

Ohio's Medical Marijuana Control Program





Timeline

- September 8, 2016 – House Bill 523 Effective
- November 5, 2016 – Deadline for first Medical Marijuana Advisory Committee meeting
- May 6, 2017 – Cultivator rules adopted
- September 8, 2017 – All other rules adopted
- September 8, 2018 – Ohio Medical Marijuana Control Program operational



Who is Responsible?

Department of Commerce

- Cultivators
- Processors
- Testing laboratories

State Board of Pharmacy

- Dispensaries
- Patients/Caregivers
- New forms and methods of medical marijuana

Medical Board

- Certified physicians
- New qualifying conditions



Medical Marijuana Process Flow Chart



Role of the Department of Commerce





Cultivators

- When drafting the regulations, the MMCP balanced the cost of compliance with the benefit of the regulation.
- The MMCP created two levels of cultivator licenses based on the feedback received from many different stakeholders, and these licenses have the ability to expand to meet demand.
- The MMCP identified the need for a plant-only processor license to allow for direct shipment of plant material from a cultivator to a dispensary.



Cultivator Final Rules

- Based on multiple rounds of public comment and feedback from the Common Sense Initiative, the JCARR filed cultivator rules:
 - Removed the designated territories from Commerce’s rule sets.
 - Reduced the financial responsibility requirements to account for industry uncertainties.
 - Limited tax documentation in the application to summary pages for any individual or entity with a 1% or greater financial interest.
 - Revised the surveillance technology requirements to provide for motion-activated recording technology and a 45 day retention period.
 - Established a review process for advertisements submitted to the Department.



Processors

- The O.R.C. 3796 establishes the approved forms and methods of administration for medical marijuana, and the processor rules accommodate the different methods used to manufacture these forms.
 - Flexibility is important as new processes and methods surface as the market matures, as well as new forms are approved by the board.
- Set the annual license fee at an amount that reflects the plant-only processor license and the limited forms available at the Program's inception.
- A ceiling was set at 40 processor licenses to allow for vertical integration and greater product variety for patients.



Testing Laboratories

- Provides a mechanism to issue public university licenses and private laboratory licenses in accordance with H.B. 523.
- Offers testing flexibility at different points during the manufacturing process to eliminate redundancies, control costs, and ensure patient safety.
- Creates a universal standard for licensed labs that can accommodate future advancements in analytical techniques without departing from that standard.

Role of the State Board of Pharmacy





Pharmacy's Role in Rule Development

Responsible for rules relating to:

- Registration of patients/caregivers
- Retail dispensaries
- Form and method of medical marijuana

Authorized to:

- Enforce rules related to patients/caregivers and dispensaries
- Use Ohio Automated Rx Reporting System for the collection of information related to dispensing medical marijuana to registered patients
- Disseminate registered patient information to retail dispensaries



Dispensaries

- The Board may issue up to 60 dispensary licenses through a competitive selection process
- Dispensaries will be required to report to the Ohio Automated Rx Reporting System in real-time
- Employees will be required to be licensed with the Board and to wear Board-issued ID cards while on dispensary premises
- Dispensaries will have to develop a policy for the education of patients and caregivers
- Dispensaries will be required to pay a \$5,000 application fee and \$70,000 biennial licensing fee



Patients and Caregivers

- All patients and caregivers must register with the Board to receive a state-issued medical marijuana patient identification card
 - Registration will be electronic and can be submitted by a patient's recommending physician or physician's delegate
 - Annual registration fee is \$50 for patients and \$25 for caregivers
- Patients under 18 must have a parent or legal representative as a caregiver
- A person must be 21 to serve as a caregiver and a patient can have up to 2 caregivers; each caregiver can have up to 2 patients



House Bill 523-Approved Forms

Oils

Tinctures

Plant
material

Edibles

Patches

House Bill 523 Prohibitions on Form and Method of Administration



Forms and methods considered attractive to children

Forms that require smoking or combustion



THC Content

- Responsible for most of the psychoactive effects of cannabis
- Best available clinical data is for less than 23% THC
 - Data focuses on efficacy based on THC content
 - Does not take into account the “Ensemble Effect” (also known as the Entourage Effect)
 - Limited studies demonstrate this effect at this time



90-Day Supply of Plant Material

Tier	THC Content	Maximum 90-Day Supply	THC Medical Efficacy	Adverse Events
Tier 1	0 – 23%	8 oz. 10 oz. (terminal exception)	+	+
Tier 2	23.1 – 35%	5.3 oz. 6.6 oz. (terminal exception)		+



90-Day supply of medical marijuana based on THC content

Form	90-Day Supply
Tier I plant material (up to 23% THC)	8 ounces of plant material; 10 ounces for terminal exception
Tier II plant material (over 23% THC)	5.3 ounces of plant material; 6.6 ounces for terminal exception
Oils for vaporizing	53.1 grams of THC; 65.7 grams for terminal exception
Patches for transdermal administration	26.6 grams of THC; 33.3 grams for terminal exception
Edibles, oils, and tinctures for oral administration	9.9 grams of THC; 11.7 grams for terminal exception

Role of the State Medical Board





Recommending v. Prescribing

- The Federal government prohibits doctors from being able to prescribe marijuana
 - Patients must have a recommendation from a certified physician
 - Interested physicians must apply for a certificate to recommend (CTR) from the State Medical Board
- The process to develop the CTR will be established in Medical Board rules
 - Must be adopted by September 2017.

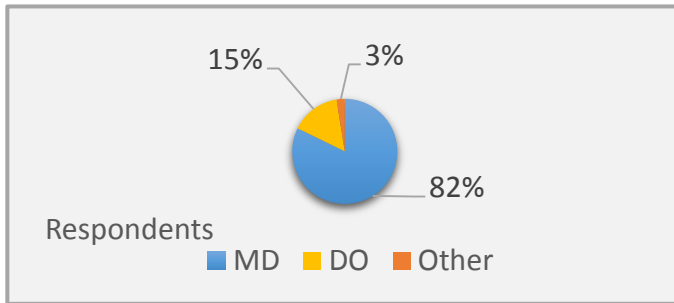


Qualifying Conditions

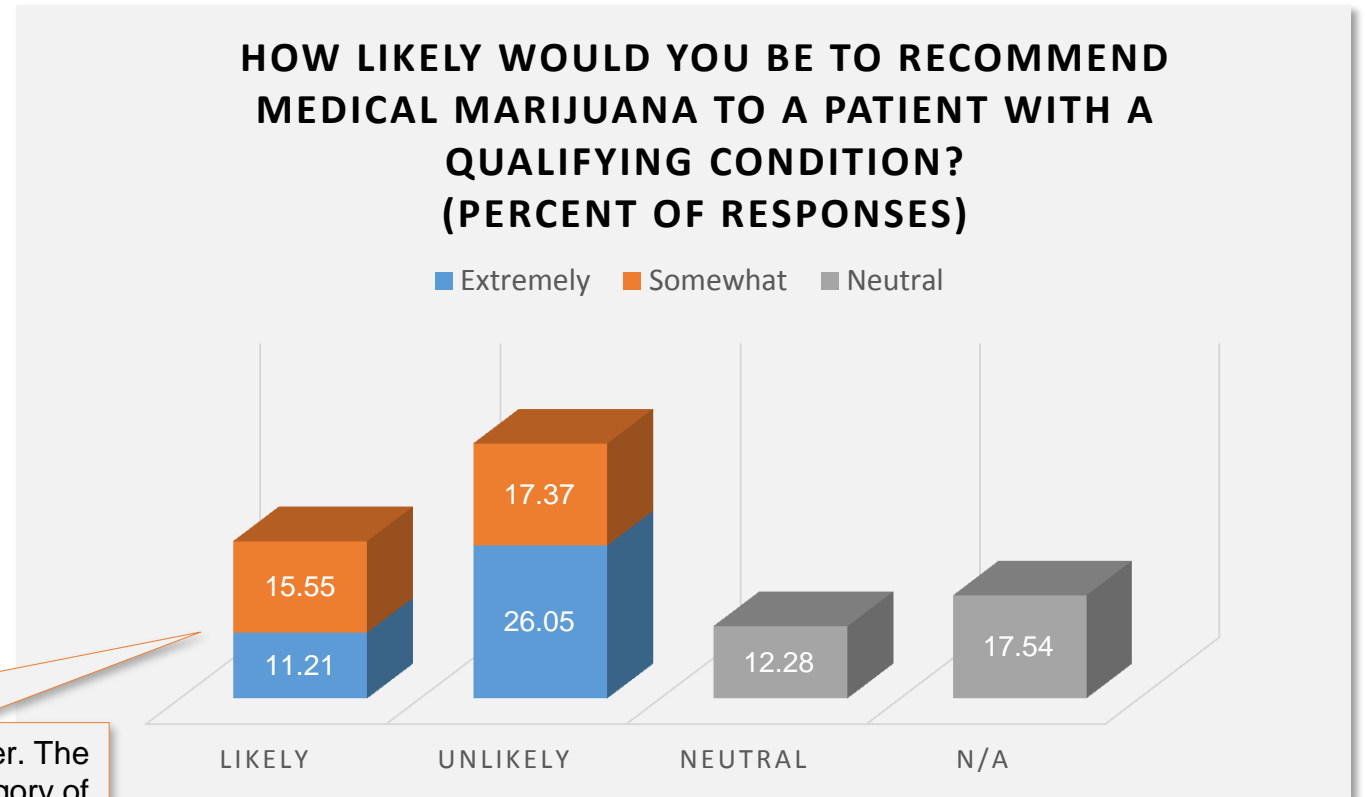
The State Medical Board has statutory authority to create a petition process used to add, not remove, qualifying conditions.

- AIDS
- Amyotrophic Lateral Sclerosis
- Alzheimer's Disease
- Cancer
- Chronic Traumatic Encephalopathy
- Crohn's Disease
- Epilepsy / Seizure Disorder
- Fibromyalgia
- Glaucoma
- Hepatitis C
- Inflammatory Bowel Disease
- Multiple Sclerosis
- Pain: Chronic/Severe or Intractable
- Parkinson's Disease
- Positive Status for HIV
- Post-traumatic Stress Disorder
- Sickle Cell Anemia
- Spinal Cord Disease or Injury
- Tourette's Syndrome
- Traumatic Brain Injury
- Ulcerative Colitis

Physician interest



More than 3,000 licensees responded. There are approximately 46,000 physicians (MDs and DOs) currently licensed with the State Medical Board of Ohio.



Down 7% from the original survey in September. The difference shows up as an increase in the N/A category of respondents who indicated they do not manage patients with qualifying conditions.

MedicalMarijuana.Ohio.Gov

Designed to keep Ohioans informed about the development of Ohio's Medical Marijuana Control Program

- Important timelines in the rule-making process
- Announcement of opportunities for public input



WELCOME

House Bill 523, effective on September 8, 2016, legalizes medical marijuana in Ohio. The Ohio Medical Marijuana Control Program will allow people with certain medical conditions, upon the recommendation of an Ohio-licensed physician certified by the State Medical Board, to purchase and use medical marijuana.

While the legislation set a basic framework for the program, it left the task of establishing specific rules and guidelines for the cultivation, processing, testing, dispensing and medical use of marijuana to different state agencies. This site is designed to keep Ohioans informed about the development of Ohio's Medical Marijuana Control Program, including important timelines in the rule-making process and the announcement of opportunities for public input.

STATEMENT ON PATIENT IDENTIFICATION CARDS

In response to a number of inquiries from Ohio residents on how to obtain a medical marijuana patient card or "affirmative defense" card, please note that no patient identification cards are being issued by the state of Ohio's Medical Marijuana Control Program (MMCP) at this time. The only valid state ID cards will be issued by the State of Ohio Board of Pharmacy once the state's