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

Cultivators → Processors → Dispensaries → Patients → Physicians

Testing Lab → Testing Lab
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
  
  o Registration will be electronic and can be submitted by a patients recommending physician or physician’s delegate
  
  o 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
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

<table>
<thead>
<tr>
<th>Tier</th>
<th>THC Content</th>
<th>Maximum 90-Day Supply</th>
<th>THC Medical Efficacy</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>0 – 23%</td>
<td>8 oz.</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 oz.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(terminal exception)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 2</td>
<td>23.1 – 35%</td>
<td>5.3 oz.</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.6 oz.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(terminal exception)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
90-Day supply of medical marijuana based on THC content

<table>
<thead>
<tr>
<th>Form</th>
<th>90-Day Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier I plant material (up to 23% THC)</td>
<td>8 ounces of plant material; 10 ounces for terminal exception</td>
</tr>
<tr>
<td>Tier II plant material (over 23% THC)</td>
<td>5.3 ounces of plant material; 6.6 ounces for terminal exception</td>
</tr>
<tr>
<td>Oils for vaporizing</td>
<td>53.1 grams of THC; 65.7 grams for terminal exception</td>
</tr>
<tr>
<td>Patches for transdermal administration</td>
<td>26.6 grams of THC; 33.3 grams for terminal exception</td>
</tr>
<tr>
<td>Edibles, oils, and tinctures for oral administration</td>
<td>9.9 grams of THC; 11.7 grams for terminal exception</td>
</tr>
</tbody>
</table>
Role of the State Medical Board
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
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