(2) Written Policies and Procedures. In addition to the written operating policies required under 935 CMR 500.105(1), prior to commencing operations, a Social Consumption Establishment shall—must maintain written policies and procedures for the sale, distribution, and serving of Marijuana and Marijuana Products; and provide in-house Responsible Vendor Training to employees to the extant not covered in a Responsible Vendor Training Program course on the such policies and procedures prior to commencing operations. In-house training provided under this 935 CMR 500.141(2) may be counted toward the eight-hour total training requirement required under 935 CMR 500.105(2)(a). Such written policies and procedures must which shall include but not be limited to without limitation: [...]

## 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

[...]

- (2) MTC Agent Training. MTCs shall ensure that all MTC Agents complete training prior to performing job functions. Training shall be tailored to the roles and responsibilities of the job function of each MTC Agent, and at a minimum must include training on confidentiality, privacy, security and other topics as specified by the Commission. MTC 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 ongoing training annually.
  - (a) MTCs shall ensure that all MTC Agents complete minimum training requirements prior to performing job functions.
    - 1. At a minimum, MTC Agents shall receive a total of eight hours of training annually. The eight-hour total training requirement shall be tailored to the roles and responsibilities of the job function of each MTC Agent.
    - 2. A minimum of four hours of training must be from Responsible Vendor Training Program courses established under 935 CMR 501.105(2)(b). Any additional RVT hours over the four-hour RVT requirement may count toward the eight-hour total training requirement.
    - 3. Non-RVT training may be conducted in-house by the MTC or by a third-party vendor engaged by the MTC. Basic on-the-job training MTCs provide in the ordinary course of business may be counted toward the eight-hour total training

**Commented [A15]:** These are the same provisions as adult RVT provisions, except that RVT delivery-specific provisions are removed for MTC agent training because those do not apply on the medical side.



#### requirement.

- 4. 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.
- 5. MTCs must maintain records of compliance with all training requirements noted above. Such records must be maintained for four years and MTCs must make such records available for inspection on request.

## (b) Responsible Vendor Training.

- 1. All current MTC Agents involved in the handling and sale of Marijuana for medical use at the time of licensure or renewal of licensure, as applicable, shall have attended and successfully completed a Responsible Vendor Training Program to be designated a "Responsible Vendor."
  - d. MTC Agents must first take the Basic Core Curriculum.
  - e. On completing the Basic Core Curriculum, an MTC Agent is eligible to take the Advanced Core Curriculum.
  - f. Exception for Administrative Employees. MTC Agents who serve as administrative employees and do not handle or sell Marijuana are exempt from the four-hour RVT requirement but may take a Responsible Vendor Training Program course on a voluntary basis as part of fulfilling the eighthour total training requirement.
- 2. Once an MTC is designated a Responsible Vendor, all MTC Agents employed by the MTC that are involved in the handling and sale of Marijuana for medical use shall successfully complete the Basic Core Curriculum within 90 days of hire.
- 3. After successful completion of the Basic Core Curriculum, each MTC Agent involved in the handling and sale of Marijuana for medical use shall fulfill the four-hour RVT requirement every year thereafter for the MTC to maintain designation as a Responsible Vendor. Failure to maintain Responsible Vendor status is grounds for action by the Commission.
- 4. Responsible Vendor Trainer Certification.
  - (a) No owner, manager or employee of a Responsible Vendor Trainer may be a Person Or Entity Having Direct Or Indirect Ownership or Control of an MTC.
  - (b) Responsible Vendor Trainers shall submit their program materials to the Commission prior to offering courses, every two years following for Commission certification of the Responsible Vendor Trainer and



Responsible Vendor Training Program curriculum, and on request. The process for certification will be in a form and manner determined by the Commission.

- (c) Responsible Vendor Training Program courses must consist of at least two hours of instruction time.
- (d) Except as provided in 935 CMR 501.105(2)(b)(4)(e), Responsible Vendor Training Program courses shall be taught in a real-time, interactive, virtual or in-person classroom setting in which the instructor is able to verify the identification of each individual attending the program and certify completion of the program by the individual.
- (e) Responsible Vendor Training Program courses may be presented in a virtual format that is not taught in a real-time, provided that the Responsible Vendor Trainer, as part of its application for certification, can demonstrate means:
  - 1. To verify the identification of each trainee participating in the program course and certify completion by the individual.
  - 2. To track trainees' time needed to complete the course training;
  - 3. To allow for the trainees to ask questions of the Responsible Vendor Trainer, for example, by email, virtual discussion board, or group/class discussion; and
  - 4. To evaluate each trainee's proficiency with course material.
- (f) Responsible Vendor Trainers shall seek certification for each Basic Core Curriculum and Advanced Core Curriculum. Applications for Advanced Core Curriculum certification will be open on or before July 1, 2022.
- (g) Responsible Vendor Trainers must maintain its training records at its principal place of business for four years,
- (h) Responsible Vendor Trainers must make the records available for inspection by the Commission and any other applicable licensing authority on request during normal business hours.
- (i) Responsible Vendor Trainers shall provide to the appropriate MTC and MTC Agent written documentation of attendance and successful evaluation of proficiency, such as passage of a test on the knowledge of the required curriculum for each attendee.
- (j) Trainees who can speak and write English fluently must successfully demonstrate proficiency, such as passing a written test with a score of 70%



#### <u>or better.</u>

- (k) MTC Agents who cannot speak or write English may be offered a verbal evaluation or test, provided that the same questions are given as are on the written test and the results of the verbal test are documented with a passing score of 70% or better.
- (1) Responsible Vendor Trainers shall solicit effectiveness evaluations from MTC Agents who have completed their program(s).
- 5. Basic Core Curriculum. The Basic Core Curriculum must cover the following subject matter:
  - (a) Marijuana's effect on the human body, including:
    - 1. Scientifically based evidence on the physical and mental health effects based on the type of Marijuana Product;
    - 2. The amount of time to feel impairment;
    - 3. Visible signs of impairment; and
    - 4. Recognizing the signs of impairment.
  - (b) Diversion prevention and prevention of sales to minors, including best practices.
  - (c) Compliance with all tracking requirements.
  - (d) Acceptable forms of identification. Training shall include:
    - 1. How to check identification;
    - 2. Spotting and confiscating fraudulent identification;
    - 3. Patient registration cards currently and validly issued by the Commission;
    - 4. Common mistakes made in identification verification.
    - 5. Prohibited purchases and practices, including purchases by persons under the age of twenty-one in violation of G.L. c. 94G, § 13.
  - (e) Other key state laws and rules affecting MTC Agents, which shall include:
    - 1. Conduct of MTC Agents;
    - 2. Permitting inspections by state and local licensing and enforcement authorities;
    - 3. Local and state licensing and enforcement, including registration and license sanctions;
    - 4. Incident and notification requirements;
    - 5. Administrative, civil, and criminal liability;
    - 6. Health and safety standards, including waste disposal;



- 7. Patrons prohibited from bringing marijuana and marijuana products onto licensed premises;
- 8. Permitted hours of sale;
- 9. Licensee responsibilities for activities occurring within licensed premises;
- Maintenance of records, including confidentiality and privacy; and
- (f) Such other areas of training determined by the Commission to be included in a Responsible Vendor Training Program.
- 6. Advanced Core Curriculum.
  - (a) Each Advanced Core Curriculum class shall be approved by the Commission prior to being offered. The curriculum shall build on the knowledge, skills, and practices covered in the Basic Core Curriculum.
  - (b) An Advanced Core Curriculum class must include standard and best practices in one or more of the following areas
    - 1. Cultivation;
    - 2. Product Manufacturing;
    - 3. Retail;
    - 4. Transportation
    - 5. Social Consumption;
    - 6. Laboratory Science;
    - 7. Energy and Environmental Best Practices;
    - 8. Social Justice and Economically Reparative Practices;
    - 9. Implicit Bias and Diversity Training;
    - 10. Worker Safety;
    - 11. Food Safety and Sanitation;
    - 12. Confidentiality and Privacy;
    - 13. In dept coverage of any topic(s) taught in the Basic Core Curriculum; or
    - 14. Such other topic as the Commission may approve in its sole discretion.

[...]

(9) Recordkeeping.

[...]

(d) The following personnel records:



- 1. Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;
- A personnel record for each MTC and Laboratory Agent. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with the MTC and shall include, at a minimum, the following:
  - All materials submitted to the Commission pursuant to 935 CMR 501.029 and 935 CMR 501.030;
  - b. Documentation of verification of references;
  - The job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision;
  - d. Documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time, and place he or she received said training and the topics discussed, including the name and title of presenters;
  - e. A copy of the application that the MTC submitted to the Commission on behalf of any prospective MTC agent;
  - f. Documentation of periodic performance evaluations; and
  - g. Notice of completed Responsible Vendor Training Program and in-house training for MTC Agents required under 935 CMR 501.105(2), and
  - g.h. A record of any disciplinary action taken.



# Topic: Personnel Policy - Code of Ethics and Whistleblower Policy

<u>Recommendation</u>: Within recordkeeping requirements, require licensees to include a code of ethics and whistleblower policy among their personnel records subject to inspection by the Commission upon request. This would provide certainty for employees who wish to access a code of ethics or whistleblower policy.

# 500.105: General Operational Requirements for Marijuana Establishments

[...]

- (9) Recordkeeping. [...]
  - (d) The following personnel records:
    - 1. Job descriptions for each employee and volunteer position, as well as organizational charts consistent with the job descriptions;
    - 2. A personnel record for each marijuana establishment agent. Such records shall be maintained for at least 12 months after termination of the individual's affiliation with the marijuana establishment and shall include, at a minimum, the following:
      - a. All materials submitted to the commission pursuant to 935 CMR 500.030(2);
      - b. Documentation of verification of references;
      - c. The job description or employment contract that includes duties, authority, responsibilities, qualifications, and supervision;
      - d. Documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time, and place he or she received said training and the topics discussed, including the name and title of presenters;
      - e. Documentation of periodic performance evaluations;
      - f. A record of any disciplinary action taken; and



- g. Notice of completed responsible vendor and eight-hour related duty training.
- 3. A staffing plan that will demonstrate accessible business hours and safe cultivation conditions;
- 4. Personnel policies and procedures, including, at a minimum, the following:

  a. Code of ethics
  - b. Whistle-blower policy; and
- 5. All background check reports obtained in accordance with M.G.L c. 6 \$ 172, 935 CMR 500.029, 935 CMR 500.030, and 803 CMR 2.00: Criminal Offender



# **Topic: Workplace Safety**

Recommendations: Amend 500.105(1)(r) and 501.105(1)(r) to:

- Incorporate by reference OSHA standards, which control in the Commonwealth of Massachusetts (we will need to obtain the current copy of the OSHA standards to file with our regulations);
- Add to the general operational requirements for MEs and MTCs that they have policies and procedures consistent with OSHA standards.

# 500.105: General Operational Requirements for Marijuana Establishments

(1) Written Operating Procedures. Every Marijuana Establishment shall have and follow a set of detailed written operating procedures. If the Marijuana Establishment has an additional location, it shall develop and follow a set of such operating procedures for that facility. Operating procedures shall include, but need not be limited to the following:

[...]

(r) Policies and procedures to promote workplace safety consistent with applicable standards set by the Occupational Safety and Health Administration, including plans to identify and address any biological, chemical or physical hazards. Such policies and procedures shall include, at a minimum, a hazard communication plan, personal protective equipment assessment, a fire protection plan, and an emergency action plan. Policies and procedures to promote workplace safety consistent with tThe standards set forth under the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651, et seq., including the general duty clause under 29 U.S.C. § 654, whereby:

Each employer (a) shall furnish to each of its employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees; (b) shall comply with occupational safety and health standards promulgated under this act. Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to 29 U.S.C. c. 651 which are applicable to the employee's own actions and conduct.





All current and updated regulations and references at 29 CFR Parts 1903, 1904, 1910, 1915, 1917, 1918, 1926, 1928, and 1977 are incorporated by reference, and applicable to all places of employment covered by 935 CMR 500.000.

### 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

(1) Written Operating Procedures. Every MTC shall have and follow a set of detailed written operating procedures. If the MTC has an additional location, it shall develop and follow a set of such operating procedures for that facility. Operating procedures shall include, but need not be limited to, the following:

[...]

(r) Policies and procedures to promote workplace safety consistent with applicable standards set by the Occupational Safety and Health Administration, including plans to identify and address any biological, chemical or physical hazards. Such policies and procedures shall include, at a minimum, a hazard communication plan, personal protective equipment assessment, a fire protection plan, and an emergency action plan. Policies and procedures to promote workplace safety consistent with the standards set forth under the Occupational Safety and Health Act of 1970, 29 U.S.C. c. 651, et seq., including the general duty clause under 29 U.S.C. § 654, whereby:

Each employer (a) shall furnish to each of its employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees; (b) shall comply with occupational safety and health standards promulgated under this act. Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to 29 U.S.C. c. 651 which are applicable to the employee's own actions and conduct.



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

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



# **Topic: Waste Receptacles**

 $\underline{Recommendation}: Amend \ 501.105(12)(a) \ and \ 502.105(12)(a) \ to \ be \ consistent \ with \ adult-use \ regulation \ 500.105(12)(a).$ 

# 501.105: General Operational Requirements for Medical Marijuana Treatment Centers.

- (12) Waste Disposal.
- (a) All recyclables and waste, including organic waste composed of or containing Finished Marijuana and MIPs, shall be stored, secured, and managed in accordance with applicable state and local statutes, ordinances, and regulations. All exterior waste receptacles located on the Marijuana Establishment's Premises shall be locked and secured to prevent unauthorized access.

# **502.105: General Operational Requirements**

- (12) Waste Disposal.
- (a) All recyclables and waste, including organic waste composed of or containing finished marijuana, MIPs, or marijuana products, shall be stored, secured, and managed in accordance with applicable state and local statutes, ordinances, and regulations. All exterior waste receptacles located on the Marijuana Establishment's Premises shall be locked and secured to prevent unauthorized access.



# **Topic: Fire Safety Requirements**

# Summary of changes:

 Add requirement to additional operational requirements for MEs and MTCs engaging in product manufacturing or cultivation to have policies and procedures to ensure compliance with the Massachusetts Fire Code (527 CMR 1.00)

# 500.120: Additional Operational Requirements for Indoor and Outdoor Marijuana Cultivators

[...]

- (12) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Cultivator, including colocated Marijuana Cultivators and MTCs, shall maintain written policies and procedures for the cultivation, production, Transfer or distribution of Marijuana, as applicable, which shall include but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(8);
  - (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by a Marijuana Establishment to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
  - (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(12);
  - (d) <u>Policies and Procedures for Transportation</u>. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(13);
  - (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(15) and 935 CMR





#### 500.120(11); and

- (f) Policies and procedures for ensuring fire safety in cultivation activities, including but not limited to the storage and processing of chemicals or fertilizers, in compliance with the standards set forth in 527 CMR 1.00: The Massachusetts Comprehensive Fire Code; and
- (f)(g)Policies and procedures for the Transfer, acquisition, or sale of Marijuana between Marijuana Establishments.

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

[...]

- (13) In addition to the written operating policies required under 935 CMR 501.105(1), MTC cultivation operations, including Colocated Marijuana Cultivators, shall maintain written policies and procedures for the cultivation, production, Transfer or distribution of Marijuana, as applicable, which shall include, but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(8);
  - (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by an MTC to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
  - (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(12);
  - (d) Policies and procedures for transportation. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(13);
  - (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(15) and 935 CMR



501.120(11); and

(e)(f) Policies and procedures for ensuring fire safety in cultivation activities, including but not limited to the storage and processing of chemicals or fertilizers, in compliance with the standards set forth in 527 CMR 1.00: The Massachusetts Comprehensive Fire Code: and

(f)(g)Policies and procedures for the Transfer, acquisition, or sale of Marijuana between MTCs and Marijuana Establishments.

# 500.130: Additional Operational Requirements for Marijuana Product Manufacturers

[...]

- (5) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Product Manufacturer shall maintain written policies and procedures for the production or distribution of Marijuana Products, as applicable, which shall include, but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(8);
  - (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana Products. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by a Marijuana Establishment to remove defective or potentially defective Marijuana Products from the market, as well as any action undertaken to promote public health and safety:
  - (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana Products is segregated from other product and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana Products. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(12);
  - (d) Policies and procedures for transportation. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(13);
  - (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(15);



- (f) Policies and procedures for the Transfer, acquisition, or sale of Marijuana Products between Marijuana Establishments;
- (g) Policies and procedures to ensure that all Edible Marijuana Products are prepared, handled, and stored in compliance with the sanitation requirements in 105 CMR 590.000: State Sanitary Code Chapter X: Minimum Sanitation Standards for Food Establishments, and with the requirements for food handlers specified in 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements; and
- (h) Policies and procedures for maintaining a product catalogue identifying all types of Marijuana Products actively manufactured at the facility. The catalog shall include a description of the product, photograph or illustration, packaging design, and dosage amounts, including expected Cannabinoid Profile; and -
- (i) Policies and procedures for ensuring safety in all processing activities and the related uses of extraction equipment in compliance with the standards set forth in 527 CMR 1.00: The Massachusetts Comprehensive Fire Code.

[...]

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

[...]

- (5) Written policies and procedures for the production and distribution of Marijuana, which shall include, but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories;
  - (b) A procedure for handling voluntary and mandatory recalls of Marijuana. Such procedure shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by an MTC to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
  - (c) A procedure for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. This procedure shall provide for written documentation of the disposition of the Marijuana. The policies and



- procedures, at a minimum, must be in compliance with 935 CMR 501.105(12);
- (d) Policies and procedures for transportation and patient or Personal Caregiver home delivery;
- (e) Policies and procedures for the Transfer, acquisition, or sale of Marijuana between MTCs, and if applicable, Marijuana Establishments and CMOs; and
- (f) Policies and procedures to ensure that all Edible MIPs are prepared, handled, and stored in compliance with the sanitation requirements in 105 CMR 500.000: Good Manufacturing Practices for Food, and with the requirements for food handlers specified in 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements.
- (6) An MTC shall have policies and procedures for ensuring safety in all processing activities and the related uses of extraction equipment in compliance with the standards set forth in 527 CMR 1.00: The Massachusetts Comprehensive Fire Code.
- (6)(7) Notwithstanding a stricter municipal or state regulation, an MTC shall identify the method of extraction (e.g., Butane, Propane, CO<sub>2</sub>) on a physical posting at all entrances of the MTC. The Posting shall be a minimum of 12" x 12" and identify the method of extraction in lettering no smaller than one inch in height. An MTC shall post a copy of a permit to keep, store, handle or otherwise use flammable and combustible material at each place of operation within the facility.
- (7)(8) Except for a Registered Qualifying Patient or Personal Caregiver, who are not subject to 935 CMR 501.105, only a licensed MTC is permitted to produce MIPs. Unless otherwise authorized by the Commission, an MIP production facility of an MTC may produce MIPs for only that MTC, and up to two additional MTCs under an entity.

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# **Topic: Limited Access Areas**

# Recommendations:

- Make clear that restrictions on entry to Limited Access Areas only apply following receipt of a
  Final License, in order to allow access to such areas by landlords, inspectors, contractors, etc.
  without registration as an Agent prior to there being product on the Premises; and
- Create the ability to have Limited Access Areas that overlap in hallways and access points, but still require operations and access to Agents to be separated based on license type.

# 500.002: Definitions

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

# 500.110: Security Requirements for Marijuana Establishments

- (1) General Requirements. [...]
  - (e) Establishing Limited Access Areas pursuant to 935 CMR 500.110(4), which, after receipt of a Final License, shall be accessible only to specifically authorized personnel, limited to include only the minimum number of employees essential for efficient operation;
- (4) <u>Limited Access Areas</u>.
  - (a) All Limited Access Areas must be identified by the posting of a sign that shall be a minimum of 12" x 12" and which states: "Do Not Enter - Limited Access Area -Access Limited to Authorized Personnel Only" in lettering no smaller than one inch in height.





- (b) All Limited Access Areas shall be clearly described by the filing of a diagram of the licensed Premises, in the form and manner determined by the Commission, reflecting entrances and exits, walls, partitions, counters, Propagation, Vegetation, Flowering, Processing, production, storage, disposal and retail sales areas.
- (c) At all times following receipt of a Final License, Aaccess to Limited Access Areas shall be restricted to employees, agents, or volunteers specifically permitted by the Marijuana Establishment, agents of the Commission, Commission Delegees, and state and local Law Enforcement Authorities acting within their lawful jurisdictions, police and fire departments, and emergency medical services acting in the course of their official capacity.
- (d) Employees of the Marijuana Establishment shall visibly display an employee identification badge issued by the Marijuana Establishment at all times while at the Marijuana Establishment or transporting Marijuana.
- (e) Following receipt of a Final License, Aall outside vendors, contractors, and Visitors shall obtain a Visitor Identification Badge prior to entering a Limited Access Area and shall be escorted at all times by a Marijuana Establishment Agent authorized to enter the Limited Access Area. The Visitor Identification Badge shall be visibly displayed at all times while the Visitor is in any Limited Access Area. All Visitors 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 Marijuana Establishment on exit
- (e)(f) A Marijuana Establishment conducting operations under multiple license types on a single Premise may establish Limited Access Areas for each licensed activity that overlap in shared hallways and access points, provided that operations under each license type are segregated and a Marijuana Establishment Agent has access only to the areas where activities are conducted pursuant to the license under which the Marijuana Establishment Agent is registered



# **Topic: Buffer Zone**

<u>Recommendation</u>: Change how 500-foot buffer zone distance is measured by considering actual accessibility to an ME/MTC from a school site, and taking into account impassable barriers such as highways or rivers when measuring the 500-foot buffer zone distance.

# 935 CMR 500.110: Security Requirements for Marijuana Establishments

(3) <u>Buffer Zone</u>. The property where the proposed Marijuana Establishment is to be located, at the time the license application is received by the Commission, is not located within 500 feet of a preexisting public or private school providing education in kindergarten or any of grades one through 12, unless a city or town adopts an ordinance or bylaw that reduces the distance requirement. The distance under 935 CMR 500.110(3) shall be measured in a straight line from the nearest point of the property line in question to the nearest point of the property line where the Marijuana Establishment is or will be located.

The nearest point of any property line on the lot where a Marijuana Establishment is located – excluding those property lines surrounding portions of irregularly-shaped lots that cannot sustain the main operational facilities required for the Marijuana Establishment, such as but not limited to property lines surrounding the "pole" of a flag lot – shall be 500 feet from the nearest entrance of any pre-existing public or private school providing education in kindergarten or any grades 1 through 12.

- (a) For the purposes of 935 CMR 500.110(3), "entrance" shall be defined as the entrance that provides ingress and egress to the students of the pre-existing public or private school at the time of the Marijuana Establishment license application.
- (b) The buffer zone distance of 500 feet shall be measured in a straight line from the approximate geometric center of the main entrance unless a generally and immediately impassable barrier, such as but not limited to a highway or river, would otherwise block pedestrian travel in those 500 feet; in these cases, the buffer zone distance shall be measured along the center of the shortest publicly-accessible pedestrian travel path from the approximate geometric center of the main entrance.

Commented [A16]: <u>Statute</u>: G.L. c. 94G, § 5(b)(3)

(3) the property where the proposed marijuana establishment is to be located, at the time the license application is received by the commission, is not located within 500 feet of a pre-existing public or private school providing education in kindergarten or any of grades 1 through 12, unless a city or town adopts an ordinance or by-law that reduces the distance requirement; and





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

#### 935 CMR 501.110: Security Requirements for Medical Marijuana Treatment Centers

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

The nearest point of any property line on the lot where an MTC is located – excluding those property lines surrounding portions of irregularly-shaped lots that cannot sustain the main operational facilities required for the MTC, such as but not limited to property lines surrounding the "pole" of a flag lot – shall be 500 feet from the nearest entrance of any pre-existing public or private school providing education in kindergarten or any grades 1 through 12.

- (a) For the purposes of 935 CMR 500.110(3), "entrance" shall be defined as the entrance that provides ingress and egress to the students of the pre-existing public or private school at the time of the MTC license application.
- (b) The buffer zone distance of 500 feet shall be measured in a straight line from the approximate geometric center of the main entrance unless a generally and immediately impassable barrier, such as but not limited to a highway or river, would otherwise block pedestrian travel in those 500 feet; in these cases, the buffer zone distance shall be measured along the center of the shortest publicly-accessible pedestrian travel path from the approximate geometric center of the main entrance.
- (c) The buffer zone distance of 500 feet may be reduced if a city or town adopts an ordinance or bylaw that reduces the distance requirement.

 $\begin{tabular}{ll} \textbf{Commented [A17]:} Same as adult provision, just replaced \\ \textbf{ME with MTC} \end{tabular}$ 



# Topic: Advertising, Marketing and Branding

# Recommendations:

- While noting that the terms "advertising, marking and branding" are used in G. L. c. 94G, § 4
  (a ½)(xxix), focusing on the terms advertising (making a product and service known to an
  audience or marketplace), and branding (a form of advertising).
- 2. Allow MEs or MTCs to use a Brand Name and put the Brand Name on Branded Goods, but not Marijuana or Marijuana Products.
- 3. Allow Brand Name Sponsorship where MEs and MTCs can sponsor events, but not advertise to underage participants or entrants.
  - a. An ME or MTC can sponsor an event and use their Brand Name. They can also advertise to entrants or participants that are 21 years of age or older, e.g., by designating a smaller space within a larger event.
  - b. An ME or MTC has to take steps to ensure that the advertising is not targeting underage entrants or participants.
- 4. Allow employee, but not consumer discounts.
- Allow MEs to target their advertising via mechanisms like geofencing (the application of a virtual boundary in which certain rules are applied when a mobile device enters or leaves).
- 6. Clarify that neon signs are prohibited.
- Eliminate certain advertising restrictions in the medical regulations because the restrictions do not apply to patients that are under 21 years of age or do not apply to the medical use program.

# 500.002: Definitions

Advertising means a form of marketing communication that employs a sponsored, non-personal message to sell or promote a Marijuana Establishment's Brand Name, Marijuana Establishment Branded Good, service, product or idea.

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





Brand Name Sponsorship means the payment by an ME in exchange for use of a Brand Name (1) to sponsor an athletic, musical, artistic, or other social or cultural event or (2) to identify, advertise, or promote such event, or an entrant, or participant of such an event.

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

# 501.002: Definitions

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

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

Brand Name Sponsorship means the payment by an ME in exchange for use of a Brand Name (1) to sponsor an athletic, musical, artistic, or other social or cultural event or (2) to identify, advertise, or promote such event or an entrant or participant of such event.

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

# 500.105: General Operational Requirements for Marijuana Establishments

(4) Marketing and Advertising Requirements.



- (a) <u>Permitted Practices</u>. The following advertising, marketing, and branding activities are permitted:
  - A Marijuana Establishment may develop a <u>Brand Name</u> <u>business name and logo</u>
    to be used in labeling, signage, and other materials; provided however, that use of
    medical symbols, images of Marijuana <u>or Marijuana Products</u>, or related
    Paraphernalia images, that are appealing to persons younger than 21 years old,
    and colloquial references to <u>Marijuana and Cannabis</u> are
    prohibited from use in <u>this business name and logo</u> the <u>Brand Name</u>;
  - Brand Name Sponsorship of a charitable, sporting or similar event, so long as the following conditions are met.
    - (a) Sponsorship of the event is limited to the Brand Name.
    - (b) Any advertising at or in connection with such an event is prohibited, unless such advertising is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching entrants or participants reasonably expected to be under 21 years of age, as determined by reliable, current audience composition data;
    - except that advertising, marketing, and branding at or in connection with such an event is prohibited, unless at least 85% of the audience reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data;
  - 3. Brand Name Sponsorship of a charitable, cultural or similar event both held and organized by the city or town in which the sponsoring Marijuana Establishment or CMO is licensed to conduct business, so long as the following conditions are met:
    - (a) Sponsorship of said event shall be included in its Positive Impact Plan submitted in accordance with 935 CMR 500.101(1)(a)11;
    - (b) Sponsorship of the event is limited to the Brand Name;
    - (c) Any advertising at or in connection with such an event is prohibited, unless such advertising is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching



entrants or participants reasonably expected to be under 21 years of age, as determined by reliable, current audience composition data;

- For this event, the audience must be at least 85 per cent of the audience is reasonably expected to be 21 years of age or older, as determined by reliable, up to date audience composition data;
- 2.4.A Marijuana Establishment may display, in secure, locked cases, samples of each product offered for sale and subject to the requirements of 935 CMR 500.110. These display cases may be transparent. An authorized Marijuana Establishment Agent may remove a sample of Marijuana from the case and provide it to the Consumer for inspection, provided the Consumer may not consume or otherwise use the sample, unless otherwise authorized herein;
- 3.5. The establishment may post prices in the store and may respond to questions about pricing. The Marijuana Establishment shall provide a catalogue or a printed list of the prices and strains of Marijuana available at the Marijuana Establishment to Consumers and may post the same catalogue or printed list on its website and in the retail store;
- 4.6.A Marijuana Establishment may engage in reasonable marketing, advertising and branding practices that are not otherwise prohibited in 935 CMR 500.105(4)(b) that do not jeopardize the public health, welfare or safety of the general public or promote the diversion of Marijuana or Marijuana use in individuals younger than 21 years old or otherwise promote practices inconsistent with the purposes of M.G.L. c. 94G or 94I. Any such marketing, advertising and branding created for viewing by the public shall include the statement "Please Consume Responsibly", in a conspicuous manner on the face of the advertisement and shall include a minimum of two of the following warnings in their entirety in a conspicuous manner on the face of the advertisement:
  - (a) "This product may cause impairment and may be habit forming.";
  - (b) "Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug.";
  - (c) "There may be health risks associated with consumption of this product.";
  - (d) "For use only by adults 21 years of age or older. Keep out of the reach of children."; or
  - (e) "Marijuana should not be used by women who are pregnant or breastfeeding."



5.7.All marketing, advertising and branding produced by or on behalf of a Marijuana Establishment for Marijuana or Marijuana Products shall include the following warning, including capitalization, in accordance with M.G.L. c. 94G, § 4(a½)(xxvi):

"This product has not been analyzed or approved by the Food and Drug Administration (FDA). There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN. There may be health risks associated with consumption of this product. Marijuana can impair concentration, coordination, and judgment. The impairment effects of Edible Marijuana Products may be delayed by two hours or more. In case of accidental ingestion, contact poison control hotline 1-800-222-1222 or 9-1-1. This product may be illegal outside of MA."

- 8. A Licensee may utilize employee discounts as part of the Marijuana Establishment's operating policy and procedure for prevention of diversion pursuant to 935 CMR 500.101(1)(c)(8.)(b.). Institution of an employee discount program under this subsection shall not be considered a prohibited practice under 935 CMR 500.105(4)(b).
- (b) <u>Prohibited Practices</u>. The following advertising <u>, marketing</u>, and <u>branding</u> activities are prohibited:
  - Advertising, marketing, and branding in such a manner that is deemed to be is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly or by omission or ambiguity;
  - Advertising, marketing and branding by means of television, radio, internet, mobile applications, social media, or other electronic communication, billboard or other outdoor advertising, or print publication, unless at least 85% of the audience is reasonably expected to be 21 years of age or older as determined by reliable and current audience composition data;



- Advertising, marketing, and branding that utilizes statements, designs, representations, pictures or illustrations that portray anyone younger than 21 years old:
- Advertising, marketing, and branding including, but not limited to, mascots, cartoons, brand sponsorships and celebrity endorsements, that is deemed to appeal to a person younger than 21 years old;
- 4.5.Brand sponsorship including, but not limited to, mascots, cartoons, and celebrity endorsements, that is deemed to appeal to a person younger than 21 years old;
- 5.6. Advertising, marketing, and branding, including statements by a Licensee, that makes any false or statements concerning other Licensees and the conduct and products of such other Licensees that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly or by omission or ambiguity;
- 6. Advertising, marketing, and branding through certain identified promotional items as determined by the Commission including, but not limited to, gifts, giveaways, discounts, points based reward systems, customer loyalty programs, coupons, or "free" or "donated" Marijuana;
- 7. Advertising, marketing, and branding by a Licensee that asserts that its products are safe, or represent that its products have curative or therapeutic effects, other than labeling required pursuant to M.G.L. c. 94G, § 4(a½)(xxvi), unless supported by substantial evidence or substantial clinical data with reasonable scientific rigor as determined by the Commission;
- 8. Advertising on any billboards, or any other public signage, which fails to comply with all state and local ordinances and requirements;
- Installation-Use of any\_illuminated, neon, or illuminated or external signage beyond the period of 30 minutes before sundown until closing, provided however, that the Commission may further specify minimum signage requirements;
- 10. The use of vehicles equipped with radio or loudspeakers for the Aadvertising of Marijuana or Marijuana Products;
- 11. The use of radio or loudspeaker equipment in any Marijuana Establishment for the purpose of <u>Advertisingattracting attention to</u> the sale of Marijuana <u>or</u> <u>Marijuana Products</u>;
- 12. Advertising Brand Name Sponsorship, marketing, and branding at, or in connection with, of a charitable, sporting or similar event, unless such advertising

 $\boldsymbol{Commented}$  [A18]: Moved down to 20 so that adult and med numbering align



is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching entrants or participants reasonably expected to be under 21 years of age, as determined by reliable, current audience composition data;

- 12. unless at least 85% of the audience is reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data;
- 13. Operation of any website of a Marijuana Establishment that fails to verify that the entrant is 21 years of age or older;
- Use of unsolicited pop-up advertisements on the internet or text message; unless the advertisement is a mobile device application installed on the device by the owner of the device who is 21 years of age or older and includes a permanent and easy opt-out feature.
- 14. Any advertising, including the use of Brand Names, -of an improper or objectionable nature including, but not limited to, the use of language or images offensive or disparaging to certain groups recipe books or pamphlets for Marijuana Products which contain obscene or suggestive statements;
- 15. Any aAdvertising, marketing or branding solely for the promotion of Marijuana or Marijuana Products, on Marijuana Establishment Branded Goods, including but not limited to clothing, cups, drink holders, apparel accessories, electronic equipment or accessories, sporting equipment, novelty items and similar portable promotional items;
- 17. Advertising, marketing, branding, The display of signs or other printed materialtter advertising any brand or any kind of Marijuana or Marijuana Products that are displayed on the exterior of any licensed Premises or interior of any licensed Premises where Marijuana Products are not regularly and usually kept for sale;
- 18. Advertising or marketing of the price of Marijuana or Marijuana Products, except as permitted above pursuant to 935 CMR 500.105(4)(a)(4.); and



- 19. Display of Marijuana or Marijuana Products so as to be clearly visible to a person from the exterior of a Marijuana Establishment.
- 20. Advertising through the marketing of free promotional items-, including, but not limited to, gifts, giveaways, discounts, points-based reward systems, customer loyalty programs, coupons, and "free" or "donated" Marijuana, except as otherwise permitted by 935 CMR 500.105(4)(a)(8.) and except for the provision of Brand Name take-away bags by a Marijuana Establishment for the benefit of customers after a retail purchase is completed;
- (e)—Nothing in 935 CMR 500.105(4) prohibits a Marijuana Establishment from using a mark provided by the Commission which uses images of Marijuana or Marijuana Products.

# 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (2) Marketing and Advertising Requirements.
  - (a) Permitted Practices.
    - 1.—An MTC may develop a Brand Name-a business name and logo to be used in labeling, signage, and other materials; provided however, that use of medical symbols, images of Marijuana or Marijuana Products, or related Paraphernalia, images that are appealing to persons younger than 21 years old, and colloquial references to Cannabis and Marijuana are prohibited from use in the Brand Name business name and logo;
    - 1.\_\_
    - Brand Nname Sponsorship of a charitable, sporting or similar event, so long as the following conditions are met:
      - (a) Sponsorship of the event is limited to the Brand Name.
      - —Any advertising at or in connection with such an event is prohibited, unless such advertising is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching entrants or participants reasonably expected to be under 21 years of age, as determined by reliable, current audience composition data; unless such



advertising is targeted to entrants or participants reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data, and reasonable safeguards have been employed to prohibit advertising from targeting or otherwise reaching entrants or participants reasonably expected to be under 21 years of age, as determined by reliable, current audience composition data; except that advertising, marketing, and branding at or in connection with such an event is prohibited, unless at least 85% of the audience is reasonably expected to be either 21 years of age or older or individuals with a debilitating condition, as determined by reliable, current audience composition data;

- (a)(b) \_\_\_An MTC may display, in secure, locked cases, samples of each product offered for sale and subject to the requirements of 935 CMR 501.110. These display cases may be transparent. An authorized MTC Agent may remove a sample of Marijuana from the case and provide it to the Registered Qualifying Patient for inspection, provided the Registered Qualifying Patient may not consume or otherwise use the sample, unless otherwise authorized in 935 CMR 501.000.
- 2.3. The MTC may post prices in the store and may respond to questions about pricing. The MTC shall provide a catalogue or a printed list of the prices and strains of Marijuana available at the MTC to Registered Qualifying Patients and may post the same catalogue or printed list on its website and in the retail store.
- 3.4. An MTC may engage in reasonable marketing, advertising reasonable advertising and branding practices that are not otherwise prohibited in 935 CMR 501.105(4)(b) that do not jeopardize the public health, welfare or safety of the general public or promote the diversion of Marijuana or Marijuana use in individuals younger than 21 years old or otherwise promote practices inconsistent with the purposes of M.G.L. c. 94G or 94I. Any such marketing, advertising and branding created for viewing by the public shall include the statement "Please Consume Responsibly", in a conspicuous manner on the face of the advertisement and shall include a minimum of two of the following warnings in their entirety in a conspicuous manner on the face of the advertisement:
  - a. "This product may cause impairment and may be habit forming";



- "Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug";
- c. "There may be health risks associated with consumption of this product"; or
- d. "For use only by adults 21 years of age or older. Keep out of the reach of children"; or
- <u>d.</u> "Marijuana should not be used by women who are pregnant or breastfeeding". 5. An MTC may provide Brand Name take-away bags for the benefit of patients after a retail purchase is completed;
- All marketing, advertising and branding produced by or on behalf of an MTC shall include the following warning, including capitalization, in accordance with
- 5. M.G.L. c. 94G, § 4(a1/2)(xxvi):

"This product has not been analyzed or approved by the Food and Drug Administration (FDA). There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN. There may be health risks associated with consumption of this product. Marijuana can impair concentration, coordination, and judgment. The impairment effects of Edible Marijuana Products may be delayed by two hours or more. In case of accidental ingestion, contact poison control hotline 1-800-222-1222 or 911. This product may be illegal outside of MA."

- (b) <u>Prohibited Practices</u>. The following advertising activities are prohibited:

  - 2.
  - 2.—Advertising\_, marketing and branding by means of television, radio, internet, mobile applications, social media, or other electronic communication, billboard or other outdoor advertising, or print publication, unless at least 85% of the audience is reasonably expected to be 21 years of age or older or comprised of individuals with debilitating conditions, as determined by reliable and current audience composition data;



 Advertising, marketing, and branding that utilizes statements, designs, representations, pictures or illustrations that portray anyone younger than 21 years old.

Advertising, marketing, and branding including, but not limited to, mascots, cartoons, brand sponsorships and celebrity endorsements, that is deemed to appeal to a person younger than 21 years old.

4.

- 5-3. Advertising, marketing, and branding, including statements by a Licensee, that makes any false or statements concerning other Licensees and the conduct and products of such other Licensees that is deceptive, misleading, false or fraudulent, or that tends to deceive or create a misleading impression, whether directly or by omission or ambiguity;
- 6. Advertising, marketing, and branding by a Licensee that asserts that its products are safe, or represent that its products have curative or therapeutic effects, other than labeling required pursuant to M.G.L. c. 94G, § 4(al/2)(xxvi), unless supported by substantial evidence or substantial clinical data with reasonable scientific rigor as determined by the Commission;
- 7.4. Advertising on any billboards or any other public signage which fails to comply with all state <u>laws</u> and local ordinances and requirements;
- 8.5. Installation of any illuminated neon signage or external signage beyond the period of 30 minutes before sundown until closing, provided however, that the Commission may further specify minimum signage requirements;
- 9.6. The use of vehicles equipped with radio or loudspeakers for the advertising of Marijuana or Marijuana Products;
- 10-7. The use of radio or loudspeaker equipment in any MTC for the purpose of attracting attention to the sale of Marijuana or Marijuana Products;
- 11. Advertising, marketing, and branding at, or in connection with, a charitable, sporting or similar event, unless at least 85% of the audience is reasonably expected to be 21 years of age or older, as determined by reliable, current audience composition data;
- <u>12-8.</u> Operation of any website of an MTC that fails to verify that the entrant is a Qualifying Patient or Caregiver 21 years of age or older or the entrant is 21 years of age or older;



- Use of unsolicited pop-up advertisements on the internet or text message; unless the advertisement is a mobile device application installed on the device by the owner of the device who is a Qualifying Patient or Caregiver or 21 years of age or older and includes a permanent and easy opt-out feature;
- 44.10. Any advertising, including the use of Brand Names, 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 the use or language or images offensive or disparaging to certain groups;
- 45.11. Any Advertising, marketing or branding advertising solely for the promotion of Marijuana or Marijuana Products on MTC Branded Goods, including but not limited to clothing, cups, drink holders, apparel accessories, electronic equipment or accessories, sporting equipment, novelty items and similar portable promotional items;
- 16.12. Advertising, marketing or branding on or in public or private vehicles and at bus stops, taxi stands, transportation waiting areas, train stations, airports, or other similar transportation venues including, but not limited to, vinyl-wrapped vehicles or signs or logos on transportation vehicles not owned by the MTCorecompany cars;
- 47.13. Advertising, marketing, branding, The display of signs or other printed matterial advertising any brand or kind of Marijuana or Marijuana Products that are displayed on the exterior or interior of any licensed Premises; where Marijuana Products are not regularly and usually kept for sale;
- 18.14. Advertising or marketing of the price of Marijuana or Marijuana Products, except as permitted above pursuant to 935 CMR 501.105(4)(a)(4.);
- 19.15. Display of Marijuana or Marijuana Products so as to be clearly visible to a person from the exterior of an MTC;
- 20.16. Advertising, marketing or branding including any statement, design, representation, picture, or illustration that encourages or represents the use of Marijuana for any purpose other than to treat a Debilitating Medical Condition or related symptoms;
- 21. Advertising, marketing or branding, including any statement, design, representation, picture, or illustration that encourages or represents the recreational use of Marijuana; and



- 22. An MTC shall not display on the exterior of the facility advertisements for Marijuana or any brand name, and may only identify the building by the registered name.
- (c) The Commission shall maintain and make available a list of all MTCs, their dispensing location, and their contact information.
- (c) Nothing in 935 CMR 501.105(4) prohibits an MTC from using a mark provided by the Commission which uses images of Marijuana.



# **Topic: Packaging and Labeling**

# Recommendations:

- Instead of allowing packaging to be tamper resistant or childproof, require that packaging be childproof.
- Require that all containers of finished marijuana and marijuana product be labelled with the US customary unit first, and the metric unit second, to bring more consistency across all labeling practices.
- 3. Remove requirement that purchased items are bagged in a sealed bag (replace 'sealed bag' with 'take-away bag';) and instead of requiring that the label be affixed to the bag that is be placed within the bag.
- 4. Reorder some provisions in the medical-use regulations to align with the adult-use regulations

# 500.105: General Operational Requirements for Marijuana Establishments

[...]

# (5) Labeling of Marijuana and Marijuana Products.

- (a) <u>Labeling of Marijuana Not Sold as a Marijuana Product</u>. Prior to Marijuana being sold or Transferred, <u>a Marijuana Cultivatora Marijuana Establishment</u> shall ensure the placement of a legible, firmly Affixed label on which the wording is no less than 1/16 of <u>an</u> inch in size on each package of Marijuana that it makes available for retail sale, containing at a minimum the following information:
  - (a) The name and registration number, telephone number and email address of the Marijuana Cultivator Licensee that produced the Marijuana, together with the retail Licensee's business telephone number, electronic mail address, and website information, if any;
  - (b) The quantity of Usable Marijuana contained within the package;
  - (e)(b) The date that the Marijuana <u>Establishment Retailer or Marijuana Cultivator</u> packaged the contents and a statement of which Licensee performed the packaging;
  - (c) A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
  - (d) Net weight or volume in US customary and metric units, -listed in that order;
  - (e) The full Cannabinoid Profile of the Marijuana contained within the package,





including THC and other Cannabinoid levels;

- (f) A statement and a seal certifying that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- (g) This statement, including capitalization;

This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.;

(h) The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product:



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



10. 935 CMR 500.105(5)(a) shall not apply to Marijuana packaged for transport of wholesale cultivated Marijuana in compliance with 935 CMR 500.105(8), shall not apply to Marijuana packaged by a Marijuana Cultivator for transport to a Marijuana Retailer in compliance with 935 CMR 500.105(13), provided however, that the Marijuana Retailer



is responsible for compliance with 935 CMR 500.105(5) for all Marijuana Products sold or displayed tofor Consumers.

- (b) <u>Labeling of Edible Marijuana Products</u>. Prior to Edible Marijuana Products being sold or Transferred, the Marijuana Product Manufacturer shall place a legible, firmly Affixed label on which the wording is no less than 1/16 of an inch in size on each Edible Marijuana Product that it prepares for retail sale or wholesale, containing at a minimum the following information:
  - The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address, and website information, if any;
  - 2. The name of the Marijuana Product;
  - 3. Refrigeration of the product is required, as applicable;
  - Total nNet weight or volume in US customary and metric units, listed in that order, of the Marijuana Product;
  - The number of servings sizes within the Marijuana Product based on the limits provided in 935 CMR 500.150(3) and the specific weight in milligrams of a serving size:
  - (a) The quantity of Usable Marijuana contained within the product as measured in ounces;
  - 4.6. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
  - 5-7. A list of ingredients, including the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol (Δ9-THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume;
    - (b) The serving size of the Marijuana Product in milligrams;
  - The number of serving sizes within the Marijuana Product based on the limits provided in 935 CMR 500.150(3);
  - 7-8. The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving;
  - 8-9. The date of creation and the recommended "use by" or expiration date which shall not be altered or changed;
  - 9.10. A batch number, sequential serial number and bar codes when used, to

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identify the batch associated with manufacturing and Processing;

- 10.11. Directions for use of the Marijuana Product;
- 11.12. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- 12.13. A warning if nuts or other Known Allergens are contained in the product; and
- <u>13.14.</u> This statement, including capitalization:

"The impairment effects of edible products may be delayed by two hours or more. This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";

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



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





- 16.17. 935 CMR 500.105(5)(b) shall apply to Edible Marijuana Products produced by a Marijuana Product Manufacturer for transport to a Marijuana RetailerLicensee in compliance with 935 CMR 500.105(813) and shall be in addition to any regulation regarding the appearance of Edible Marijuana Products under 935 CMR 500.150.
- (c) <u>Labeling of Marijuana Concentrates and Extracts</u>. Prior to Marijuana concentrates or extracts being sold or Transferred, the Marijuana Product Manufacturer shall place a legible, firmly Affixed label on which the wording is no less than 1/16 of an inch in size on each Marijuana concentrate container that it prepares for retail sale or wholesale, containing at a minimum the following information:
  - 1. The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address, and website information, if any;
  - 2. The name of the Marijuana Product;
  - 3. Product identity including the word "concentrate" or "extract" asapplicable;
  - 4. <u>Total nNet</u> weight of volume expressed in US customary units and metric units, <u>listed</u> in that order, of the Marijuana Product;
  - 5. If applicable, the A statement of the serving size and number of servings per in the Marijuana Product container or amount suggested for use based on the limits provided in 935 CMR 500.150(3) and the specific weight in milligrams of a serving size:
  - 6. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
  - 76. A list of ingredients including, but not limited to, the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta 9$ -THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume, and the amount of specific additives infused or incorporated during the manufacturing process, whether active or inactive, including, but not limited to, thickening agents, thinning agents, and specific terpenes, expressed in absolute terms and as a percentage of volume, and in a form and matter determined by the Commission.
  - 7. A statement of the serving size and number of servings per container of



amount suggested for use based on the limits provided in 935 CMR 500.150;

- 8. The date of creation and the recommended "use by" or expiration date;
- 9. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- 10. Directions for use of the Marijuana Product;
- 11. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- 12. A warning if nuts or other Known Allergens are contained in the product;
- 13. This statement, including capitalization:

"This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breastfeeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";

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



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

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16. 935 CMR 500.105(5)(c) shall apply to Marijuana concentrates and extracts produced by a Marijuana Product Manufacturer for transport to a Marijuana Retailer in compliance with 935 CMR 500.105(13).

- (d) <u>Labeling of Marijuana Infused Tinctures and Topicals</u>. Prior to Marijuana infused Tinctures or topicals being sold or Transferred the Marijuana Product Manufacturer shall place a legible, firmly Affixed label on which the wording is no less than 1/16 of an inch in size on each container of Marijuana infused Tincture or topical that it prepares for retail sale or wholesale, containing at a minimum the following information:
  - The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address, and website information, if any;
  - 2. The Marijuana Product's identity;
  - 3. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
  - 4. A list of ingredients, including the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol (Δ9-THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume;
  - Total nNet weight or volume as expressed in US customary units and or metric units, listed in that order, of the Marijuana Product;
  - If applicable, the number of servings in the Marijuana Product based on the limits provided in 935 CMR 500.150(3) and the specific weight in milligrams of a serving size;



- 6.7. The date of product creation;
- 7-8. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- 8.9. Directions for use of the Marijuana Product
- 9.10. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- 10.11. A warning if nuts or other Known Allergens are contained in the product; and
- 11.12. This statement, including capitalization:

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

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



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





- 15. 935 CMR 500.105(5)(d) shall apply to Marijuana-infused Tinctures and topicals produced by a Marijuana Product Manufacturer for transport to a Marijuana Retailer Licensee in compliance with 935 CMR 500.105(813).
- (e) <u>Labeling of Repackaged Marijuana.</u> [...]
- (f) In circumstances where the labeling of the Marijuana Product is unreasonable or impractical, the Marijuana Establishment may include the labeling information on a peel-back label or may place the product in a take-away sealed bag with an insert or additional, easily readable label firmly Affixed toplaced within that bag.
- (6) Packaging of Marijuana and Marijuana Products.
  - (a) <u>Tamper or Child-resistant Packaging</u>. Licensees licensed subject to 935 CMR 500.050(5) shall ensure that all Marijuana Products, other than those offered at wholesale by a Marijuana Cultivator, that are provided for sale to Consumers by a Licensee shall be sold in tamper or child-resistant packaging. To be in compliance with 935 CMR 500.105(6), Licensees shall ensure:
    - 1. That to the extent it is not Unreasonably Impracticable for the specific type of product, Marijuana Products are packaged in containers that are:
      - a. Opaque and plain in design;
      - b. Do not use bright colors, cartoon characters and other features designed to appeal to minorsNot be able to be opened easily with scissors if appealing to children;
      - Resealable for any marijuana product intended for more than a single use or containing multiple servings; and
      - d. Certified by a qualified third party tamper or child-resistant packaging testing firm that the packaging is in compliance with the most recent poison prevention packaging regulations of the US Consumer Product Safety Commission as



### included at 16 CFR 1700.; or

- That where compliance with the requirements of tamper or child-resistant packaging is deemed to be Unreasonably Impracticable, <u>Marijuana or Marijuana Products shall be</u> placed in an exit package that is:
  - Capable of being resealed and made tamper or child-resistant resistant again after it has been opened;
  - Includes the following statement, including capitalization, in at least tenpoint Times New Roman, Helvetica or Arial font: "KEEP OUT OF REACH OF CHILDREN."; and
  - c. Is certified by a qualified third-party tamper or child-resistant packaging testing firm that the packaging is in compliance with the most recent poison prevention packaging regulations of the us consumer product safety commission as included at 16 CFR 1700.
- (b) <u>Limits on Packaging Design</u>. Packaging for <u>Marijuana or M</u>marijuana <u>P</u>products sold or displayed for consumers, including any label or imprint affixed to any packaging containing <u>Marijuana</u>, <u>M</u>marijuana <u>P</u>products or any exit packages, shall not be attractive minors. Packaging is explicitly prohibited from:
  - 1. Using bright colors, defined as colors that are "neon" in appearance;
  - Imitating or having a semblance to any existing branded consumer products, including foods and beverages, that do not contain marijuana;
  - 3. Featuring cartoons;
  - Featuring a design, brand or name that resembles a non-cannabis consumer product of the type that is typically marketed to minors;
  - 5. Featuring symbols or celebrities that are commonly used to market products to minors;
  - 6. Featuring images of minors; and
  - Featuring words that refer to products that are commonly associated with minors or marketed to minors.
- (c) Packaging of Multiple Servings. [...]

## 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (5) <u>Labeling of Marijuana and Marijuana Products</u>.
  - (a) Labeling of Marijuana Not Sold as a Marijuana Product. Prior to Marijuana being sold or





Transferred, an MTC shall ensure the placement of a legible, firmly Affixed label on which the wording is no less than 1/16 of an inch in size on each package of Marijuana that it makes available for retail sale, containing at a minimum the following information:

- The name and registration number, telephone number, email address of the MTC that produced the Marijuana, together with the retail Licensee's business telephone number, electronic mail address, and website information, if any;
- 2. The quantity of Usable Marijuana contained within the package;
- 3-2. The date that the MTC packaged the contents and a statement of which Licensee performed the packaging;
- A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- 4. Net weight or volume in US customary or metric units, listed in that order;
- 5. The full Cannabinoid Profile of the Marijuana contained within the package, including THC and other Cannabinoid levels;
- A statement and a seal certifying that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L c. 94G, § 15;
- 7. This statement, including capitalization: "This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";
- 8. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product:





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



10.935 CMR 501.105(5)(a) shall not apply to Marijuana packaged for transport of wholesale cultivated Marijuana in compliance with 935 CMR 501.105(8), provided however, that the MTC is responsible for compliance with 935 CMR 501.105(5) for all Marijuana Products sold or displayed to Patients.

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

- The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address and website information, if any;
- 2. The name of the Marijuana Product;
- 3. Refrigeration of the product is required, as applicable;
- Total nNet weight or volume in US customary and metric units, listed in that order, of the Marijuana Product;
- The number of servings sizes within in the Marijuana Product and the specific weight in milligrams of a serving size;
- The quantity of Usable Marijuana contained within the product as measured in ounces;
- The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
- A list of ingredients, including the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-ninetetrahydrocannabinol (Δ9-THC) and other Cannabinoids in the package and in

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each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume;

- 8. The serving size of the Marijuana Product in milligrams;
- 9. The number of serving sizes within the Marijuana Product;
- 10.8. The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving;
- The date of creation and the recommended "use by" or expiration date which shall not be altered or changed;
- 42.10. A batch number, sequential serial number and bar codes when used, to identify the batch associated with manufacturing and Processing;
- 13.11. Directions for use of the Marijuana Product;
- 14.12. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- 15.13. A warning if nuts or other Known Allergens are contained in the product;
- 16.14. This statement, including capitalization:

"The impairment effects of edible products may be delayed by two hours or more. This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";

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



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



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

**Commented [A24]:** Not new. Moved here from below.

- (c) <u>Labeling of Marijuana Concentrates and Extracts</u>. Prior to Marijuana concentrates or extracts being sold or Transferred, the MTC shall place a legible, firmly Affixed label on which the wording is no less than 1/16 of an inch in size on each Marijuana concentrate container that it prepares for retail sale or wholesale, containing at a minimum the following information:
  - The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number and, e-mail address, and website information, if any;
  - 2. The name of the Marijuana Product;
  - 3. Product identity, including the word "concentrate" or "extract", asapplicable;
  - Total nNet weight of volume expressed in US customary units and metric units, listed in that order, of a Marijuana Product;
  - If applicable, A statement of the serving size and the number of servings per container in the Marijuana Product and the specific weight in milligrams of a serving size or amount suggested for use;
  - 5-6. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
  - 6.7. A list of ingredients including, but not limited to, the full Cannabinoid Profile of



the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta 9$ -THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume, and the amount of specific additives infused or incorporated during the manufacturing process, whether active or inactive including, but not limited to, thickening agents, thinning agents, and specific terpenes, expressed in absolute terms and as a percentage of volume, and in a form and matter determined by the Commission;

- A statement of the serving size and number of servings per container or amount suggested for use;
- 8. The date of creation and the recommended "use by" or expiration date;
- A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- 10. Directions for use of the Marijuana Product;
- 11. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, 8 15:
- 12. A warning if nuts or other Known Allergens are contained in the product;
- 13. This statement, including capitalization:

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

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



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



- 935 CMR 501.105(5)(c) shall apply to Marijuana concentrates and extracts produced by an MTC for transport to another Licensee in compliance with 935 CMR 501.105(7).
- (d) <u>Labeling of Marijuana-Infused Tinctures</u>, <u>Topicals or Other Non-edible Marijuana-infused Products</u>. Prior to Marijuana-infused Tinctures, topicals or other non-edible Marijuana-infused Products being sold or Transferred the MTC shall place a legible, firmly Affixed label on which the wording is no less than 1/16 of an inch in size on each container of Marijuana-infused Product that it prepares for retail sale or wholesale, containing at a minimum the following information:
  - The name and registration number of the MTC that produced the Marijuana Product, together with the MTC's business telephone number, e-mail address and website information, if any;
  - 2. The Marijuana Product's identity;
  - The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
  - 4. A list of ingredients, including the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-ninetetrahy-drocannabinol (Δ9-THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume;
  - Total nNet weight or volume as expressed in US customary units and or metric units, listed in that order, of the Marijuana Product;
  - If applicable, the number of servings in the Marijuana Product and the specific weight in milligrams of a serving size;
  - 6.7. The date of product creation;
  - 7.8. A batch number, sequential serial number, and bar code when used, to identify

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the batch associated with manufacturing and Processing;

- 8.9. Directions for use of the Marijuana Product;
- 9-10. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- 10.11. A warning if nuts or other Known Allergens are contained in the product;
- 11.12. This statement, including capitalization: "This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";
- 12.13. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product:



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



15. 935 CMR 501.105(5)(d) shall apply to Marijuana-infused Tinctures and



topicals produced by an MTC for transport to another Licensee in compliance with 935 CMR 501.105(8).

**Commented [A27]:** Not new. Moved here from below.

- (e) Labeling of Repackaged Marijuana. [...]
- (f) In circumstances where the labeling of the Marijuana Product is unreasonable or impractical, the MTC may include the labeling information on a peel-back label or may place the product in a take-away sealed bag with an insert or additional, easily readable label firmly Affixed placed within-to that bag.
- (g) 935 CMR 501.105(5)(a) shall not apply to Marijuana packaged for transport of wholesale cultivated Marijuana in compliance with 935 CMR 501.105(13), provided however, that the MTC is responsible for compliance with 935 CMR 501.105(5) for all Marijuana Products sold or displayed for Patients.
- (h) 935 CMR 501.105(5)(b) shall apply to edible Marijuana Products produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13) and shall be in addition to any regulation regarding the appearance of edible Marijuana Products under 935 CMR 501.150.
- (i) 935 CMR 501.105(5)(c) shall apply to Marijuana concentrates and extracts produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13).
- (j) 935 CMR 501.105(5)(d) shall apply to Marijuana infused Tinctures and topicals produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13).

**Commented [A28]:** These were all moved above to align with adult-use provisions.

## Medical-use 935 CMR 501.105 (6) Labelling of Marijuana and Marijuana Products

- (6) Packaging of Marijuana and Marijuana Products.
  - (a) <u>Tamper or Child-resistant Packaging</u>. MTCs engaged in product manufacturing operations shall ensure that all <u>Marijuana and Marijuana</u> Products that are provided for sale to Registered Qualifying Patients shall be sold in tamper or child-resistant packaging. To be in compliance with 935 CMR 501.105(6), Licensees shall ensure:
    - That to the extent it is not <u>U</u>unreasonably <u>I</u>unpracticable for the specific type of product, Marijuana Products are packaged in containers that are:
      - a. Opaque and plain in design;
      - b. Not be able to be opened easily with seissors if appealing to children Do not use bright colors, cartoon characters and other features designed to appeal to minors;



- c.Resealable for any Marijuana Product intended for more than a single use or containing multiple servings; and
- d.Certified by a qualified third party tamper or child-resistant packaging testing firm that the packaging is in compliance with the most recent poison prevention packaging regulations of the US Consumer Product Safety Commission as included at 16 CFR 1700.
- That where compliance with the requirements of tamper or child-resistant packaging is deemed to be Unreasonably Impracticable or too challenging for Patients to maneuver, Marijuana Products shall be placed in an exit-packaginge that is:
  - a. Capable of being resealed and made tamper or child resistant again after it has been opened;
  - b.Includes the following statement, including capitalization, in at least ten-point Times New Roman, Helvetica or Arial font: "KEEP OUT OF REACH OF CHILDREN".; and
  - c. Is certified by a qualified third party tamper or child resistant packaging testing firm that the packaging is in compliance with the most recent poison prevention packaging regulations of the US Consumer Product Safety Commission as included at 16 CFR 1700.
- (b) <u>Limits on Packaging Design</u>. Packaging for <u>Marijuana or Marijuana Products</u> sold or displayed <u>tofor Registered Qualifying</u> Patients, including any label or imprint Affixed to any packaging containing <u>Marijuana or Marijuana Products</u> or any exit packages, shall not be attractive to minors. Packaging is explicitly prohibited from:
  - Imitating or having a semblance to any existing branded consumer products, including foods and beverages, that do not contain Marijuana;
  - 2. Featuring cartoons;
  - Featuring a design, brand or name that resembles a non-Cannabis consumer product of the type that is typically marketed to minors;
  - 4. Featuring symbols or celebrities that are commonly used to market products to minors;
  - 5. Featuring images of minors; and
  - Featuring words that refer to products that are commonly associated with minors or marketed to minors.
- (c) Packaging of Multiple Servings.
  - Packaging for Marijuana Products sold or displayed for Registered Qualifying Patients in multiple servings shall include the following statement on the exterior of the package in a printed font that is no smaller than ten-point Times New Roman, Helvetica or Arial, including capitalization: "INCLUDES MULTIPLE SERVINGS."
  - 2. Packaging for Marijuana Products in solid form sold or displayed for Registered



Qualifying Patients in multiple servings shall allow a Registered Qualifying Patient to easily perform the division into single servings.

- a. Edible Marijuana Products in a solid form shall be easily and permanently scored to identify individual servings.
- b.Notwithstanding 935 CMR 501.105(6)(c)2.a., where a product is unable, because of its form, to be easily and permanently scored to identify individual servings, the product shall be packaged in a single serving size. The determination of whether a product is able to be easily and permanently scored shall be decided by the Commission consistent with sub-regulatory guidelines established by the Commission and provided to Licensees.
- (d) Each single serving of an Edible Marijuana Product contained in a multiple-serving package may be marked, stamped or otherwise imprinted with the symbol issued by the Commission under 935 CMR 501.105(5) that indicates that the single serving is a Marijuana Product.
- (e) Serving size shall be determined by the MTC.



## **Topic: Concentrate/Vaporizer Labeling**

## Recommendations:

- Specify that additives included on the FDA's list of inactive ingredients for inhalation shall be called out.
- Require that vaporizers include a statement about whether terpenes used to produce them are solely derived from cannabis or come from non-cannabis sources.
- Requires producers of vaporizers to provide Certificates of Analysis (COAs) for all additives to Retailers so that Retailers may make COAs available upon request of consumers.
- Requires vaporizer producers to collect information about the component parts they use in producing the vaporizer including information on battery types, coils, hardware.

## 500.002: Definitions

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

## 501.002: Definitions

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

# 500.105: General Operational Requirements for Marijuana Establishments

[...]

(5) <u>Labeling of Marijuana and Marijuana Products.</u>

[...]

(b) <u>Labeling of Edible Marijuana Products</u>. [...]



- (c) <u>Labeling of Marijuana Concentrates and Extracts.</u> Prior to Marijuana concentrates or extracts being sold or Transferred, the Marijuana Product Manufacturer shall place a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size on each Marijuana concentrate container that it prepares for retail sale or wholesale, containing at a minimum the following information:
  - 1. The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address, and website information, if any;
  - 2. The name of the Marijuana Product;
  - 3. Product identity including the word "concentrate" or "extract" as applicable;
  - 4. Net weight of volume expressed in US customary units and metric units;
  - 5. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
  - 6. A list of ingredients including, but not limited to, the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta 9$ -THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume, and the amount of specific additives infused or incorporated during the manufacturing process, whether active or inactive, including, but not limited to, thickening agents, thinning agents, and specific terpenes, expressed in absolute terms and as a percentage of volume, and in a form and matter determined by the Commission.

a. For Marijuana Vaporizer Devices Products, identification of specific additives shall include, but not be limited to, any additives identified on the FDA's Inactive Ingredient Database for "Respiratory (inhalation)" or "Oral" routes of administration and based on dosage form as an aerosol product or inhalant. The FDA Inactive Ingredient Database is available at <a href="https://www.fda.gov/media/72482/download">https://www.fda.gov/media/72482/download</a>. If the FDA database or its

https://www.fda.gov/media/12482/download. If the FDA database or its equivalent is no longer available, licensees must use the database identified by the Commission.

b. For Marijuana Vaporizer Devices produced using only cannabis-derived terpenes, the following statement: "This product was produced using only cannabis-derived terpenes."

c. For Marijuana Vaporizer Devices produced using terpenes other than cannabis-derived terpenes, the following statement: "This product was produced using terpenes derived from sources other than cannabis."



- 7. A statement of the serving size and number of servings per container or amount suggested for use based on the limits provided in 935 CMR 500.150;
- 8. The date of creation and the recommended "use by" or expiration date;
- 9. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- 10. Directions for use of the Marijuana Product;
- 11. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- 12. A warning if nuts or other Known Allergens are contained in the product;
- 13. This statement, including capitalization:

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

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



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





16. 935 CMR 500.105(5)(c) shall apply to Marijuana concentrates and extracts produced by a Marijuana Product Manufacturer for transport to a Marijuana Retailer in compliance with 935 CMR 500.105(13).

## 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

[...]

- (5) <u>Labeling of Marijuana and Marijuana Products</u>.
  - (c) <u>Labeling of Marijuana Concentrates and Extracts</u>. Prior to Marijuana concentrates or extracts being sold or Transferred, the MTC shall place a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size on each Marijuana concentrate container that it prepares for retail sale or wholesale, containing at a minimum the following information:
    - 1. The name and registration number of the Marijuana Product Manufacturer that produced the Marijuana Product, together with the Marijuana Product Manufacturer's business telephone number, e-mail address, and website information, if any;
    - 2. The name of the Marijuana Product;
    - 3. Product identity, including the word "concentrate" or "extract", as applicable;
    - 4. Net weight of volume expressed in US customary units and metric units;
    - 5. The type of Marijuana used to produce the product, including what, if any, Processing technique or solvents were used;
    - 6. A list of ingredients including, but not limited to, the full Cannabinoid Profile of the Marijuana contained within the Marijuana Product, including the amount of deltanine-tetrahydrocannabinol (Δ9-THC) and other Cannabinoids in the package and in each serving of a Marijuana Product as expressed in absolute terms and as a percentage of volume, and the amount of specific additives infused or incorporated during the manufacturing process, whether active or inactive including, but not limited to, thickening agents, thinning agents, and specific terpenes, expressed in absolute terms and as a percentage of volume, and in a form and matter determined by the Commission;
      - a. For Marijuana Vaporizer Devices identification of specific additives shall include, but not be limited to, any additives identified on the FDA's Inactive Ingredient Database for "Respiratory (inhalation)" or "Oral" routes of administration and based on dosage form as an aerosol product or inhalant. The FDA Inactive Ingredient Database is available at <a href="https://www.fda.gov/media/72482/download">https://www.fda.gov/media/72482/download</a>. If the FDA database or its



equivalent is no longer available, licensees must use the database identified by the Commission.

b. For Marijuana Vaporizer Devices produced using only cannabis-derived terpenes, the following statement: "This product was produced using only cannabis-derived terpenes."

c. For Marijuana Vaporizer Devices produced using terpenes other than cannabis-derived terpenes, the following statement: "This product was produced using terpenes derived from sources other than cannabis."

- 7. A statement of the serving size and number of servings per container or amount suggested for use;
- 8. The date of creation and the recommended "use by" or expiration date;
- 9. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- 10. Directions for use of the Marijuana Product;
- 11. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date(s) of testing in accordance with M.G.L. c. 94G, § 15. Marijuana products that are required to undergo more than one screening shall list all applicable dates of testing;
- 12. A warning if nuts or other Known Allergens are contained in the product;
- 13. This statement, including capitalization:

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

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





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



[...]

## 500.130: Additional Operational Requirements for Marijuana Product Manufacturers

[...]

- (4) A Marijuana Product Manufacturer selling or otherwise Transferring Marijuana to another Marijuana Establishment shall provide documentation of its compliance, or lack thereof, with the testing requirements of 935 CMR 500.160, and standards established by the Commission for the conditions, including time and temperature controls, necessary to protect Marijuana Products against physical, chemical, and microbial contamination as well as against deterioration of finished products during storage and transportation.
  - ———(a) A Product Manufacturer shall retain all records of purchases from any manufacturer or supplier of any ingredient, additive, device, component part or other materials obtained by the Product Manufacturer in relation to the manufacturing of Marijuana Vaporizer Devices and such records shall be made available to the Commission on request.
  - (b) A Marijuana Product Manufacturer shall make objectively reasonable efforts to identify and maintain records of the name and business address of the manufacturer of any cartridge, battery, atomizer coil, hardware or other component of Marijuana Vaporizer Products manufactured by the Licensee. Further, the Product Manufacturer shall, on request by the Commission, identify the materials used in the device's atomizer



coil (e.g., titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material) or state if such information cannot be reasonably ascertained.

- (c) A copy of the Certificate of Analysis for each thickening agent, thinning agent or terpene infused or incorporated into a Marijuana Vaporizer Device during production shall be retained by a Product Manufacturer and provided as a part of a wholesale transaction with any Marijuana Retailer or MTC.
- (d) A Product Manufacturer that wholesales Marijuana Vaporizer Devices to a Marijuana Retailer or MTC shall provide the recipient with the information insert required by 935 CMR 500.105 (c) or the necessary information to produce such an insert and the appropriate labeling information required by these regulations.

[...]

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

[...]

- (4) An MTC selling or otherwise Transferring Marijuana to another MTC or Marijuana Establishment shall provide documentation of its compliance, or lack thereof, with the testing requirements of 935 CMR 501.160, and standards established by the Commission for the conditions, including time and temperature controls, necessary to protect Marijuana Products against physical, chemical, and microbial contamination as well as against deterioration of finished products during storage and transportation.
  - (a) An MTC shall retain all records of purchases from any manufacturer or supplier of any ingredient, additive, device, component part or other materials obtained by the MTC in relation to the manufacturing of Marijuana Vaporizer Devices and such records shall be made available to the Commission on request.

(b) An MTC shall make objectively reasonable efforts to identify and maintain records of the name and business address of the manufacturer of any cartridge, battery, atomizer coil, hardware or other component of Marijuana Vaporizer Products manufactured by the Licensee. Further, the MTC shall, on request by the Commission, identify the materials used in the device's atomizer coil (e.g.,





titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material) or state if such information cannot be reasonably ascertained.

- (c) A copy of the Certificate of Analysis for each thickening agent, thinning agent or terpene infused or incorporated into a Marijuana Vaporizer Device during production shall be retained by an MTC and provided as a part of a wholesale transaction with any MTC or Marijuana Retailer.
- (d) An MTC that wholesales Marijuana Vaporizer Devices to an MTC or Marijuana Retailer shall provide the recipient with the information insert required by 935 CMR 501.105 (c) or the necessary information to produce such an insert and the appropriate labeling information required by these regulations.

[...]



# **Topic: Vape Sales**

<u>Recommendation</u>: Update 500.140: *Additional Operational Requirements for Retail Sale* to require Marijuana Retailers to post certain information about the testing of Marijuana Vaporizer Devices at the point of sale and to make information available to Consumers who request it about the source and testing of vapes.

## 500.002: Definitions

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

## 501.002: Definitions

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

## 500.140: Additional Operational Requirements for Retail Sale

- (1) In addition to the general operational requirements for Marijuana Establishments required under 935 CMR 500.105: <u>General Operational Requirements for Marijuana Establishments</u>, Licensees engaged in retail sales shall comply with 935 CMR 500.140.
- (2) On-Premises Verification of Identification. [...]
- (3) <u>Limitation on Sales</u>. [...]
- (4) <u>Unauthorized Sales and Right to Refuse Sales</u>. [...]
- (5) Recording Sales. [...]
- (6) Consumer Education. [...]



- (7) <u>Testing</u>. [...]
- (8) Product Database. [...]
- (9) Sale of Marijuana Vaporizer Devices.
  - (a) Marijuana Retailers offering Marijuana Vaporizer Devices for sale to Consumers shall include signage at the point of sale, that is legible and enlarged and contains the following statements:
    - "Marijuana Vaporizer Devices have been tested for Vitamin E Acetate and other contaminants, with no adverse findings. WARNING: Vaporizer Devices may contain ingredients harmful to health when inhaled."
    - "Consumers shall have access to the test results of Marijuana Vaporizer Devices including copies of any Certificates of Analysis provided by the device's manufacturer."
  - (a)(b) Marijuana Retailers shall provide a physical insert to Consumers that accompanies all purchased Marijuana Vaporizer Devices that states, including capitalization and emphasis, the following:

"Marijuana Vaporizer Devices have been tested for Vitamin E Acetate and other contaminants, with no adverse findings. WARNING: Vaporizer Devices may contain ingredients harmful to health when inhaled."

- (c) The sale of disposable and reusable vaporizer pens and devices must be accompanied by a product insert identifying the materials used in the vaporizer device's atomizer coil (e.g., titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material), and manufacturer identification of the device hardware, cartridge, battery and other components;
- (d) A Marijuana Retailer shall make available the information contained in 935 CMR 500.105(5)(c)(6) in the product description at the point-of-sale and as part of any product list posted on the Marijuana Retailer's website or third-party technology platforms or applications employed for pre-ordering or delivery.
- (e) A Marijuana Retailer shall retain all records of purchases from any Product Manufacturer or supplier of any ingredient, additive, device, component part or other



materials provided to the Marijuana Retailer about Marijuana Vaporizer Devices sold at retailers. Such records shall be made available to the Commission upon request.

## 501.140: Additional Operational Requirements for Patient Sales [Medical-use regs]

- (1) In addition to the general operational requirements for MTCs required under 935 CMR 501.105, MTCs engaged in patient sales shall comply with additional operational requirements for MTCs under 935 CMR 501.140.
- (2) <u>Verification of Patient and Caregiver Certification</u> [...]
- (3) Patient Allotment. [...]
- (4) <u>Unauthorized Sales and Right to Refuse Sales</u>. [...]
- (5) Recording Sales. [...]
- (6) Patient Education. [...]
- (7) <u>Testing</u>. [...]

## (8) Sale of Marijuana Vaporizer Devices.

- a) MTCs offering Marijuana Vaporizer Devices for sale to Registered Qualifying Patients shall include signage at the point of sale, that is legible and enlarged and contains the following statements:
  - 1. "Marijuana Vaporizer Devices have been tested for Vitamin E Acetate and other contaminants, with no adverse findings. WARNING: Vaporizer Devices may contain ingredients harmful to health when inhaled."
  - "Patients shall have access to the test results of Marijuana Vaporizer Devices including copies of any Certificates of Analysis provided be the device's manufacturer."
- (a)(b) MTCs shall provide a physical insert to Registered Qualifying Patients that accompanies all purchased Marijuana Vaporizer Devices that states, including capitalization and emphasis, the following:

"Marijuana Vaporizer Devices have been tested for Vitamin E Acetate and other contaminants, with no adverse findings. WARNING: Vaporizer Devices may contain ingredients harmful to health when inhaled."



- (c) The sale of disposable and reusable vaporizer pens and devices must be accompanied by a product insert identifying the materials used in the vaporizer device's atomizer coil (e.g., titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material), and manufacturer identification of the device hardware, cartridge, battery and other components;
- (d) An MTC shall make available the information contained in 935 CMR 501.105(5)(c)6. in the product description at the point-of-sale and as part of any product list posted on the MTC's website or third-party technology platforms or applications employed for pre-ordering or delivery.
- (e) An MTC shall retain all records of purchases from any supplier of any ingredient, additive, device, component part or other materials provided to the MTC about Marijuana Vaporizer Devices sold at MTCs. Such records shall be made available to the Commission upon request



# **Topic: Indoor/Outdoor Cultivation**

## Recommendations:

- 1. Clarify that cultivation, Processing, and packaging of Marijuana by a Marijuana Cultivator shall take place in a Limited Access Area where Marijuana is not visible, and that Marijuana is not visible if it is not reasonably identifiable.
- 2. Added clarifying language to medical regulations, 935 CMR 501.120(3), that a cultivation MTC can cultivate for up to two additional MTC locations <u>operated by the same entity Owner</u> (current language states two additional MTCs "under an entity")
- 3. Refinements to energy compliance dates, renewable energy exemption, and extension applicability. [935 CMR 500.120(11); 935 CMR 501.120(11)-(12)]
- Modify 935 CMR 500.120(12) and 935 CMR 501.120(13) to specifically account for the obligation to maintain accurate inventory in the SOR.
- Add disclosure requirement re growing media and nutrients used in the cultivation process to 935 CMR 500.120(2) and 935 CMR 501.120(2) based on consultation with Lab Analyst. G. Hall Frison.

# 500.120: Additional Operational Requirements for Indoor and Outdoor Marijuana Cultivators

- In addition to the general operational requirements for Marijuana Establishments required under 935 CMR 500.105, Marijuana Cultivators shall comply with additional operational requirements required under 935 CMR 500.120.
- (2) A Marijuana Cultivator may cultivate its own Marijuana or acquire Marijuana from other Marijuana Establishments for the purposes of Propagation. <u>Prior to commencing</u> <u>operations</u>, <u>Marijuana Cultivators must disclose all growing media and plant nutrients</u> <u>intended to be used during the cultivation process</u>. <u>In all instances</u>, <u>Marijuana Cultivators</u> <u>must disclose all growing media and plant nutrients used for cultivation upon request</u>.
- (3) Only a licensed Marijuana Cultivator or Microbusiness is permitted to cultivate Marijuana for adult use for sale to Marijuana Establishments.



- (4) All phases of the cultivation, Processing, and packaging of Marijuana by a Marijuana Cultivator shall take place in a designated <u>Limited Access Aerea where Marijuana</u> that is not visible from a public place without the use of binoculars, aircraft or other optical aids. <u>Marijuana is not visible if it cannot be reasonably identified.</u>
- (5) 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 MDAR.
- (6) A Marijuana Cultivator selling or otherwise <u>t</u>-ransferring Marijuana to another Marijuana Establishment shall provide documentation of its compliance, or lack thereof, with the testing requirements of 935 CMR 500.160.
- (7) A Marijuana Cultivator may label Marijuana and Marijuana Products with the word "organic" only if all cultivation is consistent with US Department of Agriculture organic requirements at 7 CFR 205 and consistent with MDAR requirements for Pesticide usage;
- (8) Soil for cultivation shall meet federal standards identified by the Commission including, but not limited to, the U.S. Agency for Toxic Substances and Disease Registry's Environmental Media Evaluation Guidelines for residential soil levels.
- (9) The cultivation process shall use best practices to limit contamination including, but not limited to, mold, fungus, bacterial diseases, rot, pests, Pesticides not in compliance with 935 CMR 500.120(5) for use on Marijuana, mildew, and any other contaminant identified as posing potential harm. Best practices shall be consistent with state and local law including, but not limited to, the Commission's Guidance on Integrated Pest Management in effect November 1, 2019.
- (10) Any application of plant nutrient to land used for the cultivation of Marijuana shall comply with St. 2012, c. 262, as amended by St. 2013, c. 118, § 26, and 330 CMR 31.00: Plant Nutrient Application Requirements for Agricultural Land and Non-agricultural Turf and Lawns.



- (11) A Marijuana Cultivator shall satisfy minimum energy efficiency and equipment standards established by the Commission and meet all applicable environmental laws, regulations, permits and other applicable approvals including, but not limited to, those related to water quality and quantity, wastewater, solid and hazardous waste management, and air pollution control, including prevention of odor and noise pursuant to 310 CMR 7.00: Air Pollution Control as a condition of obtaining a final license under 935 CMR 500.103(2) and as a condition of renewal under 935 CMR 500.103(4). A Marijuana Cultivator shall adopt and use additional best management practices as determined by the Commission, in consultation with the working group established under St. 2017, c. 55, § 78(b) or applicable departments or divisions of the EOEEA, to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts, and shall provide energy and water usage reporting to the Commission in a form determined by the Commission. Each license renewal application under 935 CMR 500.103(4) must include a report of the Marijuana Cultivator's energy and water usage over the 12-month period preceding the date of application. Marijuana Cultivators shall be subject to the following minimum energy efficiency and equipment standards:
  - (a) The building envelope for all facilities, except Greenhouses, must meet minimum Massachusetts Building Code requirements and all Massachusetts amendments (780 CMR: State Building Code), International Energy Conservation Code (IECC) Section C402 or The American Society of Heating, Refrigerating and Air-conditioning Engineers (ASHRAE) Chapters 5.4 and 5.5 as applied or incorporated by reference in 780 CMR: State Building Code, except that facilities using existing buildings may demonstrate compliance by showing that the envelope insulation complies with code minimum standards for Type Factory Industrial F-1, as further defined in guidelines issued by the Commission.
  - (b) Lighting used for Cannabis <u>Cultivation</u> must meet one of the following compliance requirements:
    - Horticulture Lighting Power Density must not exceed 36 watts per square foot, except for Tier 1 and Tier 2 which must not exceed 50 watts per square foot; or
    - All horticultural lighting used in a facility is listed on the current Design Lights
      Consortium Solid-state Horticultural Lighting Qualified Products List
      ("Horticultural QPL") or other similar list approved by the Commission as of the
      date of license application, and lighting Photosynthetic Photon Efficacy (PPE) is at



- least 15% above the minimum Horticultural QPL threshold rounded up to the nearest 0.1  $\mu$ mol/J (micromoles per joule).
- 3. A facility seeking to use horticultural lighting not included on the Horticultural QPL or other similar list approved by the Commission shall seek a waiver pursuant to –935 CMR 500.850 and provide documentation of third-party certification of the energy efficiency features of the proposed lighting. All facilities, regardless of compliance path, shall provide third-party safety certification by an OSHA NRTL or SCC-recognized body, which shall certify that products meet a set of safety requirements and standards deemed applicable to horticultural lighting products by that safety organization.
- (c) Heating Ventilation and Air Condition (HVAC) and dehumidification systems must meet Massachusetts Building Code requirements and all Massachusetts amendments (780 CMR State Building Code), IECC Section C403 or ASHRAE Chapter 6 as applied or incorporated by reference in (780 CMR: State Building Code). As part of the documentation required under 935 CMR 500.120(11)(b), a Marijuana Cultivator must provide a certification from a Massachusetts Licensed Mechanical Engineer that the HVAC and dehumidification systems meet Massachusetts building code as specified in this-935 CMR 500.120(11)(c) and that such systems have been evaluated and sized for the anticipated loads of the facility.
- (d) Safety protocols shall be established and documented to protect workers, and Consumers, or Visitors (e.g., eye protection near operating Horticultural Lighting Equipment).
- (e) Requirements in 935 CMR 500.120(11)(b) and (c) shall not be required if an indoor Marijuana Cultivator is generating 80% or more of the total annual on-site energy use for all fuels (expressed on a MWh basis) from an onsite clean or renewable generating source, or renewable thermal generation, as provided in M.G.L. c. 25A § 11F and 11F½. Additionally, the Marijuana Establishment must document that renewable energy credits or alternative energy credits representing the portion of the Licensee's energy usage not generated onsige haves been purchased and retired on an annual basis.
- (f) Prior to final licensure, a Marijuana Cultivator Licensee must demonstrate compliance with 935 CMR 500.120(11), by submitting an energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered



Architect with supporting documentation, together with submission of building plans under 935 CMR 500.103. For a Microbusiness or Craft Marijuana Cooperative with a cultivation location sized as Tier 1 or Tier 2, or such other Marijuana Cultivators that have been granted a meeting the requirements of waiver under 935 CMR 500.8050(1), compliance with any of the requirements of 935 CMR 500.120(11) may be demonstrated through an energy compliance letter or updated energy compliance letter prepared by one or more of the following energy professionals:

- 1. A Certified Energy Auditor certified by the Association of Energy Engineers;
- 2. A Certified Energy Manager certified by the Association of Energy Engineers;
- 3. A Massachusetts Licensed Professional Engineer; or
- 4. A Massachusetts Licensed Registered Architect.
- (g) A\_Colocated Marijuana Establishment and MTC with a final Certificate of Licensure, as defined by 935 CMR 501.002, issued before November 1, 2019 shall have until January-July 1, 2020 to comply with 935 CMR 500.120(11), except that any additions to or renovations to a facility must comply with 935 CMR 500.120(11). A Marijuana Establishment subject to 935 CMR 500.120(11)(g) this section may apply for an additional six-month extension if it agrees to install meters to monitor energy usage, water usage and other data determined by the Commission, as well as a necessary in order to provide reports on energy usage, water usage, waste production and other data in a form and manner determined by the Commission.
- (h) For purposes of 935 CMR 500.120(11), the following terms shall have the following meanings:
  - Horticultural Lighting Equipment (HLE) means any lighting equipment (e.g., fixtures, bulbs, ballasts, controls, etc.) that uses energy for the cultivation of plants, at any stage of growth (e.g., germination, cloning/Mother Plants, Propagation, Vegetation, Flowering, and harvest).
  - 2. Horticulture Lighting Square Footage (HLSF) means Canopy.
  - Lighting Power Density (HLPD) means a measure of total watts of Horticultural Lighting Equipment per total Horticulture Lighting Square Footage, (HLE / HLSF = HLPD) expressed as number of watts per square foot.
- (12) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Cultivator, including colocated Marijuana Cultivators and MTCs, shall maintain





written policies and procedures for the cultivation, production, Transfer or distribution of Marijuana, as applicable, which shall include but not be limited to:

- (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories, and for maintaining accurate inventory. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(8);
- (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by a Marijuana Establishment to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
- (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(12);
- (d) <u>Policies and Procedures for Transportation</u>. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(13);
- (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(15) and 935 CMR 500.120(11); and
- Policies and procedures for the Transfer, acquisition, or sale of Marijuana between Marijuana Establishments.
- (a) Policies and procedures for the Transfer, acquisition, or sale of Marijuana between Marijuana Establishments:
- (b) Policies and procedures for developing and providing Vendor Samples to a Marijuana Product Manufacturer or a Marijuana Retailer. Policies and procedures shall include methods by which the Marijuana Cultivator will adequately track, record, and document all Vendor Samples developed on, or provided from, the licensed Premises in satisfaction of 935 CMR 500.120(13); and



(c) Policies and procedures for developing and providing Quality Control Samples to employees for the purpose of ensuring product quality and determining whether to make the product available to sell. Policies and procedures shall include methods by which the Marijuana Cultivator will adequately track, record, and document all Quality Control Samples developed on, or provided from, the licensed Premises in satisfaction of 935 CMR 500.120(14). Policies and procedures shall further prohibit consumption of Quality Control Samples on the licensed Premises.

(13) Vendor Samples. [...]

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

- (1) In addition to the general operational requirements for MTCs required under 935 CMR 501.105, MTCs shall comply with additional operational requirements for the cultivation, acquisition, and distribution of Marijuana required under 935 CMR 501.120.
- (2) Unless otherwise authorized by the Commission, only an MTC is permitted to cultivate medical use Marijuana, except for a Registered Qualifying Patient granted a Hardship Cultivation Registration or that patient's Personal Caregiver. Prior to commencing operations, MTCs must disclose all growing media and plant nutrients intended to be used during the cultivation process. In all instances, MTCs must disclose all growing media and plant nutrients being used upon request.
- (3) Unless otherwise authorized by the Commission, a cultivation location of an MTC may cultivate Marijuana for only that MTC, and up to two additional MTC <u>locations</u> operated by the same entity Owner under an entity.
- (4) All phases of the cultivation of Marijuana shall take place in a designated, locked, Limited Access Areas that are monitored by a surveillance camera system in accordance with 935 CMR 501.110(5)(a)4. through 9. where Marijuana and that is not visible from a public place without the use of binoculars, aircraft or other optical aids. Marijuana is not visible if it cannot be reasonably identified.





- (5) Application of Pesticides shall be performed in compliance with M.G.L. c. 132B and 333 CMR 2.00: General Information through 333 CMR 14.00: Protection of Children and Families from Harmful Pesticides. Any testing results indicating noncompliance shall be immediately reported to the Commission, who may refer any such result to the MDAR.
- (6) An MTC selling or otherwise <u>t</u>ransferring Marijuana to another MTC or Marijuana Establishment shall provide documentation of its compliance, or lack thereof, with the testing requirements of 935 CMR 501.160.
- (7) An MTC may label Marijuana and MIPS with the word "organic" only if all cultivation is consistent with US Department of Agriculture organic requirements at 7 CFR Part 205 and consistent with the MDAR requirements for Pesticide usage.
- (8) Soil for cultivation shall meet federal standards identified by the Commission including, but not limited to, the US Agency for Toxic Substances and Disease Registry's Environmental Media Evaluation Guidelines for residential soil levels.
- (9) The cultivation process shall use best practices to limit contamination including, but not limited to, mold, fungus, bacterial diseases, rot, pests, Pesticides not in compliance with 935 CMR 501.120(54), mildew, and any other contaminant identified as posing potential harm. Best practices shall be consistent with state and local law including, but not limited to, the Commission's Guidance on Integrated Pest Management-in effect November 1, 2019.
- (10) Any application of plant nutrient to land used for the cultivation of Marijuana shall comply with St. 2012, c. 262, as amended by St. 2013, c. 118, § 26, and 330 CMR 31.00: Plant Nutrient Application Requirements for Agricultural Land and Non-agricultural Turf and Lawns.
- (11) MTC cultivation operations shall satisfy minimum energy efficiency and equipment standards established by the Commission and meet all applicable environmental laws, regulations, permits and other applicable approvals including, but not limited to, those related to water quality and quantity, wastewater, solid and hazardous waste management, and air pollution control, including prevention of odor and noise pursuant to 310 CMR



7.00: Air Pollution Control as a condition of obtaining a final License under 935 CMR 501.103(2) and as a condition of renewal under 935 CMR 501.103(4). MTC cultivation operations shall adopt and use additional best management practices as determined by the Commission, in consultation with the working group established under St. 2017, c. 55, § 78(b) or applicable departments or divisions of the EOEEA, to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts, and shall provide energy and water usage reporting to the Commission in a form determined by the Commission. Each License renewal application under 935 CMR 501.103(4) must include a report of the MTC cultivation operations' energy and water usage over the 12-month period preceding the date of application.

- (12) MTC cultivation operations shall be subject to the following minimum energy efficiency and equipment standards:
  - (a) The building envelope for all facilities, except Greenhouses, must meet minimum Massachusetts Building Code requirements and all Massachusetts amendments (780 CMR: State Building Code), International Energy Conservation Code (IECC) Section C.402 or The American Society of Heating, Refrigerating and Airconditioning Engineers (ASHRAE) Chapters 5.4 and 5.5 as applied or incorporated by reference in 780 CMR: State Building Code, except that facilities using existing buildings may demonstrate compliance by showing that the envelope insulation complies with code minimum standards for Type Factory Industrial F-1, as further defined in guidelines issued by the Commission.
  - (b) Lighting used for MTC cultivation operations must meet one of the following compliance paths:
    - 1. Horticulture Lighting Power Density must not exceed 36 watts per square foot, except for Tier 1 and Tier 2 which must not exceed 50 watts per square foot;
    - 2. All horticultural lighting used in a facility is listed on the current Design Lights Consortium Solid-State Horticultural Lighting Qualified Products List ("Horticultural QPL") or other similar list approved by the Commission as of the date of License application, and lighting Photosynthetic Photon Efficacy (PPE) is at least 15 % above the minimum Horticultural QPL threshold rounded up to the nearest 0.1 μmol/J (micromoles per joule); or



- 3. A facility seeking to use horticultural lighting not included on the Horticultural QPL or other similar list approved by the Commission shall seek a waiver pursuant to 935 CMR 5010.850: Waivers and provide documentation of third-party certification of the energy efficiency features of the proposed lighting. All facilities, regardless of compliance path, shall provide third-party safety certification by an OSHA NRTL or SCC-recognized body, which shall certify that products meet a set of safety requirements and standards deemed applicable to horticultural lighting products by that safety organization.
- (c) Heating Ventilation and Air Conditioning (HVAC) and dehumidification systems must meet Massachusetts State Building Code requirements and all Massachusetts amendments (780 CMR: State Building Code), IECC Section C.403 or ASHRAE Chapter 6 as applied or incorporated by reference in (780 CMR: State Building Code). As part of the documentation required under 935 CMR 501.120(11) an MTC engaged in cultivation operations must provide a certification from a Massachusetts Licensed Mechanical Engineer that the HVAC and dehumidification systems meet Massachusetts building code as specified in 935 CMR 501.120(11) and that such systems have been evaluated and sized for the anticipated loads of the facility.
- (d) Safety protocols must be established and documented to protect workers, and Qualifying Patients, or Visitors (e.g., eye protection near operating Horticultural Lighting Equipment).
- (e) The requirements inef 935 CMR 501.120(124)(b) and (c) shall not be required if an indoor MTC cultivation operation is generating 80% or more of the total annual onsite energy use for all fuels (expressed on a MWh basis) from an onsite clean or renewable generating source or renewable thermal generation, as provided in M.G.L. c. 25A, §§ 11F and 11F½. Additionally, the Licensee must document that renewable energy credits or alternative energy credits representing the portion of the Licensee's energy usage not generated onsite have s been purchased and retired on an annual basis.
- (f) Prior to final licensure, To demonstrate compliance with 935 CMR 501.120(11), an MTC applicant must demonstrate compliance with 935 CMR 501.120(11) seeking to engage in cultivation operations must by submitting an energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with submission of building plans under 935 CMR 501.103(1)(a), but prior to final licensure. To the extent updates are required to the information provided for initial



- licensure, the MTC must submit an updated energy compliance letter prepared by a Massachusetts Licensed Professional Engineer or Massachusetts Licensed Registered Architect with supporting documentation, together with a renewal application submitted under 935 CMR 501.103(4).
- (g) A colocated Marijuana Establishment and MTC with a final Certificate of Licensure issued before November 1, 2019 shall have until January July 1, 2020 to comply with 935 CMR 501.120(11), except that any additions to or renovations to a facility must comply with 935 CMR 501.120(11). An MTC\_ with a final Certificate of Licensure issued before November 1, 2019 shall have until January 1, 2021 to comply with 935 CMR 501.120(11), except that any additions to or renovations to a facility must comply with 935 CMR 501.120(11). An MTC subject to 935 CMR 501.120(12)(g) may apply for an additional six-month extension if it agrees to install meters to monitor energy usage, water usage and other data determined by the Commission, as necessary in order to well as provide reports on energy usage, water usage, waste production and other data in a form and manner determined by the Commission.
- (g)(h) For purposes of 935 CMR 501.120(11), the following terms shall have the following meanings:
  - 1. Horticultural Lighting Equipment (HLE) means any lighting equipment (*e.g.* fixtures, bulbs, ballasts, controls, *etc.*) that uses energy for the cultivation of plants, at any stage of growth (*e.g.* germination, cloning/mother plants, Propagation, Vegetation, Flowering, and harvest).
  - $2. \ \ Horticulture\ Lighting\ Square\ Footage\ (HLSF)\ means\ Canopy.$
  - 3. Lighting Power Density (HLPD) means a measure of total watts of Horticultural Lighting Equipment per total Horticulture Lighting Square Footage, (HLE/HLSF = HLPD) expressed as number of watts per square foot.
- (13) In addition to the written operating policies required under 935 CMR 501.105(1), MTC cultivation operations, including Colocated Marijuana Cultivators, shall maintain written policies and procedures for the cultivation, production, Transfer or distribution of Marijuana, as applicable, which shall include, but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories, and for maintaining accurate inventory. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(8);



- (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by an MTC to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
- (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(12);
- (d) Policies and procedures for transportation. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(13);
- (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 501.105(15) and 935 CMR 501.120(11); and
- (f) Policies and procedures for the Transfer, acquisition, or sale of Marijuana between MTCs and Marijuana Establishments.

## 502.120: Additional Operational Requirements for Cultivation

An RMD\_CMO that cultivates marijuana for adult\_use must comply with 935 CMR 500.120: Additional Operating Requirements for Indoor and Outdoor Marijuana Cultivators.



# **Topic: Retail Sale – Additional Operational Requirements**

#### Recommendation:

- 1. Limit collection of consumer data by retailers to what is currently listed in the regulations: name; date of birth; address; primary telephone number; and email address.
- Allow pre-verification at one retail location to serve as pre-verification at multiple retail locations operated by the same retail licensee for purposes of delivery, at the option of the consumer.

#### 500.140: Additional Operational Requirements for Retail Sale

- (1) In addition to the general operational requirements for Marijuana Establishments required under 935 CMR 500.105; *General Operational Requirements for Marijuana Establishments*, Licensees engaged in retail sales shall comply with 935 CMR 500.140.
- (2) On-Premises Verification of Identification.
  - (a) On entry into the Premises of a Marijuana Retailer by an individual, a Marijuana Establishment Agent shall immediately inspect the individual's proof of identification and determine the individual's age. An individual shall not be admitted to the Premises, unless the Marijuana Retailer has verified that the individual is 21 years of age or older by an individual's proof of identification.
  - (b) On point of sale by an individual, a Marijuana Establishment Agent shall inspect the individual's proof of identification and determine the individual's age.
  - (c) In accordance with G.L. c. 94G, § 4(c)(3), aA Marijuana Retailer may not acquire or record Consumer personal information other than information typically required in a retail transaction, which can include identifying information to determine the Consumer's age. A Marijuana Retailer may not record or retain any additional personal information from Consumer without the Consumer's voluntary written permission, except as provided in (d) and (e).
  - (d) A Marijuana Retailer that has entered into Delivery Agreements with Delivery-only Licensees for the purpose of transacting home deliveries to Consumers shall establish a Pre-verification process for Consumers who intend to place orders for delivery with



the Marijuana Establishment. A Marijuana Retailer that holds more than one Marijuana Retailer license may establish a process to share Pre-verification information about Consumers among their multiple locations for the purpose of enabling deliveries from any licensed location operated by the Marijuana Retailer, provided however that information shall only be shared among locations upon the affirmative election by a Consumer. To comply with the requirements of Pereverification, the Marijuana Establishment shall:

- Require the Consumer to pre-verify with the Marijuana Establishment either in person or through a Commission-approved electronic means by presenting or submitting the Consumer's valid, unexpired government-issued photo identification; and
- 2. Examine the <u>government-issued</u> identification and verify that the individual Consumer presenting or submitting the <u>government-issued</u> identification is the individual Consumer that matches the <u>government-issued</u> identification and that the individual Consumer is 21 years of age or older.
- (e) A Marijuana Retailer shall c€ollect and maintain relevant information about the individual Consumer, for the purpose of transacting a delivery and ensuring that the recipient of a delivery under 935 CMR 500.145 is legally allowed to receive Marijuana and MarijuanaProducts, which shall be limited to:
  - 1. The individual's name;
  - 2. The individual's date of birth;
  - 3. The individual's address;
  - 4. The individual's primary telephone number; and
  - 5. The individual's email address.
- (f) Any such information collected by the Marijuana Establishment shall be used solely for the purpose of transacting a delivery of Marijuana or Marijuana Products—under 935 CMR 500.145 and shall be otherwise maintained confidentially.

Commented [A29]: M.G.L. c. 94G,  $\S$  4(c)(3):

Regulations...shall not...require a customer to provide a marijuana retailer with identifying information other than identification to determine the customer's age and shall not require the marijuana retailer to acquire or record personal information about customers other than information typically required in a retail transaction.

[...]



# **Topic: Collection of Data**

Recommendation: Add to additional operational requirements for retail/patient sales that potency levels derived from the Cannabinoid Profile contained within Finished Marijuana or Marijuana Product, including the amount of delta-nine-tetrahydrocannabinol ( $\Delta 9$ -THC) and other Cannabinoids, be recorded in METRC.

### 500.140 - Additional Operational Requirements for Retail Sale

- (7) <u>Testing</u>. No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that has not first been tested by Independent Testing Laboratories, except as allowed under 935 CMR 500.000. The product must be deemed to comply with the standards required under 935 CMR 500.160.
  - (a) Potency levels derived from the Cannabinoid Profile, including the amount of deltanine-tetrahydrocannabinol (Δ9-THC) and other Cannabinoids, contained within Finished Marijuana or Marijuana Product to be sold or otherwise marketed must be recorded in the Seed-to-sale SOR.

# 501.140 - Additional Operational Requirements for Patient Sales

- (7) <u>Testing</u>. No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 501.000. The product must be deemed to comply with the standards required under 935 CMR 501.160.
  - (a) Potency levels derived from the Cannabinoid Profile, including the amount of deltanine-tetrahydrocannabinol (Δ9-THC) and other Cannabinoids, contained within Finished Marijuana or Marijuana Product to be sold or otherwise marketed must be recorded in the Seed-to-sale SOR.





# **Topic: Transfer of Product**

# Recommendations:

- 1. Currently, a CMO must submit an inventory plan every quarter Group 4 is recommending a reduced timeframe for this submission, that it be done on a biennial basis.
- 2. Based on Group 4's review of 935 CMR 500.105(13); Transportation Between Marijuana Establishments, and 935 CMR 501.105(13); Transportation Between MTCs, there does not appear to be any express regulatory language permitting transportation between MTCs and MEs. Group 4 recommends that a simple language adjustment in 500.103(13)(a)(1) and 501.103(13)(a)(1) clarifying that an ME or an MTC may transport "its Marijuana Products to other licensed establishments" which include MEs or MTCs.

# 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (8) Inventory.
  - (a) Subject to Marijuana or Marijuana Products being entered into the Seed-to-sale SOR, a Marijuana Establishment may Transfer product to an MTC, and an MTC may Transfer product to a Marijuana Establishment as long as there is no violation of the dosing limitations set forth in 935 CMR 500.150(4): Dosing Limitations or the limitations on total MTC inventory as set forth in 935 CMR 501.105(8)(jk)(2) and (3). Such Transfers cannot violate provisions protecting patient supply under 935 CMR 502.140(9). An MTC must limit its Transfer of inventory of seeds, plants, and Usable Marijuana to reflect the projected needs of Registered Qualifying Patients.

[...]

(j) An MTC may acquire Marijuana and Marijuana Product from or distribute Marijuana or Marijuana Product to another MTC or Marijuana Establishment in accordance with 935 CMR 5012.14005(8)(b) and subject to the following:



a. A documented emergency occurs such as loss of crop, vandalism, or theft, or other circumstance as approved by the Commission; or

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

Commented [A30]: Moved this to 2.

 $\begin{tabular}{ll} \textbf{Commented [A31]:} This is combined with 1. to streamline the language. No substantive change here. \end{tabular}$ 

# 502.140: Additional Operational Requirements for Retail Sales

# (9) Patient Supply.

- (a) A CMO shall ensure access to a sufficient quantity and variety of Mmarijuana Pproducts, including Mmarijuana, for patients registered under 935 CMR 501.000: *Medical Use of Marijuana*.
  - 1. Where the CMO has been open and dispensing for a period of less than six months, the license shall reserve 35% of the RMD's-MTC's Mmarijuana Pproducts.
  - 2. Where the CMO has been open and dispensing for a period of six months or longer, the licensee shall maintain a quantity and variety of Mmarijuana Pproducts for patients registered under 935 CMR 501.000: *Medical Use of Marijuana*, sufficient to meet the demand indicated by an analysis of sales data collected by the Licensee during the preceding six months in accordance with 935 CMR 500.140(6); *Recording Sales*.
- (b) Marijuana Products reserved for patient supply shall, unless unreasonably impracticable, reflect the actual types and strains of Mmarijuana Products documented during the previous six months. If a substitution must be made, the substitution shall reflect as closely as possible the type and strain no longer available.
- (c) On a quarterly-biennial basis, the CMO shall submit to the Commission an inventory plan to reserve a sufficient quantity and variety of medical-use Marijuana Pproducts for Registered Qualifying Ppatients, based on reasonably anticipated patient needs as documented by sales



records over the preceding six months. On each occasion that the supply of any product within the reserved patient supply is exhausted and a reasonable substitution cannot be made, the CMO shall submit a report to the Commission in a form determined by the Commission.

- (d) Marijuana Pproducts reserved for patient supply shall be either maintained on-site at the retailer or easily accessible at another location operated by the Licensee and transferable to the retailer location within 48 hours of notification that the on-site supply has been exhausted. CMOs shall perform audits of patient supply available on a weekly basis and retain those records for a period of six months.
- (e) The Commission shall, consistent with 935 CMR 500.300: Inspections and Compliance, inspect and audit CMOs to ensure compliance with 935 CMR 502.140. The Commission may, in addition to the issuance of a deficiency statement under 935 CMR 500.310: Deficiency Statements and a plan of correction under 935 CMR 500.320: Plans of Correction, demand that the CMO take immediate steps to replenish its reserved patient supply to reflect the amounts required under 935 CMR 502.140(9)(a). Failure to adequately address a deficiency statement or follow a plan of correction shall result in administrative action by the Commission pursuant to 935 CMR 500.450: Marijuana Establishment License: Grounds for Denial of Renewal Applications, Suspension and Revocation and 935 CMR 500.500: Hearings and Appeals of Actions on Licenses.
- (f) CMOs may transfer Mmarijuana Pproducts reserved for medical use to adult use within a reasonable period of time prior to the date of expiration provided that the product does not pose a risk to health or safety.

### 500.105: General Operational Requirements for Marijuana Establishments

- (13) <u>Transportation Between Marijuana Establishments.</u>
  - (a) General Requirements.
    - A licensed Marijuana Establishment shall, as an element of its License, be licensed to transport its <u>Marijuana and Marijuana Products</u> to other licensed establishments, <u>including MTCs</u>, except as otherwise provided herein.

# 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (13) Transportation Between MTCs.
  - (a) General Requirements.



A licensed MTC shall, as an element of its License, be licensed to transport its
 Marijuana and Marijuana Products to other licensed establishments, including Marijuana Establishments, except as otherwise provided in 935 CMR 501.105(13).



# **Topic: Sampling of Product**

<u>Recommendation</u>: For Marijuana Establishments, allow cultivators to provide Quality Control Samples to its employees, and Vendor Samples to product manufacturers and retailers. Allow product manufacturers to provide Quality Control Samples to its employees, and Vendor Samples to retailers. Allow retailers to receive Vendor Samples from product manufacturers and cultivators, and to provide those Vendor Samples to the retailers' employees.

#### 500.002: Definitions.

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

Quality Control Sample means a sample of Marijuana or Marijuana Product developed by a Marijuana Cultivator or a Marijuana Product Manufacturer licensed under the provisions of 935 CMR 500.000: Adult Use of Marijuana, that is provided internally to employees for purposes of ensuring product quality and making determinations about whether to sell the Marijuana or Marijuana Product.

# 500.120: Additional Operational Requirements for Indoor and Outdoor Marijuana Cultivators

[...]

- (12) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Cultivator, including colocated Marijuana Cultivators and MTCs, shall maintain written policies and procedures for the cultivation, production, Transfer or distribution of Marijuana, as applicable, which shall include but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(8);





- (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by a Marijuana Establishment to remove defective or potentially defective Marijuana from the market, as well as any action undertaken to promote public health and safety;
- (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana is segregated from other Marijuana and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(12);
- (d) <u>Policies and Procedures for Transportation</u>. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(13);
- (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(15) and 935 CMR 500.120(11); and
- (f) Policies and procedures for the Transfer, acquisition, or sale of Marijuana between Marijuana Establishments;-
- (g) Policies and procedures for developing and providing Vendor Samples to a Marijuana Product Manufacturer or a Marijuana Retailer. Policies and procedures shall include methods by which the Marijuana Cultivator will adequately track, record, and document all Vendor Samples developed on, or provided from, the licensed Premises in satisfaction of 935 CMR 500.120(13); and
- (h) Policies and procedures for developing and providing Quality Control Samples to employees for the purpose of ensuring product quality and determining whether to make the product available to sell. Policies and procedures shall include methods by which the Marijuana Cultivator will adequately track, record, and document all Quality Control Samples developed on, or provided from, the licensed Premises in satisfaction of 935 CMR 500.120(14). Policies and procedures shall further prohibit consumption of Quality Control Samples on the licensed Premises.



# (13) Vendor Samples.

- (a) A Marijuana Cultivator may provide a Vendor Sample of Marijuana flower to a Marijuana Product Manufacturer or to a Marijuana Retailer. Provision of a Vendor Sample under this subsection shall not be considered a prohibited practice under 935 CMR 500.105(4)(b)6.
- (b) Vendor Samples provided under this subsection:
  - 1. Shall not be consumed on any licensed Premises;
  - 2. Shall not be sold to another licensee or Consumer;
  - 3. Shall be tested in accordance with 935 CMR 500.160: Testing of Marijuana and Marijuana Products; and
  - 4. Shall be transported in accordance with 935 CMR 500.105(13): Transportation Between Marijuana Establishments. A Marijuana Cultivator may include Vendor Samples with other Marijuana flower intended for transportation to an individual Marijuana Product Manufacturer or an individual Marijuana Retailer;
- (c) Vendor Sample limits. A Marijuana Cultivator is limited to providing the following aggregate amount of Vendor Samples to an individual Marijuana Product

  Manufacturer or an individual Marijuana Retailer in a calendar month period:
  - Four grams per strain of Marijuana flower and no more than seven strains of Marijuana flower.
- (d) All Vendor Samples provided by a Marijuana Cultivator under 935 CMR 500.120(13) shall be assigned a unique, sequential alphanumeric identifier and entered into the Seed-to-sale SOR in a form and manner to be determined by the Commission, and further, shall be designated as "Vendor Sample."
- (e) Vendor Samples provided under this subsection shall have a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size containing at minimum the following information:
  - 1. A statement that reads: "VENDOR SAMPLE NOT FOR RESALE";



- 2. The name and registration number of the Marijuana Cultivator;
- 3. The quantity, net weight, and type of Marijuana flower contained within the package; and
- A unique sequential, alphanumeric identifier assigned to the Cultivation Batch associated with the Vendor Sample that is traceable in the Seed-to-sale SOR.

### (14) Quality Control Samples.

- (a) A Marijuana Cultivator may provide a Quality Control Sample of Marijuana flower to its employees for the purpose of ensuring product quality and determining whether to make the product available to sell. Provision of a Quality Control Sample under this subsection shall not be considered a prohibited practice under 935 CMR 500.105(4)(b)6.
- (b) Quality Control Samples provided to employees under this section:
  - 1. Shall not be consumed on the licensed Premises;
  - 2. Shall not be sold to another licensee or Consumer; and
  - 3. Shall be tested in accordance with 935 CMR 500.160: Testing of Marijuana and Marijuana Products.
- (c) Quality Control Sample limits. A Marijuana Cultivator is limited to providing the following aggregate amount of Quality Control Samples to all employees in a calendar month period:
  - Four grams per strain of Marijuana flower and no more than seven strains of Marijuana flower.
- (d) All Quality Control Samples provided by a Marijuana Cultivator under 935 CMR 500.120(14) shall be assigned a unique, sequential alphanumeric identifier and entered into the Seed-to-sale SOR in a form and manner to be determined by the Commission, and further, shall be designated as "Quality Control Sample."



- (e) Quality Control Samples provided under this subsection shall have a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size containing at minimum the following information:
  - 1. A statement that reads: "QUALITY CONTROL SAMPLE NOT FOR RESALE";
  - 2. The name and registration number of the Marijuana Cultivator;
  - 3. The quantity, net weight, and type of Marijuana flower contained within the package; and
  - A unique sequential, alphanumeric identifier assigned to the Cultivation Batch associated with the Quality Control Sample that is traceable in the Seed-to-sale SOR.
- (f) Upon providing a Quality Control Sample to an employee, the Marijuana Cultivator shall record:
  - The reduction in quantity of the total weight or item count under the unique alphanumeric identifier associated with the Quality Control Sample;
  - 2. The date and time the Quality Control Sample was provided to the employee;
  - The agent registration number of the employee receiving the Quality Control Sample; and
  - 4. The name of the employee as it appears on their agent registration card.

#### 500.130: Additional Operational Requirements for Marijuana Product Manufacturers

[...]

(6) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Product Manufacturer shall maintain written policies and procedures for the production or distribution of Marijuana Products, as applicable, which shall include, but not be limited to:



- (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(8);
- (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana Products. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by a Marijuana Establishment to remove defective or potentially defective Marijuana Products from the market, as well as any action undertaken to promote public health and safety;
- (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana Products is segregated from other product and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana Products. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(12);
- (d) Policies and procedures for transportation. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(13);
- (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(15);
- (f) Policies and procedures for the Transfer, acquisition, or sale of Marijuana Products between Marijuana Establishments;
- (g) Policies and procedures to ensure that all Edible Marijuana Products are prepared, handled, and stored in compliance with the sanitation requirements in 105 CMR 590.000: State Sanitary Code Chapter X: Minimum Sanitation Standards for Food Establishments, and with the requirements for food handlers specified in 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements; and
- (h) Policies and procedures for maintaining a product catalogue identifying all types of Marijuana Products actively manufactured at the facility. The catalog shall include a description of the product, photograph or illustration, packaging design, and dosage amounts, including expected Cannabinoid Profile;
- (i) Policies and procedures for developing and providing Vendor Samples to a Marijuana Retailer. Policies and procedures shall include methods by which the Marijuana Product Manufacturer will adequately track, record, and document all Vendor Samples





developed on, or provided from, the licensed Premises in satisfaction of 935 CMR 500.130(7); and

- (h)(j) Policies and procedures for developing and providing Quality Control Samples to employees for the purpose of ensuring product quality and determining whether to make the product available to sell. Policies and procedures shall include methods by which the Marijuana Product Manufacturer will adequately track, record, and document all Quality Control Samples developed on, or provided from, the licensed Premises in satisfaction of 935 CMR 500.130(8). Policies and procedures shall further prohibit consumption of Quality Control Samples on the licensed Premises.
- (7) Notwithstanding a stricter municipal or state regulation, a Marijuana Product Manufacturer shall identify the method of extraction (e.g., Butane, Propane, CO2) on a physical posting at all entrances of the Marijuana Establishment. The Posting shall be a minimum of 12" x 12" and identify the method of extraction in lettering no smaller than one inch in height. A Marijuana Product Manufacturer shall post a copy of a permit to keep, store, handle or otherwise use flammable and combustible at each place of operation within the facility.

#### (8) Vendor Samples.

- (a) A Marijuana Product Manufacturer may provide a Vendor Sample of a Marijuana
  Product to a Marijuana Retailer. Provision of a Vendor Sample under this subsection
  shall not be considered a prohibited practice under 935 CMR 500.105(4)(b)6.
- (b) Vendor Samples provided under this subsection:
  - 1. Shall not be consumed on any licensed Premises;
  - 2. Shall not be sold to another licensee or Consumer;
  - 3. Shall be tested in accordance with 935 CMR 500.160: *Testing of Marijuana and Marijuana Products*; and
  - Shall be transported in accordance with 935 CMR 500.105(13): Transportation
     Between Marijuana Establishments. A Marijuana Product Manufacturer may include Vendor Samples with other Marijuana Products intended for transportation to an individual Marijuana Retailer.
- (c) Vendor Sample limits. A Marijuana Product Manufacturer is limited to providing the following aggregate amounts of Vendor Samples to an individual Marijuana Retailer in a calendar month period:



- Five grams of Marijuana concentrate or extract, including but not limited to tinctures;
- Five hundred milligrams of Edible Marijuana Products whereby the serving size of each individual sample does not exceed five milligrams and otherwise satisfies the potency levels set forth in 935 CMR 500.150(4); and
- Five units of sale per Cannabis product line and no more than six individual Cannabis product lines. For purposes of 935 CMR 500.130(7), a Cannabis product line shall mean items bearing the same Stock Keeping Unit Number.
- (d) All Vendor Samples received from a Marijuana Cultivator pursuant to 935 CMR 500.120(13) that are used to manufacture a Marijuana Product shall be assigned a unique, sequential alphanumeric identifier and entered into the Seed-to-sale SOR in a form and manner to be determined by the Commission, and further, shall be designated as "Vendor Sample."
- (e) All Vendor Samples provided by a Marijuana Product Manufacturer under 935 CMR 500.130(7) shall be assigned a unique, sequential alphanumeric identifier and entered into the Seed-to-sale SOR in a form and manner to be determined by the Commission and shall further be designated as "Vendor Sample."
- (f) Vendor Samples provided under this section shall have a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size containing at minimum the following information:
  - 1. A statement that reads: "VENDOR SAMPLE NOT FOR RESALE";
  - 2. The name and registration number of the Marijuana Product Manufacturer;
  - 3. The quantity, net weight, and type of Marijuana Product contained within the package; and
  - A unique sequential, alphanumeric identifier assigned to the Production Batch associated with the Vendor Sample that is traceable in the Seed-to-sale SOR.
- (9) Quality Control Samples.
  - (a) A Marijuana Product Manufacturer may provide a Quality Control Sample of Marijuana Product to its employees for the purpose of ensuring product quality and determining whether to make the product available to sell. Provision of a Quality Control Sample under this subsection shall not be considered a prohibited practice under 935 CMR 500.105(4)(b)6.
  - (b) Quality Control Samples provided to employees under this subsection:
    - 1. Shall not be consumed on the licensed Premises;



- 2. Shall not be sold to another licensee or Consumer; and
- 3. Shall be tested in accordance with 935 CMR 500.160: Testing of Marijuana and Marijuana Products.
- (c) Quality Control Sample limits. A Marijuana Product Manufacturer is limited to providing the following aggregate amounts of Quality Control Samples to all employees in a calendar month period:
  - Five grams of Marijuana concentrate or extract, including but not limited to tinctures;
  - Five hundred milligrams of Edible Marijuana Products whereby the serving size of each individual sample does not exceed five milligrams and otherwise satisfies the potency levels set forth in 935 CMR 500.150(4); and
  - 3. Five units of sale per Cannabis product line and no more than six individual Cannabis product lines. For purposes of 935 CMR 500.130(8), a Cannabis product line shall mean items bearing the same Stock Keeping Unit Number.
- (d) All Quality Control Samples provided under 935 CMR 500.130(8) shall be assigned a unique, sequential alphanumeric identifier and entered into the Seed-to-sale SOR in a form and manner to be determined by the Commission, and further, shall be designated as "Quality Control Sample."
- (e) Quality Control Samples provided under this subsection shall have a legible, firmly
  Affixed label on which the wording is no less than 1/16 inch in size containing at
  minimum the following information:
  - 1. A statement that reads: "QUALITY CONTROL SAMPLE NOT FOR RESALE";
  - 2. The name and registration number of the Marijuana Product Manufacturer;
  - The quantity, net weight, and type of Marijuana flower contained within the package; and
  - A unique sequential, alphanumeric identifier assigned to the Production Batch associated with the Quality Control Sample that is traceable in the Seed-to-sale SOR.
- (f) Upon providing a Quality Control Sample to an employee, the Marijuana Product Manufacturer shall record:
  - The reduction in quantity of the total weight or item count under the unique alphanumeric identifier associated with the Quality Control Sample;
  - 2. The date and time the Quality Control Sample was provided to the employee;



- 3. The agent registration number of the employee receiving the Quality Control Sample; and
- 4. The name of the employee as it appears on their agent registration card.

# 500.140: Additional Operational Requirements for Retail Sale

[...]

- (3) <u>Testing</u>. [...]
- (4) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Retailer shall maintain written policies and procedures which shall include:
  - (a) Policies and procedures for adequately tracking, recording, and documenting all

    Vendor Samples that the Marijuana Retailer receives from a Marijuana Cultivator or a

    Marijuana Product Manufacturer; and
  - (b) Policies and procedures for adequately tracking, recording, and documenting all Vendor Samples that the Marijuana Retailer provides to employees for the purpose of assessing product quality and determining whether to make the product available to sell, in compliance with 935 CMR 500.140(9).

# (10) Vendor Samples.

- (a) A Marijuana Retailer may receive a Vendor Sample of Marijuana flower from a Marijuana Cultivator pursuant to 935 CMR 500.120(13). A Marijuana Retailer may also receive a Vendor Sample of Marijuana Product from a Marijuana Product Manufacturer pursuant to 935 CMR 500.130(7). Receipt of a Vendor Sample under this subsection shall not be considered a prohibited practice under 935 CMR 500.105(4)(b)6.
- (b) Vendor Samples shall not be sold to another licensee or Consumer.
- (c) A Marijuana Retailer may provide the Vendor Samples it receives from a Marijuana Cultivator or a Marijuana Product Manufacturer to its employees for the purpose of assessing product quality and determining whether to make the product available to sell the product. Vendor Samples shall not be consumed on any licensed Premises.
- (d) Vendor Sample limits. A Marijuana Retailer is limited to providing the following aggregate amounts of Vendor Samples to all employees in a calendar month period:



- Four grams per strain of Marijuana flower and no more than seven strains of Marijuana flower;
- Five grams of Marijuana concentrate or extract, including but not limited to Tinctures;
- Five hundred milligrams of Edible Marijuana Products whereby the serving size of each individual sample does not exceed five milligrams and otherwise satisfies the potency levels set forth in 935 CMR 500.150(4); and
- 4. Five units of sale per Cannabis product line and no more than six individual Cannabis product lines. For purposes of 935 CMR 500.140(9), a Cannabis product line shall mean items bearing the same Stock Keeping Unit Number.
- (e) Upon providing a Vendor Sample to an employee, the Marijuana Retailer shall record:
  - 1. The reduction in quantity of the total weight or item count under the unique alphanumeric identifier associated with the Vendor Sample;
  - 2. The date and time the Vendor Sample was provided to the employee;
  - 3. The agent registration number of the employee receiving the Vendor Sample; and
  - 4. The name of the employee as it appears on their agent registration card.
- (a)(f) All Vendor Samples provided by a Marijuana Retailer to its employees shall also be entered into the Point-of-Sale system and shall count against the individual employee's daily purchase limit, if applicable, consistent with 935 CMR 500.140(3).



# **Topic: Product Shape and Color**

# Summary of changes:

- Make references to defined terms consistent
- Add as prohibited shape for edibles (in both adult-use and medical-use) sporting-equipment item (i.e., soccer balls, ice skates, tennis rackets, baseball bats)
- Removed subsection (3)(c) of both the adult-use and medical-use provisions because ineffective
  means of conveying THC serving size to patients and consumers
- Provide alternative stamping directly on edible to allow wrapping individual servings and stamp
  the wrapper (see reasons 2 and 4, above)

### 500.150: Edible Marijuana Products

- (1) <u>Production of Edibles Marijuana Products.</u> <u>Production of E</u>edibles shall take <u>place be produced</u> in compliance with the following:
  - (a) Any Edible Marijuana Product that is made to resemble a typical food or Beverage product must be packaged and labeled as required by M.G.L. c. 94G, § 4(a½)(xxiv) and (xxvi), and 935 CMR 500.105(5) and (6).
  - (b) The Manufacture or sale of **Ee**dibles in the following shapes and types is prohibited:
    - 1. The distinct shape of a human, animal, or fruit, or sporting-equipment item; or
    - 2. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, or sporting-equipment item including artistic, caricature, or cartoon renderings.
  - (c) Edibles Marijuana Products that are geometric shapes and simply fruit\_flavored are not considered fruit and are permissible.
- (2) <u>Sanitary Requirements</u>. All Edibles <u>Marijuana Products</u> shall be prepared, handled, and stored in compliance with the requirements in 935 CMR 500.105(3) and 935 CMR 500.105(11).
- (3) Additional Labeling and Packaging Requirements for Edibles Marijuana Products.
  - (a) In addition to the requirements set forth in M.G.L. c. 94G, § 4(a½)(xxiv) and



(xxvi), and 935 CMR 500.105(5) and (6), every Marijuana Retailer must ensure that the following information or statement is Affixed to every container holding an Edible Marijuana Product:

- 1. If the retail Edible Marijuana Product is perishable or time and temperature controlled, a statement that the Edible Marijuana Product must be refrigerated.
- 2. The date on which the Edible Marijuana Product was produced.
- 3. A nutritional fact panel that must be based on the number of THC servings within the container.
- 4. Information regarding the size of each serving for the product by milligrams, the total number of servings of Marijuana in the product, and the total amount of active THC in the product by milligrams (mgs). For example: "The serving size of active THC in this product is X mg(s), this product contains Y servings of Marijuana, and the total amount of active THC in this product is (X\*Y) mg(s)."
- 5. A warning that the impairment effects of Edibles Marijuana Products may be delayed by two hours or more.
- (b) Once a label with a use-by date has been Affixed to a container holding an Edible Marijuana Product, a Licensee shall not alter that date or affix a new label with a later use-by date.
- 1. A Marijuana Product Manufacturer must ensure that each single serving of an Edible Marijuana Product is physically demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC.
- (c) Each serving of an Edible Marijuana Product-within a multi-serving package of Edibles Marijuana Products must be easily separable in order to allow an average person 21 years of age or older to physically separate, with minimal effort, individual servings of the product.
- (d) Each single serving of an Edible Marijuana Product contained in a multiserving packaged unit of multiple Edibles Marijuana Product shall be marked,
  stamped, or otherwise imprinted with thea symbol or easily recognizable mark issued
  by the Commission that indicates the package contains Marijuana Product consistent
  with 935 CMR 500.105(5)(a)(8.). Alternatively, a Licensee may ensure that
  individually wrap each single serving of an Edible Marijuana Product is individually
  wrapped and shall mark, stamp, or otherwise imprint each individual wrapper with
  the symbol or easily recognizable mark issued by the Commission that indicates the
  serving contains Marijuana Product consistent with 935 CMR 500.105(5)(a)8.. –
  serve items with tamper resistant packaging indicating same.

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[...]

# 501.150: Edible Marijuana-infused Products

- (1) <u>Production of Edible Marijuana-infused Products.</u> <u>Production of Eedible MIPs shall</u> <u>take placebe produced</u> in compliance with the following:
  - (a) Any <u>E</u>edible <u>Marijuana infused ProductMIP</u> that is made to resemble a typical food or beverage product must be packaged and labeled as required by M.G.L. c. 94G, § 4(a½)(xxiv) and (xxvi), and 935 CMR 501.105(5) and (6).
  - (b) The manufacture or sale of <u>Eedible MIPs</u> in the following shapes and types is prohibited:
    - 1. The distinct shape of a human, animal, or fruit or sporting-equipment item; or
    - 2. A shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, or sporting-equipment item including artistic, caricature, or cartoon renderings.
  - (c) Edible Marijuana infused Products MIPs that are geometric shapes and simply fruit-flavored are not considered fruit and are permissible.
- (2) <u>Sanitary Requirements</u>. All <u>Eedible Marijuana Products MIPs</u> shall be prepared, handled, and stored in compliance with the requirements in 935 CMR 501.105(3) and (11).
- (3) Additional Labeling and Packaging Requirements for Edibles—Marijuana infused Products.
  - (a) In addition to the requirements set forth in M.G.L. c. 94G,- §- 4(a½)(xxiv) and (xxvi), and 935 CMR 501.105(5) and (6), every MTC must ensure that the following information or statement is Affixed to every container holding an <u>Eedible Marijuana Product MIP</u>:
    - 1. If the retail <u>E</u>edible <u>Marijuana ProductMIP</u> is perishable or time and temperature controlled, a statement that the <u>E</u>edible <u>Marijuana ProductMIP</u> must be refrigerated.
    - 2. The date on which the  $\underline{\underline{Ee}}$  dible  $\underline{\underline{Marijuana\ Product\ \underline{MIP}}}$  was produced.
    - 3. A nutritional fact panel that must be based on the number of THC servings within the container
    - 4. Information regarding the size of each serving for the product by milligrams, the total number of servings of Marijuana in the product, and the total amount of active





THC in the product by milligrams (mgs). For example: "The serving size of active THC in this product is X mg(s), this product contains Y servings of Marijuana, and the total amount of active THC in this product is (X\*Y) mg(s)."

- 5. A warning that the impairment effects of <u>E</u>edible <u>Marijuana ProductsMIPs</u> may be delayed by two hours or more.
- (b) Once a label with a use-by date has been Affixed to a container holding an Eedible Marijuana Product MIP, a Licensee shall not alter that date or affix a new label with a later use-by date.
- (c) An MTC must ensure that each single serving of an edible Marijuana Product is physically demarked in a way that enables a reasonable person to intuitively determine how much of the product constitutes a single serving of active THC.
- (d)(c) Each single serving of an Eedible Marijuana ProductMIP within a multi-serving package of Eedible Marijuana ProductsMIPs must be easily separable in order to allow an average person 21 years of age or older to physically separate, with minimal effort, individual servings of the product.
- (e)(d) Each single serving of an Eedible Marijuana infused ProductMIP contained in a multi-serving packaged unit of multiple Eedible Marijuana ProductMIPs may shall be marked, stamped, or otherwise imprinted with thea symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product consistent with 935 CMR 501.105(5)(a)8. Alternatively, a Licensee may ensure that each single serving of an Edible Marijuana Product is individually wrapped and shall mark, stamp, or otherwise imprint each individual wrapper with the symbol or easily recognizable mark issued by the Commission that indicates the serving contains Marijuana Product consistent with 935 CMR 500.105(5)(a)8.



# **Topic: Product Database**

# Summary of changes:

- 1. Define packaging and labeling pre-approval process.
- Add requirements for submission of information by product manufacturers and retailers for Commission-operated Product Database.

# 500.002: Definitions

Product Database means a Commission-operated technology platform displaying information about Marijuana Products produced by licensed Marijuana Product Manufacturers and sold by licensed Marijuana Retailer pursuant to 935 CMR 500.000 and 935 CMR 501.000.

# 500.005: Fees

(1) Marijuana Establishment Application and License Fees.

[...]

(e) Other Fees (cost per License).

Change in Name Fee	\$1,000	
Change in Location Fee	50% of applicable License Fee	
Change in Building Structure Fee	\$1,000	
Change in Ownership or Control Fee (involving at least	\$5,000 per entity, per License	
one entity gaining ownership/control)		
Change in Ownership or Control Fee	\$500 per person	
(involving individuals, e.g., change of Board Member)		
Architectural Review Request Fee	\$1,500	
Packaging and Labeling Pre-Approval Application Fee	\$50 per product	

[...]



#### 500.105: General Operational Requirements for Marijuana Establishments

[...]

- (7) Packaging and Labeling Pre-approval. Prior to Marijuana or Marijuana Product being sold at a Marijuana Establishment, a Licensee or License Applicant may submit an application, in a form and manner determined by the Commission, for packaging and label approval to the Commission. An application for pre-approval may be submitted at any time prior to Marijuana or Marijuana Product being sold or at any time a substantive change is made to the packaging or labeling of Marijuana or Marijuana Product. The Commission shallmay charge a fee for packaging and labeling pre-approval pursuant to 935 CMR 500.005: Fees.
  - (a) Packaging and labeling pre-approval review shall be limited to the physical attributes of, and statutorily required warnings on, the packaging and label, including but not limited to legibility, but shall not include a review of specific Independent Testing Laboratory test results required pursuant to 935 CMR 500.105(5) and (6). The packaging and labeling pre-approval process shall in no way substitute for compliance be in addition to the requirements of with 935 CMR 500.105(4) through (6).
  - (b) In addition to an application for packaging and labeling pre-approval in a form and manner determined by the Commission, an applicant for pre-approval shall submit electronic files of the following to the Commission:
    - For packaging pre-approval, two images of the packaging, one depicting the front
      of the packaging and one depicting the back of the packaging. Photographs shall
      be electronic files in a JPEG format with a minimum photo resolution of 640 x
      480 and print resolution of 300 DPI. Photographs shall be against a white
      background.
    - For labeling pre-approval, one image of each label requested for review.
       Photographs shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.
  - (c) The Commission shall make every effort to make a pre-approval determination based on information submitted. In the event that a pre-approval determination is unable to be made conclusively based on submitted photographs, the Commission may request to view the packaging or label in person or through a video conference. Any such request by the Commission shall be made to the applicant electronically or in writing.





# 501.005: Fees

# (3) Other Fees (Cost per License).

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

# 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

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

(a) Packaging and labeling pre-approval review shall be limited to the physical attributes of, and statutorily required warnings on, the packaging and label, including but not limited to legibility, but shall not include a review of specific Independent Testing Laboratory test

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results required pursuant to 935 CMR 501.105(5) and (6). The packaging and labeling preapproval process shall be in addition to the requirements of no way substitute for compliance with 935 CMR 501.105(5) through (6).

- (b) In addition to an application for packaging and labeling pre-approval in a form and manner determined by the Commission, an applicant for pre-approval shall submit electronic files of the following to the Commission:
  - For packaging pre-approval, two images of the packaging, one depicting the front
    of the packaging and one depicting the back of the packaging. Photographs shall
    be electronic files in a JPEG format with a minimum photo resolution of 640 x
    480 and print resolution of 300 DPI. Photographs shall be against a white
    background.
  - For labeling pre-approval, one image of each label requested for review.
     Photographs shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.
- (c) The Commission shall make every effort to make a pre-approval determination based on information submitted. In the event that a pre-approval determination is unable to be made conclusively based on submitted photographs, the Commission may request to view the packaging or label in person or through a video conference. Any such request by the Commission shall be made to the applicant electronically or in writing.

# 500.130: Additional Operational Requirements for Marijuana Product Manufacturers

[...]

- (5) In addition to the written operating policies required under 935 CMR 500.105(1), a Marijuana Product Manufacturer shall maintain written policies and procedures for the production or distribution of Marijuana Products, as applicable, which shall include, but not be limited to:
  - (a) Methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(8);



- (b) Policies and procedures for handling voluntary and mandatory recalls of Marijuana Products. Such procedures shall be adequate to deal with recalls due to any action initiated at the request or order of the Commission, and any voluntary action by a Marijuana Establishment to remove defective or potentially defective Marijuana Products from the market, as well as any action undertaken to promote public health and safety;
- (c) Policies and procedures for ensuring that any outdated, damaged, deteriorated, mislabeled, or contaminated Marijuana Products is segregated from other product and destroyed. Such procedures shall provide for written documentation of the disposition of the Marijuana Products. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(12);
- (d) Policies and procedures for transportation. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(13);
- (e) Policies and procedures to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts. The policies and procedures, at a minimum, must be in compliance with 935 CMR 500.105(15);
- (f) Policies and procedures for the Transfer, acquisition, or sale of Marijuana Products between Marijuana Establishments;
- (g) Policies and procedures to ensure that all Edible Marijuana Products are prepared, handled, and stored in compliance with the sanitation requirements in 105 CMR 590.000: State Sanitary Code Chapter X: Minimum Sanitation Standards for Food Establishments, and with the requirements for food handlers specified in 105 CMR 300.000: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements; and
- (h) Policies and procedures for maintaining a product catalogue identifying all types of Marijuana Products actively manufactured at the facility. The catalog shall include a description of the product, photograph or illustration, packaging design, and dosage amounts, including expected Cannabinoid Profile.
- (6) Product Database. In addition to the requirement to establish policies and procedures for maintaining a product catalogue under 935 CMR 500.130(5)(h), a Marijuana Product Manufacturer, after receiving a Provisional License but prior to receiving a Certificate to Commence Operations, shall provide the following information about the finished Marijuana Products it intends to produce and make available at wholesale to a Marijuana



Retailer prior to commencement of operations. This information may be used by the Commission for its Product Database.

(a) The Marijuana Product Manufacturer shall provide the following:

- 1. Marijuana Product type;
- 2. Marijuana Product brand name;
- 3. List of direct ingredients;
- List of indirect ingredients;
- Serving size, including a description of what constitutes a serving size for a
  product that is not already a single serving;
- Potency
- 7. A photograph of a finished Marijuana Product outside of but next to the Marijuana Product's packaging, provided however that where single servings of a multi-serving product are unable to be easily identified because of its form, a description of what constitutes a single serving shall be provided (e.g. a single serving is a 1" x 1" square);
- 8. A photograph of the Marijuana Product inside packaging; and
- A list of Marijuana Products to be sold based on anticipated or executed agreements between the Marijuana Product Manufacturer and Marijuana Retailer.
- (b) Photographs submitted pursuant to 935 CMR 500.130(6) shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.
- (c) A Marijuana Product Manufacturer shall provide the information required under 935

  CMR 500.130(6)(a) for each Marijuana Product that it produces prior to the product
  being made available for sale through a licensed Marijuana Retailer or MTC and shall
  update the information whenever a substantial change to the product information
  occurs. Substantial changes, including changes to information listed in 935 CMR
  500.130(6)(a)1.-9., shall be submitted to the Commission for inclusion in the product
  database prior to the transfer of the Marijuana Product.
- (76) Notwithstanding a stricter municipal or state regulation, a Marijuana Product Manufacturer shall identify the method of extraction (*e.g.*, Butane, Propane, CO2) on a physical posting at all entrances of the Marijuana Establishment. The Posting shall be a minimum of 12" x 12" and identify the method of





extraction in lettering no smaller than one inch in height. A Marijuana Product Manufacturer shall post a copy of a permit to keep, store, handle or otherwise use flammable and combustible at each place of operation within the facility.

# 500.140: Additional Operational Requirements for Retail Sale

[...]

(8) Product Database. A Marijuana Retailer that purchases wholesale Marijuana Products from a licensed Marijuana Product Manufacturer for the purpose of Repackaging Marijuana Products for sale to consumers shall provide the Commission with the following information. This information may be used by the Commission for its Product Database.

(a) The Marijuana Retailer shall provide the following:

- 1. A photograph of a finished Marijuana Product outside of but next to the Marijuana Product's packaging, provided however that where single servings of a multi-serving product are unable to be easily identified because of its form, a description of what constitutes a single serving shall be provided (e.g. a single serving is a 1" x 1" square);
- 2. A photograph of the Marijuana Product inside packaging; and
- 3. The name of the Product Manufacturer that produced the Marijuana Product. (b) Photographs submitted shall be electronic files in a JPEG format with a minimum photo resolution of 640 x 480 and print resolution of 300 DPI. Photographs shall be against a white background.
- (c) Marijuana Retailers shall provide the information required under 935 CMR 500.140(8)(a) for each Marijuana Product it Repackages for sale prior to the product being made available for sale and shall update the information whenever a substantial change to packaging or label of the Marijuana Product occurs. For purposes of this section, a substantial change shall be a change to the physical attributes or content of the package or label.



# **Topic: Repackaging**

# Recommendations:

- 1. Define repackaging and add it as an activity covered by the Retailer license
- 2. Provide labeling requirements for repackaged marijuana [105(5)]
- 3. Include repackaging activity in safe-handling provisions
- 4. Require repackaged marijuana to comply with packaging provisions in 105(6)

# 500.002: Definitions

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

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

# 501.002: Definitions

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

Medical Marijuana Treatment Center (MTC), (Formerly Known as a Registered Marijuana Dispensary (RMD)), means an entity licensed under 935 CMR 501.101 that acquires, cultivates, possesses, Processes (including development of related products such as Edible Marijuana or Marijuana Products, MIPs, Tinctures, aerosols, oils, or ointments), Repackages, transports, sells, distributes, delivers, dispenses, or





administers Marijuana, products containing Cannabis or Marijuana, related supplies, or educational materials to Registered Qualifying Patients or their Personal Caregivers for medical use. Unless otherwise specified, MTC refers to the site(s) of dispensing, cultivation, and preparation of Cannabis or Marijuana for medical use.

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

# 500.050: Marijuana Establishments

# (8) <u>Marijuana Retailers</u>.

- (a) General Requirements.
  - 1. A Marijuana Retailer may purchase, transport, sell. Repackage, or otherwise Transfer Marijuana or Marijuana Products to Marijuana Establishments and sell to Consumers. A retailer cannot deliver Marijuana or Marijuana Products to Consumers or allow on-site social consumption by Consumers on the Premises of the Marijuana Establishment.
  - 2. A retailer shall operate all Marijuana-related activities solely at the address identified in the license.
- (b) A Marijuana Retailer shall provide a retail location accessible to Consumers 21 years of age or older, or, if colocated with an MTC, Registered Qualifying Patients with the Medical Use of Marijuana Program in possession of a Medical Registration Card.

# 501.050: Medical Marijuana Treatment Centers (MTCs)

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





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

# 500.105: General Operational Requirements for Marijuana Establishments

- (3) Requirements for the Handling of Marijuana.
  - (a) [...]
  - (b) All Marijuana Establishments, including those that develop, Repackage, or Process non-edible Marijuana Products, shall comply with the following sanitary requirements: [...]

[...]

- (5) Labeling of Marijuana and Marijuana Products.
  - (a) <u>Labeling of Marijuana Not Sold as a Marijuana Product</u>. [...]
  - (b) <u>Labeling of Edible Marijuana Products</u>. [...]
  - (c) <u>Labeling of Marijuana Concentrates and Extracts</u>. [...]
  - (d) <u>Labeling of Marijuana Infused Tinctures and Topicals</u>. [...]
  - (e) Labeling of Repackaged Marijuana. Prior to Repackaged Marijuana being sold, the Retailer shall place a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size on each container of Marijuana that it prepares for retail sale,
    - 1. The Affixed label shall contain at a minimum the following information:
      - a. The name and registration number of the Cultivator that produced the Marijuana;
      - Business or trade name of licensee that packaged the product, if different from the Cultivator;
      - c. Date of Harvest;
      - d. Type of Marijuana or name of strain;
      - The full Cannabinoid Profile of the Marijuana contained within the Repackaged Product, including the amount of delta-ninetetrahydrocannabinol (Δ9-THC) and other Cannabinoids in the package;



- f. The net weight or volume as expressed in US customary units or metric units;
- g. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- h. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- i. This statement, including capitalization:
  - "This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms. It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.";
- The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product:



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





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

# 501.105: General Operational Requirements for Medical Marijuana Treatment Centers

- (3) Handling of Marijuana
  - (a) [...]
  - (b) All MTCs, including those that develop, Repackage, or Process non-Edible MIPs, shall comply with the following sanitary requirements: [...]

[...]

- (5) Labeling of Marijuana and Marijuana Products.
  - (a) <u>Labeling of Marijuana Not Sold as a Marijuana Product</u>. [...]
  - (b) <u>Labeling of Edible Marijuana Products</u>. [...]
  - (c) <u>Labeling of Marijuana Concentrates and Extracts</u>.[...]
  - (d) <u>Labeling of Marijuana Infused Tinctures and Topicals</u>.
  - (e) Labeling of Repackaged Marijuana. Prior to Repackaged Marijuana being sold, the Retailer shall place a legible, firmly Affixed label on which the wording is no less than 1/16 inch in size on each container of Marijuana that it prepares for retail sale,
    - 1. The Affixed label shall contain at a minimum the following information:
      - The name and registration number of the Cultivator that produced the Marijuana;
      - Business or trade name of licensee that packaged the product, if different from the Cultivator;
      - c. Date of Harvest;
      - d. Type of Marijuana or name of strain;
      - e. The full Cannabinoid Profile of the Marijuana contained within the Repackaged Product, including the amount of delta-nine-tetrahydrocannabinol (Δ9-THC) and other Cannabinoids in the package;



- f. Weight in grams of usable marijuana used in product;
- g. A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and Processing;
- h. A statement and a seal that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with M.G.L. c. 94G, § 15;
- i. This statement, including capitalization:

  "This product has not been analyzed or approved by the FDA.

  There is limited information on the side effects of using this product, and there may be associated health risks. Marijuana use during pregnancy and breast-feeding may pose potential harms.

  It is against the law to drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN.":
- j. The following symbol or easily recognizable mark issued by the Commission that indicates the package contains Marijuana Product:



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





- In circumstances where the labeling of the Marijuana Product is unreasonable or impractical, the MTC may include the labeling information on a peel-back label or may place the product in a sealed bag with an insert or additional, easily readable label firmly Affixed to that bag.
- (fe) In circumstances where the labeling of the Marijuana Product is unreasonable or impractical, the MTC may include the labeling information on a peel-back label or may place the product in a sealed bag with an insert or additional, easily readable label firmly Affixed to that bag.
- (gf) 935 CMR 501.105(5)(a) shall not apply to Marijuana packaged for transport of wholesale cultivated Marijuana in compliance with 935 CMR 501.105(13), provided however, that the MTC is responsible for compliance with 935 CMR 501.105(5) for all Marijuana Products sold or displayed for Patients.
- (hg) 935 CMR 501.105(5)(b) shall apply to edible Marijuana Products produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13) and shall be in addition to any regulation regarding the appearance of edible Marijuana Products under 935 CMR 501.150.
- (ih) 935 CMR 501.105(5)(c) shall apply to Marijuana concentrates and extracts produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13).
- (j $\dot{z}$ ) 935 CMR 501.105(5)(d) shall apply to Marijuana-infused Tinctures and topicals produced by an MTC for transport to another MTC in compliance with 935 CMR 501.105(13).

500.140: Additional Operational Requirements for Retail Sale





[...]

(8) Repackaging. Repackaged Marijuana must comply with the labeling and packaging requirements under 935 CMR 500.105(5): Labeling of Marijuana and Marijuana Products and 935 CMR 500.105(6): Packaging of Marijuana and Marijuana Products.

# 501.140: Additional Operational Requirements for Patient Sales

[...]

(8) Repackaging. Repackaged Marijuana must comply with the labeling and packaging requirements under 935 CMR 501.105(5): Labeling of Marijuana and Marijuana Products and 935 CMR 500.105(6): Packaging of Marijuana and Marijuana Products.



## **Topic: Contactless Ordering**

<u>Recommendation</u>: Add operational requirements for advance contactless orders to 500.140: *Additional Operational Requirements for Retail Sale* and 501.140: *Additional Operational Requirements for Patient Sales*.

## 500.140: Additional Operational Requirements for Retail Sale

[add new subsection]

(XXX) Advance Contactless Order Fulfillment

(a) A Marijuana Retailer may allow for advance contactless ordering of Marijuana and Marijuana Products by telephone, website or third-party platform, which shall be available for inspection prior to commencing operations and on request.

(b) Marijuana Retailer may fulfill advance orders through contactless means by not requiring contact between a Consumer and Registered Marijuana Agent.

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

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

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

1. 935 CMR 500.105(3)(b) and (c) for the safe storage of Marijuana and Marijuana Products:

2. 935 CMR 500.110 (1)(a) and G.L. c. 94G, § 4(c)(3) for the positive identification of individuals seeking access to the Premises of the Marijuana Establishment for the purpose of obtaining an order placed in advance to limit access solely to individuals 21 years of age or older;



- 3. 935 CMR 500.110 (5)(a)(4) for the video surveillance of the advance contactless order; and
- 4. 935 CMR 500.140(8)(c) and (d).

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

## 501.140: Additional Operational Requirements for Patient Sales

[add new subsection]

(XXX) Advance Contactless Order Fulfillment

- (a) An MTC may allow for advance ordering of Marijuana and Marijuana Products by telephone, website or third-party platform, which shall be available for inspection prior to commencing operations and on request.
- (b) MTCs may fulfill advance orders through contactless means by not requiring contact between a Qualified Patient or Personal Caregiver and Registered Marijuana Agent.
- (c) Any physical unit used for the purpose of the fulfillment of an advance contactless order (order) shall ensure that access to orders of Marijuana or Marijuana Products is limited to the Qualifying Patient or Personal Caregiver who placed the advance order.
- (d) Any physical unit used for the purpose of order fulfillment of Marijuana or Marijuana Products shall be located within the MTC building and bolted or otherwise permanently affixed to the MTC Premises.
- (e) An MTC that adopts a contactless means of fulfilling orders shall have a written operations plan which shall be submitted to the Commission prior to commencing these operations and on request.. The plan shall include a detailed description of how the MTC will ensure that advance contactless order fulfillment complies with the requirements of:
  - 1. 935 CMR 501.105(3)(b) and (c) for the safe storage of Marijuana and Marijuana Products;
  - 2. 935 CMR 501.110 (1)(a) for the purposes of limiting access to Qualifying Patient or Personal Caregivers;
- 3. 935 CMR 501.110 (5)(a)(4) for the video surveillance of all advance contactless orders; and
  - 4. 935 CMR 501.140 (8)(c) and (d).



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



# **Topic: Testing**

#### Recommendations:

- Institutes regulations limiting remediation to not more than twice. If product can't pass the second test it must be destroyed.
- Institutes regulations that for failing product licensees may still have it reanalyzed but it must be by another lab in the event that the product is tested twice and receives one pass and one fail result.

## 500.002: Definitions

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

#### 501.002: Definitions

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

## 500.160: Testing of Marijuana and Marijuana Products

(1) No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 500.000: Adult Use of Marijuana. Testing of Marijuana Products shall be performed by an Independent Testing Laboratory in compliance with a protocol(s) established in accordance with M.G.L. c. 94G, § 15 and in a form and manner determined by the Commission including, but not limited to, the Protocol for Sampling and Analysis of Finished-Medical Marijuana Products and Marijuana infused Products. Testing of environmental media (e.g., soils, solid growing media, and water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission.



- (2) Marijuana 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. <u>In addition to these contaminant tests, final ready-to-sell Marijuana Vaporizer Products shall be additionally screened for heavy metals and Vitamin E Acetate (VEA) in accordance with the relevant provisions of the <u>Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products.</u></u>
- (3) The Commission may, at its discretion, require additional testing where necessitated to safeguard the public health or public safety and so identified by the Commission.
- (4) A Marijuana Establishment shall have a written policy for responding to laboratory results that indicate contaminant levels are above acceptable limits established in the protocols identified in 935 CMR 500.160(1).
  - (a) Any such policy shall include:
    - notifying the Commission within 72 hours of any laboratory testing results indicating that the contamination cannot be remediated and disposing of the Production Batch.
    - notifying the Commission of any information regarding contamination as specified by the Commission or immediately upon request by the Commission.
  - (b) The notification must be from both the Marijuana Establishment and the Independent Testing Laboratory, separately and directly.
  - (c) The notification from the Marijuana Establishment must describe a proposed plan of action for both the destruction of the contaminated product and the assessment of the source of contamination.
- (5) A Marijuana Establishment shall maintain the results of all testing for no less than one year. Testing results shall be valid for a period of one year. Marijuana or Marijuana Products with testing dates in excess of one year shall be deemed expired and may not be dispensed, sold, Transferred or otherwise conveyed until retested.
  - (6) The sale of seeds is not subject to these testing provisions.
  - (7) Clones are subject to these testing provisions, but are exempt from testing formetals.
- (8) All transportation of Marijuana to and from Independent Testing Laboratories providing Marijuana testing services shall comply with 935 CMR 500.105(13).



- (9) All storage of Marijuana at a laboratory providing Marijuana testing services shall comply with 935 CMR 500.105(11).
- (10) All excess Marijuana must be disposed of in compliance with 935 CMR 500.105(12), either by the Independent Testing Laboratory returning excess Marijuana to the source Marijuana Establishment for disposal or by the Independent Testing Laboratory disposing of it directly.
- (11) No Marijuana Product shall be sold or otherwise marketed for adult use that has not first been tested by an Independent Testing Laboratory and deemed to comply with the standards required under 935 CMR 500.160.
- (12) Single-servings of Marijuana Products tested for potency in accordance with 935 CMR 500.150(4)(a) shall be subject to a potency variance of no greater than plus/minus ten percent (+/- 10%).
- (13) A Licensee that receives notice that Marijuana or a Marijuana Pproduct it has submitted for testing has failed any test for contaminants shall either reanalyze the Marijuana or Marijuana Product without remediation, take steps to remediate the identified contaminants, or dispose of the Marijuana or Marijuana Product.
  - (a) Reanalysis by a Second ITL. If the Licensee chooses to reanalyze the sample, the same sample shall be submitted for reanalysis at the ITL that provided the original failed result. If the sample passes all previously failed tests at the initial ITL, an additional sample representing the same sample set previously tested shall be submitted to a second ITL other than the initial ITL for a Second Confirmatory Test. To be considered passing and therefore safe for sale, the sample shall have passed the Second Confirmatory Test at a second ITL. Any Marijuana and Marijuana product that fails the Second Confirmatory Test shall not be sold, transferred or otherwise dispensed to consumers, patients or Licensees. Any such product shall be destroyed.
  - (b) Remediation. If the Licensee chooses to remediate, a new test sample shall be submitted to a licensed ITL, which may include the initial ITL for a full-panel test. Any failing Marijuana or Marijuana product may be remediated a maximum of two times. Any Marijuana or Marijuana product that fails any test after the second



remediation attempt shall not be sold, transferred or otherwise dispensed to consumers, patients or Licensees. Any such product shall be destroyed.

(a)(c) If the Licensee chooses to dispose of the Marijuana or Marijuana Products it shall do so in compliance with 935 CMR 500.105(12).

(12) Marijuana and Marijuana Products submitted for retesting prior to remediation must be submitted to an Independent Testing Laboratory other than the laboratory which provided the initial failed result. Marijuana submitted for retesting after documented remediation may be submitted to the same Independent Testing Laboratory that produced the initial failed testing result prior to remediation

## 501.160: Testing of Marijuana and Marijuana Products

(1) No Marijuana Product, including Marijuana, may be sold or otherwise marketed for medical use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 501.000. Testing of Marijuana Products shall be performed by an Independent Testing Laboratory in compliance with a protocol(s) established in accordance with

M.G.L. c. 94G, § 15 and in a form and manner determined by the Commission including, but not limited to, the Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana infused. Products. Testing of environmental media (e.g., soils, solid growing media, and water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission.

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

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





- (3)(4) An MTC shall have a written policy for responding to laboratory results that indicate contaminant levels are above acceptable limits established in the protocols identified in 935 CMR 501.160(1). Such policy shall be available to Registered Qualifying Patients and Personal Caregivers.
  - (a) Any such policy shall include:
    - 1. Notifying the Commission within 72 hours of any laboratory testing results indicating that the contamination cannot be remediated and disposing of the Production Batch submission of any information regarding contamination immediately upon request by the Commission; and
    - 2. Notifying the Commission of any information regarding contamination as specified by the Commission or immediately upon request by the Commission.
  - (b) The notification must be from both the MTC and the Independent Testing Laboratory, separately and directly.
  - (c) The notification from the MTC must describe a proposed plan of action for both the destruction of the contaminated product and the assessment of the source of contamination.
- (4)(5) An MTC shall maintain the results of all testing for no less than one year. Testing results shall be valid for a period of one year. Marijuana and Marijuana Products with testing dates in excess of one year shall be deemed expired and may not be dispensed, sold, Transferred or otherwise conveyed until retested.
- (5)(6) The sale of seeds is not subject to these testing provisions.
- (6)(7) Clones are subject to these testing provisions, but are exempt from testing for metals.
- (7)(8) All transportation of Marijuana and Marijuana Products to and from Independent Testing Laboratories providing Marijuana testing services shall comply with 935 CMR 501.105(13).
- (8)(9) All storage of Marijuana and Marijuana Products at a laboratory providing Marijuana testing services shall comply with 935 CMR 501.105(11).
- (9)(10) All excess Marijuana and Marijuana Products must be disposed of in compliance with 935 CMR 501.105(12), either by the Independent Testing Laboratory returning excess



Marijuana or Marijuana Products to the source MTC for disposal or by the Independent Testing Laboratory disposing of it directly;

(10)(11) No Marijuana or Marijuana Product shall be sold or otherwise marketed for adult use that has not first been tested by an Independent Testing Laboratory and deemed to comply with the standards required under 935 CMR 501.160; and

- (11) Marijuana and Marijuana Products submitted for retesting prior to remediation must be submitted to an Independent Testing Laboratory other than the laboratory which provided the initial failed result. Marijuana and Marijuana Products submitted for retesting after documented remediation may be submitted to the same Independent Testing Laboratory that produced the initial failed testing result prior to remediation.
- (12) A Licensee that receives notice that Marijuana or a Marijuana Product it has submitted for testing has failed any test for contaminants shall either reanalyze the Marijuana or Marijuana Product without remediation, take steps to remediate the identified contaminants or dispose of the Marijuana or Marijuana Product.
- (a) If the Licensee chooses to reanalyze the sample, the same sample shall be submitted for reanalysis at the ITL that provided the initial failed result. If the sample passes all previously failed tests at the initial ITL, an additional sample representing the same sample set previously tested shall be submitted to a second ITL other than the original ITL for a Second Confirmatory Test. To be considered passing and therefore safe for sale, the sample shall have passed the Second Confirmatory Test at a second ITL. Any Marijuana and Marijuana product that fails the Second Confirmatory Test shall not be sold, transferred or otherwise dispensed to consumers, patients or Licensees. Any such product shall be destroyed.
- (b) If the Licensee chooses to remediate, a new test sample shall be submitted to any licensed ITL, which may include the initial ITL, for a full-panel test. Any failing Marijuana or Marijuana product may be remediated a maximum of two times. Any Marijuana or Marijuana product that fails any test after the second remediation attempt shall not be sold, transferred or otherwise dispensed to consumers, patients or Licensees. Any such product shall be destroyed.
- (c) If the Licensee chooses to dispose of the Marijuana or Marijuana Products it shall do so in compliance with 935 CMR 501.105(12).



## **Topic: Patient Certification and Registration**

## Recommendations:

- Remove out-of-date references to DPH documents.
- Broaden the types of physicians who can serve as the second physician making the recommendation for pediatric patients.
- Require healthcare providers to have a plan to provide discounts to low-income patients, similar
  to the MTC's requirement, but allowing them to apply for an exemption recognizing that some
  healthcare providers who do not control the costs charged may be unable to fulfill that
  requirement.
- Define Clinical Visit to include in-person or via telehealth means. Add provisions requiring
  Clinical Visits via telehealth to be done with the same standard of care and in compliance with
  licensure and registration requirements as is applicable to in-person services to patients and shall
  comply with any additional requirements established by the Commission.
- Allow certain patients with certain hardships (receiving SSDI/SSI, or with terminal illness/permanent disability) to renew every two years instead of one year, in line with many other states.
- Streamline the process to receive a Temporary Registration Card and make minor changes based on feedback from patients.
- Require Certifying Healthcare providers to include in the packet of information to patients:
  - o Guidance on patient confidentiality;
  - Written instructions in a form and manner determined by the Commission that the patient needs to complete the registration process with the Commission in order to obtain an annual Registration card; and
  - If requested, a paper copy of the Commission registration form for an annual Registration Card.
- Remove requirement that patients looking to obtain an annual patient registration card must submit a statement of whether the Qualifying Patient will be applying for a Hardship Cultivation Registration; Group 3 determined that this was unnecessary at this stage of the process.

## 501.002: Definitions



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

Medical Registration Card means an identification card <u>currently and validly</u> issued\_formerly and validly by the DPH or currently and validly by the Commission's, by the Medical Use of Marijuana Program, to a Registered Qualifying Patient, Personal Caregiver, Institutional Caregiver, MTC Agent or Laboratory Agent. The Medical Registration Card facilitates verification of an individual Registrant's status including, but not limited to, the identification by the Commission and Law Enforcement Authorities of those individuals who are exempt from Massachusetts criminal and civil penalties under St. 2016, c. 334 as amended by St. 2017, c. 55, M.G.L. c. 94I, and M.G.L. c. 94G.

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

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

Qualifying Patient means an individual Massachusetts Resident. 18 years of age or older who has been diagnosed by a Certifying Healthcare Provider as having a Debilitating Medical Condition, or an individual 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, oncologist, neurologist, or family physician as having a Debilitating Medical Condition that is also a Life-limiting Illness, subject to 935 CMR 501.010(10).

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

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

<u>Written Certification</u> means a form submitted to the Department of Public Health (DPH) or the Commission by a Massachusetts licensed Certifying Healthcare Provider describing the Qualifying Patient's pertinent symptoms, specifying the patient's Debilitating Medical Condition, and stating that in the physician's professional opinion the potential benefits of the medical use of Marijuana would likely outweigh the health risks for the patient.

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

- (1) A Certifying Healthcare Provider shall complete a program that explains the proper use of Marijuana, including side effects, dosage, and contraindications, including with psychotropic drugs, as well as on substance abuse recognition, diagnosis, and treatment related to Marijuana, which includes, but is not limited to, the following:
  - (a) A Certifying Physician issuing a Written Certification must have completed a minimum of 2.0 Category 1 continuing professional development credits as defined in 243 CMR 2.06(6)(a)1.
  - (b) A Certifying CNP issuing a Written Certification must have completed a minimum of one program meeting the requirements of 244 CMR 5.00: Continuing Education and 244 CMR 6.00: Approval of Nursing Education Programs and the General Conduct Thereof.





- (c) A Certifying Physician Assistant issuing a Written Certification must have completed a minimum of one program meeting the requirements of 263 CMR 3.05(3).
- (2) A Certifying Healthcare Provider shall issue a Written Certification that complies with generally accepted standards of medical practice including, but not limited to, the following:
  - (a) A Certifying Physician issuing a Written Certification shall comply with generally accepted standards of medical practice, including regulations of the Board of Registration in Medicine at 243 CMR 1.00 through 3.00, pursuant to M.G.L. c. 112, § 5, and M.G.L. c. 111, § 203.
  - (b) A Certifying CNP issuing a Written Certification shall comply with generally accepted standards of nursing practice, including the regulations of the Board of Registration in Nursing at 244 CMR 9.00: Standards of Conduct for Nurses.
  - (c) A Certifying Physician Assistant issuing a Written Certification shall comply with generally accepted standards of practice for physician assistants, including regulations of the Board of Registration of Physician Assistants at 263 CMR 5.09: Standards of Conduct for Physician Assistants.
- (3) A Certifying Healthcare Provider may not delegate to any other healthcare professional or any other person, authority to diagnose a patient as having a Debilitating Medical Condition.
- (3)(4)A Certifying Healthcare Provider shall have a program to provide a discount to patients with documented Verified Financial Hardship. The plan shall outline the goals, programs, and measurements the Certifying Healthcare Provider will pursue as part of the plan. A Certifying Healthcare Provider may apply to be exempt from this requirement by demonstrating in a form and manner determined by the Commission that the Certifying Healthcare Provider does not have control over the costs to its patients.
- (4)(5)A Certifying Healthcare Provider may issue a Written Certification only for a Qualifying Patient with whom the healthcare provider has a *Bona Fide* Healthcare Provider Patient Relationship.



- (5)(6)Before issuing a Written Certification, a Certifying Healthcare Provider must utilize the Massachusetts Prescription Monitoring Program, unless otherwise specified by the Commission, to review the Qualifying Patient's prescription history.
- (6)(7) A patient who has had a diagnosis of a Debilitating Medical Condition in the past, but does not have an active condition, unless the symptoms related to such condition are mitigated by Marijuana for medical use, and is not undergoing treatment for such condition, is not suffering from a Debilitating Medical Condition for which the medical use of Marijuana is authorized.
- (7)(8) An initial or renewal Written Certification submitted before a Celinical V-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.
  - (a) A Clinical Visit may occur in-person or by telehealth means.
  - (b) If a Clinical Visit is conducted by telehealth means, the Certifying Healthcare Provider shall ensure that there is an ability to deliver the service using telehealth with the same standard of care and in compliance with licensure and registration requirements as is applicable to in-person services to patients and shall comply with any additional requirements established by the Commission.
- (8)(9) 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, except that in the following circumstances, the certification may be valid for two years:
  - (a) a Certifying Healthcare Provider verifies and represents to the Commission that a Qualifying Patient is receiving Social Security Disability Insurance or Supplemental Security Income, or
  - (b) a Certifying Healthcare Provider diagnoses a Qualifying Patient after an in-person clinical visit with a terminal illness, or permanent disability and certifies the patient for two years.
- (9)(10) A Certifying Healthcare Provider may determine and certify that a Qualifying Patient requires an amount of Marijuana other than 2.5 ounces as a 14-day Supply or ten ounces as a 60-day Supply and shall document the amount and the rationale in the medical





record and in the Written Certification. For that Qualifying Patient, that amount of Marijuana constitutes a 14-day Supply or 60-day Supply.

- (11) A Qualifying Patient who is younger than 18 years old and has been diagnosed by two Massachusetts licensed Certifying Physicians, at least one of whom is a board certified pediatrician, or a board certified pediatric subspecialist, oncologist, neurologist, or family physician, with a debilitating Life-limiting Illness, may receive a Written Certification, provided however, that the physicians may certify a Qualifying Patient who is younger than 18 years old who has a Debilitating Medical Condition that is not a Life-limiting Illness if those physicians determine that the benefits of the medical use of Marijuana outweigh the risks. This 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.
- (10)(12) A Certifying Healthcare Provider, and such healthcare provider's co\_-worker, employee, or immediate family member, shall not:
  - (a) Have ever directly or indirectly accepted or solicited from, or offered to an MTC, a board member or Executive of an MTC, any MTC personnel, or any other individual associated with an MTC, or a Personal Caregiver, anything of value;
  - (b) Offer a discount or any other thing of value to a Qualifying Patient based on the patient's agreement or decision to use a particular Personal Caregiver or MTC;
  - (c) Examine or counsel a patient, or issue a Written Certification, at an MTC;
  - (d) Be a Person or Entity Having Direct or Indirect Control for an MTC; or
  - (e) Directly or indirectly benefit from a patient obtaining a Written Certification, which shall not prohibit the healthcare provider from charging an appropriate fee for the clinical visit.
- (11)(13) A Certifying Healthcare Provider shall not issue a Written Certification for himself or herself or for his or her immediate family members.
- (12)(14) A Certifying Healthcare Provider issuing a Written Certification for their employees or coworkers 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.



(13) 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: Temporary and Annual Registration of Qualifying Patients

- (2) A Qualifying Patient must apply for a temporary or annual registration according to the procedures set out in 935 CMR 501.015, unless otherwise provided by the Commission.
- (3) To obtain a temporary or an annual Registration Card, a Qualifying Patient must first obtain electronic or Written Certification(s) from the Qualifying Patient's Certifying Healthcare Provider(s).
- (4) Temporary Registration Card. A patient's Certifying Healthcare Provider(s) shall provide a Qualifying Patient who has not been issued a temporary Patient Registration Card in the 365-day period preceding the date of certification, a temporary registration in a form and a manner determined by the Commission, which will include, but not be limited to, the following:
  - (a) To generate a temporary Registration Card, a Certifying Healthcare Provider shall obtain from a Qualifying Patient, and electronically submit the information required by the Commission as part of the temporary electronic certification process;
  - (b) At a minimum, a Certifying Healthcare Provider shall submit the information required in 935 CMR 501.015(5)(a) through (d) and (f);
  - (c) On submission of the requisite information, the provider shall <u>print-provide</u> a packet of information for the patient, which includes:
    - 1. a temporary Patient Registration Card,
    - 2. Aa caregiver authorization form and instructions:
    - 3. Guidance on patient confidentiality;
    - Written instructions in a form and manner determined by the Commission that the
      patient needs to complete the registration process with the Commission in order to
      obtain an annual Registration card, and,
    - 4-5. If requested, a paper copy of the Commission registration form for an annual Registration Card÷



- (e)(d) The temporary Registration Card shall constitute a Registration Card for patients for the purposes of accessing MTCs and purchasing medical use Marijuana and MIPs;
- (d)(e) A temporary Registration Card shall expire either 14 days after the issuance of the temporary Registration Card or on the issuance and receipt of an annual Registration Card, whichever occurs first;
- (e)(f) A patient is limited to one 14-day temporary registration during any 365-day period, unless otherwise approved by the Commission;
- (f)(g) No more than 2.5 ounces of Marijuana may be dispensed by an MTC to a Qualifying Patient with a 14-day temporary registration except a Certifying Healthcare Provider may determine and certify that a Qualifying Patient requires an amount of Marijuana other than 2.5 ounces as a 14-day Supply and shall document the amount and the rationale in the medical record and in the Written Certification;
- (g)(h) It is the obligation of the MTC to track and dispense only the amount allowed for a 14-day Supply; and
- (h)(i) To obtain an annual Registration Card after receiving a temporary Registration Card, a Qualifying Patient must comply with 935 CMR 501.015(5) and complete the electronic registration process for review by the Commission.
- (5) To access MTCs and obtain medical-use Marijuana and MIPs, the patient must present their temporary Registration Card in addition to a government-issued identification. MTCs are responsible for ensuring that patients present proper documentation and verifying that the temporary Registration Card is valid, before the patient accesses the MTC and purchases Marijuana, Marijuana Products, or MIPs.
- (6) Annual Patient Registration Card: To obtain an annual Registration Card, a Qualifying Patient shall submit or verify, in a form and manner determined by the Commission, the following information:
  - (a) The Qualifying Patient's full name, date of birth, address, telephone number, and email address if any, and a statement indicating his or her age and that his or her primary residence is in Massachusetts:
    - If the Qualifying Patient is younger than 18 years old, an attestation from a parent or legal guardian granting permission for the child to register with the Commission; and



- If the Qualifying Patient is younger than 18 years old, that Qualifying Patient must have a designated Personal Caregiver, who shall be his or her parent or legal guardian.
- (b) Electronic or Written Certification(s) for the Qualifying Patient from the Qualifying Patient's Certifying Healthcare Provider(s);
- (c) name, address, and telephone number of the Qualifying Patient's Certifying Healthcare Provider(s):
- (d) Full name, date of birth, and address of the Qualifying Patient's Personal Caregiver(s), if any;
- (e) A statement of whether the Qualifying Patient will be applying for a Hardship Cultivation Registration;
- (f)(e) 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;
- (g)(f) Written acknowledgement of the limitations on his or her authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth;
- (h)(g) An attestation that the Registered Qualifying Patient shall not engage in the diversion of Marijuana and that the patient understands that protections conferred by M.G.L. c. 94I, for possession of Marijuana for medical use are applicable only within Massachusetts; and
- (i)(h) Any other information required by the Commission.
- (7) After obtaining a Registration Card, a Qualifying Patient is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any change to the information that he or she was previously required to submit to the Commission, or after he or she discovers that his or her Registration Card has been lost or stolen.
- (8) A Registered Qualifying Patient must carry his or her Registration Card at all times while in possession of medical use Marijuana or MIPs.



# **Topic: Personal Caregivers, Hardship Cultivation**

#### Recommendations

- Allow Caregivers to serve as a caregiver for up to ten patients.
- Require Caregivers to document costs for which they are reimbursed and make the
  documentation available for inspection upon request by the Commission.
- Allow Patients with Hardship Cultivation Registrations to purchase medical marijuana from MTCs in order to account for crop failure or the period between growing and harvesting
- Prohibit Caregivers from receiving kickbacks from MTCs in exchange for patients obtaining medical marijuana from that MTC.
- Allow Patients to cultivate up to 12 flowering plants without a hardship cultivation. If a Patient
  needs more, or if more than one Patient collectively need more than that amount at one
  residence, then a Hardship Cultivation is required.
- Allow out-of-state patients, often coming to Massachusetts for its top-tier hospitals, to be
  certified and registered as a patient in Massachusetts: broadened definition of "Qualifying
  Patient" by deleting Massachusetts residency requirement; amended 501.015: Temporary and
  Annual Registration of Qualifying Patients by removing requirements of proof of Massachusetts
  residency for Qualifying Patients.

## 501.002: Definitions

Qualifying Patient means an individual Massachusetts Resident-18 years of age or older who has been diagnosed by a Certifying Healthcare Provider as having a Debilitating Medical Condition, or an individual-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, oncologist, neurologist, or family physician as having a Debilitating Medical Condition that is also a Life-limiting Illness, subject to 935 CMR 501.010(10).

### 501.015: Temporary and Annual Registration of Qualifying Patients

[...]



- (9) Annual Patient Registration Card. To obtain an annual Registration Card, a Qualifying Patient shall submit or verify, in a form and manner determined by the Commission, the following information:
  - (a) The Qualifying Patient's full name, date of birth, address, telephone number, and email address if any, and a statement indicating his or her age and that his or her primary residence is in Massachusetts:
    - If the Qualifying Patient is younger than 18 years old, an attestation from a parent or legal guardian granting permission for the child to register with the Commission: and
    - If the Qualifying Patient is younger than 18 years old, that Qualifying Patient must have a designated Personal Caregiver, who shall be his or her parent or legal guardian.
  - (b) Electronic or Written Certification(s) for the Qualifying Patient from the Qualifying Patient's Certifying Healthcare Provider(s);
  - (c) name, address, and telephone number of the Qualifying Patient's Certifying Healthcare Provider(s);
  - (d) Full name, date of birth, and address of the Qualifying Patient's Personal Caregiver(s), if any;
  - (e) A statement of whether the Qualifying Patient will be applying for a Hardship Cultivation Registration;
  - (f) 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;
  - (g) Written acknowledgement of the limitations on his or her authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth;
  - (h) An attestation that the Registered Qualifying Patient shall not engage in the diversion of Marijuana and that the patient understands that protections conferred by M.G.L. c. 94I, for possession of Marijuana for medical use are applicable only within Massachusetts; and
  - (i) Any other information required by the Commission.

[...]



## 501.020: Temporary and Annual Registration of Personal Caregivers

- (5) Except in the case of a visiting nurse, home health aide, personal care attendant, or immediate family member of more than one Registered Qualifying Patient, an individual may not serve as a Personal Caregiver for more than one-ten\_Registered Qualifying Patients at one time.
- (6) A Registered Qualifying Patient may designate up to two Personal Caregivers. If the Registered Qualifying Patient has been granted a Hardship Cultivation Registration, the Personal Caregiver(s) may cultivate Marijuana on behalf of the Registered Qualifying Patient at only one location. Cultivation pursuant to a Hardship Cultivation Registration by a Personal Caregiver constitutes agreement to comply with the requirements of Hardship Cultivation Registration under 935 CMR 501.027 consent for such inspection of the cultivation site.
- (6) If a Registered Qualifying Patient has been granted a Hardship Cultivation Registration, the Personal Caregiver may cultivate a limited number of plants sufficient to maintain a 60-day supply of marijuana for each Registered Qualifying Patient solely for that patient's use, except that under no circumstances may a Personal Caregiver cultivate plants in excess of 500 square feet of Canopy.
- (7)(8) A Registered Qualifying Patient may add a second caregiver or change Personal Caregiver(s) by providing notification in a form and manner determined by the Commission, and providing the information required in 935 CMR 501.020(3) for registration of Personal Caregivers.
- (8)(9) After obtaining a Registration Card, the Personal Caregiver is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any change to the information that his or her Registered Qualifying Patient was previously required to submit to the Commission, or after the Personal Caregiver discovers that their Registration Card has been lost or stolen.

#### Commented [A32]: G.L. c. 941, § 2(d):

(d) The commission shall issue a cultivation registration to a qualifying patient applying for such registration whose access to a medical marijuana treatment center is limited by verified financial hardship, a physical incapacity to access reasonable transportation or the lack of a medical marijuana treatment center within a reasonable distance of the qualifying patient's residence. The commission may deny a registration based on the provision of false information by the applicant. Such registration shall allow the qualifying patient or the qualifying patient's personal caregiver to cultivate a limited number of plants, sufficient to maintain a 60-day supply of marijuana, and shall require cultivation and storage only in an enclosed, locked area.

#### <u>Cf</u>. 94G, § 7:

Section 7. Personal use of marijuana

(a) Notwithstanding any other general or special law to the contrary, except as otherwise provided in this chapter, a person 21 years of age or older shall not be arrested, prosecuted, penalized, sanctioned or disqualified under the laws of the commonwealth in any manner, or denied any right or privilege and shall not be subject to seizure or forfeiture of assets for:

[...]

(2) within the person's primary residence, possessing up to 10 ounces of marijuana and any marijuana produced by marijuana plants cultivated on the premises and possessing, cultivating or processing not more than 6 marijuana plants for personal use so long as not more than 12 plants are cultivated on the premises at once;



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

## 501.021: Registration of Caregiving Institutions

- (1) Prior to facilitating the medical use of Marijuana to a Registered Qualifying Patient, a hospice program, long term care facility, or hospital shall obtain a Certificate of Registration as a Caregiving Institution. To obtain a Certificate of Registration as a Caregiving Institution, the institution shall submit, in a form and manner determined by the Commission, the following:
  - (a) The name, address and telephone number of the institution, as well as the telephone number and email address for the primary contact for that Caregiving Institution;
  - (b) A copy of the Caregiving Institution's current facility licensure or certification from the Commonwealth of Massachusetts;
  - (c) Written acknowledgement by the authorized signatory of the Caregiving Institution of the limitations on the institution's authorization to cultivate, possess, and dispense to Registered Qualifying Patients, Marijuana for medical purposes in the Commonwealth:
  - (d) A nonrefundable registration fee, as required by the Commission;
  - (e)(d) An attestation by the authorized signatory of the Caregiving Institution that employees of the Caregiving Institution shall not engage in the diversion of Marijuana and that he or she understands that protections conferred by M.G.L. c. 94I, for possession of Marijuana for medical use are applicable only within Massachusetts; and
  - (f)(e) Any other information required by the Commission.
- (2) A Caregiving Institution must be granted a Certificate of Registration by the Commission prior to serving as a Caregiving Institution for any Registered Qualifying Patient. The Commission will accept certificates of registration validly issued prior to the Program Transfer. This certificate will remain valid until a new certificate is issued by the Commission. On the issuance of a new certificate, the holder of the certificate shall destroy any previously issued certificate in a responsible manner that would prevent it from being used as a certificate.



- (3) An employee of the Caregiving Institution may serve as a Caregiver for more than one Registered Qualifying Patient at one time.
- (4) An employee of the Caregiving Institution may not cultivate Marijuana for a Registered Qualifying Patient under the care of the Caregiving Institution.
- (5) A Caregiving Institution must maintain records on all Marijuana received by the institution on behalf of a Registered Qualifying Patient and the administration of such Marijuana to the Registered Qualifying Patient, and such records should be produced to the Commission upon request as permitted by law.
- (6) A Certificate of Registration for a Caregiving Institution will remain valid, unless and until the Caregiving Institution's current facility licensure or certification from the Commonwealth of Massachusetts is no longer active, or is suspended, revoked, or restricted.

## 501.025: Responsibilities of Caregivers

- (1) <u>Personal Caregivers</u>.
  - (a) A Personal Caregiver may:
    - 1. Transport a Registered Qualifying Patient to and from an MTC;
    - 2. Obtain and transport Marijuana from an MTC on behalf of a Registered Qualifying Patient:
    - Cultivate Marijuana on behalf of a Registered Qualifying Patient who has obtained a Hardship Cultivation Registration, unless the Personal Caregiver is a visiting nurse, personal care attendant, or home health aide serving as a Personal Caregiver;
    - 4. Prepare Marijuana for consumption by a Registered Qualifying Patient; and
    - 5. Administer Marijuana to a Registered Qualifying Patient.
    - 5-6.Receive reimbursement for reasonable expenses incurred in the provision of services as a Caregiver, including transportation and cultivation expenses directly related to the care of a Registered Qualifying Patient, so long as the expenses are documented and available for inspection by the Commission on request. A Caregiver may not receive reimbursement or payment for the Caregiver's time. In



the case of an individual who serves as a Personal Caregiver for more than one Registered Qualifying Patient, the individual may receive partial reimbursement from multiple patients so long as the total reimbursement received does not exceed the Caregiver's total documented expenses.

- (b) A Personal Caregiver may not:
  - Consume, by any means, Marijuana that has been dispensed to or cultivated on behalf of a Registered Qualifying Patient;
  - Sell or otherwise divert Marijuana that has been dispensed to or cultivated on behalf of a Registered Qualifying Patient;
  - Unless otherwise authorized by law, cultivate Marijuana for the Personal Caregiver's own use, unless the Personal Caregiver is also a Registered Qualifying Patient who has obtained a Hardship Cultivation Registration;
  - Unless otherwise authorized by law, cultivate Marijuana for purposes of selling or providing Marijuana to anyone other than the Registered Qualifying Patient;
  - 5. Allow a Registered Qualifying Patient who is younger than 18 years old to possess Marijuana at any time when not in the presence of the Personal Caregiver;
  - 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;
  - Offer a discount or any other thing of value to a Registered Qualifying Patient
    based on the representation that a patient will's agreement or decision to use a
    particular product or MTC;
  - 6.—Directly or indirectly accept or solicit from an MTC, a board member or Executive of an MTC, any MTC personnel, or any other individual associated with an MTC, anything of value based on the decision of representation that a Registered Qualifying Patient to agree or decide to will use a particular product or MTC; or or
  - 7.8. Receive payment or other compensation for services rendered as a Personal Caregiver other than reimbursement for reasonable expenses incurred in the provision of services as a Caregiver, provided however, that a caregiver's time is not considered a reasonable expense. In the case of a visiting nurse, personal care attendant, or home health aide serving as a Personal Caregiver, such individual may not receive payment or compensation above and beyond their regular wages.
- (c) A Personal Caregiver must notify the Commission within five calendar days upon the death of a Personal Caregiver's Registered Qualifying Patient.



- (2) <u>Institutional Caregivers</u>.
- (a) An Institutional Caregiver may:
  - Receive Marijuana delivered to the Caregiving Institution for a Registered Qualifying Patient;
  - 2. Prepare Marijuana for consumption by a Registered Qualifying Patient; and
  - Administer Marijuana to a Registered Qualifying Patient or facilitate consumption of Marijuana for medical use by the Qualifying Patient.
- (b) An Institutional Caregiver may not:
  - Consume, by any means, Marijuana that has been dispensed to or cultivated on behalf of a Registered Qualifying Patient;
  - Sell, provide, or otherwise divert Marijuana that has been dispensed to or cultivated on behalf of a Registered Qualifying Patient;
  - 3. Cultivate Marijuana for a Registered Qualifying Patient;
  - 4. Allow a Registered Qualifying Patient who is younger than 18 years old to possess Marijuana at any time when not in the presence of a Caregiver; or
  - 5. Receive payment or compensation above and beyond his or her regular wages.
- (c) An Institutional Caregiver must notify their employing Caregiving Institution of any changes in his or her registration information within 24 hours of the change.

## 501.027: Hardship Cultivation Registration

- (1) A Qualifying Patient registered with the Commission pursuant to 935 CMR 501.015 may apply for a Hardship Cultivation Registration if such patient can demonstrate that his or her access to an MTC is limited by:
  - (a) Verified financial hardship;
  - (b) Physical incapacity to access reasonable transportation, as demonstrated by an inability to use public transportation or drive oneself, lack of a Personal Caregiver with a reliable source of transportation, and lack of an MTC that will deliver Marijuana to the patient's or Personal Caregiver's primary address; or
  - (c) Lack of an MTC within a reasonable distance of the patient's primary residence and lack of an MTC that will deliver Marijuana to the patient's or Personal Caregiver's primary address.



- (e)(d) Lack of access to a medicine essential for the Qualifying Patient's treatment plan.
- (2) To obtain a Hardship Cultivation Registration, a Registered Qualifying Patient shall, in a form and manner determined by the Commission, submit the following:
  - (a) A nonrefundable registration fee, unless waived pursuant to 935 CMR 501.015(1)(g);
  - (b)(a) Information supporting a claim that access is limited due to one or more of the circumstances listed in 935 CMR 501.027(1);
  - (e)(b) An explanation, including lack of feasible alternatives, to mitigate the limitation claimed under 935 CMR 501.027(1);
  - (d)(c) A description and address of the single location that shall be used for the cultivation of Marijuana, which shall be either the Registered Qualifying Patient's or one Personal Caregiver's primary residence;
  - (e)(d) A written explanation of how the Registered Qualifying Patient will cultivate Marijuana in accordance with the requirements of 935 CMR 501.027;
  - (f)(e) A description of the device or system that will be used to ensure security and prevent diversion of the Marijuana plants being cultivated;
  - (g)(f) Written acknowledgment of the limitations on their authorization to cultivate, possess, and use Marijuana for medical purposes in the Commonwealth; and
  - (h)(g) Any other information required by the Commission.
- (3) The Commission shall review and approve or deny an application for a Hardship Cultivation Registration within 30 calendar days of receipt of a completed application.
- (4) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their Personal Caregiver(s), may cultivate only at the location specified in the application approved by the Commission.
- (5) At any given location, cultivation may occur pursuant to only one Hardship Cultivation Registration, absent proof that more than one Registered Qualifying Patient resides at the location
- (6)(5)A Hardship Cultivation Registration will be valid for one year from the date of issue. The Commission will accept certificates of registration validly issued prior to the Program





Transfer. A certificate will remain valid until a new certificate is issued by the Commission. On the issuance of a new certificate, the holder of the certificate shall destroy any previously issued certificate in a responsible manner that would prevent it from being used as a certificate.

- (7)(6) A Hardship Cultivation Registration may be renewed, in a form and manner determined by the Commission, on an annual basis, which includes, but is not limited to, meeting the requirements in 935 CMR 501.027(2).
- (7) A Hardship Cultivation Registration shall allow the Registered Qualifying Patient or their Personal Caregiver(s) to cultivate a limited number of plants sufficient to maintain a 60day Supply of Marijuana solely for that patient's use.
- (8) A Registered Qualifying Patient is prohibited from possessing or cultivating more than 12 Flowering plants and 12 immature or vegetative plants, excluding Clones and cuttings, without a Hardship Cultivation Registration.
- (9) Cultivation and storage of Marijuana shall be in an enclosed, locked area accessible only to the Registered Qualifying Patient or their Personal Caregiver(s), subject to 935 CMR 501.840. Marijuana shall not be visible from the street or other public areas.
- (10) A Registered Qualifying Patient or their Personal Caregiver(s) cultivating Marijuana pursuant to a Hardship Cultivation Registration shall adhere to industry best practices in the cultivation of Marijuana plants and storage of finished product, and any standards specified by the Commission.
- (11) A Registered Qualifying Patient and their Personal Caregiver(s) are prohibited from selling, bartering, giving away or distributing in any manner Marijuana <u>cultivated pursuant</u> to a Hardship Cultivation Registration or Paraphernalia.
- (12) The Commission may inspect the cultivation site of a Registered Qualifying Patient with a Hardship Cultivation Registration, or the cultivation site of their Personal Caregiver(s), at a reasonable time, with reasonable notice, taking into consideration the circumstances of the Registered Qualifying Patient. Acceptance of a Hardship Cultivation Registration by a



Registered Qualifying Patient constitutes consent for such inspection of the cultivation site. The Commission may not provide notice in cases of suspected diversion, where the Commission is working with Law Enforcement Authorities.

- (13) Registration for hardship cultivation may be available in a form and manner determined by the Commission. If, prior to the Program Transfer, a Registered Qualifying Patient received Written Certification of a Debilitating Medical Condition from a physician and used that Written Certification as a limited cultivation registration, the initial limited cultivation registration will remain valid until the application for the Hardship Cultivation Registration card is approved or denied by the Commission.
- (14) After obtaining a Hardship Cultivation Registration, a Registered Qualifying Patient is responsible for notifying the Commission, in a form and manner determined by the Commission, within five business days after any change to the information that they or their Personal Caregiver(s) was previously required to submit to the Commission.
- (15) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their Personal Caregiver(s) if applicable, must have the registration available at the site of cultivation. The Commission may make such registration available on request of the Registered Qualifying Patient or other government agency acting within their lawful authority.
- (16) A Registered Qualifying Patient with a Hardship Cultivation Registration, or their Personal Caregiver(s) if applicable, is prohibited from purchasing Marijuana from an MTC, provided however, that such individuals may purchase seeds.

## 501.140: Additional Operational Requirements for Patient Sales

- In addition to the general operational requirements for MTCs required under 935 CMR 501.105, MTCs engaged in patient sales shall comply with additional operational requirements for MTCs under 935 CMR 501.140.
- (2) <u>Verification of Patient and Caregiver Certification</u> [...]



#### (3) Patient Allotment.

- (a) For a Registered Qualifying Patient certified for 60 days or longer, the amount of Marijuana dispensed, including Marijuana contained in MIPs, shall be no more than a 60-day supply in each 60-day period as defined in 935 CMR 501.002 (e.g., a patient with a 60-day supply of ten ounces who is certified for 90 days may receive up to ten ounces in the first 60 days and five ounces in the remaining 30 days, while a patient certified for 180 days may receive up to ten ounces in each 60-day period).
- (b) For a Registered Qualifying Patient whose Certifying Healthcare Provider has determined that he or she requires a 60-day supply other than ten ounces in accordance with 935 CMR 501.010(9), the amount of Marijuana dispensed, including Marijuana contained in MIPs, shall be adjusted accordingly so that the amount of Marijuana dispensed, including Marijuana contained in MIPs, shall be no more than a 60-day supply as certified by the Certifying Healthcare Provider in each 60-day period.
- (b)(c) A Registered Qualifying Patient may possess up to 12 flowering plants and up to 12 immature or vegetative plants, excluding Clones and cuttings. If one or more Qualifying Patients collectively require more than this amount at one residence in order to maintain a 60-day supply, then a Hardship Cultivation Registration is required.

[...]



## **Topic: Home Delivery**

<u>Recommendation</u>: The regulation allows an MTC to deliver themselves or through a third-party company with a Delivery license. However, the regulations states that only MTC registered agents can delivery for an MTC. This is a regulatory fix that clarifies that in addition to MTC agents, registered agents under a Delivery license can also delivery for an MTC.

## 501.145: Home Delivery

- (1) General Requirements.
  - (a) An MTC<sub>2</sub> or a Delivery-only Licensee acting on behalf of an MTC<sub>2</sub> must obtain Commission approval prior to engaging in the delivery of Marijuana and Marijuana Products directly to a Registered Qualified Patients orand Caregivers. An MTC shall comply with 935 CMR 501.110(8) and adhere to its policies and procedures for home delivery approved pursuant to 935 CMR 501.101(1)(c)12.
  - (b) All individuals delivering Marijuana and Marijuana Products for an MTC directly to Registered Qualifying Patients and Cearegivers shall be employees of the MTC Licensee and shall hold a valid MTC agent registration; or, where a Delivery Licensee provides delivery services on behalf of an MTC, employees duly registered as agents of the Delivery Licensee.

## **ADULT USE 500.002: Definitions**

For the purposes of 935 CMR 500.000, the following terms shall have the following meanings:

<u>Administrative Hold</u> means a hold requiring temporary isolation of Marijuana or Marijuana Products by a Marijuana Establishment Licensee or Registrant pending further investigation.

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

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

Advanced Core Curriculum means the advanced training curriculum taught by a Responsible Vendor Trainer that may be taken by Marijuana Establishment Agents after completing the Basic Core Curriculum under 935 CMR 500.105(2)(b).

Advertising means a form of marketing communication that employs a sponsored, non-personal message to sell or promote a Marijuana Establishment's Brand Name, Marijuana Establishment Branded Good, service, product or idea.

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

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

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

Basic Core Curriculum means the foundational training curriculum required of all Marijuana Establishment Agents taught by a Responsible Vendor Trainer under 935 CMR 500.105(2)(b).

Beverage means a liquid intended for drinking.

Bona Fide Healthcare Provider Patient Relationship means a relationship between a Certifying Healthcare Provider, acting in the usual course of their professional practice, and a patient in which the healthcare provider has conducted a clinical visit, completed and documented a full assessment of the patient's medical history and current medical condition, has explained the potential benefits and risks of Marijuana use, and has a role in the ongoing care and treatment of the patient.

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

Brand Name Sponsorship means the payment by an ME in exchange for use of a Brand Name (1) to sponsor an athletic, musical, artistic, or other social or cultural event or (2) to identify, advertise, or promote such event, or an entrant, or participant of such an event.

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

<u>Cannabinoid Profile</u> means the amounts, expressed as the dry-weight percentages, of deltanine-tetrahydrocannabinol, cannabidiol, tetrahydrocannabinolic acid and cannabidiolic acid in a <u>Cannabis or</u> Marijuana Product. Amounts of other Cannabinoids may be required by the Commission.

Cannabis or Marijuana means all parts of any plant of the genus Cannabis, not excepted in 935 CMR 500.002: Cannabis or Marijuana(a) through (c) and whether growing or not; the seeds thereof; and resin extracted from any part of the plant; Clones of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin including tetrahydrocannabinol as defined in M.G.L. c. 94G, § 1; provided that Cannabis shall not include:

(a) the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil, or cake made from the seeds of the plant or the sterilized seed of the plant that is incapable of germination;

(b) Hemp; or

the weight of any other ingredient combined with Cannabis or Marijuana to prepare topical or oral administrations, food, drink or other products. Marijuana as defined herein.

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

<u>Cannabis</u> or <u>Marijuana Products</u> means Cannabis or Marijuana and its products, unless otherwise indicated. Cannabis or Marijuana Products includes products that have been Manufactured and contain Cannabis or Marijuana or an extract from Cannabis or Marijuana, including concentrated forms of Marijuana and products composed of Marijuana and other ingredients that are intended for use or consumption, including Edible Cannabis Products, Beverages, topical products, ointments, oils and Tinctures. Cannabis or Marijuana Products include Marijuana infused Products (MIPs) defined in 935 CMR 500.002.

<u>Canopy</u> means an area to be calculated in square feet and measured using clearly identifiable boundaries of all areas(s) that will contain mature plants at any point in time, including all of the

space(s) within the boundaries, Canopy may be noncontiguous, but each unique area included in the total Canopy calculations shall be separated by an identifiable boundary which includes, but is not limited to: interior walls, shelves, Greenhouse walls, hoop house walls, garden benches, hedge rows, fencing, garden beds, or garden plots. If mature plants are being cultivated using a shelving system, the surface area of each level shall be included in the total Canopy calculation.

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

Caregiver means a Personal Caregiver or Institutional Caregiver.

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

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

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

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

<u>Certificate of Registration</u> means a certificate formerly and validly issued by the Department of Public Health (DPH) or currently and validly issued by the Commission, that confirms an MTC, Independent Testing Laboratory, individual or entity has met all applicable requirements pursuant to M.G.L. c. 94I and 935 CMR 501.000 and is registered by the Commission. An MTC or Independent Testing Laboratory may have been issued a provisional or final Certificate of Registration. After November 1, 2019, new or renewal Licenses, as applicable, may be issued to MTCs and Independent Testing Labs.

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

<u>Certifying Healthcare Provider</u> means a Certifying CNP, a Certifying Physician or a Certifying Physician Assistant.

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

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

<u>Citizen Review Committee</u> means a nine-person advisory committee, the members of which will be appointed by the Commission or its designee and will serve two year terms. The committee advises the Commission on the implementation of the Social Equity Program and the use of community reinvestment funds. The committee makes specific recommendations as to the use of community reinvestment funds in the areas of programming, restorative justice, jail diversion, workforce development, industry-specific technical assistance, and mentoring services, in areas of disproportionate impact.

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

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

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

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

Commission means the Massachusetts Cannabis Control Commission as established by M.G.L. c. 10, § 76, or its representatives. The Commission has authority to implement the state Marijuana laws which include, but are not limited to, St. 2016, c. 334, The Regulation and Taxation of Marijuana Act, as amended by St. 2017, c. 55, An Act to Ensure Safe Access to Marijuana; M.G.L. 10, § 76, M.G.L. c. 94G; M.G.L. c. 94I; 935 CMR 500.000, 935 CMR 501.000: *Medical Use of Marijuana*, and 935 CMR 502.000: *Colocated Adult-use and* 

Medical-use Marijuana Operations.

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

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

Confidential Database means the Commission database that holds data concerning:

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

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

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

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

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

<u>Confidential Social Equity Application Materials</u> means any electronic or written document, communication or other record pertaining to an application for the Social Equity Program that is required to be confidential or protected from disclosure by law which includes, but is not

limited to, CORI as defined by 803 CMR 2.02: *Definitions*, or CHRI as defined in 803 CMR 7.02: *Definitions*.

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

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

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

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

<u>Debilitating Medical Condition</u> 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.

<u>Delivery Agreement</u> means a contract between a licensed Marijuana Retailer and a Delivery-only Licensee or Marijuana Establishment with a Delivery Endorsement to deliver Marijuana or Marijuana Products from the Marijuana Retailer directly to Consumers under the provisions of a Delivery-only License.

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

<u>Delivery-only Licensee</u> means an entity that is authorized to deliver <u>Marijuana or Marijuana Products</u> directly to Consumers from a Marijuana Retailer or Registered Qualifying Patients or Caregivers from an MTC-and that does not provide a retail location accessible to the public. The Delivery License shall be considered a Marijuana Retailer license in accordance with the provisions of G.L. c. 94G, § 1 and 935 CMR 500.000.

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

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

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

<u>Department of Revenue (DOR)</u> means the Massachusetts Department of Revenue, unless otherwise specified.

<u>Department of Unemployment Assistance (DUA)</u> means the Massachusetts Department of Unemployment Assistance, unless otherwise specified.

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

Economic Empowerment Priority Applicant means an applicant who <u>was certified by the Commission as such in 2018, demonstrated</u> and continues to <u>meet demonstrate</u> three or more of the following <u>six criteria, at least one of which must be a majority-equity-ownership criterion:</u>

## 1. Majority-Equity-Ownership Criteria:

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

# 2. Additional Criteria:

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

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

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

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

<u>Enclosed Area</u> means an indoor or outdoor area equipped with locks or other security devices, which is accessible only to Consumers, Marijuana Establishment Agents, Registered Qualifying Patients, or Caregivers.

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

Executive means members of the board of directors, chief executive officers, executive director, manager president, and any other officer, or their of equivalent, of the a Marijuana Establishment, MTC, or Independent Testing Laboratory.

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

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

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

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

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

Finished Marijuana Product means a Marijuana Product that is completely manufactured and ready for retail sale.

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

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

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

<u>Greenhouse</u> means a structure or thermally isolated Enclosed Area of a building that maintains a specialized sunlit environment used for and essential to the cultivation, protection or maintenance of plants are Enclosed Area where Cannabis or Marijuana plants are cultivated that has been inspected by the Commission and determined to be a Greenhouse.

<u>Healthcare Clinician or Provider</u> means a Certifying Physician, Certifying Certified Nurse Practitioner or Certifying Physician Assistant qualified under 935 CMR 501.000: *Medical Use of Marijuana*, to issue Written Certifications for the medical use of Marijuana.

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

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

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

Horticulture Lighting Square Footage (HLSF) means Canopy.

<u>Host Community</u> means a municipality in which a Marijuana Establishment or Independent Testing Laboratory is located or in which an applicant has proposed locating an establishment.

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

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

<u>Individual Order</u> means a delineated amount of Marijuana or Marijuana Products to be delivered by a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement to an individual Consumer and not to exceed the individual possession amount limits as determined

## by statute.

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

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

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

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

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

<u>Laboratory Agent</u> means an employee of an Independent Testing Laboratory registered in accordance with 935 CMR 500.029, who transports, possesses or tests Cannabis or Marijuana in compliance with 935 CMR 500.000.

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

<u>License</u> means the certificate issued by the Commission that confirms that a Marijuana Establishment or an Independent Testing Laboratory has met all applicable requirements pursuant to St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, and 935 CMR 500.000. A Marijuana Establishment or Independent Testing Laboratory may hold a provisional or final License.

<u>Licensee</u> means a person or entity on the application and licensed by the Commission to operate a Marijuana Establishment or Independent Testing Laboratory under St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, and 935 CMR 500.000. Any person or entity that solely provides initial capital to establish or operate the establishment and to whom, in return for the initial capital, requires only repayment of the loan and does not have any ownership or direct or indirect authority to control the Marijuana Establishment or Independent Testing Laboratory, will not be a Licensee.

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

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

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

Local Authorities means local municipal authorities unless otherwise indicated.

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

Marijuana (or Cannabis) means all parts of any plant of the *genus* Cannabis, not excepted in 935 CMR 500.002: *Cannabis or Marijuana* (a) through (c) and whether growing or not; the seeds thereof; and resin extracted from any part of the plant; Clones of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin including tetrahydrocannabinol as defined in M.G.L. c. 94G, § 1; provided that Cannabis shall not include:

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

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

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

<u>Marijuana Establishment</u> means a Marijuana Cultivator (Indoor or Outdoor), Craft Marijuana Cooperative, Marijuana Product Manufacturer, Marijuana Microbusiness, Independent Testing Laboratory, Marijuana Retailer, Marijuana Transporter, Delivery-only Licensee, Marijuana Research Facility, Social Consumption Establishment or any other type of licensed Marijuana-related business, except a Medical Marijuana Treatment Center (MTC).

Marijuana Establishment Branded Good means a merchandise item offered for sale by a

**Commented [PN1]:** This is the same definition but was moved to "M"

Marijuana Establishment, and identifiable as being of a particular Marijuana Establishment, distinct from those of other entities, by having the Marijuana Establishment's Brand Name. A Marijuana Establishment Branded Good does not include Marijuana, Marijuana Products, or Marijuana Accessories. It may include apparel, water bottles or other similar non-edible merchandise.

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

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

Marijuana Products (or Cannabis Products) means Marijuana and its products, unless otherwise indicated. Marijuana Products includes products that have been Manufactured and contain Cannabis, Marijuana, or an extract from Cannabis or Marijuana, including concentrated forms of Marijuana and products composed of Marijuana and other ingredients that are intended for use or consumption, including Edibles, Beverages, topical products, ointments, oils and Tinctures. Marijuana Products include Marijuana-infused Products (MIPs) defined in 935 CMR 500.002.

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

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

Marijuana Research Facility means the Premises at which a Marijuana Research Facility Licensee is approved to conduct research entity licensed to engage in research projects by the Commission.

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

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

**Commented [PN2]:** A board member is a director, which is included by using Executive

**Commented [PN3]:** A manager in the colloquial sense will be covered by "employee" and a manager in the LLC governance context is covered by Executive.

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

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

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

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

<u>Medical-use Cannabis or Marijuana (or Cannabis)</u> means Marijuana that is cultivated, Processed, Transferred, tested or sold in compliance with M.G.L. c. 94I and 935 CMR 501.000: *Medical Use of Marijuana*.

<u>Medical-use Marijuana or Marijuana Products</u> means Marijuana Products that are Manufactured, Transferred, tested or sold in compliance with M.G.L. c. 94I, and 935 CMR 501.000: *Medical Use of Marijuana*.

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

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

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

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

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

MTC Priority Applicant means a previously Medical Marijuana Treatment Center (MTC) (previously, Registered Marijuana Dispensary (RMD)) certified by the Commission as an MTC Priority Applicant in 2018 upon that demonstratinged that it had at least a provisional Certification of Registration prior to April 1, 2018, it had received a Final Certificate of Registration and is selling Marijuana or Marijuana infused Products as of the date of application; it had received a Final Certificate of Registration, but is not selling Marijuana or Marijuana infused Products as of the date of application; or it had received a Provisional Certificate of Registration, but not a Final Certificate of Registration. This applicant has priority for the purposes of the review of its license application.

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

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

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

<u>Outdoor Cultivation</u> shall mean the cultivation of mature Cannabis without the use of artificial lighting in the Canopy area at any point in time. Artificial lighting is permissible only to maintain immature or vegetative Mother Plants.

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

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

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

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

## Registration Card.

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

<u>Persons or Entities Having Direct Control</u> means any person or entity having direct control over the operations of a Marijuana Establishment, which satisfies one or more of the following criteria:

- (a) An Owner that possesses a financial interest in the form of equity of 10% or greater in a Marijuana Establishment;
- (b) A Person or Entity that possesses a voting interest of 10% or greater in a Marijuana Establishment or a right to veto significant events;
- (c) A Close Associate;
- (d) A Person or Entity that has the right to control or authority, through contract or otherwise including, but not limited to:
  - 1. to make decisions regarding operations and strategic planning, capital allocations, acquisitions and divestments;
  - 2. to appoint more than 50% of the directors or their equivalent;
  - 3. to appoint or remove Corporate-level officers or their equivalent;
  - 4. to make major marketing, production, and financial decisions;
  - 5. to execute significant (in aggregate of \$10,000 or greater) or exclusive contracts; or 6. to earn 10% or more of the profits or collect more than 10% of the dividends.
- (e) A Person or entity appointed as a receiver.

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

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

<u>Persons or Entities Having Indirect Control</u> means any person or entity having indirect control over operations of a Marijuana Establishment. It specifically includes any person with a controlling interest in Persons or Entities Having Direct Control over an indirect holding or parent company of the applicant, and the chief executive officer and executive director of those companies, or any person or entity in a position indirectly to control the decision-making of a Marijuana Establishment.

<u>Pesticide</u> means a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; provided that Pesticide shall not include any article that is a "new animal drug" within the meaning of § 201(v) of the Federal Food, Drug and Cosmetic

Act (21 U.S.C. § 321(v)), or that has been determined by the Secretary of the United States Department of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of § 201(w) of such act (21 U.S.C. § 321(w)).

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

<u>Pre-verification</u> means the process of a Marijuana Retailer examining the identification presented by an individual Consumer to confirm that the identification is valid and matches the individual presenting it and collecting the information required by 935 CMR 500.000 prior to that Consumer being able to receive deliveries of Marijuana or Marijuana Products to the Consumer's Residence. A Marijuana Retailer shall not acquire or record personal information about Consumers other than information typically required in a retail transaction.

<u>Premises</u> means any indoor or outdoor location over which a Marijuana Establishment or Independent Testing Laboratory or its agents may lawfully exert substantial supervision or control over entry or access to the property or the conduct of persons.

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

<u>Process or Processing</u> means to harvest, dry, cure, trim and separate parts of the Cannabis or Marijuana plant by manual or mechanical means, except it shall not include Manufacture as defined in 935 CMR 500.002; <u>Manufacture</u>.

Product Database means a Commission-operated technology platform displaying information about Marijuana Products produced by licensed Marijuana Product Manufacturers and sold by licensed Marijuana Retailer pursuant to 935 CMR 500.000 and 935 CMR 501.000.

<u>Production Area</u> means a Limited Access Area within the Marijuana Establishment where Cannabis or Marijuana is handled or produced in preparation for sale.

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

<u>Propagation</u> means the reproduction of Cannabis or Marijuana plants by seeds, cuttings, or grafting.

<u>Provisional Marijuana Establishment License</u> means a License issued by the Commission confirming that a Marijuana Establishment has completed the application process and satisfied the qualifications for initial licensure

Qualifying Patient means an individual Massachusetts Resident 18 years of age or older who

has been diagnosed by a Certifying Healthcare Provider as having a Debilitating Medical Condition, or an individual-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, oncologist, neurologist, or family physician as having a Debilitating Medical Condition that is also a Life-limiting Illness, subject to 935 CMR 501.010(10).

Quality Control Sample means a sample of Marijuana or Marijuana Product developed by a Marijuana Cultivator or a Marijuana Product Manufacturer licensed under the provisions of 935 CMR 500.000: Adult Use of Marijuana, that is provided internally to employees for purposes of ensuring product quality and making determinations about whether to sell the Marijuana or Marijuana Product.

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

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

Registrant means the holder of a Registration Card formerly and validly registered with the DPH or currently and validly with the Commission. It also means an RMD holder of Certificate of Registration formally and validly registered with the DPH or the Commission. After November 1, 2019, new and renewal MTC Licenses, as applicable, may be issued.

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

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

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

Research Facility means an entity licensed to engage in research projects by the Commission.

Research Permit means a certificate indicating Commission approval to conduct a specified research project over a specified and finite period of time. To the extent that a Research

Licensee is subject to other IRB, institutional, industry, or professional standards, they shall demonstrate compliance with those standards.

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

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

Responsible Vendor means a Marijuana Establishment that the Commission has determined to have completed the initial training requirements and has maintained its training requirement under 935 CMR 500.105(2).

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

Responsible Vendor Training (RVT) Program means a mandatory program operated by an education provider accredited by the Commission to provide that provides training courses taught by a Responsible Vendor Trainer for Marijuana Establishment Agents in order to satisfy the minimum training of three hours—of—required training to Marijuana Establishment Agentsunder 935 CMR 500.105(2). The program shall be mandatory and the topics covered shall include, but not be limited to: an understanding of different products and methods of consumption including Edibles; potency; effects; secondhand absorption time; procedures to ensure that Consumers are not overserved; procedures for mitigating the risk of an impaired Consumer and ensuring the safety of patrons and the general public in the event of impairment.

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

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

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

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

stable does not include "Time/Temperature Controlled for Safety Food" as it is defined in the 2013 Food Code as adopted under 105 CMR 590.001(A).

Small Business means, for the purposes of 935 CMR 500.005(1)(b), an applicant or Licensee that (i) currently employs a combined total of 50 or fewer full-time equivalent employees in all locations or employees work less than a combined total of 2,600 hours per quarter; and (ii) has gross revenues of \$15 million or less as reported to the Massachusetts Department of Revenue the year prior to the date of the Licensee's initial or renewal application or as otherwise demonstrated in a form and manner determined by the Commission.

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

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

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

<u>Summary Suspension</u> means the suspension of any license or registration issued under 935 CMR 500.000, and the cessation of all operations in order to protect the public health, safety and welfare.

<u>Third-party Technology Platform Provider</u> means an individual or entity that provides or hosts an internet-based application or group of applications developed for the facilitation of ordering and delivering Cannabis through a Delivery-only Licensee or a Marijuana Establishment with a Delivery Endorsement to a Consumer.

<u>Tincture</u> means a Cannabis-infused alcohol or oils concentrate administered orally in small amounts using a dropper or measuring spoon. Tinctures are not considered an Edibles. <u>Marijuana Product</u> under 935 CMR 500.000 and are not subject to the dosing limitations applicable to Edible. <u>Marijuana Product</u>s.

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

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

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

<u>Usable Marijuana</u> means the fresh or dried leaves and flowers of the female Marijuana plant and

Commented [A4]: Based on criteria the Commonwealth uses for eligibility to be a member of the Operational Services Division's (OSD) Small Business Purchasing Program (SBPP). See <a href="https://www.mass.gov/how-to/register-for-the-small-business-purchasing-program-sbpp">https://www.mass.gov/how-to/register-for-the-small-business-purchasing-program-sbpp</a>

any mixture or preparation thereof, including Marijuana, Marijuana Products or MIPs, but does not include the seedlings, seeds, stalks, roots of the plant, or Marijuana rendered unusable in accordance with 935 CMR 500.105(12)(c).

<u>Vegetation</u> means the sporophytic state of the Cannabis or Marijuana plant, which is a form of asexual reproduction in plants during which plants do not produce resin or flowers and are bulking up to a desired production size for Flowering.

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

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

<u>Visitor</u> means an individual, other than a Marijuana Establishment Agent or Laboratory Agent authorized by the Marijuana Establishment or Independent Testing Laboratory to on the Premises of an Establishment for a purpose related to its operations and consistent with the objectives of St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, and 935 CMR 500.000, provided, however, that no such individual shall be younger than 21 years old.

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

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

Written Certification means a form submitted to the Department of Public Health (DPH) or the Commission by a Massachusetts licensed Certifying Healthcare Provider describing the Qualifying Patient's pertinent symptoms, specifying the patient's Debilitating Medical Condition, and stating that in the physician's professional opinion the potential benefits of the medical use of Marijuana would likely outweigh the health risks for the patient.

# **MEDICAL 501.002: Definitions**

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

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

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

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

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

Advertising means a form of marketing communication that employs a sponsored, non-personal message to sell or promote a Marijuana Establishment's Brand Name, Branded Good, service, product or idea.

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

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

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

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

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

Beverage means a liquid intended for drinking.

Bona Fide Healthcare Provider - Patient Relationship means a relationship between a Certifying Healthcare Provider, acting in the usual course of their professional practice, and a patient in which the healthcare provider has conducted a clinical visit, completed and documented a full assessment of the patient's medical history and current medical condition, has explained the potential benefits and risks of Marijuana use, and has a role in the ongoing care and treatment of the patient.

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

Brand Name Sponsorship means the payment by an ME in exchange for use of a Brand Name (1) to sponsor an athletic, musical, artistic, or other social or cultural event or (2) to identify, advertise, or promote such event or an entrant or participant of such event.

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

<u>Cannabinoid Profile</u> means the amounts, expressed as the dry-weight percentages, of deltanine-tetrahydrocannabinol, cannabidiol, tetrahydrocannabinolic acid and cannabidiolic acid in a <u>Cannabis or</u> Marijuana Product. Amounts of other Cannabinoids may be required by the Commission.

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

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

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

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

### defined in 935 CMR 501.002.

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

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

Caregiver means a Personal Caregiver or Institutional Caregiver.

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

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

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

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

Certificate of Registration means a certificate formerly and validly issued by the Department of Public Health (DPH) or currently and validly issued by the Commission, that confirms an MTC or Independent Testing Laboratory, individual or entity has met all applicable requirements pursuant to M.G.L. c. 94I, and 935 CMR 501.000 and is registered by the Commission. An MTC or Independent Testing Laboratory may have been issued a provisional or final Certificate of Registration. After November 1, 2019, new or renewal Licenses, as applicable, may be issued to MTCs and Independent Testing Labs.

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

practitioner licensed pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing*, who certifies that in their professional opinion, the potential benefits of the medical use of Marijuana would likely outweigh the health risks for a Qualifying Patient.

<u>Certifying Healthcare Provider</u> means a Certifying CNP, a Certifying Physician or a Certifying Physician Assistant.

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

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

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

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

<u>Close Associate</u> means a Person who holds a relevant managerial, operational or financial interest in the business of an applicant or Licensee and, by virtue of that interest or power, is able to exercise a significant influence over the management, operations or finances of a Marijuana Establishment, an MTC or Independent Testing Laboratory licensed under 935 CMR 501.000. A person who is a Close Associate is deemed to be a Person or Entity Having Direct or Indirect Control.

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

Commission means the Massachusetts Cannabis Control Commission, as established by M.G.L c. 10, § 76, or its representatives. The Commission has authority to implement the state Marijuana laws, which include, but are not limited to, St. 2016, c. 334: *The Regulation and Taxation of Marijuana Act*, as amended by St. 2017, c. 55: *An Act to Ensure Safe Access to Marijuana*; M.G.L. 10, § 76; M.G.L. c. 94G; M.G.L. c. 94I; 935 CMR 500.000: *Adult Use of Marijuana*; 935 CMR 501.000, and 935 CMR 502.000: *Colocated Adult-use and Medical-use Marijuana Operations*.

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

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

Confidential Database means the Commission database that holds data concerning:

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

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

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

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

<u>Confidential Records</u> means any electronic or written record required to be kept confidential or protected from disclosure by law, which includes, but is not limited to, Confidential Application Materials, Confidential Social Equity Application Materials (as defined in 935 CMR 500.002: *Definitions*), Confidential Investigatory Materials, and Protected Patient Records.

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

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

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

product labeling and product recalls.

<u>Debilitating</u> 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.

<u>Debilitating Medical Condition</u> 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.

<u>Delivery only Licensee</u> means an entity that is authorized to deliver <u>Marijuana or Marijuana Products</u> directly to Consumers from a Marijuana Retailer or Registered Qualifying Patients or Caregivers from an MTC and that does not provide a retail location accessible to the <u>public</u>. The <u>Delivery License shall be considered a Marijuana Retailer license in accordance</u> with the provisions of G.L. c. 94G, § 1 and 935 CMR 500.000.

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

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

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

<u>Department of Revenue (DOR)</u> means the Massachusetts Department of Revenue, unless otherwise specified.

<u>Department of Unemployment Assistance (DUA)</u> means the Massachusetts Department of Unemployment Assistance, unless otherwise specified.

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

Economic Empowerment Priority Applicant means an applicant who was certified by the Commission as such in 2018, demonstrated and continues to meet demonstrate three or more of the following six criteria, at least one of which must be a majority-equity-ownership criterion:

# 1. Majority-Equity-Ownership Criteria:

- a. A majority of ownership belongs to people who have lived for five of the preceding ten years in an Area of Disproportionate Impact, as determined by the Commission.
- b. A majority of ownership has held one or more previous positions where the primary

- population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision or empowerment to disproportionately impacted individuals or communities.
- **a.**c. A majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent.

## 2. Additional Criteria:

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

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

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

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

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

<u>Equity Holder</u> means a person or entity that holds or will hold any amount of equity in a Marijuana Establishment or an MTC.

<u>Executive</u> means members of the board of directors, <u>chief</u> executive officers, executive director, <u>manager president</u>, <u>and any other officer</u>, <u>or their of equivalent</u>, <u>of the a Marijuana Establishment</u>, <u>MTC</u>, or Independent Testing Laboratory.

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

<u>Existing Licensee Transporter</u> means an entity that is otherwise licensed by the Commission and also licensed to purchase, obtain, and possess Marijuana or Marijuana Products solely for the purpose of transporting, temporary storage, sale and distribution on behalf of other Marijuana

Establishments or MTCs to other establishments, but not to Consumers.

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

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

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

<u>Food and Drug Administration (FDA)</u> means the United States Food and Drug Administration.

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

Greenhouse means a structure or thermally isolated Enclosed Area of a building that maintains a specialized sunlit environment used for and essential to the cultivation, protection or maintenance of plants, an Enclosed Area where Cannabis or Marijuana plants are cultivated that has been inspected by the Commission and determined to be a Greenhouse.

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

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

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

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

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

Horticulture Lighting Square Footage (HLSF) means Canopy.

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

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

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

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

<u>Individual Order</u> means a delineated amount of Marijuana, Marijuana Products or MIPs to be delivered by a Delivery-only Licensee, MTC or third-party authorized by the Commission to perform home delivery.

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

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

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

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

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

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

Law Enforcement Authorities means local law enforcement including, but not limited to, the

local police and fire departments within the municipality where the Licensee is sited, unless otherwise indicated.

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

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

<u>Life Limiting Illness</u> means a Debilitating Medical Condition that does not respond to curative treatments, where reasonable estimates of prognosis suggest death may occur within two years.

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

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

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

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

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

(a) the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil, or cake made from the seeds of the plant or the sterilized seed of the plant that is incapable of germination;

(b) Hemp; or

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

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

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

<u>Marijuana Establishment</u> means a Marijuana Cultivator (Indoor or Outdoor), Craft Marijuana Cooperative, Marijuana Product Manufacturer, Marijuana Microbusiness, Independent Testing Laboratory, Marijuana Retailer, Marijuana Transporter, Delivery-only Licensee, Marijuana Research Facility (as defined in 935 CMR 500.002: *Definitions*), Social Consumption Establishment (as defined in 935 CMR 500.002), or any other type of licensed Marijuana-related business subject to the regulations in 935 CMR 500.000: *Adult Use of Marijuana*.

<u>Marijuana Establishment Agent</u> means any <u>board member</u>, <u>directorOwner</u>, employee, Executive, <u>manager</u>, or volunteer of a Marijuana Establishment, who is 21 years of age or older. Employee includes a consultant or contractor who provides on-site services to a Marijuana Establishment related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of Marijuana.

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

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

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

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

Marijuana Research Facility-means the Premises at which a Marijuana Research Facility Licensee is approved to conduct research an entity licensed to engage in research projects by the Commission.

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

Marijuana Retailer means an entity licensed to purchase, Repackage, and transport

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Marijuana Cannabis or Marijuana Product from Marijuana Establishments and to Transfer or otherwise Transfer this product to Marijuana Establishments and to sell to Consumers. Unless licensed, retailers are prohibited from offering Marijuana or Marijuana Products for the purposes of on-site social consumption on the Premises of a Marijuana Establishment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

<u>Other Jurisdiction</u> shall mean the United States, another state, or foreign jurisdiction, or a military, territorial or Native American tribal authority.

<u>Outdoor Cultivation</u> shall mean the cultivation of mature Cannabis without the use of artificial lighting in the Canopy area at any point in time. Artificial lighting is permissible only to maintain immature or vegetative Mother Plants.

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

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

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

Patient Registration Card means a Registration Card formerly and validly issued by DPH or a temporary or an annual Registration Card currently and validly issued by the Commission, to a Registered Qualifying Patient. The Patient Registration Card facilitates verification of an individual Registrant's status including, but not limited to, identification by the Commission and Law Enforcement Authorities, of those individuals who are exempt from Massachusetts

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criminal and civil penalties under M.G.L. c. 94I, and 935 CMR 501.000 through Commission-supported databases. A Temporary Patient Registration issued to a Qualifying Patient shall be deemed a Registration Card.

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

<u>Persons or Entities Having Direct Control</u> means any person or entity having direct control over the operations of an MTC, which satisfies one or more of the following criteria:

- (a) An Owner that possesses a financial interest in the form of equity of 10% or greater in an MTC;
- (b) A Person or Entity that possesses a voting interest of 10% or greater in an MTC or a right to veto significant events;
- (c) A Close Associate;
- (d) A Person or Entity that has the right to control, or authority through contract, or otherwise including, but not limited to:
  - 1. to make decisions regarding operations and strategic planning, capital allocations, acquisitions and divestments;
  - 2. to appoint more than 50% of the directors or their equivalent;
  - 3. to appoint or remove Corporate-level officers or their equivalent;
  - 4. to make major marketing, production, and financial decisions;
  - to execute significant (in aggregate of \$10,000 or greater) or exclusive contracts; or
- 6. to earn 10% or more of the profits or collect more than 10% of the dividends.
- (e) A Person or entity appointed as a receiver.

<u>Persons or Entities Having Indirect Control</u> means any person or entity having indirect control over operations of MTC. It specifically includes <u>Persons or Entities Having Direct Control overany person with a controlling interest in</u> an indirect holding or parent company of the applicant, and the chief executive officer and executive director of those companies, or any person or entity in a position indirectly to control the decision-making of MTC.

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

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

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

§ 201(w) of such act (21 U.S.C. § 321 (w)).

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

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

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

Product Database means a Commission-operated technology platform displaying information about Marijuana Products produced by licensed Marijuana Product Manufacturers and sold by licensed Marijuana Retailer pursuant to 935 CMR 500.000 and 935 CMR 501.000.

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

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

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

<u>Propagation</u> means the reproduction of Cannabis or Marijuana plants by seeds, cuttings, or grafting.

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<u>Protected Patient Records</u> means any document, record or electronic or written communication related to their care provided by a medical use Marijuana Licensee or establishment or by a registered healthcare professional that is required to be confidential or protected from disclosure by law.

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

Qualifying Patient means an individual Massachusetts Resident 18 years of age or older who has been diagnosed by a Certifying Healthcare Provider as having a Debilitating Medical Condition, or an individual-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, oncologist, neurologist, or family physician as having a Debilitating Medical Condition that is also a Life-limiting Illness, subject to 935 CMR 501.010(10).

Quality Control Sample means a sample of Marijuana or Marijuana Product developed by a Marijuana Cultivator or a Marijuana Product Manufacturer licensed under the provisions of 935 CMR 500.000: *Adult Use of Marijuana*, that is provided internally to employees for purposes of ensuring product quality and making determinations about whether to sell the Marijuana or Marijuana Product.

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

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

Registrant means the holder of a Registration Card formerly and validly registered with the DPH or currently and validly with the Commission. It also means an RMD holder of Certificate of Registration formally and validly registered with the DPH or the Commission. After November 1, 2019, new and renewal MTC Licenses, as applicable, may be issued.

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

<u>Removal of Product</u> means an order issued against an MTC to remove and prohibit sales of categories of products, product types, specific product types or specific brands of products

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after notice and on a determination that the Marijuana or Marijuana Product poses a substantial risk to the public health, safety or welfare including, but not limited to, when the product is especially appealing to persons younger than 21 years old.

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

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

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

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

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

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

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

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

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

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

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

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

Small Business means, for the purposes of 935 CMR 500.005(1)(b), an applicant or Licensee that (i) currently employs a combined total of 50 or fewer full-time equivalent employees in all locations or employees work less than a combined total of 2,600 hours per quarter; and (ii) has gross revenues of \$15 million or less, as reported to the Massachusetts Department of Revenue the year prior to the date of the Licensee's initial or renewal application or as otherwise demonstrated in a form and manner determined by the Commission.

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

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

<u>Third-party Technology Platform Provider</u> means an individual or entity that provides or hosts an internet-based application or group of applications developed for the facilitation of ordering and delivering Marijuana or Marijuana Products through an MTC to a Registered Qualifying Patient or Caregiver.

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

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

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

Unreasonably Impracticable means that the measures necessary to comply with the

Commented [A5]: Based on criteria the Commonwealth uses for eligibility to be a member of the Operational Services Division's (OSD) Small Business Purchasing Program (SBPP). See <a href="https://www.mass.gov/how-to/register-for-the-small-business-purchasing-program-sbpp">https://www.mass.gov/how-to/register-for-the-small-business-purchasing-program-sbpp</a>

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

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

<u>Vegetation</u> means the sporophytic state of the Cannabis or Marijuana plant, which is a form of asexual reproduction in plants during which plants do not produce resin or flowers and are bulking up to a desired production size for Flowering.

<u>Verified Financial Hardship</u> 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.

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

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

<u>Visitor</u> means an individual, other than an MTC Agent or Laboratory Agent, authorized by the MTC or Independent Testing Laboratory to be on the Premises of an MTC for a purpose related to its operations and consistent with the objectives of M.G.L. c. 94I, and 935 CMR 501 000

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

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

<u>Written Certification</u> means a form submitted to the Department of Public Health (DPH) or the Commission by a Massachusetts licensed Certifying Healthcare Provider describing the Qualifying Patient's pertinent symptoms, specifying the patient's Debilitating Medical Condition, and stating that in the physician's professional opinion the potential benefits of the medical use of Marijuana would likely outweigh the health risks for the patient.

14-day Supply means that amount of Marijuana, or equivalent amount of Marijuana in MIPs,

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that a Registered Qualifying Patient would reasonably be expected to need over a period of 14 calendar days for his or her personal medical use, which is 2.5 ounces, subject to 935 CMR 501.010(9), unless otherwise determined by a Certifying Healthcare Provider.

<u>60-day Supply</u> means that amount of Marijuana, or equivalent amount of Marijuana in MIPs, that a Registered Qualifying Patient would reasonably be expected to need over a period of 60 calendar -days for his or her personal medical use, which is ten ounces, subject to 935 CMR 501.010(9), unless otherwise determined by a Certifying Healthcare Provider.

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#### **COLOCATED 502.002: Definitions**

Adult use Cannabis or Marijuana means Marijuana that is cultivated, processed, transferred, tested or sold to adults 21 years of age or older in compliance with 935 CMR 500.000: Adult Use of Marijuana.

<u>Adult use Cannabis or Marijuana Products</u> means Marijuana Products that are processed manufactured, transferred, tested or sold to adults 21 years of age or older in compliance with 935 CMR 500.000: Adult Use of Marijuana.

<u>Cannabis or Marijuana Products</u> means cannabis or marijuana and its products unless otherwise indicated. <u>Cannabis or Marijuana Products</u> includes products that have been manufactured and contain cannabis or marijuana or an extract from cannabis or marijuana, including concentrated forms of marijuana and products composed of marijuana and other ingredients that are intended for use or consumption, including edible products, beverages, topical products, ointments, oils and tinctures. Cannabis or marijuana products are the equivalent of marijuana infused products (MIPs) defined in 935 CMR 501.003: *Definitions*.

Caregiver means a personal caregiver or caregiving institution.

<u>Caregiving Institution</u> 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.

<u>Certificate of Registration</u> 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. 94I, and 935 CMR 501.000: *Medical Use of Marijuana*, 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.

Clone means a clipping from a cannabis or marijuana plant which can be rooted and grown.

<u>Colocated Marijuana Operations (CMO)</u> 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.

Commission means the Massachusetts Cannabis Control Commission established by M.G.L. c. 10, § 76, or its representatives. The Commission has authority to implement the state marijuana laws, which include, but are not limited to, St. 2017, c. 55; M.G.L. c. 94G; M.G.L. c. 94I; 935 CMR 500.000: Adult Use of Marijuana, 935 CMR 501.000: Medical Use of Marijuana, and 935 CMR 502.000.

Commission Designee(s) means other state or local officials or agencies working in cooperation with

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the Commission and as designated by the Commission to carry out the Commission's responsibilities and to ensure compliance with the adult use, medical use, and colocated operations laws.

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

Delivery means the lawful delivery of marijuana or MIPs for medical use to a patient or caregiver.

<u>Department of Public Health or Department</u> means the Massachusetts Department of Public Health, unless otherwise specified. The Department had the authority to implement and regulate the medical use of marijuana program before the Program Transfer.

Edible Marijuana infused Products (Edible MIPs) means a Marijuana infused Product (MIP) that is to be consumed by eating or drinking. Edible MIPs are the equivalent of edible marijuana products under 935 CMR 500.000: Adult Use of Marijuana.

Finished Marijuana means usable marijuana, cannabis resin or cannabis concentrate.

<u>Hardship Cultivation Registration</u> means a registration issued to a registered Qualifying Patient under the requirements of 935 CMR 501.035: *Hardship Cultivation Registration*.

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

<u>Identification Badges</u> are badges issued by an RMD, a Marijuana Establishment or the Commission, which must be used while on CMO premises. <u>Identification badges must be issued in a form and manner determined by the Commission.</u>

Independent Testing Laboratory means a laboratory qualified to test medical use marijuana in compliance with M.G.L. c. 94I; 935 CMR 501.000: Medical Use of Marijuana, or adult use marijuana licensed in accordance with M.G.L. c. 94G and 935 CMR 500.000: Adult Use of Marijuana. Testing by either a registered or licensed Independent Testing Laboratory may be deemed by the Commission to satisfy the requirements of M.G.L. c. 94G, § 15.

<u>Laboratory Agent</u> means an employee of an independent testing laboratory registered in accordance with 935 CMR 501.032: Registration of Testing Laboratory Agents, who transports or tests medical use marijuana or MIPs; or an employee of an Independent Testing Laboratory registered in accordance with 935 CMR 500.029: Registration and Conduct of Laboratory Agents, who transports, possesses or tests cannabis or marijuana in compliance with 935 CMR 500.000: Adult Use of Marijuana.

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<u>License</u> means the certificate issued by the Commission that confirms that a Marijuana Establishment has met all applicable requirements pursuant to St. 2017, c. 55, M.G.L. c. 94G, and 935 CMR 500.000: *Adult Use of Marijuana*. An applicant may be eligible for a provisional or final license.

<u>Licensee</u> means a person or entity licensed by the Commission to operate a Marijuana Establishment under 935 CMR 500.000: *Adult Use of Marijuana*.

<u>Limited Access Area</u> means an indoor or outdoor area on the registered premises of a CMO where cannabis or MIPs or marijuana products, or their byproducts are cultivated, stored, weighed, packaged, processed, or disposed, under the control of a CMO, with access limited only to those persons that are essential to operations in these areas designated by the CMO, representatives of the Commission as authorized by the adult use, medical use, and colocated operations laws, Commission designee(s), and law enforcement authorities acting within their lawful jurisdiction. An RMD agent can also access this area for adult use if they are also a marijuana establishment agent designated by the establishment.

Marijuana or Cannabis means all parts of any plant of the genus Cannabis, not excepted in 935 CMR 501.003: Definitions, and whether growing or not; the seeds thereof; and resin extracted from any part of the plant; clones of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin including tetrahydrocannabinol as defined in M.G.L. c. 94G, § 1; provided that cannabis shall not include:

(a) the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil, or cake made from the seeds of the plant or the sterilized seed of the plant that is incapable of germination;

(b) hemp; or

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

<u>Marijuana Establishment</u> means an adult-use Marijuana Cultivator, Craft Marijuana Cooperative, Marijuana Product Manufacturer, Marijuana Retailer, Independent Testing Laboratory, Marijuana Research Facility, Marijuana Transporter, Marijuana Microbusiness or any other type of licensed marijuana related business.

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

Marijuana infused Product (MIP) means a product infused with marijuana that is intended for use or consumption including, but not limited to, edible products, ointments, aerosols, oils, and tinctures. Marijuana infused Product (MIP), when created or sold by an RMD, shall not be considered a food or a drug as defined in M.G.L. e. 94, § 1. MIPs are the equivalent of marijuana products under 935 CMR 500.000: Adult Use of Marijuana.

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

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Medical use Cannabis or Marijuana means Marijuana that is cultivated, processed, transferred, tested or sold in compliance with 935 CMR 501.000: Medical Use of Marijuana.

Medical use Cannabis or Marijuana Products means Marijuana Products that are manufactured, transferred, tested or sold in compliance with 935 CMR 501,000: Medical Use of Marijuana.

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.

Person means an individual or an entity.

<u>Personal Caregiver</u> 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.

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

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

Qualifying Patient means 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(10).

Registered Marijuana Dispensary (RMD) means an entity formerly and validly registered under 935 CMR 501.000: Medical Use of Marijuana or currently and validly registered under 935 CMR 501.100: Registration of Registered Marijuana Dispensaries, 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.

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Registered Qualifying Patient means 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. Seed to sale Electronic Tracking System shall utilize a unique plant identification and unique batch identification. It will also be able to track agents' and registrants' involvement with the marijuana product. Any secondary system used by the RMD or Independent Testing Laboratory must integrate with the SOR in a form and manner determined by the Commission.

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

<u>Visitor</u> means an individual, other than an RMD agent or Marijuana Establishment agent, authorized by the CMO to be on the premises of an establishment for a purpose related its operations, provided however, that no such individual shall be younger than 21 years old.

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<b>Colocated Section</b>	Adult	Medical	Notes			
502.002 Definitions	500.002 Definitions	501.002: Definitions	Definitions in colocated regulations were out of date and there were no definitions that need to carry over not already in adult/medical. Slight update of the Definition of CMO.			
502.003: Colocated Marijuana Operations	500.003: Colocated Marijuana operations	501.003: Colocated Marijuana Operations	adult/medical. Portion of section deleted as it is covered by definition of CMO. Language added to clarify			
502.005: Fees	500.005: Fees - subsections (4)-(5) 500.030:	501.005: Fees Subsections (5)-(6) 501.030: Registration	CMO ranguage littiet as subsections to fees section for each			
502.028: Registration of Agents Affiliated with CMOs		of Marijuana Treatment Center Agents - Subsection	Modified slightly and added as a subsection to each adult/medical.			
502.101: Application Requirements	500.101:	501.101: Application Requirements - Subsection (3)	subsection to each adult/medical.  Potentially adding provisions from licensing guidance - need to connect			
502.102: Action on Applications	X	X	To be deleted as superfluous, per discussion with licensing.			
502.103: Licensure and Renewal	500.103: Licensure and Renewal Subsection (4)	501.203: Licensure and Renewal (4)	adding provision from licensing guidance with respect to CMO			
502.104: Notification and Approval of Change	X	X	To be deleted as superfluous, per discussion with licensing.			
502.105: General Operating Requirements for CMOs						
502.105(1) Written Operating Procedures	Lucadimas	501.105(1): Written Operating Procedures	section 105(1) in each adult and			
502.105(2): Agent Training	500.105(2) Agent Training - Subsection (a)(6)	501.105(2) Agent Training - Subsection (a)(6)	New subsection added to each adult and medical sections on agent training.			
502.105(3): Requirements of Handling of Marijuana	Requirements for the Handling of Marijuana -	501.105(3): Handling of Marijuana - subsection €	New subsection added to each adult and medical sections on Handling Marijuana, with slight update to regulatory citations The provisions of 302.103(4) were			
502.105(4:) Marketing and Advertising Requirements	Marketing and Advertising Requirements -	501.105(4): Marketing and Advertising Requirements - Subsection (d)	duplicative of Adult and medical, so a subsection (d) will be added to each adult and medical to make each			

	Ι		The provisions of 302.103(3) were
502.105(5): Labeling of Marijuana, MIPs, or Marijuana Products	500.105(5): Labeling of Marijuana and Marijuana Products - subsection (d)	501.105(5): Labeling of Marijuana and Marijuana Products - subsection (d)	partially out of date, so a simple requirement to comply with both adult and medical was added to a new subsection (d) in each adult and The provisions of 502.105(e) were
502.105(6): Packaging of Marijuana, MIPs, or Marijuana Products	500.105(6): Packaging of Marijuana and Marijuana Products - subsection (f)	501.105(6): Packaging of Marijuana and Marijuana Products - subsection (f)	partially out of date, so a simple requirement to comply with both adult and medical was added to a new subsection (f) in each adult and
Packaging and Labeling Pre-	Packaging and Labeling Pre-	501.105(7) Packaging and Labeling Pre- approval	Minor insertion in each medical and adult.
Inventory and	Inventory -	501.105(8): Inventory - subsections (g) and (h)	Provisions from 502
502.105(9): Record Keeping	X 500.105(10):	X	simply references the provisions of
502.105(10): Liability Insurance Coverage or Maintenance of Escrow	Liability Insurance Coverage or Maintenance of Escrow -	500.105(10): Liability Insurance Coverage or Maintenance of Escrow - subsection (e)	medical are the same, so a subsection (e) was added to each to clarify that a CMO need only fulfill the requirement per location, rather than
502.105(11): Storage Requirements	X	X	medical are identical, so no need to
502.105(12): Waste Disposal	X	X	The fequinements for each adult and medical are identical, so no need to clarify. Recommended change from Group 4 not needed provided the change recommended for the fequinement and the f
502.105(13): Transportation	500.105(13): Transportation between Marijuana Establishments - subsection (i)	500.105(13): Transportation between MTCs	medical are substantially similar, so a subsection (i) was created in each to carry over the requirement to apply the strictest security
502.105(14)	X	X	medical are the same, and the colocated regulations are partially based on the old DPH medical use
502.105(15): Energy Efficiency and Conservation	X	X	medical are the same and the colocated regulations simply refer to
502.105(16): Bond	X	X	The requirements or each adult and medical are the same and the colocated regulations simply refer to

502.105(17): Social Equity Program	X	X	licensees and the colocated regulations simply refer to the
502.110: Security Requirements	X	X	medical are the same and the colocated regs either restate or cross
502.120: Additional Operating Requirements for Cultivation	X	X	medical are substantially similar, so no need to clarify application for CMOs and to certain provisions already contemplate CMO
502.130: Additional Operating Requirements for Product Manufacturing	X	X	medical are substantially similar, so no need to clarify application for CMOs and to certain provisions already contemplate CMO
502.140: Additional Operating Requirements for Retail Sales	500.140: Additional Operational Requirements for Retail Sales - subsections (8) and (9)	500.140: Additional Operational Requirements for Patient Sales - subsections (8) and (9)	The requirements for each adult and medical are the same, with most provisions from 502 covered in adult/medical or outdated.  Provisions with respect to separation of adult/medical product and patient supply being carried over. Includes recommendation from Group 5.
502.150: Edible MIPs or Marijuana Products	X	X	are the same (except potency in adult), and the provisions of 502 were outdated. Potency provisions in adult are written to not need a
502.160: Testing of Marijuana, MIPs, or Marijuana Products	X	X	The provisions of adult and medical are the same (except potency in adult), and cover everything in 502.
502.300 Inspections	X	X	Covered by 500.300 and 501.300
502.700: Waivers	X	X	Covered by 500.850 and 501.850
502.900: Severability	X	X	Covered by 500.900 and 501.900

#### Topic: Review of 502.000(CMO Regulations).

<u>Recommendation</u>: Merge all of the provisions of the CMO Regulations into the corresponding into the adult-use and medical-use regulations, as needed. (See changes to 500 and 501 below, beginning on the next page.)

The Trace-through Chart attached as **Attachment D** provides a quick glance of each section (or subsection) of the CMO Regulations showing (1) whether/where any provision needs to be inserted into the adult-use or medical-use regulations and (2) an explanation of for each. The Draft Provisions below show the proposed language to be inserted into adult-use and medical use regulations, as applicable.

#### **CMO Definition:**

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

#### <u>502.003 – Colocated Marijuana Operations (CMOs</u>

500.003: Colocated Marijuana Operations (CMOs).

An adult-use Marijuana Cultivator, Product Manufacturer or Retailer also be registered as an MTC as defined in to 935 CMR 501.002. No other adult-use license type qualifies to be a CMO. Unless otherwise specified, CMOs must comply with the requirements of each the adult-use and medical-use license or registration located on the Premises of the CMO.

501.003: Colocated Marijuana Operations (CMOs).

A Marijuana Treatment Center may also be licensed to conduct adult-use operations as a Cultivator, Product Manufacturer and Retailer, as defined in 935 CMR 500.002. No other medical-use license or registration type qualifies for CMOs. Unless otherwise specified, CMOs must comply with the requirements of each the adult-use and medical-use license or registration located on the Premises of the CMO.

#### **502.005** – **Fees**

500.005: Fees

- (4) For CMOs, an applicant must pay all of the following fees:
  - (a) Marijuana Establishment Application Fee. A Marijuana Establishment that will be colocated with a MTC shall pay the respective application fee for each type of Marijuana Establishment set forth in 935 CMR 500.005: *Fees*.
  - (b) MTC Application Fee. A MTC that will be colocated with a Marijuana Establishment shall pay the applicable fee set forth in 935 CMR 501.004: Fees.
  - (c) License Fees. A CMO must pay the respective registration fee(s) for operating an MTC, and the respective licensing fee(s) for operating a Marijuana Establishment.
- (5) The fees identified in 935 CMR 500.005 do not include the cost associated with preapproval of packaging in accordance with 500.105(7).

501.005: Fees

(5) For CMOs, an applicant must pay all of the following fees:

- (a) Marijuana Establishment Application Fee. A Marijuana Establishment that will be colocated with a MTC shall pay the respective application fee for each type of Marijuana Establishment set forth in 935 CMR 500.005: *Fees*.
- (b) MTC Application Fee. A MTC that will be colocated with a Marijuana Establishment shall pay the applicable fee set forth in 935 CMR 501.005: Fees.
- (c) License Fees. A CMO must pay the respective licensing fee(s) for operating an MTC, and the respective licensing fee(s) for operating a Marijuana Establishment.
- (6) The Fees identified in 935 CMR 501.005 do not include the cost associated with preapproval of packaging in accordance with 501.105(7).

#### **502.028:** Registration of Agents Affiliated with CMOs

#### 500.030: Registration of Marijuana Establishment Agents

(9) An agent working in CMOs may only perform tasks and duties permitted by the license under which they are registered and may only perform both medical- and adult-use tasks and duties if registered under both 935 CMR 500.000 and 501.000.

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

(10) An agent working in a CMO may only perform tasks and duties permitted by the license under which they are registered and may only perform both medical- and adult-use tasks and duties if registered under both 935 CMR 500.000 and 501.000.

#### **502.101: Application Requirements**:

#### 500.101

(4) CMO License Requirements. Marijuana Establishment applicants seeking to operate as an MTC must also comply with the application requirements in 935 CMR 501.000: *Medical Use of Marijuana*.

#### 501.101

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

#### 502.103: Licensure and Renewal

500.103: Licensure and Renewal

- (4) (i) Colocated Marijuana Retailers shall submit the following information pertaining to patient supply of marijuana:
  - 1. The licensee's policy and the procedures (e.g., data points, formulas) relied on to determine what constitutes a sufficient quantity and variety of marijuana products consistent with 935 CMR 500.140(9); and
  - 2. The licensee's policy and procedures for determining what qualifies as a reasonable substitution for a medical marijuana product under 935 CMR 500.140(9) and its policy for communicating reliance on the substitution to patients.

#### 501.103: Licensure and Renewal

- (4) (j) Colocated Marijuana Retailers shall submit the following information pertaining to patient supply of marijuana:
  - 1. The licensee's policy and the procedures (e.g., data points, formulas) relied on to determine what constitutes a sufficient quantity and variety of marijuana products consistent with 935 CMR 501.140(9); and
  - 2. The licensee's policy and procedures for determining what qualifies as a reasonable substitution for a medical marijuana product under 935 CMR 501.140(9) and its policy for communicating reliance on the substitution to patients.

#### **502.105(1): Written Operating Procedures**

#### 500.105(1)

Written Operating Procedures. Every Marijuana Establishment shall have and follow a set of detailed written operating procedures. If the requested by the Commission, written operating procedures must be submitted to the Commission in searchable, electronic form. If the Marijuana Establishment has an additional location, it shall develop and follow a set of such operating procedures for that facility. A CMO must have written operating procedures that comply with both 935 CMR 500.105(1): Written Operating Procedures and 935 CMR 501.105(1): Written Operating Procedures and may do so by having two sets of written operating procedures applicable to each medical-use and adult-use operations or having one set of written operating procedures, provided it complies with both medical-use and adult-use requirements. Operating procedures shall include, but need not be limited to the following:

501.105(1)

(1) <u>Written Operating Procedures</u>. Every MTC shall have and follow a set of detailed written operating procedures. If the requested by the Commission, written operating procedures must be submitted to the Commission in searchable, electronic form. If the MTC has an additional location, it shall develop and follow a set of such operating procedures for that facility. <u>A CMO</u>

must have written operating procedures that comply with both 935 CMR 501.105(1): Written Operating Procedures and 935 CMR 500.105(1): Written Operating Procedures and may do so by having two sets of written operating procedures applicable to each medical-use and adult-use operations or having one set of written operating procedures, provided it complies with both medical-use and adult-use requirements. Operating procedures shall include, but need not be limited to, the following:

#### **502.105(2): Agent Training.**

500.105(2)

(a)(6) An individual who is both a Marijuana Establishment Agent and MTC Agent at a CMO location must receive the training required for each license under which the agent is registered, including, without limitation, with respect to patient privacy and confidentiality requirements, which may result in instances that would require such an agent to participate in more than 8 hours of training.

501.105(2)

(a)(6) An individual who is both a Marijuana Establishment Agent and MTC Agent at a CMO location must receive the training required for each license under which the agent is registered, including, without limitation, with respect to patient privacy and confidentiality requirements, which may result in instances that would require such an agent to participate in more than 8 hours of training.

#### 502.105(3): Requirements for the Handling of Marijuana

500.105(3): Requirements for the Handling of Marijuana

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

501.105(3): Handling of Marijuana

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

#### 502.105(4) Marketing and Advertising Requirements

500.105(4): Marketing and Advertising Requirements

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

#### 501.105(4): Marketing and Advertising Requirements

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

#### 502.105(5): Labeling of Marijuana, MIPs, or Marijuana Products

#### 500.105(5) Labeling of Marijuana and Marijuana Products

(f) CMOs must comply with the labeling requirements in 935 CMR 500.105(5): *Labeling of Marijuana and Marijuana Products* for all adult-use sales and 935 CMR 501.105(5): *Labeling of Marijuana and Marijuana Products* for all medical-use sales.

#### 501.105(5): Labeling of Marijuana and Marijuana Products

(j) CMOs must comply with the labeling requirements in 935 CMR 500.105(5): *Labeling of Marijuana and Marijuana Products* for all adult-use sales and 935 CMR 501.105(5): *Labeling of Marijuana and Marijuana Products* for all medical-use sales.

#### 502.105(6): Packaging of Marijuana, MIPs, or Marijuana Products

#### 500.105(6): Packaging of Marijuana and Marijuana Products

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

#### 501.105(6): Packaging of Marijuana and Marijuana Products

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

#### 502.105(7): Packaging and Labelling Pre-approval

#### 500.105(7): Packaging and Labeling Pre-approval

Prior to a Marijuana Product being sold at a Marijuana Establishment, <u>a CMO</u>, a Licensee, or License applicant may submit an application, in a form and manner determined by the Commission, for packaging and label approval to the Commission. The Commission may charge a fee for packaging and labeling preapproval. The packaging and labeling preapproval process shall in no way substitute for compliance with 935 CMR 500.105(4) through (6).

#### 501.105(7): Packaging and Labeling Pre-approval

Prior to a Marijuana Product being sold at an MTC, <u>a CMO</u>, a Licensee, or License applicant may submit an application, in a form and manner determined by the Commission, for packaging and label approval to the Commission. The Commission may charge a fee for packaging and labeling pre-approval. The packaging and labeling preapproval process shall in no way substitute for compliance with 935 CMR 501.105(5) through (6).

#### 502.105(8) Inventory and Transfer

#### 500.105(8): Inventory

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

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

#### 501.105(8): Inventory and Transfer

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

#### 502.105(10): Liability Insurance Coverage or Maintenance of Escrow

500.105(10): Liability Insurance Coverage or Maintenance of Escrow

(e) A CMO shall maintain the insurance coverage or escrow account required under 500.105(10):

<u>Liability Insurance Coverage or Maintenance of Escrow or 501.105(10): Liability Insurance Coverage or Maintenance of Escrow per location.</u>

#### 501.105(10): Liability Insurance Coverage or Maintenance of Escrow

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

#### **501.105(13)** Transportation

#### 500.105(13): Transportation between Marijuana Establishments

(i) A CMO can transport adult-use and medical-use marijuana and Marijuana Products if it is appropriately registered and licensed to do so. Where a CMO is transporting both adult-use and medical-use marijuana, MIPs and marijuana products, the CMO must comply with the more restrictive security provisions.

#### 501.105(13): Transportation between Marijuana Establishments

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#### 502.140: Additional Operational Requirements for Retail Sales

#### 500.140: Additional Operational Requirements for Retail Sale

- (XXX) Physical Separation of Marijuana and MIPs or Marijuana Products for Medical or Adult Use. A CMO shall provide for physical separation between medical- and adult-use sales areas. Separation may be provided by a temporary or semi-permanent physical barrier, such as a stanchion, that, in the opinion of the Commission, adequately separates sales areas of MIPs for medical-use from sales areas of marijuana products for adult-use for the purpose of patient confidentiality.
  - (a) A CMO shall provide for separate lines for sales of marijuana or MIPs for medical-use from marijuana products for adult-use within the sales area, provided that the holder of a patient registration card may use either line and shall not be limited only to the medical-use line, so long as the CMO can record the patient's transaction in accordance with 935 CMR 501.105(5)(d).
  - (b) A CMO shall additionally provide a patient consultation area, an area that is separate from the sales floor that is enclosed to allow privacy and for confidential visual and auditory consultation with Qualifying Patients.
  - (c) A CMO's patient consultation area must have signage stating, "Consultation Area".

The private consultation area must be separate from the sales area. It must be accessible by a Qualifying Patient or caregiver without having to traverse a Limited Access Area.

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

#### (XXX) Patient Supply.

- (a) A CMO shall ensure access to a sufficient quantity and variety of marijuana products, including marijuana, for patients registered under 935 CMR 501.000: *Medical Use of Marijuana*.
  - 1. Where the CMO has been open and dispensing for a period of less than six months, the license shall reserve 35% of the MTC's marijuana products.
  - 2. Where the CMO has been open and dispensing for a period of six months or longer, the licensee shall maintain a quantity and variety of marijuana products for patients registered under 935 CMR 501.000: *Medical Use of Marijuana*, sufficient to meet the demand indicated by an analysis of sales data collected by the licensee during the preceding six months in accordance with 935 CMR 501.140(5) *Recording Sales* and 935 CMR 501.140(5): *Recording Sales*.
- (b) Marijuana products reserved for patient supply shall, unless unreasonably impracticable, reflect the actual types and strains of marijuana products documented during the previous six months. If a substitution must be made, the substitution shall reflect as closely as possible the type and strain no longer available.
- (c) On a quarterly biennial basis, the CMO shall submit to the Commission an inventory plan to reserve a sufficient quantity and variety of medical-use Marijuana Products for Registered Qualifying Patients, based on reasonably anticipated patient needs as documented by sales records over the preceding six months. On each occasion that the supply of any product within the reserved patient supply is exhausted and a reasonable substitution cannot be made, the CMO shall submit a report to the Commission in a form determined by the Commission.
- (d) Marijuana products reserved for patient supply shall be either maintained on-site at the retailer or easily accessible at another location operated by the licensee and transferable to the retailer location within 48 hours of notification that the on-site supply has been exhausted. CMOs shall perform audits of available patient supply on a weekly basis and retain those records for a period of six months.
- (e) The Commission shall, consistent with 935 CMR 500.301: Inspections and Compliance or 501.301: Inspections and Compliance, inspect and audit CMOs to ensure compliance with 935 CMR 500.140. The Commission may, in addition to the issuance of a deficiency statement under 935 CMR 500.310: Deficiency Statements or 501.310: Deficiency Statements and a plan of correction under 935 CMR 500.320: Plans of Correction or 935 CMR 501.320: Plans of Correction, demand that the CMO take immediate steps to replenish its reserved patient supply to reflect the amounts required under 935 CMR 500.140(9)(a) or 935 CMR 501.140(9)(a). Failure to adequately address a deficiency statement or follow a plan of correction shall result in administrative action by the Commission pursuant to 935 CMR 500.450: Marijuana Establishment License: Grounds for Denial of Renewal Applications, Suspension and Revocation and 935 CMR 500.500: Hearings and Appeals of Actions on Licenses or 935 CMR 501.450: Marijuana Establishment License: Grounds for Denial of Renewal Applications, Suspension and

Revocation and 935 CMR 501.500: Hearings and Appeals of Actions on Licenses.

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

#### 501.140: Additional Operational Requirements for Patient Sales

- (XXX) Physical Separation of Marijuana and MIPs or Marijuana Products for Medical or Adult Use. A CMO shall provide for physical separation between medical- and adult-use sales areas. Separation may be provided by a temporary or semi-permanent physical barrier, such as a stanchion, that, in the opinion of the Commission, adequately separates sales areas of MIPs for medical-use from sales areas of marijuana products for adult-use for the purpose of patient confidentiality.
  - (a) A CMO shall provide for separate lines for sales of marijuana or MIPs for medical-use from marijuana products for adult-use within the sales area, provided that the holder of a patient registration card may use either line and shall not be limited only to the medical-use line, so long as the CMO can record the patient's transaction in accordance with 935 CMR 501.105(5)(d).
  - (b) A CMO shall additionally provide a patient consultation area, an area that is separate from the sales floor that is enclosed to allow privacy and for confidential visual and auditory consultation with Qualifying Patients.
  - (c) A CMO's patient consultation area must have signage stating, "Consultation Area". The private consultation area must be separate from the sales area. It must be accessible by a Qualifying Patient or caregiver without having to traverse a Limited Access Area.
  - (d) A CMO shall use best efforts to prioritize patient and caregiver identification verification and physical entry into its retail area.

#### (XXX) Patient Supply.

- (a) A CMO shall ensure access to a sufficient quantity and variety of marijuana products, including marijuana, for patients registered under 935 CMR 501.000: *Medical Use of Marijuana*.
  - 1. Where the CMO has been open and dispensing for a period of less than six months, the license shall reserve 35% of the MTC's marijuana products.
  - 2. Where the CMO has been open and dispensing for a period of six months or longer, the licensee shall maintain a quantity and variety of marijuana products for patients registered under 935 CMR 501.000: *Medical Use of Marijuana*, sufficient to meet the demand indicated by an analysis of sales data collected by the licensee during the preceding six months in accordance with 935 CMR 501.140(5) *Recording Sales* and 935 CMR 501.140(5): *Recording Sales*.
- (b) Marijuana products reserved for patient supply shall, unless unreasonably impracticable, reflect the actual types and strains of marijuana products documented during the previous six months. If a substitution must be made, the substitution shall reflect as closely as possible the type and strain no longer available.
- (c) On a quarterly basis, the CMO shall submit to the Commission an inventory plan to reserve a sufficient quantity and variety of medical-use products for registered patients,

- based on reasonably anticipated patient needs as documented by sales records over the preceding six months. On each occasion that the supply of any product within the reserved patient supply is exhausted and a reasonable substitution cannot be made, the CMO shall submit a report to the Commission in a form determined by the Commission.
- (d) Marijuana products reserved for patient supply shall be either maintained on-site at the retailer or easily accessible at another location operated by the licensee and transferable to the retailer location within 48 hours of notification that the on-site supply has been exhausted. CMOs shall perform audits of available patient supply on a weekly basis and retain those records for a period of six months.
- (e) The Commission shall, consistent with 935 CMR 500.301: Inspections and Compliance or 501.301: Inspections and Compliance, inspect and audit CMOs to ensure compliance with 935 CMR 500.140. The Commission may, in addition to the issuance of a deficiency statement under 935 CMR 500.310: Deficiency Statements or 501.310: Deficiency Statements and a plan of correction under 935 CMR 500.320: Plans of Correction or 935 CMR 501.320: Plans of Correction, demand that the CMO take immediate steps to replenish its reserved patient supply to reflect the amounts required under 935 CMR 500.140(9)(a) or 935 CMR 501.140(9)(a). Failure to adequately address a deficiency statement or follow a plan of correction shall result in administrative action by the Commission pursuant to 935 CMR 500.450: Marijuana Establishment License: Grounds for Denial of Renewal Applications, Suspension and Revocation and 935 CMR 500.500: Hearings and Appeals of Actions on Licenses or 935 CMR 501.450: Marijuana Establishment License: Grounds for Denial of Renewal Applications, Suspension and Revocation and 935 CMR 501.500: Hearings and Appeals of Actions on Licenses.
- (f) CMOs may transfer marijuana products reserved for medical-use to adult-use within a reasonable period of time prior to the date of expiration provided that the product does not pose a risk to health or safety.





# Cannabis Control Commission

Draft Regulations

July 20, 2020 at 10:00 a.m. via Microsoft Teams Live





# Agenda

- 1. Call to Order
- 2. Chairman's Comments and Updates
- 3. Commission Discussion and Votes on Draft Regulations
- 4. Next Meeting
- 5. Adjournment





# Public Comments

- Please send all public comments on draft regulations to <u>Commission@CCCMass.com</u>
- Public comment period closes at 5pm on August 14, 2020







# Regulatory Calendar

# **July 20**

- Vote on proposed Regulations
- Public comment period opens

### August 3

 Public Hearing on proposed regulations

## August 6

 Regularly scheduled monthly Commission meeting

## August 14

• Public comment period closes

# **September 10**

 Regularly scheduled monthly Commission meeting

## **September 24**

 Public meeting for vote on final regulations