



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

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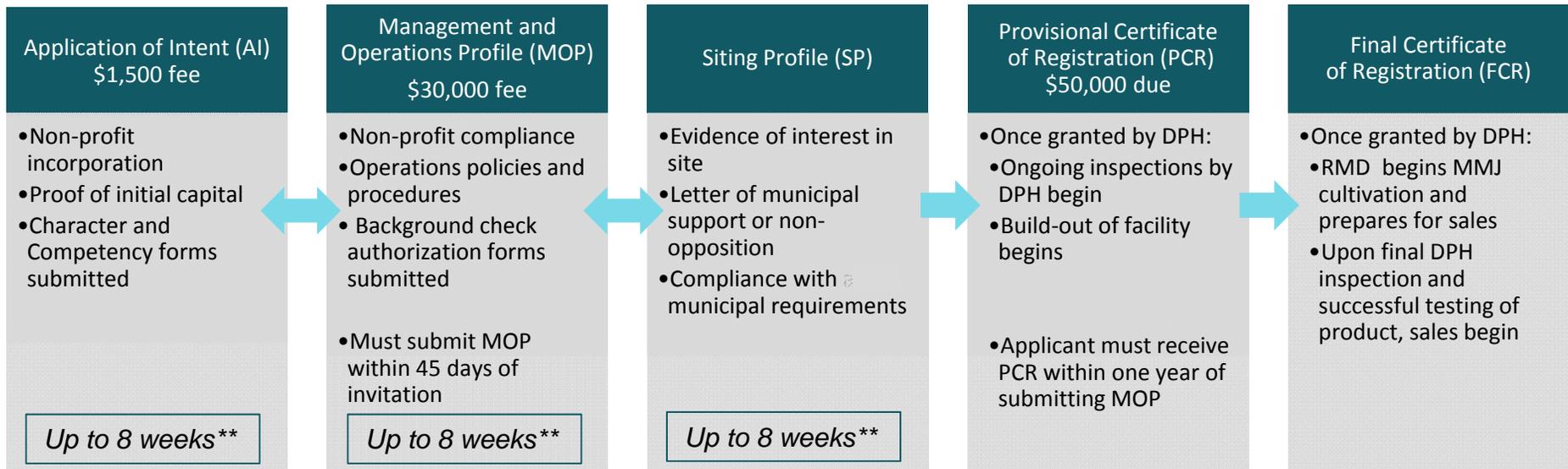


Background

- 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.



RMD Application Process Overview



** Represents estimated time for DPH to process an application that is submitted as complete and in compliance with the law and regulations. The submission of revised or additional information may require additional time to process.

- Applicants have the opportunity to provide clarifications and updates to DPH throughout the application review process.
- Applications are accepted on a rolling basis.
- Municipal permitting may take place at any time throughout the process.
- Program staff is available to answer questions from applicants by emailing RMDapplication@state.ma.us or by calling 617.660.5370.
- Applications are posted at mass.gov/medicalmarijuana after receipt by DPH.
- Written guidance regarding background checks and non-profit compliance is posted at mass.gov/medicalmarijuana.



- 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**



- 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)

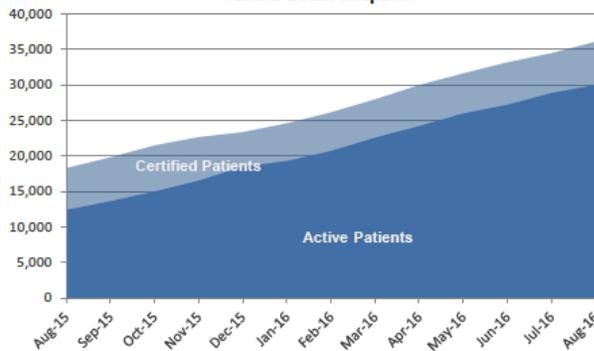


Massachusetts Medical Use of Marijuana Program: External Dashboard

Aug-16

REGISTRATION

Patient Count Snapshot



Patient and Caregiver Metrics

Total Active Patient Certifications
Total Active* Patients
Total Active** Caregivers

New in August
2,587

Total through August 31
36,080

2,056

29,999

261

2,252

* certified and registered with DPH
** registered with DPH

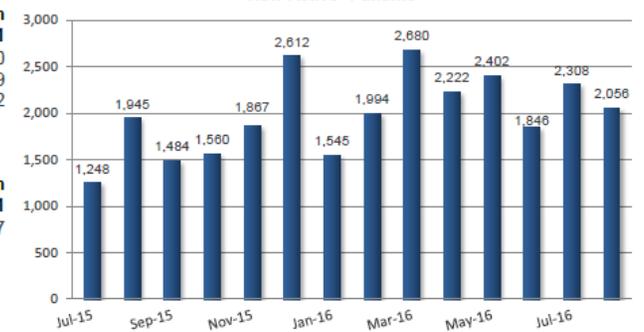
Physician Metrics

Registered Physicians

New in August
6

Total through August 31
167

New Active* Patients



COMPLIANCE

| | August | FY Total through August |
|---|----------------------|-------------------------|
| Aggregate RMD Business Activity | | 31 |
| Unique Patients Served | 15,232 | 18,532 |
| Unique Caregiver Served | 133 | 169 |
| MMJ Sold, oz. | 14,917 | 28,750 |
| | New in August | Total |
| RMD Status | | |
| RMDs With Final Certificate, selling | 1 | 7 |
| RMDs with Final Certificate, not yet selling | 1 | 3 |
| RMDs with Provisional Certificates, in Inspection Phase | 8 | 48 |

Patients who Purchased Medical Marijuana





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.



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



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



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



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



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.



Administrative Streamlining: Registration & Confidentiality

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.



Proposed Amendment Highlights: Administrative Streamlining: Hearings & Waivers

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.



Proposed Amendment Highlights: Operations Clarification

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.



Proposed Amendment Highlights: Operations Clarification

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



Proposed Amendment Highlights: Operations Clarification

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



- 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.



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.



- 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>