



# Massachusetts Department of Public Health Medical Use of Marijuana Program Update

May 3, 2016

2016 Work Related Injuries Workshop

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# Agenda

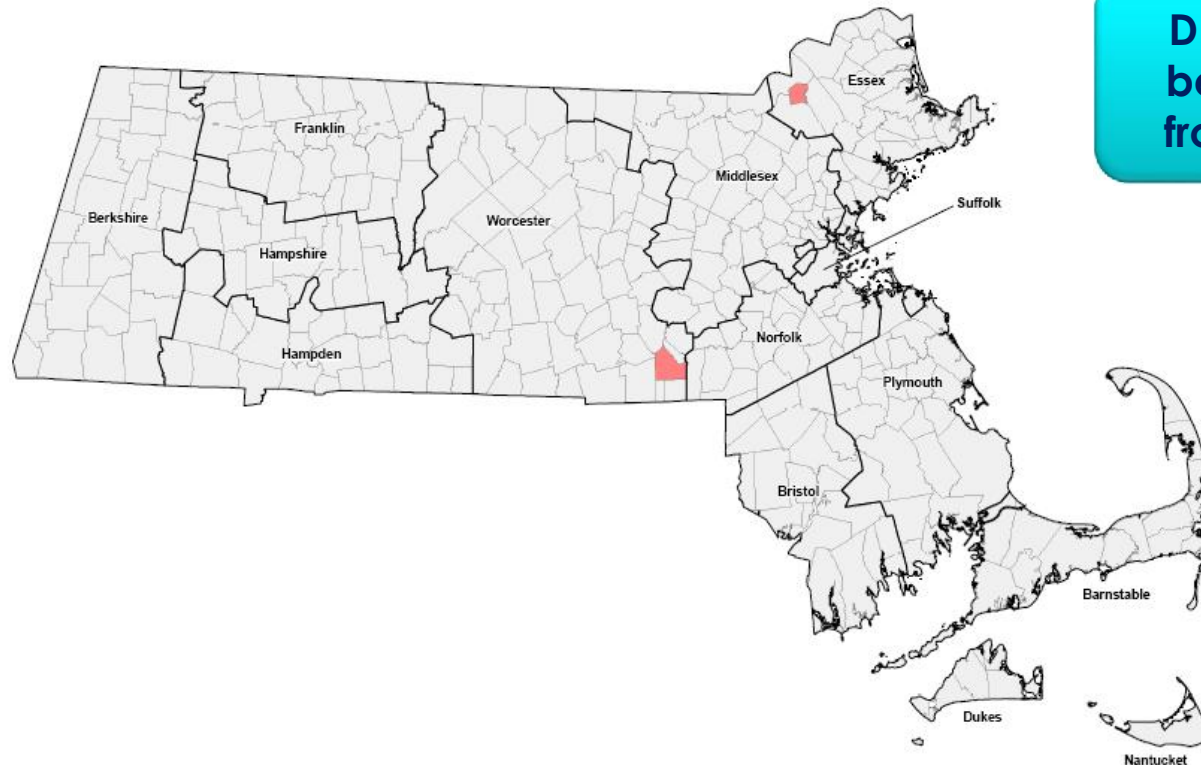
- Introduction
- Legal and Regulatory
- Program Operations
- Product Testing
- Questions





# Will of the Voters

- November 2012 ballot initiative passed with
  - 63 % of the vote
  - 349 of 351 cities and towns

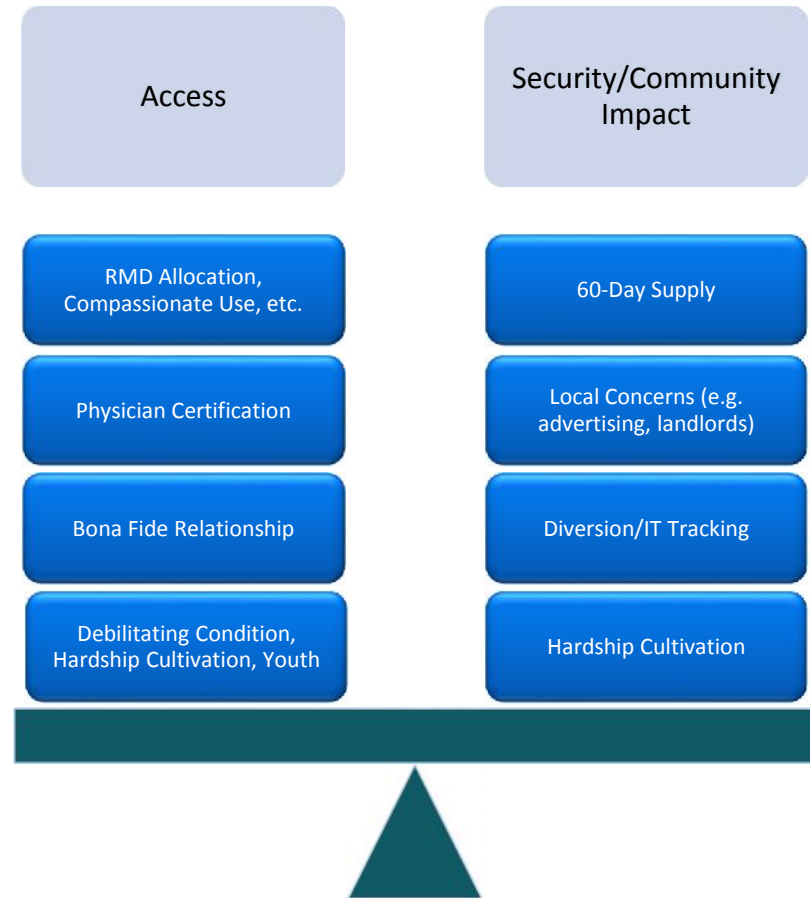


**DPH reviewed  
best practices  
from 17 states.**



# Regulations: Public Process

- Public Hearings
  - 80+ attendees, 75+ testified
- Stakeholder Meetings
  - 25+ with patient advocates, industry experts, law enforcement, physicians, local officials, and more
- Written Comments
  - 197 diverse stakeholders
- Public Health Council
  - May 8, 2013





# Certifying Physicians

- Mandatory physician training:
  - Minimum of 2.0 Category 1 CMEs about proper use of marijuana
- Must hold active MA license and have medical practice in MA
  - With no prescribing restriction
  - Must have a Massachusetts Controlled Substances Registration (MCSR)





# Certifying Physicians

Physician



Patient

- Only a patient with a **bona fide relationship** with a physician, who has diagnosed the patient with a debilitating medical condition, is qualified for medical use of marijuana.
- To establish a **bona fide relationship**, physicians must:
  - Conduct clinical visit, complete and document medical history and current condition
  - Explain potential benefits and risks
  - Have role in the ongoing care and treatment of the patient



# Debilitating Medical Condition

- Balance of promoting appropriate access but limiting inappropriate use
- Includes:
  - Cancer
  - ALS
  - Glaucoma
  - Crohn's Disease
  - HIV, AIDS
  - Parkinson's Disease
  - Hepatitis C
  - MS
  - Other debilitating conditions determined by certifying physician





## A qualifying patient who is under 18 years of age

- Must be diagnosed by two MA licensed certifying physicians with a debilitating life-limiting illness
  - At least one physician must be a board-certified pediatrician or a board-certified pediatric subspecialist
- Can be certified for a debilitating medical condition if physicians determine that the benefits of the medical use of marijuana outweigh the risks and:
  - A discussion of potential negative impacts on neurological development with the parent or legal guardian of the qualifying patient
  - Written consent of the parent or legal guardian
  - Documentation of the rationale in the medical record and the written certification.





# Patient Registration

- Physicians:
  - Look up patients in Prescription Monitoring Program
  - Start a new record in MMJ Online System with patient background and debilitating medical condition information
  - Complete certification, sign attestations, and submit electronic certification
  - Provide copy of Patient registration number and instructional material to patient
- All steps conducted in physician's office
- Minors under the age of 18 have unique protocol





# Patient Registration

- After physician submits electronic certification, patients must:
  - Register in MMJ Online System
  - Pay registration fee
  - Receive Program ID card
- Patients can designate personal caregiver
  - Caregiver also needs to register and receive Program ID card



Laser Perforation  
(Integrated in card core.  
Visible with light source)

Ghost Portrait

\*Variable Micro-Script  
(Logic = 1st initial of first name, 1st initial of last name and last 2 digits of year of expiration date. In the instance where a cardholder has one legal name (either first or last), the field would print as follows: "W15" or "W15". No spaces or hyphens.)

WW15

\*Altered Font  
("E" in DATE is "E")

Overlapping Data  
(Static overt and covert data, such as the perforated feature will be "overlapped" with other variable and static fields, such as photo images.)



## Patient Certifications

- Certification can be valid for 15 days to 1 year
- 60 day supply presumed to be 10 ounces, but physician may certify for higher amount.





# Personal Caregivers

- Assist qualifying patient
- Must be over the age of 21
- May only care for one qualifying patient
  - Except in cases of:
    - Employee of a hospice provider, nursing facility, medical facility
    - Visiting nurse
    - Home health aide
    - Personal care attendant
    - Immediate family member of more than one qualifying patient
- Qualifying patients may designate up to 2 personal caregivers
- May be reimbursed for expenses, but not paid for services





## Hardship Cultivation

- Only permitted for those who qualify
- Requires DPH approval
- Must be at patient's or caregiver's primary residence
- Must be in enclosed, locked area that is not visible from the street or other public areas
- Limited to the necessary amount for patient's 60 day supply





# Medical Use of Marijuana Program

## 3 Main Departments



Support Center



Compliance Unit



RMD Applications



- MMJ Support Center Overview
  - 5 dedicated Support Center Coordinators, 1 Support Center Manager
  - Field 150-250 calls each day into the MMJ Program from various stakeholders (mostly patients)
  - 100 – 150 applications are processed daily in the MMJ Online System
- As of January 31, 2016 (Dashboard posted at [mass.gov/medicalmarijuana](http://mass.gov/medicalmarijuana))
  - 19,729 active patients
  - 1,064 active caregivers
  - 132 certifying physicians





# Registered Marijuana Dispensaries

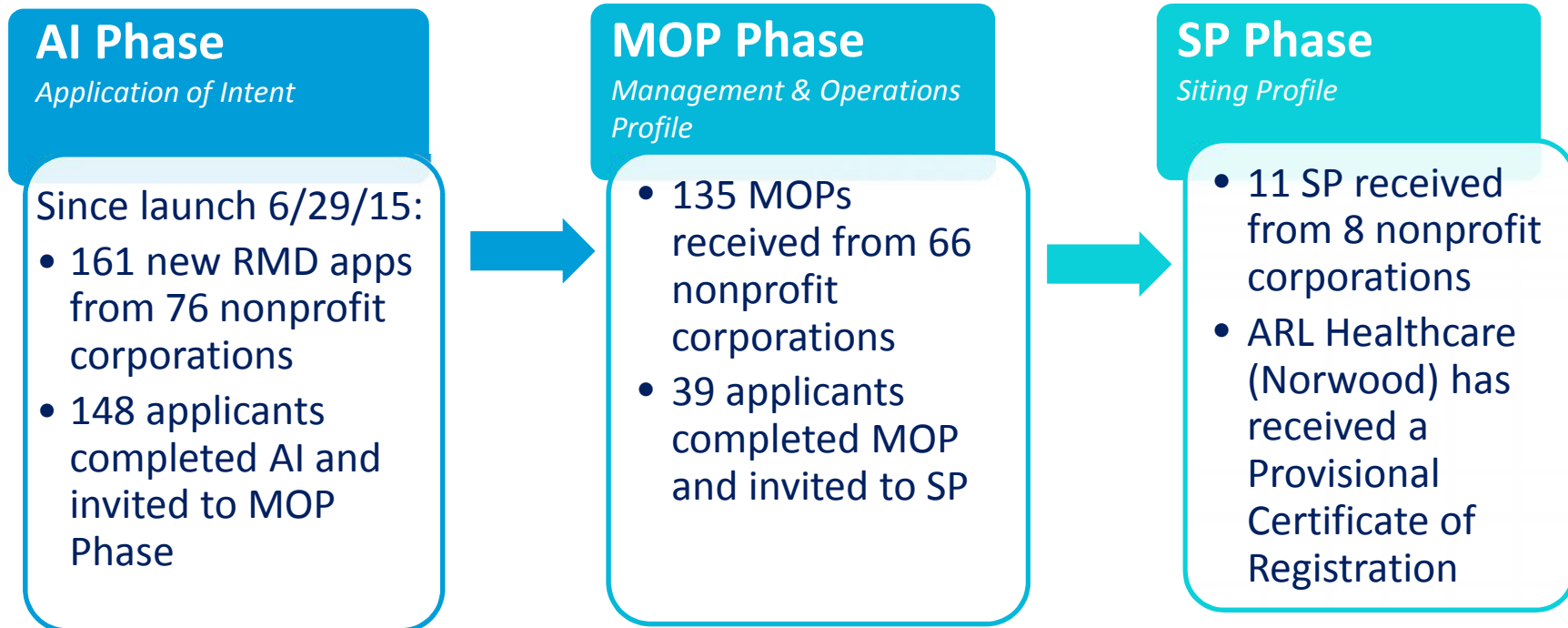
- Non-profit corporations
- Cultivate, process, and dispense marijuana
  - Edible Marijuana Infused Products (MIPs), Non-Edible MIPs, Dry Leaf, Oil
- Sell only to registered qualified patients & caregivers
- Must provide discounted marijuana to verified financial hardship patients
- Home delivery allowed







# RMD Applications





- 11 RMDs with a Provisional Certificate of Registration
  - In the Inspection Phase (build out)
- 6 RMDs are now Open and Selling Product
  - Alternative Therapies, Inc. (Salem)
  - In Good Health, Inc. (Brockton)
  - Central Ave Compassionate Center, Inc. (Ayer)
  - New England Treatment Access, Inc. (Northampton)
  -  New England Treatment Access, Inc. (Brookline)
  -  Patriot Care Corp. (Lowell)



## What does Massachusetts DPH test for?

- Microbiological screen
- Heavy metals screen
  - Arsenic, Cadmium, Lead, Mercury
- Mycotoxin screen
- Cannabinoid Profile
- Residual solvents
- Environmental media testing





For more information, visit [www.mass.gov/medicalmarijuana](http://www.mass.gov/medicalmarijuana)

The screenshot shows the Mass.gov website interface. At the top, there is a navigation bar with links for 'State Offices & Courts', 'State A-Z Topics', and 'State Forms'. A search bar is located in the top right corner. Below the navigation bar, the main header identifies the site as 'The Official Website of the Executive Office of Health and Human Services (EOHHS)'. The page title is 'Health and Human Services' with a sub-header 'Departments & Divisions'. A search bar is also present in the header area. Below the header, there is a navigation menu with tabs for 'A-Z Topic Index', 'Health Care & Insurance', 'Consumer', 'Licensing', 'Provider', 'Researcher', 'Government Agencies', and 'Departments'. The 'Government Agencies' tab is currently selected. The main content area displays a breadcrumb trail: 'Home > Government Agencies > Departments & Divisions > Public Health > Bureaus and Programs > Health Care Safety and Quality > Medical Marijuana > Sampling & Analysis: Finished Medical Marijuana / MIPS'. The main heading is 'Sampling and Analysis: Finished Medical Marijuana and MIPS'. Below this heading, there is a list of links to various exhibits and documents, including 'Revised Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries (posted February 12, 2016)', 'Exhibit 1. Overview of Medical Marijuana Production', 'Exhibit 2. Contaminants of Concern and Testing Requirements for Medical Marijuana Products', 'Exhibit 3. Representative Sample Program Design', 'Exhibit 4. Analysis Requirements and Recommended Limits for Metals in Finished Medical Marijuana Products', 'Exhibit 5. Minimum Analysis Requirements for Residues of Pesticides and Plant Growth Regulators Commonly Used in Cannabis Cultivation', 'Exhibit 6. Analysis Requirements for Microbiological Contaminants and Mycotoxins in Medical Marijuana Products', 'Exhibit 7. Concentration Limits for Residual Solvents', and 'Exhibit 8. Actions in Response to Laboratory Analytical Results'. At the bottom of the list, there is a note: 'Comments or questions regarding the Testing Protocols should be emailed to [RMDCompliance@state.ma.us](mailto:RMDCompliance@state.ma.us), or mailed to Medical Use of Marijuana Program, Attn: RMD Compliance, 99 Chauncy St., 11<sup>th</sup> Floor, Boston MA 02111.'