



Public Meeting Packet- June Regulatory Policy Discussion

June 19, 2020

Microsoft Teams Live

Please note that the list of policy topics for discussion at this public meeting is not an exhaustive list of the changes that will be proposed to the regulations.

Meeting Book - Public Meeting Packet- June Regulatory Policy Discussion

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June 17, 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

**June 19, 2020
10:00AM**

Remote Participation via [Microsoft Teams Live](#)*

PUBLIC MEETING AGENDA

- 1) Call to Order
- 2) Chairman's Comments and Updates
- 3) Staff Recommendations on Provisional Licenses
 - a. Hidden Hemlock, LLC (#MBN281355), Microbusiness
- 4) Regulatory Policy Discussion**
- 5) Next Meeting Date
- 6) Adjournment

*Closed captions available

**Please note that the policy topics discussed at this meeting are not an exhaustive list of proposed changes to the regulations.



HIDDEN HEMLOCK, LLC
MBN281355

BACKGROUND & APPLICATION OF INTENT REVIEW

1. Name and address of the proposed Marijuana Establishment:

Hidden Hemlock, LLC
370 Wareham Street, Middleborough, MA 02346

2. Type of license sought (if cultivation, its tier level and outside/inside operation) and information regarding the application submission:

Microbusiness (Cultivation and Product Manufacturing Operations)

The application was reopened two (2) times for additional information.

3. The applicant is a licensee or applicant for other Marijuana Establishment and/or Medical Marijuana Treatment Center license(s):

The applicant is not an applicant or licensee for any other license type.

4. List of all required individuals and their business roles in the Marijuana Establishment:

Individual	Role
Gregory Bellino	Owner / Partner
Jeffrey Bellino	Owner / Partner
Michael Bellino	Owner / Partner
Brett Esber	Owner / Partner

5. List of all required entities and their roles in the Marijuana Establishment:

No other entity appears to have ownership or control over this proposed Marijuana Establishment.

6. Applicant's priority status:

Expedited Applicant (License Type)

Provisional License Executive Summary 1



7. The applicant and municipality executed a Host Community Agreement on February 8, 2019.
8. The applicant conducted a community outreach meeting on October 25, 2018 and provided documentation demonstrating compliance with Commission regulations.
9. The Commission received a municipal response from the municipality on April 1, 2020 stating the applicant was in compliance with all local ordinances or bylaws.
10. The applicant proposed the following goals for its Positive Impact Plan:

#	Goal
1	Recruit 20% of its staff who are Massachusetts residents who reside in Taunton, Wareham, Brockton, Mansfield, New Bedford, Randolph, Braintree and Fall River; Massachusetts residents who have past drug-convictions; and Massachusetts residents with parents or spouses who have past drug-convictions.
2	Organize an annual river cleanup in Taunton, Wareham, Brockton, Mansfield, New Bedford, Randolph, Braintree and Fall River to improve the health of local waterways while educating participants of the importance of a clean environment and proper waste management.
3	Utilize contractors based out of areas of disproportionate impact.

SUITABILITY REVIEW

11. There were no disclosures of any past civil or criminal actions, occupational license issues, or marijuana-related business interests in other jurisdictions.
12. There were no concerns arising from background checks on the individuals or entities associated with the application.

MANAGEMENT AND OPERATIONS REVIEW

13. The applicant states that it can be operational within five (5) months of receiving the provisional license(s).
14. The applicant's proposed hours of operation are the following:

Monday – Saturday: 7:00 a.m. – 5:00 p.m.
 Sunday: 9:00 a.m. – 1:00 p.m.



15. The applicant submitted all applicable and required summaries of plans, policies, and procedures for the operation of the proposed establishment. The summaries were determined to be substantially compliant with the Commission's regulations.

16. The applicant proposed the following goals for its Diversity Plan:

#	Goal
1	Recruit at least 10% of its staff who are minorities, women, veterans, people with disabilities, and people of all gender identities and sexual orientations (LGBTQ).
2	Secure one or more single purchase orders or wholesale supply agreements with licensed marijuana establishments within the Social Equity Program.

17. Summary of cultivation plan (if applicable):

The applicant submitted a cultivation plan that demonstrates the ability to comply with the Commission's regulations.

18. Summary of products to be produced and/or sold (if applicable):

#	Product
1	Flower
2	Bubble Hash
3	Rosin
4	Pre-roll Joints
5	Infused Joints with Hash and/or Rosin

19. Plan for obtaining marijuana or marijuana products (if applicable):

Not applicable.

RECOMMENDATION

Commission staff recommend provisional licensure with the following conditions:

1. Final license is subject to inspection to ascertain compliance with Commission regulations;
2. Final license is subject to inspection to ascertain compliance with applicable state laws and local codes, ordinances, and bylaws;
3. The applicant shall cooperate with and provide information to Commission staff;
4. Provisional licensure is subject to the payment of the appropriate license fee; and
5. Final licensure is subject to the applicant ensuring that all remaining required individuals be fingerprinted pursuant to previous Commission notifications.



The applicant has demonstrated compliance with the laws and regulations of the Commonwealth and suitability for licensure. Therefore, the applicant is recommended for provisional licensure.



TOPICS* FOR POLICY DISCUSSION AT THE JUNE 19, 2020 MEETING

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*Please note that the list of topics for discussion at this meeting is not an exhaustive list of the proposed regulatory changes.

Slides & Meeting Packet Material

Slide 1



Cannabis Control Commission

Cannabis Control Commission Regulatory Policy Discussion

June 19, 2020 at 10:00 a.m. via Microsoft Teams Live

Meeting materials available at masscannabiscontrol.com/documents

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Slide 2



Agenda

1. Call to Order
2. Chairman's Comments and Updates
3. Staff Recommendation on Provisional Licensure
4. Regulatory Policy Discussion
5. Next Meeting
6. Adjournment

Meeting materials available at masscannabiscontrol.com/documents

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Slide 3




Staff Recommendation on Provisional Licensure

Meeting materials available at masscannabiscontrol.com/documents


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Slide 4



Staff Recommendation on Provisional Licensure


- Hidden Hemlock, LLC. (#MBN281355), Microbusiness



Meeting materials available at masscannabiscontrol.com/documents

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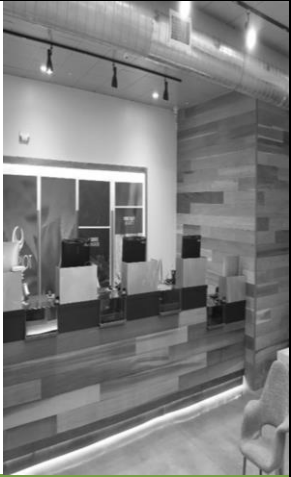
Slide 5



Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Topics


1. Leadership ratings
2. Receivership and change of control
3. Ownership and control
4. Expanding SEP to other categories
5. Social Equity Program for EEAs
6. ME/MTC Agent Registration
7. Research licenses
8. Delivery
9. Additional Retail Operations - Contactless Retail Operations



Meeting materials available at masscannabiscontrol.com/documents

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Slide 6



Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

Topics

10. Vaping Regulations
11. Testing
12. Economic Empowerment Applicants
13. SEP - Equity Ownership Threshold for Social Equity Program Participants to Receive License Benefits
14. Buffer zone
15. Giving commission authority to expand delivery endorsements to other groups
16. Verified Financial Hardship Documentation
17. Personnel Policy - Require Code of Ethics and Whistleblower Policy



Meeting materials available at masscannabiscontrol.com/documents

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The image shows the exterior of the Massachusetts State House, a large, ornate building with two prominent towers and a central dome. The building is made of light-colored stone or concrete. The sky is overcast. In the top left corner, there is a logo for the Cannabis Control Commission, which consists of a stylized green 'C' followed by the text 'Cannabis Control Commission' and 'MASSACHUSETTS' below it.

Regulatory Policy Discussion

Meeting materials available at masscannabiscontrol.com/documents

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1. LEADERSHIP RATINGS – *Temperature check*

[PowerPoint: Slides 8-9]

Leadership Ratings

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

Recommendations:

1. **Social Justice Leadership award** - clarify existing criterion for a Social Justice Leadership Award that contribution to the Social Equity Training and Technical Assistance Fund can be prospective, upon establishment of the fund (or a similar fund) by the Legislature.
2. **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. **Compliance Leader Rating** - change criterion 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.
4. **Local Employment Leader** – add criterion for rating include supporting other local businesses.
5. The writing group was asked to consider the employment of veterans as a criterion, by adding a new category or integrating it into the employment leader award. The group recommends no change, because it feels this would result in a complex debate among Commissioners and external stakeholders with respect to the host of various categories that could/should be included for the employment leader award.
6. Adopt the Leadership Rating Program in the medical-use of marijuana regulations (Social Justice Leader; Local Employment Leader; Energy and Environmental Leader; Compliance Leader) and add new Leader type, “MTC Leader.”

[Meeting Packet Material] Same as slide.

2. RECEIVERSHIP AND CHANGE OF CONTROL - *Temperature check*

[PowerPoint: Slide 10]

Receivership and Change of Control

Recommendation: To establish a process for the Commission to have notice and oversight over Marijuana Establishments (MEs) and Medical Marijuana Treatment Centers (MTCs) placed under the control of a receiver by a Massachusetts court or otherwise designated.

Rationale: MEs and MTCs may be put into receivership in a variety of circumstances including, without limitation, insolvency or malfeasance by Executives (as defined in the regulation). Given the activities of MEs and MTCs are illegal under federal law, MEs and MTCs cannot avail themselves of bankruptcy proceedings, and thus would have to rely on state law receivership. The following option would create a process for the Commission to have notice and oversight over a receiver, since it could implicate issues of control.

[Meeting Packet Material]

Receivership and Change of Control

Explanation: The benefit of this approach is that the Commission has oversight over a receiver. Potential drawbacks may be that this process could slow the appointment of a receiver when receivership is often something that necessitates expediency.

The recommendation to add a new section specific to receivership is largely based on the same provisions as the State of Washington (though Group 1 also looked to Oregon as an example) and creates a notice requirement and processes by which receivers may be (pre)approved by the Commission. The language also establishes that receivers must still satisfy the requirements of the Commission's regulations and limitations on control of licenses. The benefits of this approach are that it creates a process by which receivers can be pre-approved, and therefore allow for the expediency often required under the circumstances necessitating a receivership. The drawback is that it creates a new process/set of approvals for the Commission to manage. While this approach requires an entire section to be included in the regulations the change will be necessary as this industry develops and potential issues arise.

An alternative approach would be to simply update the definition and require a licensee to file an application for Change in Control upon the appointment of a receiver and the receiver would be required to register as an Agent in the ordinary course. Under this approach, a potential receiver would be still be required to register as an Agent and abide by all the rules of a Person/Entity with Direct Control. The drawback is that the Change of Control application process may not move at the pace required in the circumstances that necessitate receivership.

3. OWNERSHIP AND CONTROL – *Temperature check*

[PowerPoint: Slides 11-12]

Ownership and Control

Recommendation:

1. Update the definition of Control and Ownership to specify that a “significant” contract is one that exceeds \$10,000
2. With respect to requiring Executives of Entities Having Direct Control over an ME to register as Agents, the recommendation is to make no change at this time.
3. To delegate authority to the Executive Director the ability to review and approve certain changes in information under 935 CMR 500.104. The options for this recommendation are:
 - a. State in the regulations that the Commission may delegate this authority to the Executive Director (which would be subject to subsequent votes of the Commission to make specific delegations); or
 - b. State in the regulations that the Commission is delegating the following approvals to the Executive Director: (i) changes to location (ii) any new equity owner, provided that the equity acquired is below 10%; (iii) any new Executive or Director, provided that the equity acquired is below 10%; (iv) a reorganization, provided that the ownership and their equity does not change; and (v) Receiverships

Rationale:

1. The definition change would give greater clarity over what a “significant” contract means.
2. The group felt that making a change to the requirements regarding Direct/Indirect Control within a year of the most recent changes could create confusion and difficulty around compliance. Requiring Executives of an Entity Having Direct Control over an ME to register as Agents may be easier to implement once the Commission’s screening/background check process allows for individuals to be screened out of state.
3. The delegation of authority would allow for expediency on (i) changes to location (ii) any new equity owner, provided that the equity acquired is below 10%; (iii) any new Executive or Director, provided that the equity acquired is below 10%; (iv) a reorganization, provided that the ownership and their equity does not change; and (v) Receiverships.

[Meeting Packet Material] Same as slide.

4. EXPANDING SOCIAL EQUITY PROGRAM TO OTHER CATEGORIES – *Temperature check*

[PowerPoint: Slides 13-14]

Expanding SEP to Other Categories

935 CMR 500.105(17): General Operational Requirements for Marijuana Establishments – Social Equity Program

Issue: Whether to expand SEP participation to include other categories, such as veterans.

Options:

- A. No change.
- B. Amend 935 CMR 500.105(17) to specifically include veterans as a group eligible to participate in the SEP program.
- C. Amend 935 CMR 500.105(17) to state that the Commission may, by vote, expand the categories of people eligible to participate in the SEP.

Pros/Cons:

Option A: Keeps the program focused on people disproportionately impacted by Marijuana prohibition but does not reach other groups that could benefit from the program.

Option B: Allows veterans, a group still being harmed by federal prohibition, to get into the industry and benefit from the program, but would require a change in regulations to allow other groups to be eligible to participate in the SEP.

Option C: Gives the commission flexibility to react to new data (such as the upcoming Disproportionate Impact Study) and allow new eligible categories of people to participate in the SEP without an amendment to the regulations.

Recommendation: Option C.

[Meeting Packet Material] Same as slide.

5. SOCIAL EQUITY PROGRAM FOR EEAs – *Temperature check*

[PowerPoint: Slide 15]

Social Equity Program Participants

935 CMR 500.105(17): General Operational Requirements for Marijuana Establishments – Social Equity Program

Recommendation: Expand eligibility to participate in the Social Equity Program to individual listed as an owner on the original certification of an Economic Empowerment Priority Applicant, who satisfy one of the following criteria to be eligible for the Social Equity Program:

1. Lived for five of the preceding ten years in an Area of Disproportionate Impact, as determined by the Commission
2. 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;
3. Black, African American, Hispanic or Latino descent; or
4. Other significant articulable demonstration of past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact.

Rationale: Data and feedback collected by the Commission demonstrate that Economic Empowerment Applicants need additional tools and resources, including technical assistance, in order to utilize their priority review status.

[Meeting Packet Material]

For context here is the Definition of Economic Empowerment Applicant: 935 CMR 500.002

Economic Empowerment Priority Applicant means an applicant who demonstrated and continues to demonstrate three or more of the following criteria:

- [1] 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;
- [2] 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;
- [3] 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%;
- [4] at least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises;
- [5] a majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent; and
- [6] 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.

6. ME/MTC Agent Registration – Temperature check

[PowerPoint: Slides 16-17]

ME/MTC Agent Registration

500.005: Fees

935 CMR 500.030: Registration of Marijuana Establishment Agents

935 CMR 501.030: Registration of Medical Marijuana Treatment Center Agents

Recommendation:

1. 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.
5. 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.

Rationale:

Recommendations 1 & 2:

- It puts the financial and administrative burden on the employer to register the Agent and pay the associated fees – a favorable arrangement from the social equity perspective. Given that Diversity/Positive Impact Plans often include hiring staff from socio-economically diverse communities, passing the cost onto the employees could, in part, serve to defeat the purpose of these initiatives.
- The Agent’s registration is linked to the license rather than to the individual Agent, making Licensees more likely to take seriously the responsibility of ensuring and monitoring employee compliance and reporting issues related to Agent conduct, such as diversion, to the Commission.

Recommendation 3: Helps cover the cost of the badges.

Recommendation 4: 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.

Recommendation 5: Amendment to the medical-use regulations make cross-referencing the regulations easier for the Commission and the public, and brings more consistency to the registration process for ME and MTC Agents.

Agent Registration Process

The current agent registration process places the responsibility on the licensee to register its employees, i.e. Agents, including paying a registration fee with the Commission. This means if an Agent works at more than one facility, even if it is owned by the same company, the Agent must be registered at each facility. In considering ways streamline the registration process, the writing group looked at a ‘free agent model,’ under which the registration runs with the Agent instead of the licensee. Instead of their employer/licensee, the Agent would be responsible for registering themselves, and paying for the background check and registration fees.

After weighing the pros and cons of the free agent model, the group recommends keeping the current agent registration model, with some changes, because:

- It puts the financial and administrative burden on the employer to register the Agent and pay the associated fees – a favorable arrangement from the social equity perspective. Given that Diversity/Positive Impact Plans often include hiring staff from socio-economically diverse communities, passing the cost onto the employees could, in part, serve to defeat the purpose of these initiatives.
- The Agent’s registration is linked to the license rather than to the individual Agent, making Licensees more likely to take seriously the responsibility of ensuring and monitoring employee compliance and reporting issues related to Agent conduct, such as diversion, to the Commission.

As a change to the current process, the group recommends that the first renewal for an Agent occur after 12 months, and subsequent registration renewals occur every 3 years instead of every year. Stated differently, the first registration is effective for 12 months, and could be seen as a ‘probationary period’ by employers; at renewal and all other following renewals, the registration is effective for 3 years. A benefit to this change would be that Agents may be viewed less as ‘disposable’ because their registrations are effective longer, and in turn, employers may invest more training and resources to support the employees’ growth in the company.

Note: General Counsel raises a concern about the frequency of background checks under this proposal, and recommends that the Commission consider imposing on the sponsor ME/MTC the requirement that they conduct a background check according to industry standard (rather than on the 3-year renewal cycle) and report any adverse findings, and a requirement that they produce this report on request by enforcement and compliance officers.

The writing group notes for the Commission’s consideration that the change to the renewal requirement from 1 year to every 3 years may impact revenue sources.

Proposed Changes to Cards

Commission staff and external groups (IT, CFO, and vendor JD Software) are looking into the possibility of a solution to address the issue of Agents having to carry multiple cards for each license with which they are registered. Under this solution, an Agent would carry one card and the card would feature some kind of unique identifier, such as a QR code or a bar code, that would correspond with the Agent’s full registration details when cross referenced in the database.

Because discussions are still in the preliminary stages, the writing group recommends making no change to the regulations on this issue until the technical solution is more developed or implemented, and the financial implications of such a solution is evaluated.

Changes to the Medical-use Regulations

The writing group made some changes to 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. These changes make cross-referencing the regulations easier for the Commission and the public, and brings more consistency to the registration process for ME and MTC Agents.

Proposed Regulatory Amendment:

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 \$1 ~~1500~~ 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 \$1 ~~1500~~.

[...]

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 a ~~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 validated that is 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;

~~(c)~~(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 another 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 another Jurisdiction, relating to any professional or occupational or fraudulent practices;

3. a description and relevant dates of any past or pending denial, suspension, or revocation of a license or registration, or the denial of a renewal of a license or registration, for any type of business or profession, by any federal, state, or local government, or any foreign jurisdiction;

4. a description and relevant dates of any past discipline by, or a pending disciplinary action or unresolved complaint by, the Commonwealth, or another Jurisdiction, with regard to any professional license or registration held by the applicant; and

~~(e)~~(g) An attestation that the individual will not engage in the diversion of marijuana or marijuana products;

~~(f)~~(h) A nonrefundable application fee paid by the MTC with which the MTC Agent will be associated; and

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

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

~~(7)~~ After obtaining a Registration Card for an MTC agent, an MTC is responsible for notifying the Commission, in a form and manner determined by the Commission, as soon as possible, but in any event, within five business days 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.

~~(8)~~ 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 is 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.~~

7. RESEARCH LICENSES – *Temperature check*

[PowerPoint: Slide 18]

Research Licenses

Recommendation: Establish the process for:

1. receiving a Research Facility License and Research Permit to engage in specific research projects;
2. information required for a Research Permit application;
3. allowed activities;
4. the Commission approval process and Commission authority to audit.

Licensees may be academic institutions and non-profit institutions, including hospitals, as well as businesses including Marijuana Establishments. The key component of allowing research to proceed by granting a Research Permit is reliance on an Institutional Review Board (“IRB”), which is required for every research project. The regulations anticipate plant-based research, as well as animal and human research. There is a built-in presumption that the Commission as an agency may choose to take a phased in approach to allowing particular types of research to proceed.

Note: The writing group reviewed regulations from CO and CT and members had calls with senior staff from both jurisdictions to discuss their models. The group took those models into consideration when contemplating our Massachusetts regulations and borrowed aspects of both regulatory structures when drafting the regulations.

[Meeting Packet Material] Research Licenses

[Cross-walk of CO and CT regs w/ MA considerations as determined by our writing group.]

	Colorado	Connecticut	MA Considerations
License type	Marijuana Research and Development Facility	Research Program License (under medical marijuana statutes/regs)	Marijuana Research Facility (already authorized under 935 CMR 500.050(11)) NEW: Research permit needed for each unique research project.
What are the licensed premises?	Multiple types: Solo; shared location with medical marijuana testing facility; or be co-located with licensed medical product manufacturer or cultivation facility or licensed retail product manufacturer or cultivation facility. All co-located facilities must be commonly owned. R&D operations must be physically separated from other co-located facility operations	Multiple types: Licensed healthcare institute licensed by state; licensed institute of higher education licensed by state; licensed medical marijuana dispensary; licensed medical marijuana producer (cultivation, PM)	Academic institution (university); nonprofit corporation (hospital); or domestic corporation or entity authorized to do business in the Commonwealth (already authorized). NEW: Research facilities co-located with an existing Marijuana Establishment may be allowed, but must be physically separated. Co-located facilities must be commonly owned.
Do licensees need to couple with an institute of higher education or other previously accredited, non-marijuana business research institution (i.e., hospital)?	R&D facility licensee is not required to partner with a higher ed institution, but they may partner with a public higher education institution, or another R&D facility licensee. All contracts or agreements with a public higher ed institutions or other R&D facilities must be disclosed.	No, but a medical doctor or NP is needed to certify patients if researchers want to move forward with research.	NEW: Higher ed institutions and nonprofits need to source from an existing licensee. Existing licensees do not need to partner but may partner with each other to obtain a license and/or acquire product.

	Colorado	Connecticut	MA Considerations
	<p>All employees of a higher ed institution involved in the research project must be registered as an R&D employee.</p> <p>If there is an agreement between an R&D facility and public higher ed institution to conduct research, all activities that involve marijuana possession must occur at the R&D facility and may not occur at the institute of higher education. (CO ADC 212-3; 5-715)</p>		
Must employees be registered/licensed?	Yes.	Yes and subject to suitability check. (see CT Sec. 21a-408-24). Employees apply after research program approved	Yes, including researchers otherwise affiliated with an institute of higher education or nonprofit/hospital-- anyone working at a research facility must be a registered agent, subject to background check. This is already included in our regs.
What are the sources of marijuana?	<p>Medical marijuana PM or cultivation facility may transfer medical marijuana to Marijuana Research and Development Facility; and/or</p> <p>Marijuana Research and Development Facility may cultivate; and/or</p>	Licensed dispensaries	<p>NEW: Licensed MTC, Retailer, Product Manufacturer, Cultivator, Microbusiness or Craft Marijuana Cooperatives</p> <p>NEW: For non-Marijuana Establishment Research Licensees wishing to perform plant research, institution conducting research must partner with a Cultivation Licensee to</p>

	Colorado	Connecticut	MA Considerations
	<p>Marijuana Research and Development Facility may produce marijuana products</p> <p>R&D facility authorized to transfer marijuana cultivated under its licenses to another R&D licensee may not have more than 500 medical marijuana plants or 20 pounds of medical marijuana.</p>		<p>grow the marijuana on behalf of the institution.</p> <p>NEW: Limits on amount sourced as determined by research program projected needs.</p>
What are the controls for tracking marijuana? Seed-to-sale? Inventory?	Required to be able to differentiate R&D marijuana from co-located operations' marijuana	Not clear	Seed-to-sale required by statute (94G, s.4 (a ½)(xvii))
Is testing of marijuana used by R&D facility required?	No. Marijuana cultivated by an R&D facility licensee does not need to be tested, but it does need to be disclosed to participants that it has not been tested.		NEW: Yes.
What activities are allowed at licensee premises?	<p>Consumption of marijuana is not allowed unless consumption is part of an approved research project and the premises is not shared by another licensed marijuana business.</p> <p>Transfers of marijuana are restricted to transfers for testing to a testing facility; research participants; or to another R&D facility.</p> <p>All activities of an R&D facility must be in furtherance of an approved research project</p>	Not consumption. In example of Yale, participants did not consume at Yale facility. Participants were sent to the dispensary Yale partnered with, they self-ingested and then blood work was done at Yale.	NEW: Consumption of marijuana at a licensed Research Program Facility may be authorized if it is in furtherance to an approved research project and if the licensed facility is not co-located with another Marijuana Establishment.

	Colorado	Connecticut	MA Considerations
Does the regulatory body affirmatively approve research projects?	Yes. CO MED also approves quantity of marijuana/marijuana products to be used.	Leans heavily on IRB and takes light touch to approving specific projects as long as reasonably have merit	<p>NEW: CCC would license research facilities and approve research projects by granting a permit based on submission of required information. IRB's required for any human- or animal-based research. IRB would need to approve a project in order for applicant to receive a Research Permit for a specific project. We'd differentiate "institutional IRB's" with more familiarity with research approval processes and oversight from private IRBs and give discretion to Commission delegee to require additional information.</p> <p><u>Note:</u> Colorado currently only has 1 applicant for an R&D license and it is still very early in the process. No protocols have been submitted by applicant and MED hasn't developed its review process yet.</p>
What types of research may be performed?	Specifically spelled out: chemical potency and composition; clinical investigations of marijuana-derived products; efficacy and safety of marijuana administration as part of medical treatments; genomic research; horticultural research; agricultural research; pesticides research (CO ADC 212-3; 5-720)	The Department may approve a program that is intended to increase knowledge or information regarding the growth, processing, medical attributes, dosage forms, administration or use of marijuana to treat or alleviate symptoms of any medical conditions or the effects of such symptoms.	<p>NEW: Spell out types of research authorized similar to CO, not overly specific ("Including but not limited to...") but require a detailed explanation of the research in application submission.</p> <p>NEW: Make clear that this research license does not take the place of the</p>

	Colorado	Connecticut	MA Considerations
		Purely observational research (no administration) need not be licensed.	<p>drug approval process operated under the FDA.</p> <p>NEW : Any research involving human subject must have at least one licensed medical doctor in good standing registered as an agent under the licensee for the duration of the project; any research involving animal research must have at least one veterinary doctor registered as an agent under the license for the duration of the project.</p>
What must be submitted for consideration of a research project?	Description of the research project's defined protocol, clearly articulated goal(s); defined methods and outputs, and defined start and end date. The proposal must include the quantity of marijuana or marijuana products reasonably believed to be needed for project. Quantity subject to approval by CO MED.	<p>Submit:</p> <ol style="list-style-type: none"> 1. Research institution 2. Lead investigators name(s) and sub-investigators; 3. Publication-ready summary of research project; 4. Detailed research protocol 5. Lab intended to use if any 6. Informed consent form intended to use if any 7. Study duration 8. Max number of participants 9. IRB members 10. CV for lead researcher 11. Drug disposal protocol 12. Application fee 	<p>Submission of application for licensure as a Research Program Facility and application for a project Research Permit should be separate applications.</p> <p>NEW: Need to collect:</p> <ol style="list-style-type: none"> 1. Research institution 2. Lead investigators name(s) and sub-investigators; 3. Publication-ready summary of research project; 4. Detailed research protocol; 5. Safety protocols; 6. Articulated goals of project; 7. Start and end dates; 8. Quantity of marijuana anticipated to need; 9. Testing lab where marijuana will be tested;

	Colorado	Connecticut	MA Considerations
			10. Informed consent form or waiver of consent (if applicable); 11. Study duration; 12. Max number of participants 13. IRB members 14. CV for lead researcher 15. Marijuana disposal protocol 16. Application fee NEW: Disclosure whether Registered Patients are participants at Permit application phase (but no collection of specific information for permit purposes).
What is the research project approval process?	<p>If “private” research, review independent reviewer qualifications and assertions about proposed research.</p> <p>If the research is “private” research (not affiliated with a public institution) an independent review is required to be conducted by independent reviewers. The R&D facility licensee nominates one or more reviewers to perform oversight of the research and the CO MED has authority to accept or reject reviewers. As part of the application for research project, the independent reviewer(s) must submit required information disclosing ties, compensation, qualifications as well as an</p>	<p>Look at study design; total enrollment; who the players are; how participants are getting the marijuana</p> <p>Research project participants need to be registered but different registration than patient registration—they are registered separately.</p>	<p>NEW: At provisional licensure stage:</p> <ol style="list-style-type: none"> 1. Is it one of the research areas we allow? 2. Are the safety protocols sufficient? 3. Are the ethical considerations sufficient? 4. Is the design reasonable? <p>At final licensure:</p> <ol style="list-style-type: none"> 1. Has the IRB approved it? <p><u>Note:</u>Colorado as a statutorily authorized Scientific Advisory Council intended to work with MED to help review public institution research proposals.</p>

	Colorado	Connecticut	MA Considerations
	<p>assessment of the merits of the research being proposed. (CO ADC 212-3; 5-715)</p> <p>If it's a public institution, the Scientific Advisory Board performs review of proposal.</p> <p>Practically speaking, CO treats it like a grant proposal review; they look at the abstract; how much marijuana will be used and how; safety protocols; what is the background and lit review.</p>		CT has had 3 research projects, 2 currently on-going; one complete at Trinity Health re: pain treatment.
On what basis may research projects be denied?	<ol style="list-style-type: none"> 1. Research poses danger to public health or safety; 2. Project lacks scientific value or validity; 3. Applicant is not qualified to do the research; 4. The applicant's protocols or resources are insufficient to perform the research; 5. The applicant lacks the resources, personnel, facilities, expertise, funding, animals, humans or other requirements to be successful 	If no scientific merit; no IRB; but state takes very light touch.	NEW: Similar to CO
Is an Institutional Review Board (IRB) required?	Yes, for any research involving human subjects and IRB must be registered and in good standing with the Office for Human Research	Yes. An Institutional Review Board ("IRB"), for purposes of the State's medical marijuana program, means a "specifically constituted review body established or designated by an	<p>NEW: Yes, for human- and animal-based research projects..</p> <p>NEW: Disclosure of IRB in application materials. Certification</p>

	Colorado	Connecticut	MA Considerations
	Protections, U.S. Dept. of Health and Human Services	organization to protect the rights and welfare of persons recruited to participate in biomedical, behavioral or social science research.” In assessing whether a research program meets the requirement of having IRB oversight, DCP will be guided by the role that IRBs play in federal research programs as set out in 45 CFR 46. An IRB, however, need not be registered with HHS for DCP approval of a research program.	by IRB that research project approved prior to Permit being granted.
Is the licensee required to report to the regulatory agency during the course of the research? At the conclusion?	Yes. Periodic reports are required. Reports must include any changes in protocols, enrollment numbers and any adverse events for studies involving humans. Final reports of research findings are required. (CO ADC 212-3; 5-720)	Not during, but at conclusion. They are pretty strict about end date; researchers need to apply for extensions.	NEW: Incremental reports required; end report required.
Are audits authorized?	Yes. The CO MED and licensee may attempt to agree upon an auditor, but the MED always has final authority to select the auditor.	Not clear	NEW: Yes.
Does the regulator have authority to test marijuana used in research?	Yes, samples of marijuana used in research may be required by MED at any time. (CO ADC 212-3; 5-725)	Testing is required before use	NEW: Yes
On what basis may licenses be suspended or revoked?		For sufficient cause, including: fraud; failure to maintain sufficient controls to prevent diversion of marijuana; criminal conviction for drug crimes; failure to maintain	

	Colorado	Connecticut	MA Considerations
		accurate records; failure to account for disposition of marijuana. Each instance of contact or consultation with a research participant that is in violation of statutes or regs shall be a separate violation. Discontinuance of a business for more than 60 days shall be grounds for action.	
Are there security requirements that are different from other licensees?	No	No, security requirements same as for dispensaries, producers	Same as existing security protocols b/c those most closely mirror federal requirements (but want to hear during public comment from research institutions.)

Notes:

- Potential suggestions for legislative changes:
 - Immunity for research employees (would include institutional employees acting in capacity as research employees) (see CT sec. 21a-408u)
 - Establishment of Scientific Advisory Board to assist in review of research proposals, perhaps to act as an appeal board. In Colorado, this Board functions to review institutional research proposals. I see a need for assistance in reviewing research proposals from private, non-institutional entities. (see Colorado statute).
 - Establish a research facility at one of our public universities or community colleges with a focus on research to promote public health and public safety.

8. DELIVERY – temperature check

[PowerPoint: Slide 19]

Delivery

935 CMR 500.002: Definitions

935 CMR 500.050(8) (Marijuana Retailer) and (11) (Marijuana Research Facility)

935 CMR 500.145: Additional Operational Requirements for Delivery of Marijuana and Marijuana Products to Consumers

Recommendations:

1. Change the definition of “Delivery-Only License” to Delivery License;
2. Clarify that Marijuana Retailers may hold a Delivery License as a separate license;
3. Enable Delivery Licensees to also hold an interest in other license types and vice versa, provided, however, that even if Delivery Licensees hold an interest in a Marijuana Cultivator or Product Manufacturer they may not delivery directly from them;
4. Allow Delivery Licensees to sell Marijuana Accessories and Marijuana Establishment Branded Goods, such as t-shirts, direct to consumers.

Rationale: The economic model of the Delivery-Only License model constrains economic growth for licensees; these changes make the license more attractive, and clarifying that Marijuana Delivery Licensees may also have an interest in Marijuana Retailers reflects the policy decisions voted on last year.

[Meeting Packet Material] Same as slide.

**9. ADDITIONAL RETAIL OPERATIONS - CONTACTLESS RETAIL OPERATIONS –
*temperature check***

[PowerPoint: Slide 20]

Contactless Retail Operations

935 CMR 500.050: Marijuana Establishments

Recommendation: Allow contactless means of providing product to consumers at Marijuana Retailers

Rationale: Provides a safe alternative to person-to-person sales.

[Meeting Packet Material] Same as slide.

10. VAPING REGS – *policy discussion*

[PowerPoint: Slides 21-22]

Vaping Regulations

935 CMR 500.105 (5)(c)
NEW Vaporizer Sampling & Testing Protocol

Recommendation: Require

1. Notice at point of sale and disclosure on packaging that vapes have been tested for VEA, but that the vape may nevertheless be harmful to a consumer's health.
2. Disclosure of all active ingredients, including terpenes, and make Safety Data Sheets (SDS) available upon request to the Commission or a consumer.
3. Product manufacturers to maintain information on vape hardware, including the type of coil, type of battery and, using best efforts, determine the source of the materials and maintain that information for Commission review upon request.
4. Labeling indicating whether the terpenes are cannabis-derived or non-cannabis-derived.

Rationale: There continues to be much that is unknown about the potential for harm caused by additives used in vapes. The approach that best balances the Commission's obligation to ensure products are tested, with unknowns about the potential for harm of particular products and product components, is to require disclosure of as much information as we can accurately assess at this point while continuing to gather information and data as we build analytical competency.

[Meeting Packet Material]

[See separate attachment, *Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products*]

11. TESTING – policy discussion

[PowerPoint: Slide 23]

Testing

*935 CMR 500.160: Testing of Marijuana and Marijuana Products
NEW Protocol for Sampling and Analysis of Finished Marijuana and Marijuana-Infused Products*

Recommendation:

1. Reanalysis/Remediation: Product that fails initial contaminant screens may be 1) reanalyzed; 2) remediated and retested; or 3) disposed of. Product that is reanalyzed must receive 2 passing tests: one at the original lab and a confirmatory test at a different ITL. Product that is remediated must be retested at a different ITL. Licensees may attempt remediation of a batch twice; if batch doesn't pass after two remediation attempts it must be disposed of.
2. Pesticides: Adds 14 pesticides to the 9 pesticides currently tested for. The 14 additional pesticides are pesticides that have been recently identified or are suspected of use in some form or fashion in either CCC or MDAR investigations. Commission should phase-in over 2-3 months to allow ITLs to develop methodologies and purchase equipment.
3. Vapes: Require continued testing for VEA and a secondary screen for heavy metals from finished vapes pursuant to the Sampling and Testing Protocol for Finished Marijuana and Marijuana Products (see also Vaping slide for labeling requirements).

Rationale: Health and safety of consumers requires more fulsome testing of finished marijuana products so that more complete disclosures can be provided.

[Meeting Packet Material]

[See separate attachment, *Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products*]

12. ECONOMIC EMPOWERMENT APPLICANTS - *Policy discussion*

[PowerPoint: Slide 24]

935 CMR 500.002 - Definition of Economic Empowerment Applicants

Economic Empowerment Priority Applicant means an applicant who demonstrated and continues to demonstrate three or more of the following criteria:

- [1] 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;
- [2] 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;
- [3] 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%;
- [4] at least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises;
- [5] a majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent; and
- [6] 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.

[PowerPoint: Slides 25-26]

Issue 1 - Economic Empowerment Priority Applicants

Issue 1: Whether an applicant/licensee:

- (1) must satisfy at least one of the criteria listed in subsections (1), (2), or (5) of the definition of EEA (each an Equity-Based Criterion) to obtain/maintain EEA status or
- (2) may rely on the three non-Equity-Based Criteria in subsections (3), (4), and (6) of the EEA Definition to qualify for/maintain EEA status.

Options:

- A. Allow an applicant to qualify as an EEA without satisfying an Equity-Based Criterion.
- B. Require applicants to satisfy at least one of the Equity-Based Criterion to obtain EEA status.

Pros/Cons:

Option A: Would allow applicants that are not owned by members of a Target Community to obtain EEA status, provided it can demonstrate past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact. This would not require a change to the regulations but may require additional clarification in guidance or bulletins for EEAs.

Option B: Ensures EEA benefits are limited to Target Community members. Would require a change to the definition of Economic Empowerment Applicant in the regulations and associated changes in guidance or bulletins.

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

[Meeting Packet Material]

Issue # 1 – Equity-Based Criteria

At its public meeting on May 7, 2020, the Commission voted to direct the Executive Director to update a previously issued guidance to EEAs. Specifically, the previous guidance informed EEAs that in order to maintain EEA status, that the classes of people intended to benefit from EEA status (Target Communities) needed to hold 10% or more of the equity of the EEA in order to receive the associated benefits of EEA status. The Commission voted reissue of the guidance to require that Target Communities must make up more than 50% of equity holders in a given EEA applicant/licensee in order to retain status and benefits.

The Commission's May 7, 2020 decision can be interpreted to be in conflict with its regulations. The definition of EEA (copied below) allows a business entity to qualify as an EEA if it satisfies three of six criteria. Three of the criteria (criteria 1, 2, and 5) are Equity-Based Criteria – i.e. a majority of equity ownership must be held by a Target Community. The remaining three criteria (criteria 3, 4, and 6) do not contain an equity ownership component.

As currently written, a business entity could qualify as an EEA by relying on the three non-Equity-Based Criteria. The conflict between the Commission's May 7, 2020 vote and the regulations exists if a business entity relied on the criteria 3, 4, and 6 to obtain EEA status. Such an EEA would automatically

lose their status by virtue of not having 51% equity ownership by one or more members of a Target Community identified in criteria 1, 2, or 5. Specifically, the definition implies that, even if an EEA falls below 50% equity ownership (for example, by selling equity to bring in outside capital) it should retain its status if it continues to meet the 3 non-equity-based.

Resolving this will require a Commission discussion and vote with resultant changes to the definition and related sections of the regulations.

500.002: Definitions states that:

“Economic Empowerment Priority Applicant means an applicant who demonstrated and continues to demonstrate three or more of the following criteria:

1. 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
2. A majority of ownership is held by one or more people who worked in previous positions where the primary population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision or empowerment to disproportionately impacted individuals or communities
3. 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%
4. At least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises
5. A majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent
6. Other significant articulable demonstration of past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact.”

Option 1 – No change to regulations or guidance. Not recommended, because of the conflict between the Commission’s guidance and the regulations as written.

Option 2 – Update the definition to be consistent with the with the Commission’s decision. Specifically, change the definition to read:

“Economic Empowerment Priority Applicant” means an applicant who demonstrated and continues to demonstrate three or more of the following criteria, **provided however, the applicant must meet at least one of the criteria listed in 1, 2, or 5, and any two other additional criteria:**

1. 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
2. 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
3. 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%

4. At least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises
5. A majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent
6. Other significant articulable demonstration of past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact.”

Option 3 – Update and reissue guidance sent to EEAs. Not recommended due to likely poor community response and potential confusion resulting from another change to the guidance in such a short time period.

Current Guidance (after May 7 meeting):

In order to use their status as an Economic Empowerment Applicant, and receive the benefits listed above, an individual or group of individuals associated with an approved Economic Empowerment application must be listed on the license application as a Person Having Direct or Indirect Control. **Additionally, that individual or group of individuals must have, and maintain, at least majority ownership (greater than 50%) in the proposed Marijuana Establishment.**

Proposed change:

In order to use their status as an Economic Empowerment Applicant, and receive the benefits listed above, an individual or group of individuals associated with an approved Economic Empowerment application must be listed on the license application as a Person Having Direct or Indirect Control. **Additionally, that individual or group of individuals must have, and maintain, at least three of the six criteria for EEA status**

Issue 2 - Economic Empowerment Priority Applicants

Issue 2: With respect to Equity-Based Criteria, whether to allow ownership by Target Community members to be as low as 33%, provided such community members (1) retain direct control under subsection (d)(1)-(5) of the definition of Persons or Entities Having Direct Control and (2) receive profits or dividends in proportion to or greater than their equity share.

Options:

- A. Require majority ownership by Target Community members to satisfy Equity-Based Criteria.
- B. Allow applicants to satisfy Equity-Based Criteria with at least 33% ownership by Target Community members, provided those Target Community members retain a certain type of control and receive a certain amount of economic benefit.

Pros/Cons:

Option A: Ensures that EEAs are being majority owned, and thereby control shareholder votes by Target Community members. The drawback is that it does not allow for as much flexibility for EEAs and Target Community members with respect to capital structure. Would not require revisions to the Equity-Based Criteria and associated changes to guidance or bulletins.

Option B: Could allow flexibility to obtain capital and allow Target Community members to leverage EEA status to gain more immediate economic benefits but would result in less control over shareholder votes. Would require revisions to the Equity-Based Criteria and associated changes to guidance or bulletins.

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

[Meeting Packet Material]

Issue 2 – Equity Thresholds

If the Commission determines that a business entity must satisfy at least one Equity-Based Criteria to qualify as an EEA, it might be desirable to allow EEA's to go below 50% equity ownership by Target Communities. In some cases, in order to realize more immediate economic benefits of EEA status or to obtain capital, members of a Target Community may be able to leverage their EEA status. It is recommended Allowing a lower equity threshold under the Equity-Based Criteria would give Target Community members additional flexibility to modify the definition of EEA and the related Change of Control section (500.104.1.b.3) to allow for the following:

Option 1 – No change. Require majority ownership by Target Communities under criteria 1, 3, or 5, whether or not the Commission requires that at least one of the Equity-Based Criteria be met under Issue 1. The benefit of this is that it ensures that EEAs are being majority owned, and thereby controlled, by Target Community members. The drawback is that it does not allow for as much flexibility for EEAs and Target Community members.

Option 2 – Allow for 1/3 ownership by Target Community members, provided they retain a certain type of direct control and receive the commensurate amount of profits/dividends (i.e. their right to dividends cannot be diluted by preferred shares or debt agreements by which profits are directed elsewhere – allocations of

profits can have tax consequences). The language below assumes the Commission will require EEAs to satisfy an Equity-Based Criteria but can easily be modified if that is not the Commission's decision.

"Economic Empowerment Priority Applicant means an applicant who demonstrated and continues to demonstrate three or more of the following criteria, provide however, the applicant must meet at least one of the criteria listed in 1, 2, or 5, and any two other additional criteria:

1. 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 or at least one third of ownership belongs to people who have lived for five of the preceding ten years in an Area of Disproportionate Impact provided such individuals retain Direct Control through one of the means listed in subsections (d)(1)-(5) of the definition of Persons or Entities Having Direct Control and earn profits or dividends in proportion to or greater than their equity share.
2. A majority of ownership belongs to individuals who have~~has~~ held one or more previous positions where the primary population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision to, or empowerment ~~to of~~ disproportionately impacted individuals or communities or at least one third of ownership belongs to people who have held one or more previous positions where the primary population served were disproportionately impacted, or where primary responsibilities included economic education, resource provision to, or empowerment of dipropionate impacted individuals or communities, provided such individuals retain Direct Control through one of the means listed in subsections (d)(1)-(5) of the definition of Persons or Entities Having Direct Control and earn profits or dividends in proportion to or greater than their equity share.
3. 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%
4. At least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises
5. A majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent, or at least one third of ownership belongs to individuals from Black, African American, Hispanic, or Latino descent, provided such individuals retain Direct Control through one of the means listed in subsections (d)(1)-(5) of the definition of Persons or Entities Having Direct Control and earn profits or dividends in proportion to or greater than their equity share..
6. Other significant articulable demonstration of past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact."

Issue 3 - Economic Empowerment Applicants

Issue 3: If the Commission determines that an applicant/licensee must satisfy at least one of the Equity-Based Criteria to obtain EEA status, whether and which EEA benefits an applicant can retain if the applicant or licensee loses its EEA status as a result of failing to satisfy the Equity-Based Criteria.

Options:

- A. Make EEA benefits all or nothing with EEA status.
- B. Allow EEAs to maintain some EEA benefits if, after initial certification, it fails to fulfill the EEA criteria.

Pros/Cons:

Option A: Ensures that regulatory benefits are restricted to entities that are majority owned by Target Community members.

Option B: Allows flexibility and retention of some benefits if the EEA loses its status by failing to meet one of the criteria, which it could later satisfy?

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

[Meeting Packet Material]

Issue # 3 – Benefits of EEA Status

Depending on the Commission's decision with respect to Issue 1, the question remains as to which, if any, EEA benefits an applicant or licensee may retain if it loses its EEA status. If the Commission determines that a business entity must satisfy at least one of the Equity-Based Criteria to qualify as an EEA, should a business lose all or some of the benefits of EEA status if it drops below that equity threshold. If the Commission determines that a business entity can obtain/maintain EEA status without satisfying one of the Equity-Based Criteria, is there any circumstance under which it can lose its benefits as a result of the capital structure of the business. Likewise, if, under Issue 2, the commission determines that equity may drop below majority to 1/3, what, if any, benefits should be lost as a result of that lowered threshold?

The benefits of EEA status include the following:

- Prioritized review of applications
- Waived license application fees
- Reduced annual license fees
- Waived monthly METRC fees
- Ability to apply for Delivery and Social Consumption licenses during the period of exclusivity

Regardless of the Commission's decision under Issue 1 (Equity-Based Criteria), the opportunity to participate in Social Consumption and Delivery, as currently provided under 500.050(6)(b) and subsection (10)(b), is only available to applicants with EEA status by virtue of majority ownership by Target Community members. If the Commission determines under Issue 1 not to require Equity-Based Criteria to gain EEA status, then it should determine whether EEA applicants/licensees who do not satisfy

an Equity-Based Criteria can still apply for Social Consumption and Delivery-only licenses. Those regulatory provisions are listed below:

500.050(6)(b) states that “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”; and

500.050(10)(b) states that “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”

Issue 4 - Economic Empowerment Applicants

Issue 4: Whether to require Commission staff to produce a list, updated for each public meeting, that lists all applicants/licensees with EEA status (current and lapsed).

Options:

- A. No Change.
- B. A Vote by the Commission requiring staff, through the Executive Director, to produce a list, updated for each public meeting, that lists all applicants/licensees with EEA status (current and lapsed).
- C. Add a subsection (e) to 935 CMR 500.102(2) requiring staff, through the Executive Director, to produce a list, updated for each public meeting, that lists all applicants/licensees with EEA status (current and lapsed).

Pros/Cons:

Option A: Would not require a new process for Commission staff but would not ensure that the Commission had up to date information with respect to EEAs when having policy discussions.

Option B: Would give the commission up to date information with respect to EEAs when having policy/licensing discussions without including internal Commission procedures in the regulations, but would create a new process for Commission staff that could be changed by a vote of the Commission without a regulation review process.

Option C: Would give the Commission up to date information with respect to EEAs when having policy/licensing discussions. This would establish a new process for Commission staff and would require an amendment to the regulations to make any changes to this requirement.

Recommendation: Option B.

[Meeting Packet Material]

Issues # 4 – Maintaining a list of (current and lapsed) EEAs

In order to ensure the Commission has up to date information with respect to EEA applicants/licensees, whether and how to require Commission staff to provide an up to date list of all current and lapsed EEAs at each public meeting.

Option 1 – No change. This option is not recommended as it would leave the Commission without the most up to date information about EEA applicants and licensees as it has licensing and policy discussions.

Option 2 – The Commission takes a vote to require Commission staff, through the Executive Director, to produce a list of licensees with EEA status to be maintained by the Commission and updated in each public meeting packet, and the list will also note licensees who previously held EEA status and no longer meet the requirements. The benefit of this option is it establishes the requirement of an up to date list but does not create internal agency requirements within the regulations if the Commission should determine to change operation procedure.

Option 3 – Add a subsection (e) to 500.102(2) that establishes the requirement that Commission staff produce a list of licensees with current or lapsed EEA status. The benefit of this approach is that it creates a more permanent requirement for maintaining the list and puts EEAs on notice that the Commission is tracking EEA status, but would create an internal operational requirement within the regulations, which can't be changed without amending the regulations.

(e) The Commission shall maintain a list of licensees and applicants that are certified as Economic Empowerment Priority Applicants, which shall be updated and presented to the Commission at its regularly scheduled public meetings. This list will include current Economic Empowerment Priority Applicants and applicants and licensees who previously held economic empowerment priority applicant status, but no longer satisfy the requirements of such status.

Issue 5 - Economic Empowerment Applicants

Issue 5: Whether to require EEAs to report all changes in ownership to the Commission (while approval by the Commission is still only required for changes greater than 10%).

Options:

- A. No change.
- B. Require a new subsection (e) under 935 CMR 500.104(1)(b)(3) that requires reporting (but not approval) of all changes in ownership of an EEA applicant/licensee.

Pros/Cons:

Option A: Would not establish an additional regulatory requirement for EEA licensee/applicants or a new process for Commission staff but would not ensure the Commission has the most up to date information about EEA ownership.

Option B: Would ensure Commission has up to date information about EEA ownership, but would establish an additional regulatory requirement for EEA licensees/applicants and create a new process for Commission staff to manage.

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

[Meeting Packet Material]

Issues # 5 – Reporting of changes of ownership for EEAs.

In order to ensure that Target Communities continue to hold the requisite amount of ownership, whether to require EEAs to provide annual certification with respect to EEA status.

Option 1 – No change. This would require EEAs to only to seek approvals from the Commission of changes in control or ownership. The benefit would be not creating an additional regulatory requirement for EEAs, however, making no change does not aid the Commission in ensuring the spirit of EEA status is being fulfilled.

Option 2 – All changes in ownership, regardless of size, for all EEAs must be reported to the Commission. The benefit here is that it helps the Commission ensure the spirit of EEA status is being fulfilled. The drawback is that it creates additional processes for EEAs and the Commission to maintain.

Proposed Regulatory Amendment:

500.104(1)(b)

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

~~d.e.~~ Economic Empowerment Priority Applicants must report to the Commission 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). This requirement is satisfied when an applicant seeks approval pursuant to 935 CMR 500.104(1)(b).

Issue 6 - Economic Empowerment Applicants

Issue 6: Whether to require Target Community Members to certify each year that they have exercised control and retain requisite ownership over the EEA for which they were listed on the EEA certification.

Options:

- A. No Change.
- B. Create a subsection (j) under 935 CMR 500.104(4) for EEAs to certify that they still satisfy the requirements of EEA status.

Pros/Cons:

Option A: Would not establish an additional regulatory requirement for EEA licensees/applicants or a new process for Commission staff but does not aid the Commission in ensuring the spirit of EEA status is being fulfilled.

Option B: Would help the Commission ensure the spirit of EEA status is being fulfilled, but would create additional regulatory requirements for EEA licensees/applicants and a new process for Commission staff.

Recommendation: Update Regulation, guidance, or bulletin to reflect commission decision, as needed.

[Meeting Packet Material]

Issue # 6 – Certifications of ownership and control.

In order to ensure that Target Communities are exercising ownership and control over EEAs, it may make sense to require Target Community members that have control and majority ownership over an EEA provide an annual certification that such Target Community members have exercised control and continue to exercise control, and that the entity continues to meet the EEA criteria.

Option 1 – No change. The benefit of making no change is that it does not create additional regulatory requirements for EEAs, however, making no change does not aid the Commission in ensuring the spirit of EEA status is being fulfilled.

Option 2 – Amend 500.104(4) Expiration and Renewal of Licensure to require a certification by EEAs that they continue to satisfy the requirements of EEA status. The benefit here is that it helps the Commission ensure the spirit of EEA status is being fulfilled. The drawback is that it creates additional processes for EEAs and the Commission to maintain.

Option 2a - assumes the Commission does not vote to require Equity-Based Criteria for EEA status.

(j) All Economic Empowerment Priority Applicants must submit, as part of its renewal application, an attestation that the licensee or applicant still satisfies the requirements to qualify as an Economic Empowerment Priority Applicant.

Option 2b – assumes that the Commission votes to require Equity-Based Criteria for EEA status.

(j) All Economic Empowerment Priority Applicants must submit, as part of its renewal application, an attestation by the individuals who, through ownership, allow an applicant or licensee to qualify as an Economic Empowerment Priority Applicant, that:

1. Such individuals have had control and ownership since licensure, or the most recent renewal;
2. Will continue to have control and ownership; and
3. The licensee will continue to satisfy the requirements to qualify as an Economic Empowerment Priority Applicant.

13. SEP - EQUITY OWNERSHIP THRESHOLD FOR SOCIAL EQUITY PROGRAM PARTICIPANTS TO RECEIVE LICENSE BENEFITS - *Policy discussion*

[PowerPoint: Slides 34-35]

SEP - Equity Ownership Threshold for Social Equity Program Participants to Receive License Benefits

Issue: Discuss the current ownership threshold of 10% ownership by a Social Equity Program Participant required in order for a business to access license-related benefits including fee waivers, discounts, and expedited review.

Options:

- A. No change
- B. Require 51% ownership by SEPs for fee waivers and discounts; allow microbusinesses and minority-owned, veteran-owned, and women-owned businesses to access the same fee waivers and discounts.

Pros/Cons:

Option A:

Pros: Allow more flexibility and value for SEP individuals

Cons: Would provide discounts to companies that may not have a need for discounts, depending on who owns the other 90% of the business. Fiscal impact may add up given hundreds of SEPs in each cohort.

Option B:

Pros: Broadens availability of discounts to more groups; keeps discounts to companies that are majority-owned by targeted groups.

Cons: Prevents SEPs who own the minority of a company from accessing discounts.

Recommendation: Option B.

[Meeting Packet Material]

SEP - Equity Ownership Threshold for Social Equity Program Participants to Receive License Benefits

Relevant Regulation:

500.005: Fees

(2) 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.

1. Application fees are waived for Social Equity Program Participants and Economic Empowerment Priority Applicants. This does not include the costs associated with background checks.
2. For Annual License Fees, Social Equity Program Participants and Economic Empowerment Priority Applicants receive a 50% reduction in the fee associated with an application.
3. Seed-to-sale SOR monthly program fees are waived for Economic Empowerment Priority Applicants, Social Equity Program Participants, Craft Marijuana Cooperatives, and Microbusinesses. This waiver does not include other costs associated with the Seed-to-sale licensing system, specifically the fees for plant and package tags.
4. 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.

[...]

14. BUFFER ZONE - Policy discussion

[PowerPoint: Slide 36]

Buffer Zones

935 CMR 500.110(3): Buffer Zones

935 CMR 501.110(3): Buffer Zones

Issue: Chapter 94G creates a 500-foot buffer zone between an ME/MTC and a school but does not define how it should be measured. The current buffer zone regulation provides that the required 500-foot distance be measured from property to property. The purpose of this recommended change is to take into account impassable barriers such as highways or rivers.

Option: Propose new method for measuring the 500-foot distance that considers accessibility to an ME/MTC from a school site, for example by taking into account impassable barriers.

Pros:

- Clearer and accounts for impassable barriers such as highways and rivers between the ME/MTC and the school site

Cons:

- Would need to update municipal guidance

Recommendation: Change how the 500-foot distance is measured in certain cases.

[Meeting Packet Material] Buffer Zones

Buffer Zones

Relevant Regulations: 935 CMR 500.110(3): *Buffer Zones*
935 CMR 501.110(3): *Buffer Zones*

Issue: Chapter 94G creates a 500-foot buffer zone between an ME/MTC and a school but does not define how it should be measured. The current buffer zone regulation provides that the required 500-foot distance be measured from property to property.

To quote our own municipal equity guidance: large buffer zones sharply limit the number of parcels available to potential operators. This favors large businesses with substantial financial resources that can outbid other potential operators and overpay for a lease or purchase of property—often at the expense of smaller, local companies—and tends to direct large rewards to a small handful of landlords and property owners. This is consistent with feedback from constituents at our hearings and forums.

The purpose of this change is to account for exceptions, such as highways, rivers, or other impassable barriers, between a school and a ME/MTC.

Statute: 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

Current regulations: 935 CMR 500.110(3) (parallel provision in the medical regulations)

(3) Buffer Zone. 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.

Proposed Regulatory Amendment:

(3) Buffer Zone. ~~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.

(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.

15. FLEXIBILITY TO EXPAND DELIVERY-ONLY LICENSES AND DELIVERY ENDORSEMENTS – *policy discussion*

[PowerPoint: Slide 37-38]

Flexibility to expand Delivery-only Licenses and Delivery Endorsements to Cooperatives and Women-, Minority-, Veteran-owned Businesses During the Exclusivity Period Without Requiring a Regulatory Change

500.050(10) - Delivery-only Licensee.

Issue: Under the current regulations, there is an exclusivity period restricting Delivery-only licenses and Delivery endorsements for 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 of the first notice to commence operations. Depending on the demand for delivery and the number of businesses operating, this proposal gives the Commission the flexibility to expand the exclusive delivery licenses just to these groups, if the Commission feels it is appropriate.

Recommendation: Add provision to the regulations that the Commission may choose to expand Delivery-only licenses and Delivery endorsements to cooperatives and women-, minority-, veteran-owned businesses during the exclusivity period. [See handout for proposed change to the regulatory language]

Pros:

- Does not require the Commission to expand delivery to those groups but makes it an option if the number of businesses with exclusive access currently are unable to meet demand
- The flexibility is useful because there is currently no basis to predict whether the number of delivery businesses can meet demand
- One step toward meeting our statutory requirements for minority-, women-, and veteran-owned businesses
- Encourage more worker-owned cooperatives

Cons:

- If implemented prematurely, could dilute the benefits for Economic Empowerment Priority Applicants or Social Equity Program Participants

[Meeting Packet Material]

Flexibility to expand Delivery-only Licenses and Delivery Endorsements to Cooperatives and Women-, Minority-, Veteran-owned Businesses During the Exclusivity Period Without Requiring a Regulatory Change

Proposed regulatory change:

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) 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 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.

(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 been met; and the Commission may vote to make Delivery-only Licenses available to minority-owned businesses, women-owned businesses, veteran-owned businesses, and cooperatives during the exclusivity period.

16. VERIFIED FINANCIAL HARDSHIP DOCUMENTATION - Policy discussion

[PowerPoint: Slides 39-40]

Verified Financial Hardship Documentation

501.002: Definitions

501.010(4): Written Certification of a Debilitating Medical Condition for a Qualifying Patient

501.050(1)(h): Medical Marijuana Treatment Centers (MTCs) – General Requirements

Issue: Patients report that MTCs are inconsistent in what they accept as proof of eligibility of Verified Financial Hardship for the purpose of a MTC program to provide reduced cost or free marijuana under 501.050(1)(h). The purpose of this change is to specify that a valid MassHealth card or Social Security benefit verification letter is acceptable documentation.

Option: Specify in the definition of Verified Financial Hardship that a valid MassHealth card or Social Security benefit verification letter is acceptable documentation for the purposes of receiving reduced cost or free marijuana through the RMD program required by 935 CMR 501.050(1)(h) to provide.

Pros:

- Consistency across MTCs
- Does not limit acceptable documentation to the stated documents

Cons

- Leaves the documentation for proof that the individual's income does not exceed 300% of the federal poverty level, adjusted for family size, unspecified

Recommendation: Specify acceptable documentation.[See handout for proposed change to the regulatory language]

[Meeting Packet Material]

Verified Financial Hardship Documentation

Proposed regulatory amendment:

501.002: Definitions

Verified Financial Hardship means that an individual is a recipient of MassHealth, or Supplemental Security Income, or the individual's income does not exceed 300% of the federal poverty level, adjusted for family size. A valid MassHealth card or Social Security benefit verification letter is acceptable documentation of a Verified Financial Hardship for the purposes of 935 CMR 501.050(1)(h) and 935 CMR 501.010(4).

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

- (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.

501.050: Medical Marijuana Treatment Centers (MTCs)

(1) General Requirements. [...]

(h) An MTC must have a program to provide reduced cost or free Marijuana to patients with documented Verified Financial Hardship. The plan shall outline the goals, programs, and measurements the MTC will pursue as part of the plan.

17. PERSONNEL POLICY – REQUIRE CODE OF ETHICS AND WHISTLEBLOWER POLICY - *Policy discussion*

[PowerPoint: Slide 41]

Personnel Records – Require Code of Ethics and Whistleblower Policy

935 CMR 500.105(9)(d): *General Operational Requirements for Marijuana Establishments - Recordkeeping*

Issue: The purpose of this change is to require licensees to include a code of ethics and whistleblower policy among their personnel records.

Option: Within recordkeeping requirements, require personnel policies and procedures subject to inspection by the Commission upon request to include a code of ethics and whistleblower policy.

Pros:

- Provide certainty for employees who wish to access a code of ethics or whistleblower policy.

Cons:

- Require licensees to create a code of ethics or whistleblower policy if they do not already have one.

Recommendation: Require code of ethics and whistleblower policy.

[Meeting Packet Material]

Personnel Records – Require Code of Ethics and Whistleblower Policy

Proposed regulatory amendment:

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 Record Information (CORI)*.

Memorandum

To: Chairman Hoffman, Commissioner Title, Commissioner McBride, Commissioner Flanagan
Cc: Shawn Collins, ED
From: Pauline Nguyen, DGC
Date: June 15, 2020
Subject: Materials for June 19, 2020 Policy Discussion Meeting

Attached please find the following documents:

1. The PowerPoint that will be used at the meeting;
2. The meeting packet (in both Word and PDF) for your review; and
3. A separate attachment, *Protocol for Sampling and Analysis of Finished Marijuana and Marijuana Products*, (Word and PDF) that corresponds with the topics 1) testing and 2) vaping in the handout.

If accessing the meeting packet using Microsoft Word, please go to **View → Navigation Pane** (make sure the check box is marked) to make navigating the document easier.

I have also included the PDF version of this packet for convenience. The Table of Contents in the PDF is clickable and allows you to navigate to a topic quickly.

The meeting packet provides a list of the 17 topics on the agenda for discussion*. For each topic, I have provided the corresponding slide number as well as the slide's content, and any relevant background material for that topic.

Please reach out to me if you have questions or concerns.

*Please note that the list of topics for discussion at this meeting is not an exhaustive list of the proposed regulatory changes.

1



**Protocol for Sampling and Analysis of Finished ~~Medical~~ Marijuana Products and Marijuana-
Infused Products for Massachusetts Registered Marijuana ~~Establishments~~, Marijuana Treatment
Centers and ~~Colocated Marijuana Operations, Establishments~~**

Revised – ~~June~~, 2020 ~~December 1, 2017~~

This document ~~is issued by the Cannabis Control Commission. was issued originally by the Department of Public Health (DPH). As part of the transfer of the medical use of Marijuana program on or before December 31, 2018, the Massachusetts Cannabis Control Commission adopted this document. We suggest that before you rely on the contents of this document, you check~~ the applicable medical use Marijuana laws, which include M.G.L. c. 94I, 94G and 935 CMR 500.000, 935 CMR 501.000 and 935 CMR 502.000, should be reviewed as they may provide or clarify the legal requirements related to this document. ~~We also suggest that you~~ This protocol document should be periodically checked periodically for revisions to this document. Questions with regards to this document may be directed to Commission@CCCMass.com. ~~CannabisCommission@Mass.gov.~~

Summary of Edits/Changes:

- Change all references from Department of Public Health (DPH) to Cannabis Control Commission (Commission)
- Change all references from Registered Marijuana Dispensaries (RMDs) to “Licensees” (to refer to MEs, MTCs and CMOs collectively).
- Updated 1.0 Purpose and Applicability
- Updated 2.0 Definitions and Acronyms – to reflect Commission regulatory definitions
- Updated 3.0 Applicable Regulations – to reflect Commission regulations
- Updated 4.0 Concentrate - Vaporizer Guidance
- Updated 7.0 Sample Analysis – Updated Pesticide, Heavy Metals and NEW Vape Section
- Updated 8.0 Data Evaluation – Added remediation language

The Protocol contains the following sections:

- 1.0 Purpose and Applicability**
- 2.0 Definitions and Acronyms**
- 3.0 Applicable Regulations**
- 4.0 Sampling and Analysis Requirements**
- 5.0 Sampling Program Design**
- 6.0 Sample Collection Procedures**



7.0 Sample Analysis
8.0 Data Evaluation
9.0 References

1.0 Purpose and Applicability

1.1 Purpose

The purpose of this Protocol is to provide Massachusetts Registered [Adult-use Marijuana Establishments \(MEs\)](#), [Medical Marijuana Treatment Centers \(MTCs\)](#) and [Colocated Marijuana Operations \(CMOs\)](#)(herein referred to collectively as “Licensees”) ~~Dispensaries (RMDs)~~ with required and recommended best practices for the collection and analysis of plant material and other finished [adult-use and medical Marijuana products](#) and Marijuana-infused products (MIPs) to comply with Massachusetts [Cannabis Control Commission’s \(Commission\)](#) regulations: [935 CMR 500.000: Adult Use of Marijuana](#); [935 CMR 501.000: Medical Use of Marijuana](#) and [935 CMR 502.000: Colocated Adult Use and Medical Use Marijuana Operations](#). ~~105 CMR 725.000, Implementation of an Act for the Humanitarian Medical Use of Marijuana.~~

This protocol is subject to revision based on evolving best practices, updated scientific information or standards/guidelines, or other information relevant to the contents of the protocol.

1.2 Applicability

This protocol applies only to Massachusetts ~~Licensee~~[RMD](#) operations, and not hardship cultivation operations. Testing requirements in the protocol apply only to the [adult-use and medical-use Marijuana and Marijuana products](#) dispensed by Massachusetts ~~Licensees~~[RMD](#), including finished ~~medical Marijuana and Marijuana products~~ (i.e., plant material, resin, concentrates and MIPs) made with finished ~~medical~~ Marijuana ingredients. The protocol only addresses sampling and analysis to characterize cannabinoid identity and content profiles, and biological (microbial and fungal) and chemical (e.g., solvents, pesticides, growth enhancers, metals) contaminants introduced through cultivation of Marijuana plants and post-harvest processing and handling of Marijuana products and ingredients.

This protocol does not apply to nutritional product testing, allergen testing, or characterization of non-Marijuana ingredients in MIPs [except as noted for vaporizer products](#). It does not address sampling and analysis to verify compliance with state regulations or best practices for production and handling of food products, pharmaceuticals, or dietary supplements, except for criteria for biological and chemical contaminants that may be introduced through inclusion of ~~medical~~ Marijuana as an ingredient.

Sampling and analysis of environmental media used for cultivation are addressed in a companion protocol, Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries.

2.0 Definitions and Acronyms



Terms listed in italic typeface are those defined in [935 CMR 500.002](#), [935 CMR 501.002](#) and [935 CMR 502.002](#)~~105 CMR 725.004~~. Additional terms defined for this protocol are not in italic typeface.

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

Cannabinoid Profile means amounts, expressed as the dry-weight percentages, of ~~delta-nine-D9-~~tetrahydrocannabinol (~~D9-THC~~), cannabidiol (~~CBD~~), tetrahydrocannabinolic acid (~~THCa~~) and cannabidiolic acid (~~CBDa~~) in a ~~Cannabis or medical~~ Marijuana ~~P~~product. Amounts of other cannabinoids may be reported, but are not required.

Cannabis or Marijuana means all parts of any plant of the genus Cannabis, ~~not excepted~~~~excepted~~ in [935 CMR 500.002](#) or [935 CMR 501.002](#): Cannabis or Marijuana (a) through (c) and whether ~~growing~~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~~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~~sterilized seed of the plant that is incapable of germination;
- (b) Hemp; or
- (c) the weight of any other ingredient combined with Cannabis or -to prepare topical or oral administrations, food, drink or other products.

~~Cannabis Concentrate means a Marijuana product derived by using solvents to extract and concentrate cannabinoid compounds. Concentrates are typically in the form of oils, pastes, waxes, or solids.~~

~~Cannabis Resin, commonly known as “hashish,” “hash,” or “bubble hash,” means a solid medical Marijuana product produced by gathering and compressing the cannabinoid rich trichomes (i.e., keif) of the Marijuana plant.~~

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

Commission or CCC 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: Medical Use of Marijuana, and 935 CMR 502.000: Colocated Adult-use and Medical-use Marijuana Operations.

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

Cultivation Batch means a collection of Cannabis or Marijuana plants from the same seed or plant stock and that are cultivated and harvested together, and receive an identical propagation and cultivation treatment including, but not limited to: -Because they are cultivated in the same location and time, plants in a cultivation batch receive an identical propagation and cultivation treatment (e.g., growing media, ambient conditions, watering and light regimes, agricultural or hydroponic inputs). The Licensee ~~RMD~~ shall ~~must~~ assign and record a unique, sequential alphanumeric identifier to each Ceultivation Bbatch for the purposes of production tracking, product labeling, and product recalls.

Department of Public Health or *DPH* means the Massachusetts Department of Public Health.

Dispensary Agent means a board member (including advisory board members), director, employee, executive, manager, or volunteer of a RMD, who is at least 21 years of age. Employee includes a consultant or contractor who provides on-site services to a RMD related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of Marijuana.

Duplicate Samples means two samples taken from and representative of the same material that are carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples may be used to evaluate variance in the evaluation ~~assessment~~ method, including sampling and analysis.

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

First Amended Quarantine Order means the *First Amended Quarantine Order Applying To Vaporizer Products With Conditions* M.G.L. c.94I, M.G.L., c. 94G, § 4(a)(xix) and (a^{1/2})(xxxi), 935 CMR 500.340: *Quarantine Order*, and 935 CMR 501.340: *Quarantine Order* issued by the Massachusetts Cannabis Control Commission on December 12, 2019.

Finished ~~Medical~~ *Marijuana* means Uusable Marijuana, Cannabis resin, or Cannabis concentrate.

Finished Plant Material means usable Marijuana that has been trimmed and dried. Trimming includes removing the leaves immediately subtending the buds as well as any dead leaves or stems.

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

Hardship Cultivation Registration means a registration issued to a Rregistered Qqualifying Ppatient under the requirements of 935 CMR 501.027.405 ~~CMR 725.035~~.

Independent Testing Laboratory or ITL means a laboratory that is licenses 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 from any Marijuana Establishment, Marijuana Treatment Center, Colocated Marijuana Operation 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, 935 CMR 501.000, 935 CMR 502.000 and Commission protocol(s).

Licensee means a person or entity on the application and licensed by the Commission to operate a Marijuana Establishment, Marijuana Treatment Center, Colocated Marijuana Operator or Independent Testing Laboratory under St. 2016, c. 334, as amended by St. 2017, c. 55, M.G.L. c. 94G, 935 CMR 500.000, 935 CMR 501.000 and 935 CMR 502.000. Any person or entity that solely provides 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 et-or indirect authority to control the Marijuana Establishment, Marijuana Treatment Center, Colocated Marijuana Operation or Independent Testing Laboratory, will not be a licensee. For the purposes of this Guidance Document, Licensee will be used to to-referred to as Marijuana Establishments, Marijuana Treatment Centers and Colocated Marijuana Operations collectively.

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

Marijuana Establishment (ME) 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-Infused Product (MIP) means a Marijuana Pproduct infused with Marijuana that is intended for use or consumption, including but not limited to Eedible Marijuana-infused Pproducts, ointments, aerosols, oils, and Tinctures. A Marijuana-infused Product (MIP) These products, when created or sold by a Marijuana Establishment or MTC-RMD, shall not be considered a food or a drug as defined in M.G.L. c. 94, s. 1.

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), 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.

Mycotoxin means a secondary metabolite of a microfungus that is capable of causing death or illness in humans and other animals. For the purposes 935 CMR 500.000 and 935 CMR 501.000, of this regulation ~~M~~mycotoxins shall include aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A.

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

Production Batch means a batch of finished plant material, Cannabis resin, Cannabis concentrate, or Marijuana-infused Product ~~MIP~~ made at the same time, using the same methods, equipment, and ingredients. The ~~Licensee~~RMD shall must assign and record a unique, sequential alphanumeric identifier to each ~~P~~production Bbatch for the purposes of production tracking, product labeling, and product recalls. All ~~P~~production Bbatches shall must be traceable to one or more Cannabis or Marijuana Ccultivation ~~B~~batches(es).

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

~~Registered Marijuana Dispensary (RMD) means a not-for-profit entity registered under 105 CMR 725.100, that acquires, cultivates, possesses, processes (including development of related products such as edible MIPs, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers Marijuana, products containing Marijuana, related supplies, or educational materials to registered qualifying patients or their personal caregivers. Unless otherwise specified, RMD refers to the site(s) of dispensing, cultivation, and preparation of Marijuana.~~

Residual Solvent means a volatile organic chemical used in the ~~M~~manufacture of a ~~medical~~ Marijuana ~~P~~product ~~and~~ that is not completely removed by practical manufacturing techniques.

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

Tincture means a Cannabis-infused alcohol or oils concentrate administered orally in small amounts using a dropper or measuring spoon. Tinctures are not considered an Edible Marijuana Product under 935 CMR 500.000 and 935 CMR 501.000 and are not subject to the dosing limitations applicable to Edible Marijuana Products under 935 CMR 500.150(4). an extract, typically in ethanol, of usable Marijuana. Marijuana tinctures sometimes are made with glycerin or other alternatives to ethanol.

Trichome means a cannabinoid-producing glandular structure that grows on the plant surface of Marijuana plants, particularly on the buds of the female plant.



Usable Marijuana means a Cannabis-infused alcohol or oils concentrate administered orally in small amounts using a dropper or measuring spoon. Tinctures are not considered an Edible Marijuana Product under 935 CMR 500.000 and 935 CMR 501.000 and are not subject to the dosing limitations applicable to Edible Marijuana Products under 935 CMR 501.000. the fresh or dried leaves and flowers of the female Marijuana plant and any mixture or preparation thereof, including MIPs, but does not include the seedlings, seeds, stalks, or roots of the plant.

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

3.0 Applicable Regulations

This protocol was developed to provide LicenseesRMDs with guidance on complying with the 935 CMR 500.000, 935 CMR 501.000 and 935 CMR 502.00 105 CMR 725.00 regulations. In particular, the detailed steps outlined in this protocol address requirements of the following sections of the regulations. LicenseesRMDs should be familiar with the applicable regulations to ensure full compliance.

- 935 CMR 500.105(1)(h), 935 CMR 501.105(1)(h) and 935 CMR 502.105(1) - Plans for quality control, including Marijuana product testing for contaminants.
- 935 CMR 500.105(3), 935 CMR 501.105(3) and 935 CMR 502.105(3) - Handling of Marijuana
- 935 CMR 500.105(5), 935 CMR 501.105(5) and 935 CMR 502.105(5) - Labeling of Marijuana and Marijuana products.
- 935 CMR 500.120(6), 935 CMR 500.130(4), 935 CMR 501.120(6) and 935 CMR 501.130(4) - Marijuana and Marijuana products obtained from another Licensee.
- 935 CMR 500.160, 935 CMR 501.160 and 935 CMR 502.160 - Testing of Marijuana and Marijuana products

~~• 725.105(A)(7) Requirement of plans for quality control, including product testing for contaminants~~

~~• 725.105(B) Cultivation, acquisition, and distribution requirements~~

~~• 725.105(B)(2) Marijuana obtained from another RMD~~

~~• 725.105(C) Requirements for handling and testing Marijuana and for production of MIPs~~

• 725.105(E)(2) Labeling of Marijuana

• 725.300(E) Testing pursuant to DPH inspection



4.0 Sampling and Analysis Requirements

Sampling and analysis requirements apply to all Marijuana-containing products dispensed by [registered](#) Massachusetts [Licensees RMDs](#), which may include finished plant material, Cannabis resin, Cannabis concentrates [\(including vaporizer products\)](#), and MIPs. Because the nature and concentrations of contaminants and cannabinoid compounds may change throughout the production process, from cultivation through packaging, this section identifies the types of sampling and analysis that are required for each type of product. The results of the sampling and analysis are required for both quality control and labeling requirements (e.g., cannabinoid profile, testing certification). [Licensees RMDs](#) must ensure and be able to demonstrate to [the Commission inspectors](#), that product label information [complies with all applicable sections of 935 CMR 500.105\(5\)\(a\), 935 CMR 501\(5\)\(a\) and 935 CMR 502.105\(5\).](#) ~~(has been verified for all products).~~

4.1 Overview of ~~Medical~~ Marijuana Products and their Production

~~Medical~~ Marijuana products that may be dispensed by [Licensees RMDs](#) in Massachusetts include finished plant material, Cannabis resin, Cannabis concentrates, and a variety of MIPs. Marijuana for all of these product categories must originate with plants cultivated by [a Licensee the RMD operator \(105 CMR 725.105\(B\)\)](#) and all product labeling must include a batch number to identify the batch associated with manufacturing and processing [\(935 CMR 500.105\(5\), 935 CMR 501.105\(5\) and 935 CMR 502.105\(5\)\)](#) ~~105 CMR 725.105(E))~~. Therefore, [Licensees RMDs](#) are responsible for carefully tracking ~~medical~~ Marijuana throughout the production cycle, from cultivation through dispensing to [consumers and](#) patients. ~~Medical~~ Marijuana [and Marijuana Products](#) procured by a [Licensee RMD](#) from another [Licensee RMD](#) pursuant to [935 CMR 500.105 CMR 725.105\(B\)\(2\)](#) must be tested by the supplying [Licensee RMD](#) and documentation of testing consistent with this protocol must be provided to the receiving [Licensee RMD](#) by the supplying [Licensee RMD](#), along with chain-of-custody documentation.

Exhibit 1 provides an overview of the [adult use and](#) medical Marijuana production process as regulated in Massachusetts [by the Commission](#). During cultivation, plants are typically grown from seed, cuttings, or through a tissue culture method called micropropagation (AHP 2013). Plants may be grown in soil, other solid growth media, or in hydroponic systems. All cultivation methods place the plants in contact with environmental media and other inputs, such as soil or agricultural products, which have the potential to introduce chemical or biological contaminants. Because medically-active compounds are at their highest concentration on the inflorescences of the female plant, Marijuana plants are harvested when the plants reach peak maturity. Post-harvest handling steps include drying and trimming, which should be managed carefully to avoid mold and bacterial growth and to preserve medicinally-active compounds. For further details on medical Marijuana cultivation and post-harvest handling methods, refer to AHP (2013).

Harvested and dried Marijuana plants can be used directly to produce any of the three finished ~~medical~~ Marijuana types:-

1. Dried and trimmed usable Marijuana, ~~most importantly~~ the inflorescences (i.e., “buds”), may be used directly (e.g., smoked) ~~as a medical product~~ without further processing. It also may be used as a source material for other finished Marijuana products or as an ingredient in MIPs.



2. Cannabis resin, commonly referred to as “hashish” or “hash,” is formed by collecting and compressing cannabinoid-containing resin glands (i.e., trichomes). Cannabis resin also includes “bubble hash,” which is made by extracting the resin glands using cold water and physical separation (Colorado Pot Guide, 2014).

1.3. Concentrates, which include various oils, waxes, and solids, are produced with solvent extraction methods. Vape products that heat Cannabis oils fall under this classification. Concentrates have higher cannabinoid concentrations than other finished Marijuana products, but also may contain residuals of potentially harmful solvents if not manufactured properly. In addition, any contaminants present in the source plant material may be concentrated in a resin or concentrate product.

1 Testing for media used in Marijuana cultivation is discussed in the companion Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries.

Exhibit 1. Overview of ~~Medical~~ Marijuana Production

Under 935 CMR 500.002, 935 CMR 501.002 and 935 CMR 502.002~~105 CMR 725.004~~, a MIP is defined as a Marijuana Product infused with Marijuana that is intended for use or consumption, including but not limited to Edible Marijuana-infused Products, ointments, aerosols, oils, and Tinctures. A Marijuana-infused Product (MIP) 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, s. 1. “a product infused with Marijuana that is intended for use or consumption, including but not limited to edible products, ointments, aerosols, oils, and tinctures.” MIPs available to patients and consumers may include, but are not limited to baked goods; lozenges and candies; teas and other beverages; creams and salves; tinctures; and products for vaporization.

4.2 Commission~~Medical~~ Marijuana Testing Requirements

Testing for finished ~~medical~~ Marijuana and Marijuana products ~~MIPs~~ includes screening for chemical and biological contaminants (Section 4.2.1) and cannabinoid profile testing (Section 4.2.2). Section 4.2.3 discusses methods for determining the amount of usable Marijuana contained within a dispensed product, as required for product labeling. Sections 5.0 through 7.0 further describe the detailed sampling frequency, sample collection procedures, and analyses required for contaminant and cannabinoid profile testing.

This protocol defines the minimum testing required to conform with the 935 CMR 500.000, 935 CMR 501.000 and 935 CMR 502.000~~105 CMR 725~~ regulations. Licensees~~RMDs~~ have discretion to perform analysis beyond these requirements.

Product problems should be reported to the Commission ~~MDPH~~ when there is a concern about the quality, authenticity, performance, or safety of any finished ~~medical~~ Marijuana or Marijuana product. ~~MIPs~~. Problems with product quality may occur during manufacturing, shipping, or storage. These may include:



- suspect counterfeit product;
- product contamination;
- defective components;
- poor packaging or product mix-up;
- questionable stability;
- labeling concerns; and-
- [unknown and fillers and cutting agents](#)

Testing laboratories and [Licensees/RMDs](#) are often the first to recognize a product quality problem. Individuals ~~shall be encouraged to~~ report any concerns to [the Commission MDPH](#) by phone: [\(774\) 415-0200/617-660-5370](#); email: [Commission@CCCMass.com](#) ~~RMDCompliance@state.ma.us~~; or via Mail to:

[Cannabis Control Commission 2 Washington Square, Union Station 2nd Floor, Worcester, MA 01604](#)
[RMD Compliance](#)
[99 Chauncy St., 11th Floor Boston, MA 02111](#)

4.2.1 Contaminant Testing

Contaminant testing requirements are based on the contaminants potentially introduced at each stage of production. Exhibit 2 identifies the potential contaminants of concern during each stage of [medical](#) Marijuana production and the testing requirements for each product type.

Cultivation

Cultivation is not in the scope of testing of this protocol, but is included in Exhibit 2 to identify the contaminants of concern potentially introduced during cultivation. These include non-organic pesticides, metals, and other synthetic organic compounds in environmental media or other cultivation inputs (e.g., soil amendments, hydroponic products), as well as fungal and bacterial growth on the plants. Environmental media must be tested, as described in the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries, to reduce the introduction of chemical contaminants during cultivation. However, this testing will not necessarily ensure that the Marijuana plants are free of chemical contaminants, and does not address fungal/bacterial infestation. Therefore, [medical](#) Marijuana products must be tested for chemical contamination before they can be distributed, [sold and consumed](#).

Marijuana should be cultivated and harvested in traceable “cultivation batches,” such that all Marijuana within a cultivation batch has been produced with the same seed or plant stock, soil or other solid growing media, water, other agricultural/hydroponic inputs, and growing conditions. Cultivation batches should be sequentially numbered and traced throughout post-harvest production steps, and manufacturing/processing batch numbers must be included on the labels of all products to facilitate product recalls ~~(105-CMR 725.105(E)(2)(e) and 725.105(E)(3)(g))~~.

Finished Plant Material

Finished plant material dispensed to [consumers and](#) patients consists of usable Marijuana that has been trimmed and dried. Trimming includes removing the leaves immediately subtending the buds as well as



any dead leaves or stems (AHP 2013). A “production batch” of finished plant material must be traceable to one or more cultivation batch(es). All production batches of finished plant material must be tested for pesticides and metals, which may be introduced during cultivation. Production batches intended for dispensing and direct use as [adult use or](#) medical product must also be tested for biological contaminants (bacteria, fungi, and mycotoxins), as shown in Exhibit 2.

Finished plant material is tested instead of living or freshly harvested plants because drying and trimming may affect the concentrations of contaminants and because fungal/bacterial growth may occur during finishing.

Finished plant material that exceeds a limit (see Section 7.0) for any contaminant included in the required testing cannot be distributed as finished ~~medical~~ Marijuana [without first being reanalyzed and/or remediated pursuant to 935 CMR 500.160\(12\) and 935 CMR 501.160\(11\). The Commission may require additional contaminant screenings to ensure compliance.](#)

Cannabis Resins and Concentrates

Cannabis resins and concentrates may be produced from the finished plant material of one or more cultivation batches. If the finished plant material fails to meet a required testing requirement, but the finished plant material is not dispensed to a [consumer or](#) patient, then it may be used to derive resins and concentrates. The resins and concentrates may be dispensed as long as they meet the respective concentration limit identified in Section 7.0. Each production batch of Cannabis resin or concentrate must be given a sequential identifier for product tracking and labeling. The [Licensee](#) ~~RMD~~ must keep records of the Marijuana cultivation batch(es) used for each production batch, and include the manufacturing/processing batch number on product labels.

Testing requirements for Cannabis resins and concentrates are summarized in Exhibit 2. Because these products may be made only from plant material that has already tested below limits for pesticides, testing for these contaminants is not required again. However, Cannabis concentrates must be tested for metals, as well as residual solvents if solvents were used in their production. [If Cannabis concentrates are produced or extracted with solvent free processes, a solvent screening is not required.](#) Specifically, testing is required for any solvent used to make a Cannabis concentrate production batch.

All Cannabis resin or concentrate production batches intended for distribution to [consumers and](#) patients as finished ~~medical~~ Marijuana products must be tested for bacteria, fungi, and mycotoxins. Testing for these biological contaminants is not required for Cannabis resin or concentrate production batches that will be used only to manufacture MIPs.

If required testing finds that a production batch of Cannabis resin or concentrate exceeds any applicable contaminant limit (see Section 7.0), the production batch cannot be dispensed as a finished ~~medical~~ Marijuana product [without first being reanalyzed and/or remediated followed by additional required contaminant screening to ensure compliance.](#)

Marijuana Vaporizer Products



The provisions set forth in this Guidance Protocol, in conjunction with 935 CMR 500.105(5)(c) and 500.160(1)&(2) and 935 CMR 501.105(5)(c) and 501.160(1)&(2), aim to mitigate the known risks associated with Marijuana vaporizer products that utilize concentrated marijuana oils (vape products). At the time of adoption of this protocol there remain many unknown factors and variables regarding the long-term use and overall effects of using vape products. This section of the guidance protocol addresses several issues and challenges faced when regulating legal vape products in the Commonwealth.

The Commission will continue to facilitate the availability of regulated, legal vape products while also taking steps toward mitigating potential health risks associated with vape products. The Commission understands the need to continue to develop and implement regulations and guidance informed by scientific research that will reflect additional studies into the health effects of utilizing vape products. This Guidance Protocol document shall be updated as new information becomes available to the Commission through its ongoing investigations and findings, as well as through industry research and scientific studies.

MIPs

The CommissionDPH assumes that all MIP production batches will be destined for dispensation and consumer or patient use. Therefore, all MIP production batches must be tested for biological contaminants (bacteria, fungi, and mycotoxins). Production batches must be discarded and not dispensed to patients if any biological contaminant limit is exceeded.

MIPs may be made only with finished ~~medical~~ Marijuana products that have passed applicable metals, pesticide, and solvent testing requirements. For this reason, testing MIPs for metals, pesticide, and solvent contaminants is not required. However, LicenseesRMDs have discretion to perform this testing of MIPs voluntarily.

Each MIP production batch must be given a sequential identifier (ID) for product tracking and labeling. Records must be kept that identify the cultivation batch(es) and finished ~~medical~~ Marijuana production batches associated with each MIP production batch. The manufacturing/processing batch number must be included on product labels to aid in product tracking and recalls.

4.2.2 Cannabinoid Profile Testing

All ~~medical~~ Marijuana products, shown in Exhibit 1, including any finished ~~medical~~ Marijuana or MIP, must bear a label that identifies the list of ingredients, including the cannabinoid profile of the Marijuana contained within the product, including the THC level (935 CMR 500.105(5), 935 CMR 501.105(5) and 935 CMR 502.105(5))~~(105 CMR 725.105(E)(2)(f) and 725.105(E)(3)(e))~~. Therefore, for the purposes of labeling ~~medical~~ Marijuana products in Massachusetts, the cannabinoid profile must include, at a minimum, the percentage by dry weight (i.e., the weight of the material remaining after it has been thoroughly dried) of D9- tetrahydrocannabinol (D9-THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa), and cannabidiolic Acid (CBDa). Medicinal benefits have been attributed to other cannabinoids, and these compounds may be included in the cannabinoid profile at the discretion of the LicenseeRMD.



It is important to note that heat (including combustion) can cause chemical reactions that convert cannabinoids to more or less potent forms. For example, combustion (e.g., during smoking) causes non-psychoactive cannabinoid acids, abundant in the plant material, to be converted to psychoactive forms. However, medical users report health benefits from products that do not require high temperatures or combustion for production or use (AHP 2013).

Because production of finished [medical](#) Marijuana products and MIPs may affect cannabinoid chemistry, as well as the concentration or dilution of active ingredients, each product type must be tested to characterize the cannabinoid content and profile.

4.2.3 Usable Marijuana Content

105 CMR 725.105(E)(2)(c) and 725.105(E)(3)(d) require labels of [medical](#) Marijuana products to identify the quantity of usable Marijuana contained within the product, as measured in ounces. For finished plant material and products containing finished plant material, the quantity of usable Marijuana is simply the weight in ounces of the plant material in the product. Massachusetts has determined that 10 ounces of finished plant material is the maximum 60-day supply allowed for medical Marijuana patients. This is the largest amount of usable medical Marijuana that may be dispensed by any RMD in Massachusetts.

When finished plant material is used to derive Cannabis resin or concentrates, processing alters the physical form and quantity (i.e., weight and volume) of the usable Marijuana. To enable the comparison of usable Marijuana in the various product types, DPH [originally](#) developed assumptions that should be used to express the quantity of usable Marijuana in Cannabis resins or concentrates in terms of the equivalent ounces of plant material. Based on Colorado Department of Revenue (2015) sources [previously](#) reviewed by DPH, it can be assumed that the yield of a Cannabis resin or concentrate is 19 percent of the starting weight of plant material. This is based on the assumption that a typical butane extraction from 28.4 g (1 oz.) of flower will yield 5.5 g of oil.

When the weight of Cannabis resin or concentrate in a dispensed product is known, the quantity of usable Marijuana, expressed in equivalent plant material weight, should be calculated by multiplying the resin or concentrate weight by 5.3 (i.e., $1 \div 0.19$). For example, the quantity of usable Marijuana in 1.9 ounces of Cannabis oil is 10 ounces (1.9 ounces of Cannabis oil \times 5.3 = 10 ounces of usable Marijuana). Therefore, 1.9 ounces of Cannabis oil is equivalent to the maximum 60-day supply of useable plant material.

The amount of usable Marijuana in a MIP is equal to the amount of usable Marijuana included in the product ingredients, measured before mixing, baking, or other processing or manufacturing steps. If more than one type of finished Marijuana ingredient is used to prepare a MIP, the amount of usable Marijuana in the MIP is the sum of the usable Marijuana in the ingredients.

5.0 Sampling Program Design

Under [935 CMR 500.160\(2\) AND 935 CMR 501.160\(2\)](#), [105 CMR 725.105\(C\)](#), [medical](#) Marijuana must be tested for the cannabinoid profile and contaminants. The [medical](#) Marijuana products to be tested include: finished plant material (i.e., inflorescences or “buds”), Cannabis resin, Cannabis concentrates, and various types of MIPs. The purpose of testing is to ensure product quality and safety, and to provide information needed for product labeling requirements.



Because it is not possible to test all ~~medical~~ Marijuana, ~~LicenseesRMDs~~ must collect representative samples to provide to one of the Commission's licensed ITLs analytical laboratory. Specifically, each medical Marijuana production batch must be sampled and analyzed, and the samples collected for a production batch must be representative of all of the medical Marijuana in the batch. The protocol provides the following definition of production batch:

Production Batch means a batch of finished plant material, Cannabis resin, Cannabis concentrate, or MIP made at the same time, using the same methods, equipment, and ingredients. The ~~Licensee RMD~~ must assign and record a unique, sequential alphanumeric identifier to each production batch for the purpose of production tracking, product labeling, and product recalls. All production batches must be traceable to one or more Marijuana cultivation batch(es).

Samples from each production batch must be collected in a ready-to-use condition. For production batches that will be dispensed to patients, ready-to-use means ready for packaging or post-packaging. For other production batches, ready-to use means ready for use as an intermediate or ingredient in making other products. After samples are collected, the entire production batch must be stored in a secure, cool, and dry location until analytical results are returned by the laboratory.

Sampling frequency is dictated by the production schedules, which may vary among ~~LicenseesRMDs~~ due to scale, product types dispensed, and consumer and patient demand. The ~~LicenseeRMD~~ is responsible for implementing a production batch tracking approach that meets the regulatory needs and definitions as well as ensuring representative sample collection and analysis of those batches. The ~~LicenseesRMDs~~ must be able to demonstrate to the Commission inspectors that the production tracking, sampling, and analysis procedures are capable of obtaining representative samples. The guidelines below are provided to aid ~~LicenseesRMDs~~ in developing an approach that meets CommissionDPH requirements for representativeness.

To perform required testing, ~~LicenseesRMDs~~ will collect samples to be analyzed by licensed independent and appropriately certified ITLs laboratories, as noted in Section 7 of this protocol. The amounts of sample required for cannabinoid or contaminant testing may vary by analytical method and laboratory-specific procedures, therefore the ~~LicenseeRMD~~ should confer with the ITL laboratory to determine the minimum sample size required for evaluation. In all cases, the amount of sample supplied to the laboratory should be large enough and sufficiently homogenized to provide a representative sample of the production batch but not in excess to raise issues with possible diversion or waste disposal.

5.1 *Representative Sampling*

Specific procedures for collecting representative samples of ~~medical~~ Marijuana production batches are likely to vary depending on several attributes of the products and production methods:

Homogeneity – A sample is more likely to accurately represent the production batch if the material is homogenous (i.e., well mixed). Mixing or other homogenization steps help to homogenize the product before sample collection.

Physical Form – Production batches will vary in physical form (e.g., liquids, solids), density, and viscosity. Physical form can affect homogeneity, homogenization steps, and sample collection methods.



For example, liquid products can be homogenized by stirring. Grinding and other methods described further below can be used to homogenize solid products.

Quantity – Because production batches may vary in scale (i.e., volume or weight), varying numbers or sizes of samples may be required to promote representativeness.

In addition, sample representativeness can be affected by the timing and frequency of sample collection. Because of variation among production schedules (e.g., due to product type, production scale, patient demand), sampling frequencies will vary among [Licensees/RMDs](#) and production batches. However, representativeness will be ensured by the requirement that all production batches are tested.

5.2 *Representative Sampling by Physical Form and Quantity*

Exhibit 3 provides instructions for representative sampling of [medical](#) Marijuana production batches, including finished [medical](#) Marijuana products and MIPs. These instructions were developed based on sampling guidance for food products and herbal medicines developed by the Codex Alimentarius Commission (1999) and the United States Pharmacopeia Chapter 561 (USP, Undated-b), respectively, and account for differences in the physical forms of the production batches as they relate to homogeneity and quantity. If application of these guidelines is impractical for specific products, it is the responsibility of the [Licensee/RMD](#) to develop and document a scientifically-defensible sampling approach.

Homogeneity plays an important role in methods for representative sampling. While liquid products such as Cannabis oil and liquid MIPs can be stirred or mixed to homogenize the product before sampling, other products such as Cannabis resin, baked goods, or hard candies cannot. Homogenization of some solid products, such as ground plant material or semi-solid resin is possible. Because of its importance, further guidance on homogenization methods is provided in Section 5.3.

5.3 *Sampling Guidance by Matrix*

Finished Marijuana products and MIPs can be in varied physical states or matrix (e.g., liquids to hard solids). To better understand the specific requirements the following guidance is provided based on the matrix of the material to be characterized.

Liquids (Cannabis Oil and Some MIPs)

Liquid products such as Cannabis oil or liquid MIPs should be thoroughly stirred or mixed before sampling to ensure homogenization of the sample. Cannabis oil or other liquid Cannabis from each production batch should be sampled using units of volume. Samples of concentrates or oils should be collected following each production batch if they are to be sold, and before any further processing into MIPs.

Finished Plant Material or Friable MIPs



Sampling shall be performed such that the dried and trimmed inflorescences, or buds, of the [medical](#) Marijuana plant that are collected are representative in maturity and composition of the entire production batch of finished plant material. The sampling timeframe for Marijuana buds should be after the completion of the finishing (i.e., drying and trimming) of the plant material production batch.

Homogenization of the finished plant material may be difficult to accomplish prior to sampling due to the heterogeneous nature of the finished plant material. Recommendations from ISO 1839-1980 guidelines for sampling loose leaf tea (i.e., a material similar in nature to Cannabis plant material) state that in most cases it is “impracticable and purposeless” to re-blend the contents of a large container of tea in order to obtain a representative sample. USP guidance for sampling articles of botanical origin (USP Chapter <561>) recommends that, for items with component parts larger than 1 cm in any dimension, samples should be withdrawn by hand, then combined and mixed prior to analysis. ISO 1839-1980 also states that if the primary samples consist of loose material, they should be combined to constitute the bulk sample for evaluation.

Quartering is a method to promote the representativeness of a homogenized [medical](#) Marijuana sample. Quartering involves heaping the adequately mixed and homogenized ground product into a square shape, dividing the heap into four equal quarters, and selecting samples from two of the opposite quarters, which are mixed and sampled (Sexton and Ziskind, 2013; USP Chapter <561>; WHO, 2007). The remaining quarters may then be combined and mixed, then used for microbiological and contaminant testing (Sexton and Ziskind, 2013; USP Chapter <561>; WHO, 2007). The quartering process may be repeated until the required quantity is obtained, and the remaining material may be returned to the batch if possible (USP Chapter <561>; WHO, 2007).

Solids and semi-solids (Cannabis Resin and Some MIPs)

Solid and semi-solid products such as resin should be ground and thoroughly mixed, if possible, to be homogenized (USP Chapter <561>; WHO, 2007). A grinding device that minimizes loss (e.g., leaching of resins from finished plant material) should be used, and the grinding device should be cleaned thoroughly after each use. Once ground, quartering, as described above, can be used to collect the sample.

If grinding is impracticable, subsamples of the product should be taken from different areas of the product mass. For example, it might be possible to slice the product mass in sections prior to collection of subsamples or take the subsamples directly from different locations on the product surface (e.g., lower, middle, and upper).

Resin and other solids should not be melted as a means of homogenization. Heating the product may alter the cannabinoid profile or contaminant levels (WHO, 2005) thereby rendering the sample unrepresentative of the source product.

When subsamples are required, subsamples should be composited (combined), if possible, and mixed to obtain a quantity sufficient for evaluation. The quantity sufficient for evaluation may vary by analytical method and laboratory-specific procedures, therefore the [LicenseeRMD](#) should confer with the [ITL laboratory](#) to determine the minimum sample quantity required for evaluation.



Compositing subsamples may be impractical for some product types (e.g., hard candies or other products in discrete solid units). In these cases, individual product units can be provided to the [ITL laboratory](#) as samples for analysis. In some cases the [ITL laboratory](#) may combine extracts or digestates prepared from the solid subsamples and analyze the volumetrically combined extract/digestate as a composite.

5.4 *Quality Control (QC) Samples*

Duplicate samples shall be collected to provide verification of sampling and laboratory procedures. Specifically, a duplicate should be collected for 5 percent (1 per 20) of the samples collected for each [medical](#) Marijuana product type. Duplicate samples shall not be identified to the [ITL laboratory](#) (this is considered blind quality control). Duplicate samples are used to evaluate any variance in the sampling and analysis procedures. To ensure authenticity, it should be noted that QC samples should be taken on the same day, be derived from the same batch and documented on the [Commission DPH](#) test results tracking sheet.

6.0 **Sample Collection Procedures**

This section describes sample collection procedures that are generally applicable to any [medical](#) Marijuana product that [LicenseesRMDs](#) may dispense, including, but not limited to, finished plant material; liquid concentrates or MIPs; resins, waxes, creams, or other semi-solid products; or solid concentrates or MIPs ; or [vape products](#). Because of the wide range of [medical](#) Marijuana products that [LicenseesRMDs](#) may offer, particularly MIPs, these sample collection procedures may require adaptation in some cases.

In all cases, sample collection must be conducted in a manner that provides analytically sound and representative samples so that all [medical](#) Marijuana products dispensed are safe, effective, and accurately labeled. The [LicenseeRMD](#) must document every sampling event and provide this documentation to the [Commission Department](#) upon request.

Prior to Sample Collection. The [LicenseeRMD](#) should assemble all equipment and information needed before beginning. Items to assemble before sampling include, but are not limited to, the following:

- Sample collection plan for each product type;
- Logbook or sample collection forms;
- Chain-of-custody forms (COCs);
- Disposable gloves;
- Decontaminated tool(s), such as a spatula, knife, sampling spear, or pipette;
- Stainless steel bowl and implement to homogenize the product (e.g., by stirring, chopping, or grinding);
- Clean, decontaminated surface for sample processing;
- Sample containers appropriate for the analyses required;
- Container labels and pen with indelible ink;
- Supplies to thoroughly clean, decontaminated and dry sampling equipment between samples; and
- A cooler with ice to keep samples cool until refrigeration or shipment to the laboratory.

Sample collection personnel should create a new entry for each sampling event in a sample collection logbook or prepare sample collection forms for documentation of sample collection. Sample collection



documentation should identify the sample collection date and start time, participating personnel, a general description of the product type and batch number sampled, a description of the sampling procedures used, and a record of batches that would potentially be impacted should analysis results indicate unacceptable contamination levels.

Sample collection personnel shall identify or determine the cultivation batch number, production batch, and number of samples to be collected based on the guidance provided in Section 5, as well as further guidance obtained in consultation with the [ITLs laboratory](#). The number of samples taken from each cultivation and/or production batch must be recorded in the sample collection logbook or forms. Record the sample cultivation and production batch identifiers (ID) for each sample. The batch IDs will be included on sample labels. In addition to the batch ID, create a unique sample ID for each sample. Sample identifiers should be unique for a given sample event. Record the batch and sample IDs in the sample collection logbook.

Any tools that contact the samples should be made of stainless steel or other inert material to avoid potential contamination of the sample. Appropriate sample containers should be made of suitable materials.

Preparing sample labels and affixing them to sample containers immediately before sampling is recommended. Information to include on the label includes at a minimum the batch and sample IDs and date/time of collection and by whom. Additional information that must be recorded in documentation, if not on the label, includes sample collector's name, product type, collection method, and other details about the product, such as MIP type or production method.

Sample Collection. Collect the planned samples from each cultivation or production batch one at a time. Follow these basic steps for each sample:

1. Wear disposable gloves to mitigate potential for contamination of samples.
2. Ensure that the sampling area is clean and decontaminated and lay out any tools and equipment needed.
3. Collect the sample using an appropriate tool. Do not touch the sample with your hands or allow the sample to touch anything that might cause cross contamination.
4. If necessary, place the sample in the stainless steel bowl or on a decontaminated cutting surface for homogenizing the sample using either the sample collection tool or separate clean, decontaminated implement.
5. Record the time each sample was collected and record any difficulties, inconsistencies with the sampling plan, or other remarks (e.g., environmental conditions) that might be relevant to data analysis or quality assurance.
6. To avoid cross contamination of samples, any tools or equipment that comes in contact with the finished plant material or other Marijuana products should be cleaned before collecting the next sample.
7. All samples should be placed in clean, airtight sample containers that are large enough to hold the prescribed sample quantity with minimal headspace. Sample containers must be firmly closed and appropriately labeled.
8. To preserve the chemical and biological composition of the samples, they should be refrigerated or maintained on ice until shipped to the analytical laboratory.



9. Chain-of-custody paperwork should be completed immediately prior to shipment to the analytical laboratory.

~~Medical~~ Marijuana products and MIPs, especially solids or semi-solids such as finished plant material, may be heterogeneous with respect to distribution of cannabinoids or contaminants. To obtain a representative sample, liquid products should be thoroughly stirred or mixed before sampling. Solid and semi-solid products must be ground and thoroughly mixed. A grinding device that minimizes loss (e.g., leaching of resins) should be used, and the grinding device should be cleaned thoroughly after each use.

Another method to promote the representativeness of a ground ~~medical~~ Marijuana product is quartering. Quartering involves heaping the ground product, dividing the heap into four equal quarters, and selecting samples from two of the quarters, which are combined and mixed (Sexton and Ziskind, 2013). The remaining quarters may then be combined and mixed, then used for microbiological and contaminant testing (Sexton and Ziskind, 2013).

Resin and other solids should not be melted as a means of homogenization. Heating the product may alter the cannabinoid profile or contamination levels (WHO, 2005) thereby rendering the sample unrepresentative of the source product.

Edible products tend to be relatively homogeneous (Sexton and Ziskind, 2013), so a selection of packaged or ready-to-dispense MIPs may be provided to the analytical laboratory to represent a given production batch (Sexton and Ziskind, 2013). MIPs may be either liquid or solid, and the solid MIPs may be of varying density (e.g., baked goods, candies, etc.). Laboratory samples of MIPs shall be homogenized prior to testing such that the sample is representative of the whole product. Homogenized samples should be mixed and quartered similar to the procedure described above. If production batches of individually packaged MIPs are sampled, multiple packaged products should be sampled such that they are representative of the production batch size.

7.0 Sample Analysis

All sample analyses described in this protocol shall be conducted by an independent laboratory that is either:

1. Accredited to International Organization for Standardization (ISO) 17025 by a third party accrediting body such as A2LA or ACLASS, or
2. Certified, registered, or accredited by an organization approved by the Massachusetts Department of Public Health.
3. [Licensed and registered with the Massachusetts Cannabis Control Commission pursuant to 935 CMR 500 , 935 CMR 501 and 935 CMR 502 .](#)

Further requirements concerning the eligibility and responsibilities of analytical laboratories are provided in [935 CMR 500.029 and 935 CMR 501.029.](#) ~~105 CMR 725.105(C)(2).~~

In addition to the regulatory qualifications and requirements referenced above, the independent laboratory should have a demonstrated ability to perform the specific analytical methods required and to provide defensible documentation and quality assurance.



The sections below identify the analytical methods and analyses required for characterizing the cannabinoid profile of ~~medical~~ Marijuana products, as well as the presence and levels of potential contaminants, including metals, pesticides and plant growth regulators, microbiological contaminants and mycotoxins, and residual solvents.

7.1 Cannabinoid Profile

~~The optimal cannabinoid profile for medical Marijuana has not been definitively determined, and this balance may differ depending on the medical condition being treated (AHP, 2013).~~

Although many cannabinoids and related compounds are present in the Cannabis plant, characterization of the cannabinoid profile should include, at a minimum, the dry-weight percentage of ~~delta-nine~~~~D9~~-tetrahydrocannabinol (D9-THC) and cannabidiol (CBD).

Because target cannabinoid contents and ratios may vary depending on the desired dosage, medical condition, and other use considerations, minimum profile standards are not mandated. However, the cannabinoid profile must be included in product labeling under 935 CMR 500.105(5), 935 CMR 501.105(5) and 935 CMR 502.105(5)~~as an aid to patients and caregivers~~. Analytical procedures for determining cannabinoid profiles are available in AHP (2013).

7.2 Metals

Finished ~~medical~~ Marijuana products must be tested for the four metals listed in Exhibit 4. Quantification of metals must be performed with a validated method such as those provided by USP (Chapter <233>) or FDA (2011). A production batch of finished ~~medical~~ Marijuana products (e.g., finished plant material, Cannabis resin, or Cannabis concentrate) may only be dispensed to patients if all four of the metals are below the upper limits for the respective product and intended use specified in Exhibit 4 (e.g., ingestion only or all other uses). These limits are in micrograms (µg) of contaminant per kilogram (kg) of product.

Once a production batch of finished ~~medical~~ Marijuana has been determined to meet the limits in Exhibit 4, it must bear the following label:

This product has been evaluated for environmental contamination (impurities) assuming that no more than 10 grams (0.35 ounces) of finished plant material (or the equivalent amount of concentrate) will be consumed per day.

In addition to the above labeling requirement for all production batches of finished ~~medical~~ Marijuana, if the quantification of metals is below the upper limits specified for “Ingestion Use Only”, as described in Exhibit 4 (b), the production batch of finished ~~medical~~ Marijuana must bear the additional label:

This product has been evaluated for impurities based on oral consumption only.
DO NOT INHALE THIS PRODUCT.

7.2.1 Metals and Marijuana Vape Products

Heavy metal accumulations are an issue of particular concern when analyzing and assessing the potential health impacts associated with the use of vape products. Instances of elevated levels of heavy metals have



been identified in vape products tested by the Commission that have been subject to quarantine in accordance with the *First Amended Quarantine Order Applying to Vaporizer Products with Conditions* (“First Amended Quarantine Order”), issued on December 12, 2019. In some cases the sampled vape product(s) failed testing due to heavy metal concentrations in excess of allowable limits. The upper allowable limit for heavy metals in marijuana and marijuana products is 500 parts per billion (ppb) for all uses and 1,000 ppb for ingestion only as stated in Exhibit 4.

The leaching of heavy metals into vape products may be due to a number of factors including time, device composition, temperature and usage. The factor of time is particularly concerning because it is not known how long leaching occurs after vape devices are filled with cannabis oil. In the absence of sufficient information developed over the course of long-term studies regarding vape devices that all potential contributing factors that impact the leaching of metals into vape products will continue to be monitored and investigated by the Commission. Accordingly, Licensees shall continue to conduct a second heavy metal screening requirement on all finished vape products subject to the First Amended Quarantine Order.

Every vape product sold must be accompanied with a written insert at the point of sale which identifies the manufacturer of the device and its known components, including the battery, and discloses materials used in the device’s atomizer coil (e.g. titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified materials). Specific additives used in the production of the vape product, including thickening agents, thinning agents and terpenes, shall also be disclosed along with their Certificates of Analysis. The Commission will continue to gather information regarding the manufacturing and design specifications of the vape cartridge and devices and will update this Guidance Protocol regarding heavy metal accumulations in vape products accordingly.

7.3 *Pesticides Residues and Plant Growth Regulators*

Non-organic pesticides may not be used to cultivate ~~medical~~ Marijuana in Massachusetts (935 CMR 500.120(5) and 935 CMR 501.120(5).~~(105 CMR 725.105(B)(1)(d)).~~ As discussed in Section 5, all production batches of finished plant material must be tested for residues of prohibited pesticides. At a minimum, samples of finished plant material must be tested for the pesticides, including plant growth regulators, listed in Exhibits 5 and 5 a. ~~These pesticides were identified by AHP (2013) as commonly used in Cannabis cultivation.~~ Exhibits 5 and 5a identifies appropriate analytical methods for each of the listed pesticides.

A production batch of finished plant material may be dispensed to consumers, patients or be used to make other Marijuana products if no individual pesticide or plant growth regulator is detected above 10 ppb. A laboratory that is unable to perform the required testing of pesticide residues at or below the 10 parts per billion (ppb) criteria may determine compliance by ensuring that any pesticide residues are present at a level less than or equal to 5 percent of the US EPA tolerance for the specific residue. EPA pesticide tolerances are available from Title 40 of the Code of Federal Regulations (CFR). In such circumstances, DPH should be notified regarding the specific pesticides to which this method is being applied.

Marijuana and Marijuana products shall be tested for contaminants specified by the Commission but not limited to any plant growth regulators and the presence of pesticide. Although the Commission currently enforce a no tolerance pesticide policy, a 10 parts per billion (10 ppb) threshold has been established. Any



product that obtains a true value at the LOD concentration means there is at least a 99% probability of reporting a detection. Pesticide detection above the limit of detection (LOD) but below the quantification limit (BQL) is also considered out of compliance.

The ITL's shall report the pesticide levels in Marijuana products that are detected in the certificate of analysis. If a sample is found to contain pesticides or is above the permissible limits in the pesticides table (exhibit 5), it is considered out of compliance and or a failure. Under 935 CMR 500.120(5) and 935 CMR 501.120(5) licensees are required to immediately report to the Commission any test result indicating pesticide noncompliance. The associated product batch may not be released for retail sale and may not be remediated

~~Exhibit 5 includes only a small number of the many prohibited non-organic pesticides registered for use in the U.S. To test medical Marijuana for pesticides beyond the minimum list in Exhibit 5, Massachusetts recommends additional testing based on the approach USDA Certifying Agents use to analyze prohibited pesticides in organic food.~~

Exhibit 5 requires Marijuana and Marijuana products to be tested for the following pesticides:

1. Bifenazate (Miticide)
2. Bifenthrin (Insecticide)
3. Cyfluthrin (In
4. Extoxazole (Insecticide/Insect Growth Regulator)
5. Imazalil (Fungicide)
6. Imidacloprid (Insecticide)
7. Myclobutanil (Fungicide)
8. Spiromesifen (Insecticide)
9. Trifloxystrobin (Fungicide)

Exhibit 5-a requires Marijuana and Marijuana products to be tested for the following pesticides (in addition to those specified in Exhibit 5):

1. Abamectin
2. Azadirachtin
3. Azoxystrobin
4. Boscalid
5. Carbaryl
6. Chlorfenapyr
7. Dinotefuran
8. Lambda-Cyhalothrin
9. Paclobutrazol
10. Permethrin
11. Piperonylbutoxide
12. Pyrethrin
13. Spinosad
14. Spirotetramat



Acknowledging that no method currently exists that analyzes all registered pesticides efficiently (USDA, 2012a), USDA developed a “target” analyte list of 195 prohibited pesticides (USDA, 2011). Under USDA procedures for pesticide residue testing in organic food (USDA, 2013; USDA, 2014), ~~laboratories employed by organic Certifying Agents should “attempt to analyze as many compounds on [the USDA target analyte list] as possible.” Analytical laboratories employed by RMDs for medical Marijuana testing in Massachusetts should follow the same approach.~~ Specifically, pesticide testing should be performed consistent with the following sections of National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations (USDA, 2014):

NOP 2611: Laboratory Selection Criteria for Pesticide Residue Testing NOP 2611-1: Prohibited Pesticides for NOP Residue Testing

NOP 2613: Responding to Results from Pesticide Residue Testing

A further discussion of the application of this testing approach is available in USDA’s 2010 - 2011 Pilot Study Pesticide Residue Testing of Organic Produce (USDA, 2012b).

7.4 *Microbiological Contaminants and Mycotoxins*

Analytical requirements for microbiological contaminants and mycotoxins are listed in Exhibit 6. Requirements for total viable aerobic bacteria, total yeast and mold, total coliforms, and bile-tolerant gram-negative bacteria are given in colony forming unit (CFU) counts per mass of product sample. The requirement for pathogenic *E. coli* and *Salmonella* spp. is based on detection in a 1 gram sample, and the requirement for mycotoxins is based on the concentration per kilogram of sample. Analytical methods for enumerating and identifying specific microbiological contaminants must be consistent with the following United States Pharmacopeia (USP) chapters:

- USP Chapter <61>: Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. USP 36, Chapter <61>
- USP Chapter <62>: Microbiological Examination of Nonsterile Products: Tests for specified Microorganisms. USP 36, Chapter <62>

Analytical methods for mycotoxins must be consistent with USP chapter:

- USP Chapter <561>: Articles of Botanical Origin. USP 36, Chapter <561>

7.5 *Residual Solvents*

As discussed in Section 4.2.1, residual solvents testing is required only for Cannabis resins and concentrates where solvents have been used in the production process. In particular, a production batch of Cannabis oil may be dispensed as a finished ~~medical~~ Marijuana product or used to make another ~~medical~~ Marijuana product only if:



- Laboratory analysis verifies that all solvents used at any stage of Cannabis oil production, except in cleaning equipment, are below the limits provided in Exhibit 6; and
- The production batch passes all other applicable testing requirements.

Only solvents listed in Exhibit 7 may be used in the production of Cannabis oil. A [LicenseeRMD](#) is required to test only for those solvents used, and it is not required to test for any residual solvents if it can document that no solvents were used in the Cannabis oil production process.

The upper limits for residual solvents in Exhibit 7 are given as milligrams of residual solvent per kilogram of Cannabis oil. ~~DPH developed~~ the upper limits [are](#) based on residual solvent standards provided by the United States Pharmacopeia (USP Chapter <467>), the International Conference on Harmonization (ICH, 2011), and AHP (2013). Consistent with the standards provided by these sources, “Class 1” solvents including benzene, carbon tetrachloride, 1,2- dichloroethane, 1,1-dichloroethene, and 1,1,1-trichloroethane may not be used in the production of any [medical](#) Marijuana product.

Analyses to determine residual solvent concentrations in [medical](#) Marijuana products must be performed in accordance with the methods identified in USP Chapter <467>.

7.6 Vitamin E Acetate (NEW SECTION)

[Vitamin E Acetate \(VEA\) is a contaminant of concern that has been linked to unregulated, vape products acquired on the illicit market. The Center for Disease Control and Prevention has previously identified VEA as a potential contributor to the 2019 EVALI \(e-cigarette or vaping product use associated lung injury\) outbreak. While results from tests ordered by the Commission show that no licensed vape product tested positive for VEA. the Commission ~~will~~should continue to require mandatory VEA testing on final, ready-to-sell vape products until a final determination between VEA and EVALI has been reached by the CDC or until the Commission rescinds the First Amended Quarantine Order .](#)

[The Marijuana vape product guidance protocol recommends that for a final, ready-to-sell vape product, a test sample of the finished product containing at least one \(1\) gram of marijuana oil must be sent to one of the Commission’s licensed ITLs for heavy metal and VEA testing. A one \(1\) gram test sample will provide the ITLs with enough source material to run the required tests in addition to any duplicative screenings if needed. The one \(1\) gram sample size amount takes into consideration the inherent challenges and difficulties with extracting marijuana oil from final, ready-to-sell vape products.](#)

[Marijuana vape products will continue to receive all required contaminant testing for concentrates as required under 935 CMR 500.160.105\(5\)\(e\) and 935 CMR 501.160.105\(5\)\(e\). Additionally, per the Commission’s First Amended Vape Order and 935 CMR 500.160.05\(5\)\(e\)\(16\) and 501.160.05\(5\)\(e\)\(16\) \(if adopted\), final ready-to-sell vape products must also pass a second heavy metal screen in addition to a Vitamin E Acetate \(VEA\) screen.](#)

[To date, a standardized method for opening Marijuana vape products and extracting the oil contents has not been developed by any of the Commission’s licensed ITLs. The Marijuana oil from the pre-filled vape](#)



products must first be carefully extracted from the device or cartridge before conducting the heavy metal and VEA tests to prevent introducing contaminants. Many of the vaporizer product devices are not constructed in a manner that easily allows them to be reopened after being sealed. These vaporizer products are not easily opened once sealed partly due to concerns with tampering of finished devices. Care must be taken during the extraction process such as not to introduce metal fragments that may inadvertently become loose from tools or instruments. The Commission will continue to work with the ITLs and vape product device manufacturers in efforts to eventually create standardized instructions for extracting marijuana oils from final, ready-to-sell vape products.

8.0 Data Evaluation

Licensees are required to reanalyze or remediate failed Marijuana and Marijuana products pursuant to 935 CMR 500.160(12) and 935 CMR 501.160(11). Upon receiving notification that Marijuana or Marijuana product has failed any test for contaminants, the Licensee shall either reanalyze the Marijuana or Marijuana product, shall take steps to remediate the Marijuana or Marijuana product or destroy the Marijuana and Marijuana product. Licensees must ensure that any failed Marijuana and Marijuana product are properly remediated through the Commission's Seed-to-sale System of Record (Metr).

Reanalysis

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 original ITL, an additional sample representing the same sample set previously tested shall be submitted to an 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 an ITL other than the ITL that provided the initial failed result. 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 is subject to an Order of Destruction to be issued by the Commission at its discretion.

Remediation

If the Licensee chooses to remediate, a new test sample shall be submitted to any licensed ITL, which may include the ITL that provided the initial failed result, 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 is subject to an Order of Destruction to be issued by the Commission at its discretion.

Destruction



If the Licensee chooses to destroy the failed Marijuana and Marijuana product it shall do so in accordance with 935 CMR 500.105(12) and 935 CMR 501.105(11~~2~~).

Licensees are required under 935 CMR 500.160(4)~~1~~&(3) and 935 CMR 501.160(4)~~1~~&(3) to “have a written policy for responding to laboratory results that indicate contaminant levels are above acceptable limits established in the protocols.” The analytical results provided by the ITLs, including those for finished Marijuana and Marijuana productsdiscussed in this protocol, will be a primary means for Licensees to ensure compliance with this requirement.

The ~~ITL~~independent laboratory results must include, at a minimum, the following in the laboratory data package:

- Case Narrative:
 - o The narrative, written on laboratory letterhead, shall describe any sample receipt, preparation, or analytical issues encountered as well as any method non- conformances or exceedance of QA/QC criteria used by the laboratory.
- The narrative shall identify the preparation and analytical methods utilized by the laboratory.
- The narrative shall include a signed statement by an authorized laboratory representative as to the accuracy, completeness, and compliance with the methods of the results presented.
- Chains-of-custody (COC) information or other paperwork indicating requested analyses and documentation of sample collection and receipt.
- Summary of analytical results including sample identifier, methods performed, target analytes analyzed for, result or reporting limit, proper qualifier according to laboratory standard procedures, units of measure, preparation date(s), where applicable, and analysis date(s).

It is highly recommended that the laboratory data package also include sufficient data to evaluate the laboratory results, including a summary of laboratory QA/QC results. The type of applicable QA/QC results differ by analysis method, but can include surrogates or deuterated monitoring compounds, laboratory QC samples such as spikes, blanks, and duplicates, and calibration summaries. It is the responsibility of the Licensee~~RMD~~ to provide information sufficient to demonstrate that the results are accurate and precise, and in line with method capabilities and project data quality objectives (DQOs).

Depending on the outcome of the analysis, the Licensee~~RMD~~ may need to take action to address unacceptable levels of contamination or to perform follow-up investigation. Exhibit 8 is a flowchart Licensee~~the RMD~~ should use to determine the correct course of action in response to each laboratory analytical data package. As discussed above, if any analysis fails to meet all applicable DQOs, then the finished ~~medical~~ Marijuana product or MIP cannot be dispensed. In this case, the production batch may be resampled for follow-up testing. A production batch may be retested once and records of the original



analysis must be retained. If applicable DQOs are not met, the production batch cannot be dispensed to consumers or patients, or used in the production of MIPs.

If a batch of finished plant material fails to meet a metal or a bacteria/fungi/mycotoxin standard described in Exhibits 4 and 6, the finished plant material cannot be dispensed to a consumer or patient as finished ~~medical~~ Marijuana without first being reanalyzed and/or remediated pursuant to 935 CMR 500.160(13)(42), 935 CMR 501.160(12)(4) or 935 CMR 502.160(1). Finished plant material that fails to meet a metal or a bacteria/fungi/mycotoxin standard It may be used to derive other finished ~~medical~~ Marijuana products (e.g., resins, concentrates). While the finished plant material or finished ~~medical~~ Marijuana product may be treated in a manner to reduce the concentration of metals or bacteria/fungi/mycotoxin contaminants, the finished plant material or finished ~~medical~~ Marijuana product may not be treated to bind or restrict the availability of the metals or bacteria/fungi/mycotoxin in an analysis without reducing the total contaminant content.

If a batch of finished plant material fails to meet a pesticide residue and plant growth regulator limit described in Exhibit 5, Exhibit 5a and Section 7.3, ~~it~~ cannot be dispensed to consumers or patients or used to derive other products. Marijuana and Marijuana products that fail for pesticides or plant growth regulators may not be remediated and the associated batch will be subject to an Order of Destruction issued by the Commission at its discretion. The batch may be retested once. If the batch fails the retest it must be destroyed.

If a concentrate or resin exceeds the residual solvent requirements described in Exhibit 7 and Section 7.5 it cannot be dispensed to consumers or patients without first being reanalyzed and/or remediated pursuant to 935 CMR 500.160(12) and/or 935 CMR 501.160(11). ~~The concentrate/resin may be processed and retested.~~ If upon reanalysis and/or remediation ~~retest~~ the concentrate/resin meets the residual solvent standard, the ultimate finished ~~medical~~ Marijuana product may be dispensed to consumers and patients as long as all applicable limits are met.

As required by 935 CMR 500.160(54), 935 CMR 501.160(54) and 935 CMR 502.160(1) ~~105 CMR 725.105(C)(2)(b)~~, the Licensee/RMD must maintain the results of all testing for no less than one year. These records must be available for inspection by the Commission/Department, upon request. ~~(105 CMR 725.105(I)), and maintained at the RMDs expense in a form and location acceptable to the Department for at least two years after closure (105 CMR 725.105(I)(7)).~~

9.0 References

AHP. 2013. Cannabis Inflorescence, Cannabis spp., Standards of Identity, Analysis, and Quality Control. American Herbal Pharmacopoeia. 2013. Available at: <http://www.herbal-ahp.org/index.html>

Codex Alimentarius Commission. 1999. Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs. CAC/GL 33.

Colorado Pot Guide. 2014. "Different types of Marijuana concentrates available in Colorado," Website: Colorado Pot Guide, February 6, 2014. Available at: <http://www.coloradopotguide.com/colorado-marijuana-blog/2014/february/06/different-types-of-Marijuana-concentrates-available-in-colorado/>



Colorado Department of Revenue. 2015. “Marijuana Equivalency in Portion and Dosage”. August 10, 2015. Available at:
https://www.colorado.gov/pacific/sites/default/files/MED%20Equivalency_Final%2008102015.pdf

FDA. 2011. Analysis of Foods for As, Cd, Cr, Hg and Pb by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS). United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, Current Method CFSAN/ORS/DBC/CHCB April 25, 2011. Available at:
<http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM272693.pdf>

Mechtler, K., Bailer, J., and de Hueber, K. 2004. Variations of Δ^9 -THC Content in Single Plants of Hemp Varieties. *Industrial Crops and Products*. 19 (1): 19-24.

Sexton, M. and Ziskind, J. 2013. Sampling Cannabis for Analytical Purposes. BOTECH Analysis Corp. I-502 Project #430-1e.

USDA. 2014. National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations, U.S. Department of Agriculture, National Organic Program. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5096778>

USDA. 2013. “Periodic Residue Testing of Organic Products,” memorandum from Miles McElvoy, Deputy Administrator, U.S. Department of Agriculture, National Organic Program, to National Organic Program Accredited Certifying Agents, February 28, 2013. Available at:
<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101236>

USDA. 2012a. “Laboratory Selection Criteria for Pesticide Residue Testing,” Document NOP 2611 of “National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations.” U.S. Department of Agriculture, National Organic Program, Effective November 8, 2012. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088988>

USDA. 2012b. 2010—2011 Pilot Study Pesticide Residue Testing of Organic Produce. U.S. Department of Agriculture, National Organic Program and National Science and Technology Programs. November 2012. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101234>

USDA. 2011. “Prohibited Pesticides for NOP Residue Testing,” Document NOP 2611-1 of “National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations.” U.S. Department of Agriculture, National Organic Program, Effective July 22, 2011. Available at: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088987>

U.S. FDA. 1999. Pesticide Analytical Manual, Volume I: Multiresidue Methods (3rd ed., updated October 1999). Center for Food Safety and Applied Nutrition, Office of Plant, Dairy Foods and Beverages. Available at:
<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006955.htm>

United States Pharmacopeia. 2008. “Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.” USP 31, Chapter <61>. Available at: <https://mc.usp.org/sites/default/files/documents/GeneralChapterPDFs/61MicroEnum.pdf>



United States Pharmacopeia. 2008. “Microbiological Examination of Nonsterile Products: Tests for specified Microorganisms.” USP 31, Chapter <62>.

Available at:

<https://mc.usp.org/sites/default/files/documents/GeneralChapterPDFs/62TestForSpecMicro.pdf>

United States Pharmacopeia. 2015. General Chapter <232> Elemental Impurities – Limits: To be Published in 2nd Supplement of USP 38-NF 33. April 17, 2015.

http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/key-issues/c232.pdf

United States Pharmacopeia. General Chapter <232> Elemental Contamination in Dietary Supplements.

http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/key-issues/232_elemental_contaminants_in_dietary_supplements.pdf

United States Pharmacopeia. 2015. “Elemental Impurities -- Procedures.” USP 36, Chapter <233>. April 17, 2015.

Available at: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/key-issues/c233.pdf

United States Pharmacopeia. Undated-a. “Residual Solvents.” First Supplement to USP 36–NF 31, Chapter <467>.

Available at: <https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467%20S%20USP36.pdf>

United States Pharmacopeia. 2008. “Microbial Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Use.” USP 31, Chapter <1111>.

Available from: <http://www.usp.org/>

United States Pharmacopeia. Undated-b. “Articles of Botanical Origin.” USP 36, chapter <561>.

Available at: <https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c561%20USP36.pdf>

WHO. 2005. Annex 4: WHO Guidelines for sampling of pharmaceutical products and related materials. WHO Technical Report Series, No. 929. World Health Organization, Geneva, Switzerland.

WHO. 2007. WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues. World Health Organization, Geneva, Switzerland. Available at: <http://apps.who.int/medicinedocs/index/assoc/s14878e/s14878e.pdf>, Accessed June 12, 2014





Cannabis Control Commission

Cannabis Control Commission Regulatory Policy Discussion

June 19, 2020 at 10:00 a.m. via Microsoft Teams Live

Agenda

1. Call to Order
2. Chairman's Comments and Updates
3. Staff Recommendation on Provisional Licensure
4. Regulatory Policy Discussion
5. Next Meeting
6. Adjournment



Staff Recommendation on Provisional Licensure

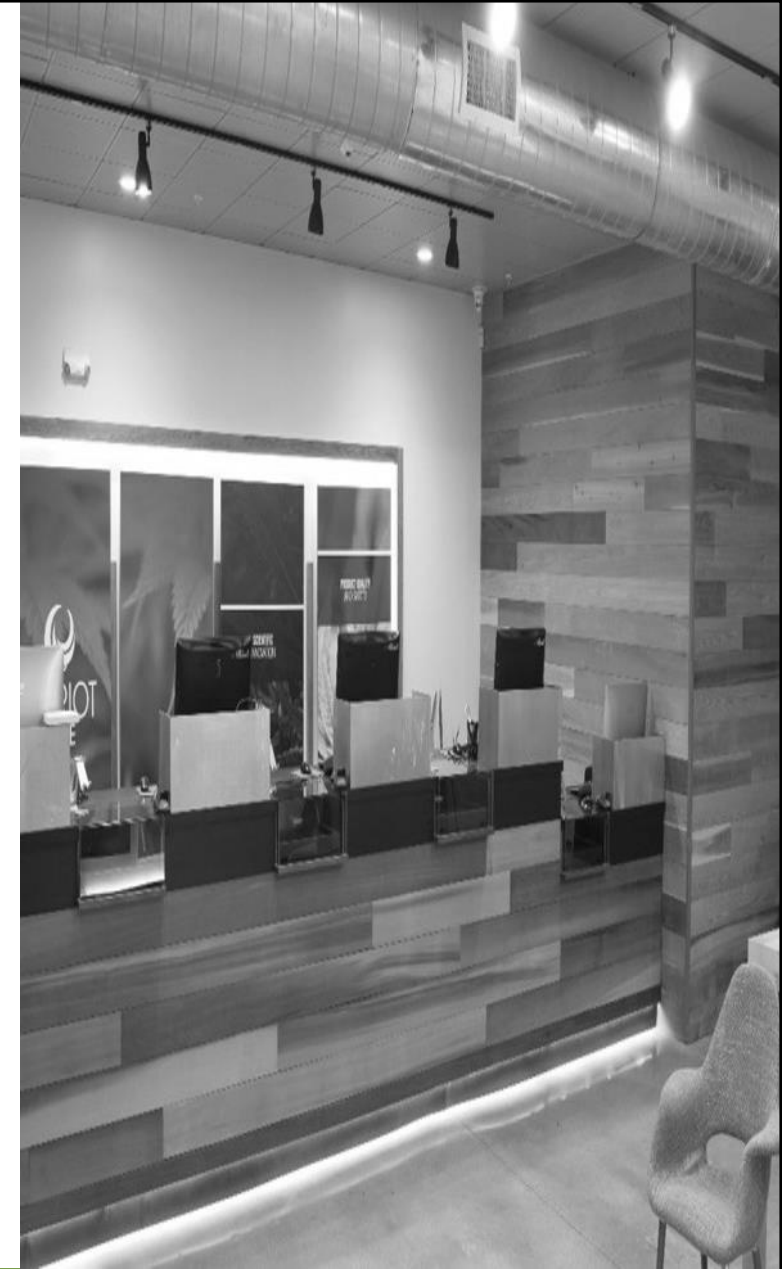
Staff Recommendation on Provisional Licensure

- Hidden Hemlock, LLC. (#MBN281355), Microbusiness



Topics

1. Leadership ratings
2. Receivership and change of control
3. Ownership and control
4. Expanding SEP to other categories
5. Social Equity Program for EEAs
6. ME/MTC Agent Registration
7. Research licenses
8. Delivery
9. Additional Retail Operations - Contactless Retail Operations



Topics

- 10. Vaping Regulations
- 11. Testing
- 12. Economic Empowerment Applicants
- 13. SEP - Equity Ownership Threshold for Social Equity Program
Participants to Receive License Benefits
- 14. Buffer zone
- 15. Giving commission authority to expand delivery endorsements to
other groups
- 16. Verified Financial Hardship Documentation
- 17. Personnel Policy – Require Code of Ethics and Whistleblower Policy



Regulatory Policy Discussion

Recommendations:

1. Leadership Ratings

1. **Social Justice Leadership award** - clarify existing criterion for a Social Justice Leadership Award that contribution to the Social Equity Training and Technical Assistance Fund can be prospective, upon establishment of the fund (or a similar fund) by the Legislature.
2. **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. **Compliance Leader Rating** - change criterion 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.

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

1. Leadership Ratings (*cont'd*)

Recommendations:

4. **Local Employment Leader** – add criterion for rating include supporting other local businesses.
5. The writing group was asked to consider the employment of veterans as a criterion, by adding a new category or integrating it into the employment leader award. The group recommends no change, because it feels this would result in a complex debate among Commissioners and external stakeholders with respect to the host of various categories that could/should be included for the employment leader award.
6. Adopt the Leadership Rating Program in the medical-use of marijuana regulations (Social Justice Leader; Local Employment Leader; Energy and Environmental Leader; Compliance Leader) and add new Leader type, “**MTC Leader**.”

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

2. Receivership and Change of Control

Recommendation:

To establish a process for the Commission to have notice and oversight over Marijuana Establishments (MEs) and Medical Marijuana Treatment Centers (MTCs) placed under the control of a receiver by a Massachusetts court or otherwise designated.

Rationale:

MEs and MTCs may be put into receivership in a variety of circumstances including, without limitation, insolvency or malfeasance by Executives (as defined in the regulation). Given the activities of MEs and MTCs are illegal under federal law, MEs and MTCs cannot avail themselves of bankruptcy proceedings, and thus would have to rely on state law receivership. The following option would create a process for the Commission to have notice and oversight over a receiver, since it could implicate issues of control.

3. Ownership and Control

Recommendations:

1. Update the definition of Control and Ownership to specify that a “significant” contract is one that exceeds \$10,000
2. With respect to requiring Executives of Entities Having Direct Control over an ME to register as Agents, the recommendation is to make no change at this time.
3. Delegate authority to the Executive Director the ability to review and approve certain changes in information under 935 CMR 500.104. The options for this recommendation are:
 - a) State in the regulations that the Commission may delegate this authority to the Executive Director (which would be subject to subsequent votes of the Commission to make specific delegations); or
 - b) State in the regulations that the Commission is delegating the following approvals to the Executive Director: (i) changes to location (ii) any new equity owner, provided that the equity acquired is below 10%; (iii) any new Executive or Director, provided that the equity acquired is below 10%; (iv) a reorganization, provided that the ownership and their equity does not change; and (v) Receiverships

3. Ownership and Control (*cont'd*)

Rationale:

1. The definition change would give greater clarity over what a “significant” contract means.
2. The group felt that making a change to the requirements regarding Direct/Indirect Control within a year of the most recent changes could create confusion and difficulty around compliance. Requiring Executives of an Entity Having Direct Control over an ME to register as Agents may be easier to implement once the Commission’s screening/background check process allows for individuals to be screened out of state.
3. The delegation of authority would allow for expediency on (i) changes to location (ii) any new equity owner, provided that the equity acquired is below 10%; (iii) any new Executive or Director, provided that the equity acquired is below 10%; (iv) a reorganization, provided that the ownership and their equity does not change; and (v) Receiverships.

4. Expanding SEP to Other Categories

Issue: Whether to expand SEP participation to include other categories, such as veterans.

Options:

- A. No change.
- B. Amend 935 CMR 500.105(17) to specifically include veterans as a group eligible to participate in the SEP program.
- C. Amend 935 CMR 500.105(17) to state that the Commission may, by vote, expand the categories of people eligible to participate in the SEP.

935 CMR 500.105(17): General Operational Requirements for Marijuana Establishments – Social Equity Program

4. Expanding SEP to Other Categories (*Cont'd*)

Pros/Cons:

- Option A: Keeps the program focused on people disproportionately impacted by Marijuana prohibition but does not reach other groups that could benefit from the program.
- Option B: Allows veterans, a group still being harmed by federal prohibition, to get into the industry and benefit from the program, but would require a change in regulations to allow other groups to be eligible to participate in the SEP.
- Option C: Gives the commission flexibility to react to new data (such as the upcoming Disproportionate Impact Study) and allow new eligible categories of people to participate in the SEP without an amendment to the regulations.

Recommendation: Option C.

935 CMR 500.105(17): General Operational Requirements for Marijuana Establishments – Social Equity Program

5. Social Equity Program for EEAs

Recommendation: Expand eligibility to participate in the SEP to individual listed as an owner on the original certification of an Economic Empowerment Priority Applicant, who satisfy one of the following criteria to be eligible for the Social Equity Program:

1. Lived for five of the preceding ten years in an Area of Disproportionate Impact, as determined by the Commission.
2. 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.
3. Black, African American, Hispanic or Latino descent; or
4. Other significant articulable demonstration of past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact.

Rationale: Data and feedback collected by the Commission demonstrate that Economic Empowerment Applicants need additional tools and resources, including technical assistance, in order to utilize their priority review status.

935 CMR 500.105(17): General Operational Requirements for Marijuana Establishments – Social Equity Program

6. ME/MTC Agent Registration

Recommendations:

1. 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.
5. 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.

6. ME/MTC Agent Registration (*cont'd*)

Rationale:

Recommendations 1 & 2: Puts the financial and administrative burden on the employer to register the Agent and pay the associated fees – a favorable arrangement from a social equity perspective. Given that Diversity/Positive Impact Plans often include hiring staff from socio-economically diverse communities, passing the cost onto the employees could, in part, serve to defeat the purpose of these initiatives. **The Agent's registration is linked to the license rather than to the individual Agent, making Licensees more likely to take seriously the responsibility of ensuring and monitoring employee compliance and reporting issues related to Agent conduct, such as diversion, to the Commission.**

Recommendation 3: Helps cover the cost of the badges.

Recommendation 4: 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.

Recommendation 5: Amendment to the medical-use regulations make cross-referencing the regulations easier for the Commission and the public, and brings more consistency to the registration process for ME and MTC Agents.

7. Research Licenses

Recommendations: Establish the process for:

1. receiving a Research Facility License and Research Permit to engage in specific research projects;
2. information required for a Research Permit application;
3. allowed activities;
4. the Commission approval process and Commission authority to audit.

Licensees may be academic institutions and non-profit institutions, including hospitals, as well as businesses including Marijuana Establishments.

The key component of allowing research to proceed by granting a Research Permit is reliance on an **Institutional Review Board (“IRB”)**, which is required for every research project. The regulations anticipate plant-based research, as well as animal and human research. There is a built-in presumption that the Commission as an agency may choose to take a phased in approach to allowing particular types of research to proceed.

Note: The writing group reviewed regulations from CO and CT and members had calls with senior staff from both jurisdictions to discuss their models. It took those models into consideration when contemplating our Massachusetts regulations and borrowed aspects of both regulatory structures when drafting our regulations.

8. Delivery

Recommendations:

1. Change the definition of “Delivery-Only License” to Delivery License;
2. Clarify that Marijuana Retailers may hold a Delivery License as a separate license;
3. Enable Delivery Licensees to also hold an interest in other license types and vice versa, provided, however, that even if Delivery Licensees hold an interest in a Marijuana Cultivator or Product Manufacturer they may not delivery directly from them;
4. Allow Delivery Licensees to sell Marijuana Accessories and Marijuana Establishment Branded Goods, such as t-shirts, direct to consumers.

Rationale: The economic model of the Delivery-Only License model constrains economic growth for licensees; these changes make the license more attractive, and clarifying that Marijuana Delivery Licensees may also have an interest in Marijuana Retailers reflects the policy decisions voted on last year.

935 CMR 500.002: Definitions

935 CMR 500.050(8) (Marijuana Retailer) and (11) (Marijuana Research Facility)

935 CMR 500.145: Additional Operational Requirements for Delivery of Marijuana and Marijuana Products to Consumers

9. Additional Retail Operations – Contactless Retail Operations

Recommendation:

Allow contactless means of providing product to consumers at Marijuana Retailers

Rationale:

Provides a safe alternative to person-to-person sales.

935 CMR 500.050: Marijuana Establishments

10. Vaping Regulations

Recommendation:

Require:

- Notice at point of sale and disclosure on packaging that vapes have been tested for VEA, but that **the vape may nevertheless be harmful to a consumer's health.**
- Disclosure of all active ingredients, including terpenes, and make Safety Data Sheets (SDS) available upon request to the Commission or a consumer.
- Product manufacturers to maintain information on vape hardware, including the type of coil, type of battery and, using best efforts, determine the source of the materials and maintain that information for Commission review upon request.
- Labeling indicating whether the terpenes are cannabis-derived or non-cannabis-derived.

935 CMR 500.105 (5)(c)
NEW Vaporizer Sampling & Testing Protocol

10. Vaping Regulations (*cont'd*)

Rationale:

There continues to be much that is unknown about the potential for harm caused by additives used in vapes. **The approach that best balances the Commission's obligation to ensure products are tested,** with unknowns about the potential for harm of particular products and product components, is to require disclosure of as much information as we can accurately assess at this point while continuing to gather information and data as we build analytical competency.

935 CMR 500.105 (5)(c)
NEW Vaporizer Sampling & Testing Protocol

11. Testing

Recommendation:

1. Reanalysis/Remediation: Product that fails initial contaminant screens may be 1) reanalyzed; 2) remediated and retested; or 3) disposed of. Product that is reanalyzed must receive 2 passing tests: one at the original lab and a confirmatory test at a different ITL. Product that is remediated must be retested at a different ITL. Licensees may attempt remediation of a batch twice; if batch **doesn't pass after two remediation attempts it must be disposed of.**
2. Pesticides: Adds 14 pesticides to the 9 pesticides currently tested for. The 14 additional pesticides are pesticides that have been recently identified or are suspected of use in some form or fashion in either CCC or MDAR investigations. Commission should phase-in over 2-3 months to allow ITLs to develop methodologies and purchase equipment.
3. Vapes: Require continued testing for VEA and a secondary screen for heavy metals from finished vapes pursuant to the Sampling and Testing Protocol for Finished Marijuana and Marijuana Products (see also Vaping slide for labeling requirements).

Rationale:

Our procedure has been to require retesting upon failure, but it is not explicitly stated.

935 CMR 500.160: Testing of Marijuana and Marijuana Products
NEW Protocol for Sampling and Analysis of Finished Marijuana and Marijuana-Infused Products

12. Economic Empowerment Priority Applicant Policy Issues

Economic Empowerment Priority Applicant means an applicant who demonstrated and continues to demonstrate three or more of the following criteria:

- (1) 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;
- (2) 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;
- (3) 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%;
- (4) at least 51% of employees or subcontractors have drug-related CORI and are otherwise legally employable in Cannabis enterprises;
- (5) a majority of the ownership is made up of individuals from Black, African American, Hispanic or Latino descent; and
- (7) 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.

935 CMR 500.002: Definition of Economic Empowerment Applicants

12. Economic Empowerment Priority Applicant Policy Issues

Issue 1: Whether an applicant/licensee

- (1) must satisfy at least one of the criteria listed in subsections (1), (2), or (5) of the definition of EEA (each an Equity-Based Criterion) to obtain/maintain EEA status or
- (2) may rely on the three non-Equity-Based Criteria in subsections (3), (4), and (6) of the EEA Definition to qualify for/maintain EEA status.

Options:

- A. Allow an applicant to qualify as an EEA without satisfying an Equity-Based Criterion.
- B. Require applicants to satisfy at least one of the Equity-Based Criteria to obtain EEA status.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 1:

Pros/Cons:

- Option A: Would allow applicants that are not owned by members of a Target Community to obtain EEA status, provided it can demonstrate past experience in or business practices that promote economic empowerment in Areas of Disproportionate Impact. This would not require a change to the regulations but may require additional clarification in guidance or bulletins for EEAs.
- Option B: Ensures EEA benefits are limited to Target Community members. Would require a change to the definition of Economic Empowerment Applicant in the regulations and associated changes in guidance or bulletins.

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 2: With respect to Equity-Based Criteria, whether to allow ownership by Target Community members to be as low as 33%, provided such community members (1) retain direct control under subsection (d)(1)-(5) of the definition of Persons or Entities Having Direct Control and (2) receive profits or dividends in proportion to or greater than their equity share.

Options:

- A. Require majority ownership by Target Community members to satisfy Equity-Based Criteria.
- B. Allow applicants to satisfy Equity-Based Criteria with at least 33% ownership by Target Community members, provided those Target Community members retain a certain type of control and receive a certain amount of economic benefit.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 2:

Pros/Cons:

- Option A: Ensures that EEAs are being majority owned, and thereby control shareholder votes by Target Community members. The drawback is that it does not allow for as much flexibility for EEAs and Target Community members with respect to capital structure. Would not require revisions to the Equity-Based Criteria and associated changes to guidance or bulletins.
- Option B: Could allow flexibility to obtain capital and allow Target Community members to leverage EEA status to gain more immediate economic benefits but would result in less control over shareholder votes. Would require revisions to the Equity-Based Criteria and associated changes to guidance or bulletins.

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 3: If the Commission determines that an applicant/licensee must satisfy at least one of the Equity-Based Criteria to obtain EEA status, whether and which EEA benefits an applicant can retain if the applicant or licensee loses its EEA status as a result of failing to satisfy the Equity-Based Criteria.

Options:

- A. Make EEA benefits all or nothing with EEA status.
- B. Allow EEAs to maintain some EEA benefits if, after initial certification, it fails to fulfill the EEA criteria.

Pros/Cons

- Option A: Ensures that regulatory benefits are restricted to entities that are majority owned by Target Community members.
- Option B: Allows flexibility and retention of some benefits if the EEA loses its status by failing to meet one of the criteria, which it could later satisfy?

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 4: Whether to require Commission staff to produce a list, updated for each public meeting, that lists all applicants/licensees with EEA status (current and lapsed).

Options:

- A. No Change.
- B. A Vote by the Commission requiring staff, through the Executive Director, to produce a list, updated for each public meeting, that lists all applicants/licensees with EEA status (current and lapsed).
- C. Add a subsection (e) to 935 CMR 500.102(2) requiring staff, through the Executive Director, to produce a list, updated for each public meeting, that lists all applicants/licensees with EEA status (current and lapsed).

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 4:

Pros/Cons:

- Option A: Would not require a new process for Commission staff but would not ensure that the Commission had up to date information with respect to EEAs when having policy discussions.
- Option B: Would give the commission up to date information with respect to EEAs when having policy/licensing discussions without including internal Commission procedures in the regulations, but would create a new process for Commission staff that could be changed by a vote of the Commission without a regulation review process.
- Option C: Would give the Commission up to date information with respect to EEAs when having policy/licensing discussions. This would establish a new process for Commission staff and would require an amendment to the regulations to make any changes to this requirement.

Recommendation: Option B.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 5: Whether to require EEAs to report all changes in ownership to the Commission (while approval by the Commission is still only required for changes greater than 10%).

Options:

- A. No change.
- B. Require a new subsection (e) under 935 CMR 500.104(1)(b)(3) that requires reporting (but not approval) of all changes in ownership of an EEA applicant/licensee.

Pros/Cons:

- Option A: Would not establish an additional regulatory requirement for EEA licensee/applicants or a new process for Commission staff but would not ensure the Commission has the most up to date information about EEA ownership.
- Option B: Would ensure Commission has up to date information about EEA ownership, but would establish an additional regulatory requirement for EEA licensees/applicants and create a new process for Commission staff to manage.

Recommendation: Update regulation, guidance, or bulletin to reflect commission decision, as needed.

12. Economic Empowerment Priority Applicant Policy Issues (*cont'd*)

Issue 6: Whether to require Target Community Members to certify each year that they have exercised control and retain requisite ownership over the EEA for which they were listed on the EEA certification.

Options:

- A. No Change.
- B. Create a subsection (j) under 935 CMR 500.104(4) for EEAs to certify that they still satisfy the requirements of EEA status.

Pros/Cons:

- Option A: Would not establish an additional regulatory requirement for EEA licensees/applicants or a new process for Commission staff but does not aid the Commission in ensuring the spirit of EEA status is being fulfilled.
- Option B: Would help the Commission ensure the spirit of EEA status is being fulfilled, but would create additional regulatory requirements for EEA licensees/applicants and a new process for Commission staff.

Recommendation: Update Regulation, guidance, or bulletin to reflect commission decision.

13. SEP - Equity Ownership Threshold for Social Equity Program Participants to Receive License Benefits

Issue: Discuss the current ownership threshold of 10% ownership by a Social Equity Program Participant required in order for a business to access license-related benefits including fee waivers, discounts, and expedited review.

Options:

- A. No change
- B. Require 51% ownership by SEPs for fee waivers and discounts; allow microbusinesses and minority-owned, veteran-owned, and women-owned businesses to access the same fee waivers and discounts.

13. SEP - Equity Ownership Threshold for Social Equity Program Participants to Receive License Benefits (cont'd)

Pros/Cons:

- Option A:

Pros: Allow more flexibility and value for SEP individuals

Cons: Would provide discounts to companies that may not have a need for discounts, depending on who owns the other 90% of the business. Fiscal impact may add up given hundreds of SEPs in each cohort.

- Option B:

Pros: Broadens availability of discounts to more groups; keeps discounts to companies that are majority-owned by targeted groups.

Cons: Prevents SEPs who own the minority of a company from accessing discounts.

Recommendation: Option B.

14. Buffer Zones

Issue: Chapter 94G creates a 500-foot buffer zone between an ME/MTC and a school but does not define how it should be measured. The current buffer zone regulation provides that the required 500-foot distance be measured from property to property. The purpose of this recommended change is to take into account impassable barriers such as highways or rivers.

Option: Propose new method for measuring the 500-foot distance that considers accessibility to an ME/MTC from a school site, for example by taking into account impassable barriers.

Pros: Clearer and accounts for impassable barriers such as highways and rivers between the ME/MTC and the school site

Cons: Would need to update municipal guidance

Recommendation: Change how the 500-foot distance is measured in certain cases.

935 CMR 500.110(3): Buffer Zones
935 CMR 501.110(3): Buffer Zones

15. Flexibility to Expand Delivery-Only Licenses and Delivery Endorsements

Issue: Under the current regulations, there is an exclusivity period restricting Delivery-only licenses and Delivery endorsements for 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 of the first notice to commence operations. Depending on the demand for delivery and the number of businesses operating, this proposal gives the Commission the flexibility to expand the exclusive delivery licenses just to these groups, if the Commission feels it is appropriate.

Recommendation: Add provision to the regulations that the Commission may choose to expand Delivery-only licenses and Delivery endorsements to cooperatives and women-, minority-, veteran-owned businesses during the exclusivity period.

935 CMR 500.050(10): Delivery-only Licensee

15. Flexibility to expand Delivery-only licenses and Delivery endorsements (*Cont'd*)

Pros:

- Does not require the Commission to expand delivery to those groups but makes it an option if the number of businesses with exclusive access currently are unable to meet demand
- The flexibility is useful because there is currently no basis to predict whether the number of delivery businesses can meet demand
- One step toward meeting our statutory requirements for minority-, women-, and veteran-owned businesses
- Encourage more worker-owned cooperatives

Cons:

- If implemented prematurely, could dilute the benefits for Economic Empowerment Priority Applicants or Social Equity Program Participants

935 CMR 500.050(10): Delivery-only Licensee

16. Verified Financial Hardship Documentation

- Issue: Patients report that MTCs are inconsistent in what they accept as proof of eligibility of Verified Financial Hardship for the purpose of a MTC program to provide reduced cost or free marijuana under 501.050(1)(h). The purpose of this change is to specify that a valid MassHealth card or Social Security benefit verification letter is acceptable documentation.
- Option: Specify in the definition of Verified Financial Hardship that a valid MassHealth card or Social Security benefit verification letter is acceptable documentation for the purposes of receiving reduced cost or free marijuana through the RMD program required by 935 CMR 501.050(1)(h) to provide.

935 CMR 501.002: Definitions

935 CMR 501.010(4): Written Certification of a Debilitating Medical Condition for a Qualifying Patient

935 CMR 501.050(1)(h): Medical Marijuana Treatment Centers (MTCs) – General Requirements

16. Verified Financial Hardship Documentation (*Cont'd*)

Pros:

- Consistency across MTCs
- Does not limit acceptable documentation to the stated documents

Cons:

- Leaves the documentation for proof that the individual's income does not exceed 300% of the federal poverty level, adjusted for family size, unspecified

Recommendation: Specify acceptable documentation.

935 CMR 501.002: Definitions

935 CMR 501.010(4): Written Certification of a Debilitating Medical Condition for a Qualifying Patient

935 CMR 501.050(1)(h): Medical Marijuana Treatment Centers (MTCs) – General Requirements

17. Personnel Records

Require Code of Ethics and Whistleblower Policy

Issue: The purpose of this change is to require licensees to include a code of ethics and whistleblower policy among their personnel records.

Option: Within recordkeeping requirements, require personnel policies and procedures subject to inspection by the Commission upon request to include a code of ethics and whistleblower policy.

Pros: Provide certainty for employees who wish to access a code of ethics or whistleblower policy.

Cons: Require licensees to create a code of ethics or whistleblower policy if they do not already have one.

Recommendation: Require code of ethics and whistleblower policy.

Recess until

We will be back momentarily.

For updates on COVID-19 related to
Commission business, please visit
MassCannabisControl.com/COVID19.



Upcoming Meetings: June 25, 2020 (tentative) July 9, 2020 via Microsoft Teams Live