



Proposed Amendments to 105 CMR 725.000: *Implementation of an Act for the Humanitarian Medical Use of Marijuana*

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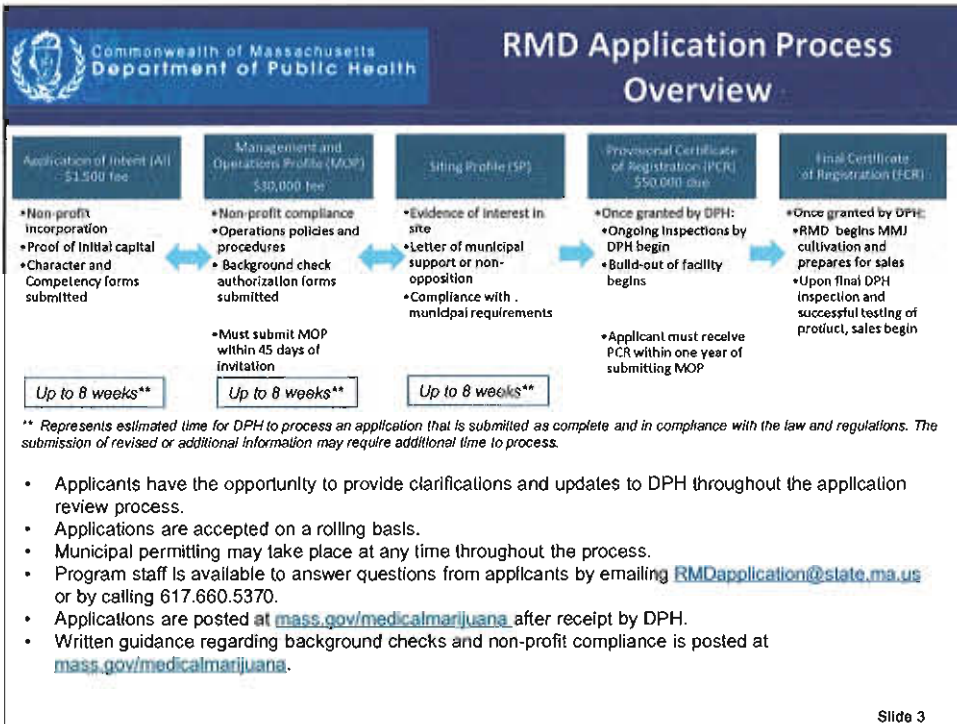
Public Health Council
September 14, 2016

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- In November, 2012, the Humanitarian Medical Use of Marijuana ballot initiative passed with 63% of the vote in 349 of 351 cities and towns. DPH promulgated a regulation to implement the initiative.
- The regulation, 105 CMR 725.000, *Implementation of an Act for the Humanitarian Medical Use of Marijuana*, sets forth standards for the medical use of marijuana, the registration of patients, physicians, caregivers and registered marijuana dispensaries, and the operation of the registered marijuana dispensaries.
- The Public Health Council approved the regulation on May 8, 2013 and it became effective on May 24, 2013.
- The regulation ensures a high quality of care, industry standardization, and strong consumer protection for individuals in need of medical marijuana.

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- Commonwealth of Massachusetts
Department of Public Health
- ## New Application Process
- Applications Received
 - Application of Intent
 - Submitted: **175** applications
 - Management & Operations Profile
 - Submitted: **147** applications
 - Siting Profile
 - Submitted: **63** applications
 - Total Provisional Certificates of Registrations issued: **41**
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- 7 RMDs are currently open and dispensing marijuana for medical use
 - Alternative Therapies Group (Salem)
 - Central Ave. Compassionate Care (Ayer)
 - In Good Health (Brockton)
 - New England Treatment Access (Northampton)
 - New England Treatment Access (Brookline)
 - Patriot Care (Lowell)
 - Patriot Care (Boston)

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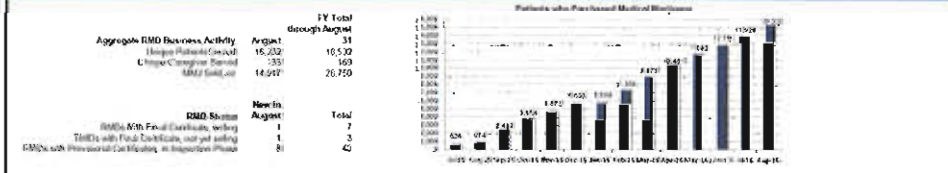
Massachusetts Medical Use of Marijuana Program: External Dashboard

Aug 16

REGISTRATION



COMPLIANCE



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Proposed Amendments

- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each and every regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.
- They embody common sense reforms to simplify and clarify the regulation and emphasize the program's ongoing goal of being transparent, streamlined, and efficient.

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Proposed Amendment Topics

The proposed amendments will cover the following:

- Certified Nurse Practitioners
- Caregiving Institutions & Institutional Caregivers
- Independent Testing Laboratories & Laboratory Agents
- Administrative Streamlining
- Operations Clarification

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Proposed Amendment Highlights: Certified Nurse Practitioners & Physicians

Proposed Amendment:

- Adds definitions for
 - Certifying Certified Nurse Practitioner (CNP); and
 - Healthcare Provider (CNP or physician)
- Adds Registration Requirements for CNPs, as well as criteria for revocation of registration
- Allows a CNP to be one of the 2 certifying healthcare providers for minors, but still requires 1 physician to be a board-certified pediatrician or pediatric subspecialist to be the other
- Allow healthcare providers more flexibility to certify for less than 10 ounces for 60 day supply

Rationale:

- Updates the regulations to be consistent with an amendment to Board of Nursing Regulations, 244 CMR 4.06, allowing CNPs to certify for medical use of marijuana

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Proposed Amendment Highlights: Caregiving Institutions & Institutional Caregivers

Proposed Amendment:

- Creates separate category of caregiver & their employing institutions
- Must be hospice, nursing or medical facility
- Similar registration model to RMDs & RMD agents
- Caregiving Institutions get Certificate of Registration
- Institutional Caregivers registered by Caregiving Institution
- Personal caregivers will remain individuals, such as immediate family members, as well as visiting nurses and personal care attendants
- Care will only be on premises of caregiving institution

Rationale:

- Addresses the operational realities of facilitating the medical use of marijuana in an institutional setting and in a manner more akin to the administration of prescription medication for resident patients

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Proposed Amendment Highlights: Independent Testing Laboratories & Laboratory Agents

Proposed Amendment:

- Creates opportunity for Independent Testing Laboratories to receive Certificate of Registration (same standard as in existing regulations)
- Labs can register their own laboratory agents – no longer required to register through the RMDs they service
- Similar registration model to RMDs and RMD agents
- Language clarifying labs as protected destination and requiring same protocols for transportation as RMDs

Rationale:

- The 2012 ballot initiative did not provide any legal protection for testing laboratories, requiring laboratories to be affiliated with RMDs to be protected until a 2015 amendment to M.G.L. c. 94C § 34 provided legal protection for laboratories
- Provides a more streamlined and transparent process for the registration of laboratories and their agents
- Serves to preserve the independence of the laboratories

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Proposed Amendment Highlights: Administrative Streamlining: Applications

Proposed Amendment:

- Clarify regulatory language re: background checks for RMD agents
- Move background check information to the management and operations phase of the application process
- Move requirement to show RMD floor plan and demonstrate RMD compliance with ADA from Phase II to architectural review phase
- Replaces concept of “scoring” application with “evaluation”

Rationale:

- Consistent with Program transition away from the competitive procurement-like process of the first year of the Program to a standards-based and compliance-focused application process.
- Streamlines application process based upon lessons learned.

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Proposed Amendment:

- Clarifies language regarding the Certificate of Registration to explicitly recognize Provisional Certificates of Registration and the Inspections Phase
- Eliminates confidentiality protection for address of cultivation/MIP production facility (futile due to disclosure at municipal level)

Rationale:

- Streamlines registration process for clarity while maintaining safe patient access.

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Proposed Amendment:

- Clarifies language regarding appeals process to the Division of Administrative Law Appeals (DALA)
- Expands availability of waiver process to applicants

Rationale:

- Streamlines administrative procedures for clarity while maintaining safe patient access.

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The proposed amendments provide the following clarification to RMD operations:

- Require RMDs to maintain policy regarding handling of cash
- Authorizes use of motion detection cameras if RMD demonstrates adequate recording
- Authorizes use of alternate security safeguards rather than second backup alarm company

Rationale:

- Allows alternate security methods and more flexible options to achieve security objectives while maintaining safe patient access.

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The proposed amendments provide further clarification to RMD operations:

- Organic cultivation only required if labelled “organic”
- Non-organic pesticide must be approved by DPH
- Allows cultivation from clones, not just seeds
- Add 72 hour notification requirement for contamination
- Requires DPH approval of tracking methodology

Rationale:

- Provides more flexibility in cultivation methods
- Encourages innovation in cultivation
- Protects patient safety

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The proposed amendments provide further clarification to RMD operations:

- Allows more flexibility for product transactions between RMDs with same tracking requirements
- Requires labels on products to include pregnancy/breastfeeding warnings
- Clarifies language to allow RMDs to post price lists on their website
- Clarification of insurance policy requirements

Rationale:

- Enhances patient access to different strains
- Protects patient health and safety
- Encourages transparency of RMD pricing
- Clarifies insurance requirements for RMDs

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- The regulations proposed today accomplish four goals:
 - Existing processes are streamlined;
 - Clarifying language is added;
 - Consistency with changes made to related laws is accomplished; and
 - Patient access and public safety are promoted.
- These regulations update the program in a meaningful way, incorporating lessons learned during the three years of experience regulating Marijuana for Medical Use.

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Next Steps

- The Department will conduct a public hearing to solicit comments on the proposed amendments.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to these amendments, and seek final promulgation.

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Contact Information

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 725.000, *Implementation of an Act for the Humanitarian Medical Use of Marijuana*, please find the relevant statutory language (chapter 369 of the acts of 2012) and the full current regulation here:
<https://malegislature.gov/Laws/SessionLaws/Acts/2012/Chapter369>
<http://www.mass.gov/eohhs/docs/dph/regs/105cmr725.pdf>
- For other information regarding the Medical Use of Marijuana Program, please check the Program website:
<http://www.mass.gov/medicalmarijuana>

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