

# Ohio Medical Marijuana Control Program



# Guiding Principles

Ohio Medical Marijuana Control Program is:

1. Patient-centered and safe
2. Responsive, data-driven, and transparent
3. Flexible, scalable, and sustainable
4. Characterized by consistency, integrity, and collaboration across one program

# Timeline

- September 8, 2016 – House Bill 523 Effective
- May 6, 2017 – Cultivator rules adopted
- September 8, 2017 – All other rules adopted
- September 8, 2018 – Ohio Medical Marijuana Control Program operational
- October 8, 2021 – Medical Marijuana Advisory Committee abolished

# Rules Status Update

1<sup>st</sup> Opportunity: Initial Public Comment  
following Advisory Committee presentation

2<sup>nd</sup> Opportunity: Common Sense Initiative

3<sup>rd</sup> Opportunity: Public Hearing

4<sup>th</sup> Opportunity: Joint Committee on Agency  
Rule Review Hearing

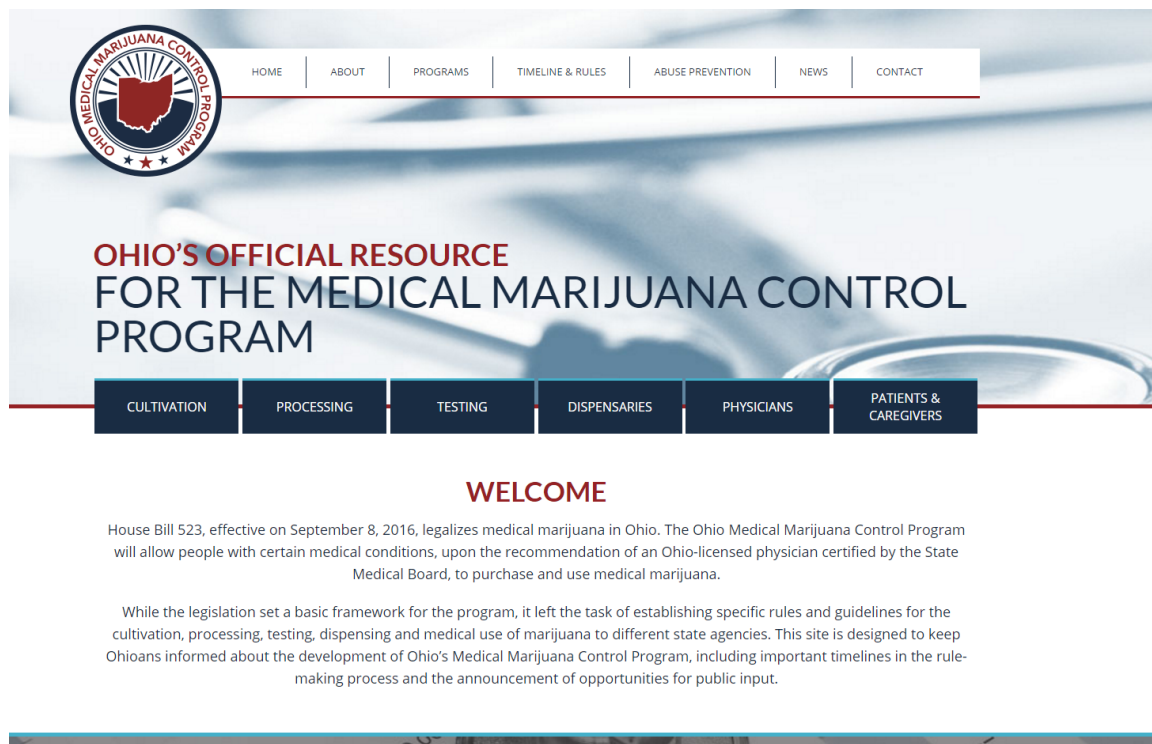
# Rules Status Update

Rule Set	Implementing Agency	Status
Cultivators	Commerce	Filed with Joint Committee on Agency Rule Review 2/17/17; Public Hearing scheduled for 3/20/17
Processors	Commerce	Public comment closed 2/10/17; Comments being reviewed/revisions made prior to CSI filing
Testing Labs	Commerce	Presented before Advisory Committee 2/23/17; Public comment closes 3/10/17
Dispensaries	Pharmacy Board	Public comment closed 1/13/17; Comments being reviewed/revisions made prior to Board review and CSI filing
Patients and Caregivers	Pharmacy Board	Public comment closed 2/10/17; Comments being reviewed/revisions made prior to Board review and CSI filing
Form and Method	Pharmacy Board	Presented before Advisory Committee 2/23/17; Public comment closes 3/10/17
Physicians	Medical Board	Public comment closed 1/13/17; Comments being reviewed/revisions made prior to Board review and CSI filing

# 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





# Ohio Department of Commerce

## Justin Hunt, COO

Medical Marijuana Control Program

# 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.

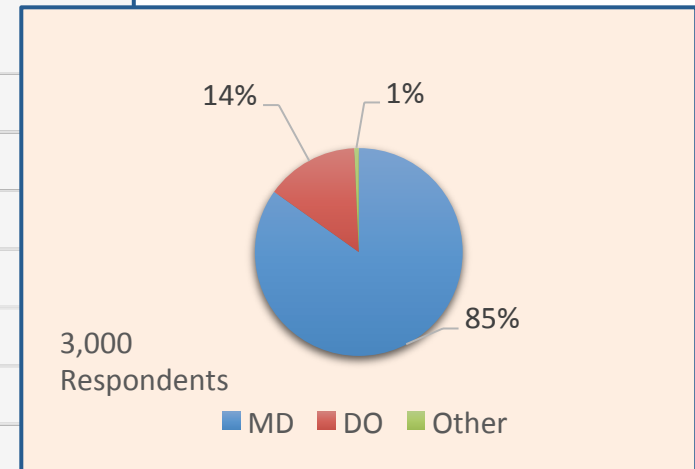
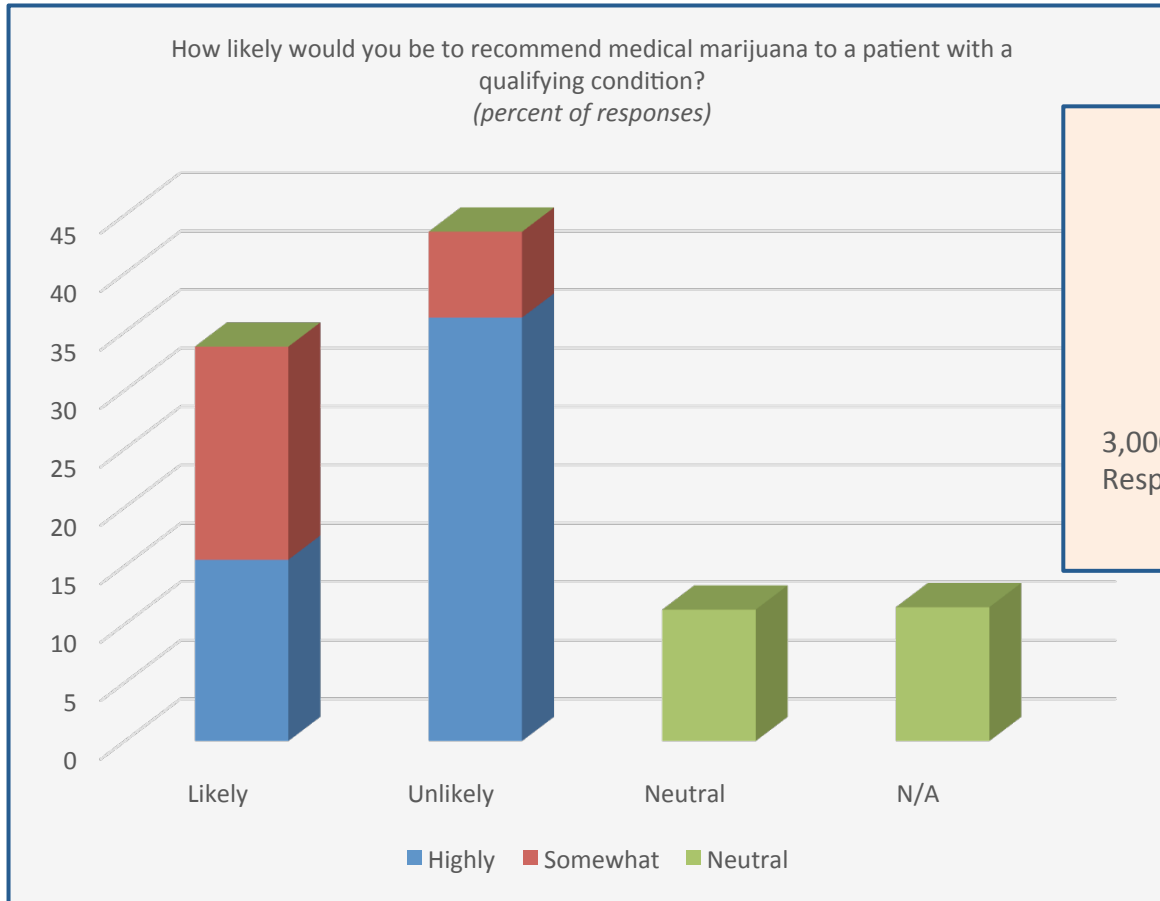


State Medical Board of Ohio  
Kimberly Anderson, Chief Legal  
Medical Marijuana Control Program

# Background

- Balances access for patients with qualifying medical conditions with patient safety
- Benchmarked with:
  - Other states
  - Ohio physicians
  - Patient advocates
- Physician survey to determine interest

# Initial Physician Survey



# Initial Physician Survey

**What kind of information  
would you like to learn  
from Ohio's Medical  
Marijuana Control  
Program outcomes?**



efficacy, side effects,  
patient demographics



vehicle accident & OVI data

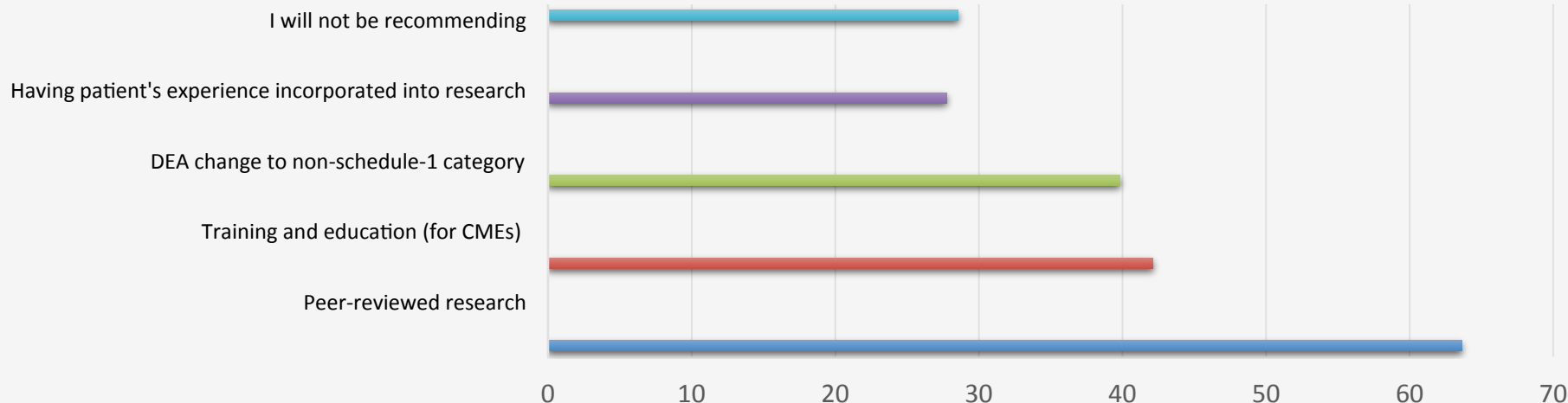


substance use  
disorder & diversion

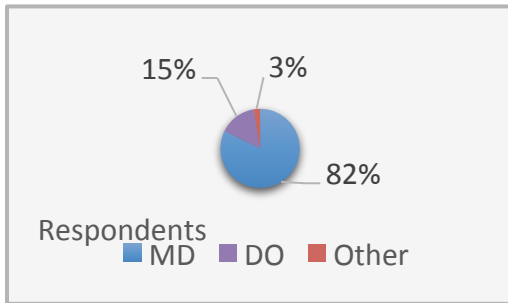


mental health events

## **What would increase your likelihood of recommending?** *(percent of responses)*

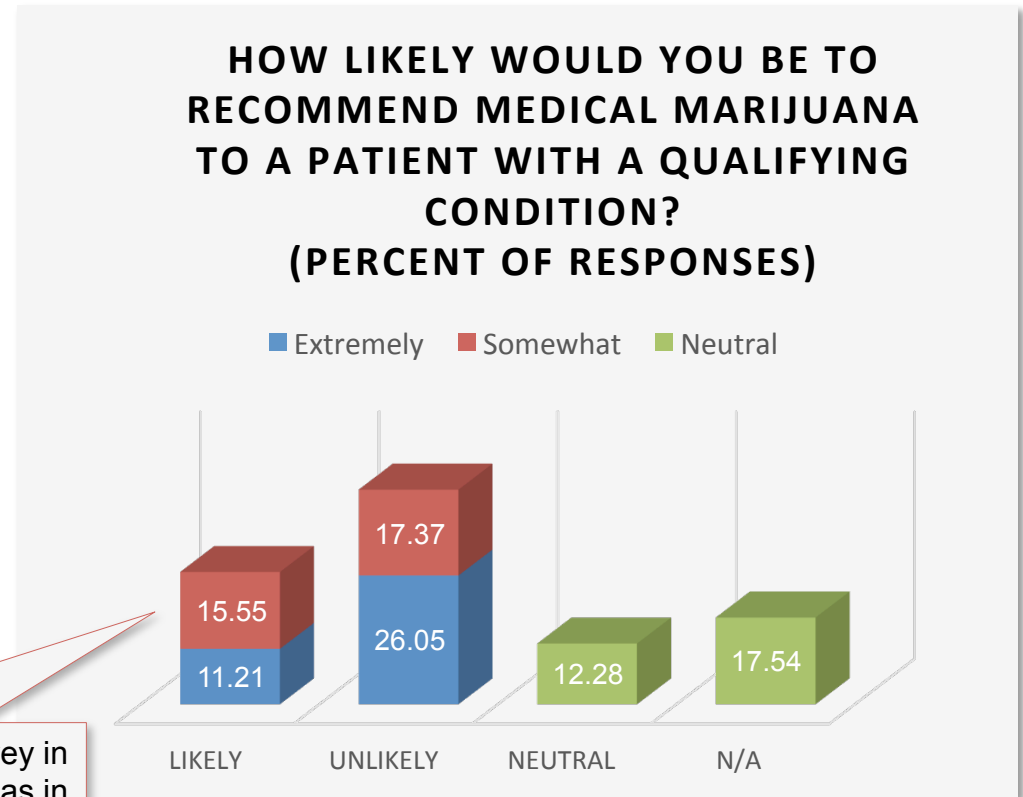


# Follow-up Survey Results



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.





# Follow-up Survey Results

## Has your employer indicated if they will allow you to recommend medical marijuana?



# House Bill 523

The Board's rules establish following:

- Procedures when applying for a certificate to recommend medical marijuana
- Conditions that must be met to be eligible for a certificate to recommend
- Schedule and procedures for renewing a certificate to recommend

# House Bill 523

- Reasons for which a certificate to recommend may be suspended or revoked
- Standards under which a suspension of a certificate to recommend may be lifted
- Minimal standards of care when recommending treatment with medical marijuana

# Next Steps

- Rules sent out for public comment in December
  - Received 54 email comments
  - 3,429 doctors responded to survey
- Medical Board Members will consider the rules during the March board meeting



State of Ohio Board of Pharmacy  
Steve Schierholt, Executive Director  
Erin Reed, Senior Legal Counsel

Medical Marijuana Control Program

# Dispensaries

- The Board may issue up to 60 dispensary licenses
- 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

# Patients and Caregivers

- All patients and caregivers are required to register with the Board to receive a state-issued medical marijuana patient identification card
  - Registration will be electronic and can be submitted by a patients 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 patient can have up to 2 caregivers; each caregiver can have up to 2 patients

# THC Level

- 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
- Encouraging stakeholders to provide us with additional studies



# Draft Rule

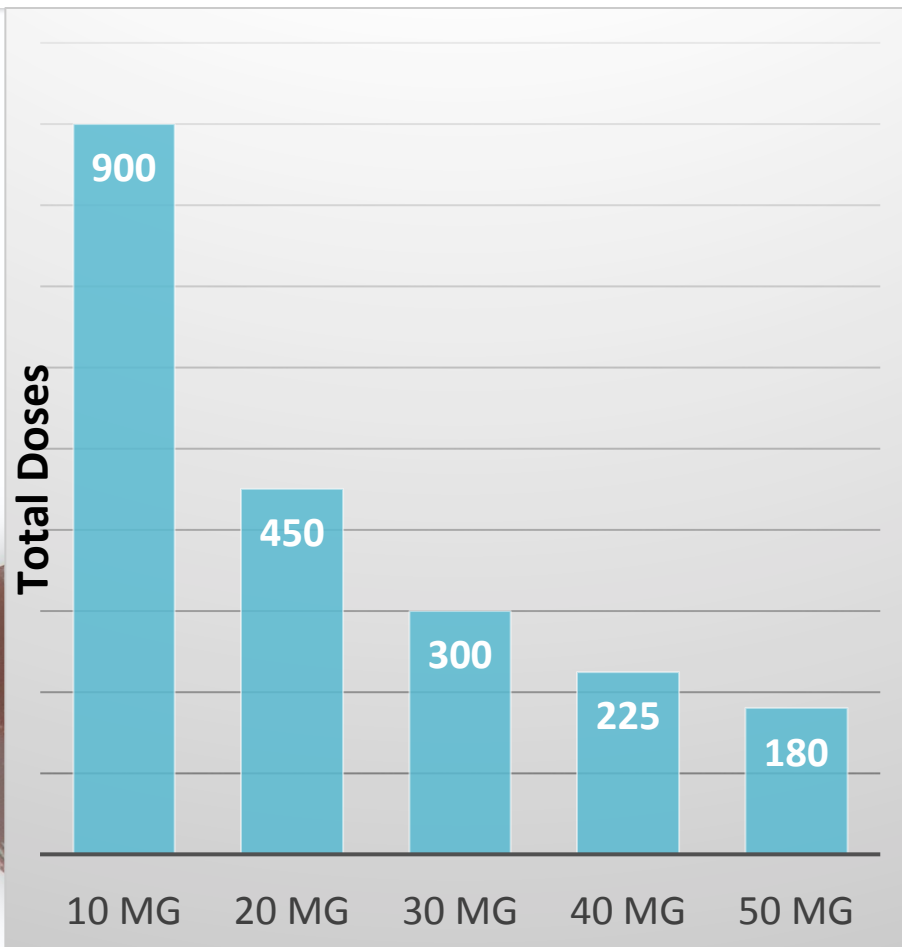
- Consolidation of tiers based on THC medical efficacy

Tier	THC Content	Maximum 90-Day Supply	THC Medical Efficacy	Adverse Events
Tier 1	0 – 23%	6 oz.	+	+
Tier 2	23.1 – 35%	4 oz.		+

# 90-Day supply of medical marijuana based on THC content

Form	90-Day Supply
Tier I plant material (up to 23% THC)	6 ounces of plant material
Tier II plant material (over 23% THC)	4 ounces of plant material
Oils for vaporizing	40.5 grams of THC
Patches for transdermal administration	19.8 grams of THC
Edibles, oils, and tinctures for oral administration	9 grams of THC

# Doses in a 90-day Supply for Oral Administration



# Purchasing Scenario

<b>Form</b>	<b>THC Content</b>	<b>Days Supply</b>	<b>Total THC Content</b>
Patches	220	30	6600
Tincture	100	20	2000
Edible	100	15	1500
Oils for Vaping	450	25	11250
<b>Total</b>		<b>90</b>	<b>21350</b>

# Questions?

