Proposed Regulations Governing the Sale and Use of Medical Marijuana: A Summary

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Acknowledgements

- Memorandum to Interim Commissioner Lauran Smith and Members of the Public Health Council entitled "Informational Briefing on Proposed Regulations at 105 CMR 725.000: *Implementation of An Act for Humanitarian Medical Use of Marijuana (Chapter 369 of the Acts of 2012).*
- www.mass.gov
  - Proposed regulations
  - Draft memorandum

Background

- November 6, 2012 Ballot Question 3 passed with a 63% - 37% vote.
  - “Landslide”
  - Only 2 municipalities voted no:
    - Mendon
    - Lawrence
- Massachusetts is 18th state in U.S. in addition to the District of Columbia to approve the use of medical marijuana.
- Became law on January 1, 2013.

Summary of Law

- Allows “qualifying patients” with certain defined medical conditions or debilitating symptoms to obtain and use marijuana for strictly medicinal purposes.
- Requires DPH to promulgate regulation relative to the implementation of the law by May of 2013.
- Eliminates state criminal and civil penalties for the medical use of marijuana by qualifying patients.

Criteria

- Qualifying Patient:
  - Diagnosed with a listed debilitating condition:
    - Cancer, glaucoma, AIDS or HIV, Hepatitis C, ALS, Crohn's disease, Parkinson's disease, Multiple Sclerosis, and other conditions as determined in writing by a qualifying patient's physician.
  - Obtained a written certification from a physician with whom the patient has a *bona fide* physician-patient relationship.
    - Certification must state the patient's debilitating medical condition, its symptoms, and that the potential benefits of marijuana use outweigh health risks for the patient.
  - Patient may possess up to a "60-day supply" for patient's personal use.
    - DPH charged with defining 60-day supply.

Criteria

- Patient may designate a “personal care giver.”
  - Must be at least 21.
  - Must be registered with DPH.
  - Cannot consume the medical marijuana.
- Qualifying patient with “verified financial hardship, a physical inability to access reasonable transportation, or the lack of a treatment center within a ‘reasonable’ distance of the patient’s residence” may obtain a “hardship cultivation registration” from DPH.
  - Permits cultivation of enough plants in an enclosed, locked facility to maintain a 60-day supply for personal use.

DPH's intention relative to home-cultivation:

- DPH will seek to minimize the need for home-cultivation as follows:
  - Stringent caregiver provisions
  - Incentivized "compassion programs" at Treatment Centers
    - Low or no-cost means tested programs at Centers
  - Permitting home delivery
- Medical Marijuana Treatment Centers (MMTCs)
  - May cultivate, process and provide medical marijuana to patients and caregivers.
  - Must be non-profit
  - Must be registered with DPH

MMTC's

- Must complete several mandatory conditions:
  - Paying a fee
  - Identifying a location, with up to 1 additional cultivation location
  - Submit operating procedures, including cultivation and storage of marijuana in enclosed, locked facilities.
- "Dispensary Agents"
  - MMTC's personnel.
  - Must register with DPH.
  - Must be at least 21.
  - Must have no prior felony drug convictions.
- DPH may register up to 35 MMTCs in 2013.
  - At least 1, but no more than 5 in each county.
  - Number can be modified by DPH in future year.

Fraudulent Use of Registration Cards

- Registration cards and cultivation registration can be revoked for violation of the law or the regulations.
- Fraudulent use is a crime punishable by up to 6 months in the House of Correction.
- If fraudulent use was for the sale, distribution or trafficking of marijuana for non-medical use, it is a crime punishable for up to 5 years in state prison.

What the Law Does NOT Do:

- Change federal law making possession of marijuana illegal.
  - Controlled substance under the Controlled Substance Act.
- Obstruct federal enforcement of federal law.
- Preempt Massachusetts state law prohibiting marijuana use, sale, etc. for non-medical purposes.
- Permit operating under the influence of marijuana.
- Require any health insurer or government entity to reimburse expenses of medical marijuana use.
- Require accommodation of medical marijuana use in any workplace, school bus or grounds, youth center or correctional facility.
- Require any accommodation of smoking marijuana in any public place.
- Require accommodation of smoking marijuana in public housing.

Between 1/1/13 (effective date) and May 2013

- Written certification by a physician will constitute a registration card for a qualifying patient.
- Certified mail, return receipt showing that patient applied to DPH and photocopy of actual application will constitute a registration card for a personal caregiver.
- Written recommendation of a qualifying patient's physician will constitute a "limited cultivation registration."
- Qualifying patients may cultivate his/her own supply.

Public Engagement and Comment

- Listening sessions held on February 13, 14 and 27, 2013.
  - Worcester, Boston, Holyoke.
  - 200+ attendees at each session.
  - Legislators, patient-advocates, nationally-recognized dispensaries, prevention advocates, leading clinician and physician groups, municipal leadership, law enforcement.
- 68 letters, written comments from 16 organizations, DPH staff met with more than 20 organizations individually, and engaged legislative leadership.
- Also solicited input from other states.
- Goal of regulations: put in place a system that insures both appropriate access and safe municipalities.

Key Policy Recommendations

- Continuing Medical Education
  - Physicians must complete a minimum of 2.0 Category 1 continuing professional education credits (CMEs) on medical marijuana before issuing any certifications.
    - Implementation of this requirement delayed for at least 6 months after promulgation of regulations.
    - Programs planned and implemented by an organization accredited by the Accreditation Council for Continuing Medical Education (ACCME), American Academy of Family Physicians or a state medical society recognized by ACCME.
- Session should include explanation of proper use of medical marijuana, including contraindications side effects, dosage and should provide information on substance abuse recognition, diagnosis and treatment.

Debilitating Medical Condition

- Proposed regulation defines debilitating condition as follows:
- "Cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, and multiple sclerosis ***when such diseases are debilitating*** and other ***debilitating*** conditions as determined in writing by a qualifying patient's physician."

60-Day Supply

- Up to 10 ounces of finished product in leaf form (or equivalent).
- Based on a review and comparison of dispensing across states and stakeholders' feedback.
- Physicians will have discretion.
- Time period for certification may not exceed 1 year.

Bona-Fide Physician-Patient Relationship

- “a relationship between a physician, acting in the usual course of his or her professional practice, and a patient in which the physician has conducted a clinical visit, completed and documented a full assessment of the patient’s medical history and current medical condition, has explained the potential benefits and risks of marijuana use, and has a role in the ongoing care and treatment of the patient.”
- Physician must be licensed in Massachusetts.
- Must utilize Massachusetts Prescription Monitoring Program unless otherwise specified by DPH.

Fees

- Fee framework will be developed upon finalization of the proposed budget.
- Fees will be annualized.
- Fees will be revenue neutral.
- MMTC fees will provide the primary source of revenue.
- Final fee proposal will be announced for public comment in a parallel process to regulation comment.
- Comment on fees will probably be in late spring.

Hardship Cultivation

- Massachusetts will be the first state to require financial, physical or geographic hardship in order to cultivate at home.
- In place to avoid diversion of marijuana and security complications associated with widespread home-cultivation.
- DPH is attempting to minimize home-cultivation:
  - Mandate provision of low-income subsidies at MMTCs.
  - Allow secure home delivery where necessary.
  - Encourage caregivers to pick up product.
  - Regulation requires physical incapacity to access reasonable transportation, verified financial hardship and lack of treatment center within a reasonable distance of residence and MMTC has no home delivery.
  - Must utilize “industry best practices” in cultivation.

Laboratory Testing

- Regulation requires a quality assurance and periodic testing plan in the application for a MMTC.
- Regulation requires MMTC to test for contaminants, including pests, mold, mildew, heavy metals and pesticides.
- DPH can require additional testing without amending regulations.

Municipal Oversight

- "Inclusive, but non-burdensome framework for engaging municipal government."
- No other state describes a role for local health.
- DPH has responsibility for medical marijuana program, including registration of patients, caregivers, dispensary agents and MMTCs.
  - This incudes a comprehensive data base for all registrants.
- DPH will not mandate local involvement.
- DPH will not preempt local involvement.
  - Zoning, local fees, etc.

My Questions on Local Involvement

- Regulation provides that DPH, Emergency Responders and Law Enforcement have access to MMTCs without restriction.
- Does this include local public health?
- If not, it should.
  - If state inspector not available immediately and BOH gets complaint.
- MMTC's operational procedures are extremely strict and DPH intends to hire state inspectors do enforce the CMRs involved.
  - Food code, plumbing, waste, etc.

Patient Designation of MMTCs

- Qualifying patient must designate MMTC.
- Can only designate 1 MMTC.
- MMTC must plan for and cultivate only the amount of marijuana to meet their patients' needs.
  - Accounting for a small amount of new patients.
  - This will cut down on waste and waste disposal issues.
- Patient can change designation once in a 120-day period with notice to DPH.
- MMTC must limit their inventory of seeds, plants and useable marijuana.

Personal Caregivers

- "Agrees" to assist qualifying patient.
  - Informal relationship – not a contract
- Must be 21.
- No criminal record for felony drug violations.
- May only serve one patient.
- Employee of hospice or medical facility can serve more than one patient.
- Patient may have 2 caregivers.
  - Only 1 can cultivate at home.

Youth Access

- More restrictive model for minors.
- 2 physicians must certify that patient's debilitating medical condition, at least 1 of whom is a board-certified pediatrician.
- Parental/guardian consent required.
- Access restricted to youth with life-limiting illness.
  - 6 months.

Advertising/Communications

- Strict advertising restrictions.
- No lit signs
- No t-shirts or other promotional items.
- No reference to medical benefits of medical marijuana without clear scientific supported evidence.

Marijuana Infused Product (MIP)

- Product infused with marijuana that is intended for use or consumption other than by smoking or vaporizing, including but not limited to edible products, ointments, aerosols, oils, and tinctures.
- They can only be created and sold by a MMTC
- Not considered a food or drug.
  - No local permit needed?

MMTCs

- Must meet strict sanitary requirements
  - Requirements for food handlers
    - 105 CMR 300.00
  - Hand washing facilities
  - Good sanitary practices
  - Waste disposal
  - Water supply
  - Plumbing
- Strict security measures must be in place.

Timeline

- April 10th: Regulation draft presented to Public Health Council.
- April 19th: Public hearings held in Plymouth, Boston, Northampton.
- April 20th: Public comment period concludes.
- May 8th: Revised draft presented to Public Health Council.
- May 24th: Projected effective date.