

# Ohio's Medical Marijuana Law and Regulations



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# HB 523

- On June 8<sup>th</sup>, Ohio became the 25<sup>th</sup> state to enact medical marijuana legislation.
- Bill went into effect on September 8, 2016.
- Qualified doctors may make a recommendation, rather than a prescription, to individuals with one or more of the following qualifying diagnosis:

(a) Acquired immune deficiency syndrome;	(g) Epilepsy or another seizure disorder;	(m) Pain that is either of the following:	(q) Sickle cell anemia;
(b) Alzheimer's disease;	(h) Fibromyalgia;	(i) Chronic and severe;	(r) Spinal cord disease or injury;
(c) Amyotrophic lateral sclerosis;	(i) Glaucoma;	(ii) Intractable.	(s) Tourette's syndrome;
(d) Cancer;	(j) Hepatitis C;	(n) Parkinson's disease;	(t) Traumatic brain injury;
(e) Chronic traumatic encephalopathy;	(k) Inflammatory bowel disease;	(o) Positive status for HIV;	(u) Ulcerative colitis;
(f) Crohn's disease;	(l) Multiple sclerosis;	(p) Post-traumatic stress disorder;	(v) Any other disease or condition added by the state medical board under section 4731.302 of the Revised Code.

- Patients are permitted to use marijuana in the following manners:
  - Vaporization, tinctures, edibles, patches, and oils
- Dispensaries may **sell** plant material BUT smoking marijuana is **not** permitted.
- Individuals may currently utilize affirmative defense for drug charges.

# HB 523

- Does not require an employer to permit or accommodate an employee's use, possession, or distribution of medical marijuana or from establishing or enforcing Drug Free Workplace policies.
- Rebuttable presumption that an employee is ineligible for worker's compensation if the proximate cause of the worker's injury was being under the influence of medical marijuana.
- Prohibits cultivation of marijuana for personal, family, or household use.
- Exempts financial institutions that provide financial services to a licensed medical marijuana business from certain criminal offenses, including marijuana trafficking.
  - Financial institutions may request certain information from the Department of Commerce and the Board of Pharmacy regarding a person whom the institution is seeking to do business with.
- Authorizes Director of Commerce to establish a closed-loop payment processing system.
- HB 523 requires the Department of Commerce and the Board of Pharmacy to administer the Medical Marijuana Control Program.



# Medical Marijuana Control Program

- Medical marijuana program must be fully operational by September 8, 2018.
- Medical Marijuana Advisory Committee charged with proposing and adopting regulations
- Medical Marijuana Control Program has published tentative rules, but only rules for cultivators have been finalized.
  - Cultivator regulations are complete. Applications for cultivators are available on the State's website ([www.medicalmarijuana.ohio.gov](http://www.medicalmarijuana.ohio.gov)). Applications for small cultivation sites (Level II) are due June 5-June 16, 2017. Level I applications (large cultivation sites) are due June 19-June 30, 2017.
  - A list of approved pesticides has also been released.
  - All other regulations must be adopted by September 8, 2017.

# Medical Marijuana Control Program

## Public Input

After rules have been proposed:

- Initial public comment.
  - Anyone can submit comments to the rules.
- Common Sense Initiative (CSI)
  - Dept. of Commerce or Board of Pharmacy must produce a “Business Impact Analysis” and submit BIA to the CSI.
    - CSI Ohio was launched in 2011 and is tasked with reviewing Ohio’s regulatory system to eliminate excessive rules and regulations that stand in the way of job creation.
  - Interested parties may submit comments to CSI.
  - CSI may recommend changes to the rules.
- Public hearing after filing rules with Joint Committee on Agency Rule Review (JCARR)
  - Agency must hold a public hearing 30-41 days after filing rules.
  - Anyone may testify at the hearing.
- JCARR Hearing
  - Public may submit comments about the rules, but only addressing six limited topics about technical details of rulemaking (i.e. the rules conflict with the intent of the statute, rules exceed the agency’s statutory authority, etc.).



# Rules for other entities

- Patient and caregiver rules have been submitted to the CSI.
- Form and method of administration rules have been submitted to the CSI.
- Testing lab rules have been submitted to the CSI.
- Processor rules have been submitted to the CSI.
- All of these rules must be completed and adopted by September 8, 2017.

# Medical Marijuana Control Program

## Regulations for Cultivators

### Cultivator

- Two types of cultivators:
  - Level I cultivator
    - May initially operate up to 25,000 sq. feet of designated marijuana cultivation space.
    - Application fee is \$20,000. Applicants granted a provisional license must pay an additional \$180,000 fee. Annual renewal fee is \$200,000.
  - Level II cultivator
    - May initially operate up to 3,000 sq. feet of designated marijuana cultivation space.
    - Application fee is \$2,000. Applicants granted a provisional license must pay an additional \$18,000 fee. Annual renewal fee is \$20,000.
- Entities may apply only for a Level I or Level II license (not both)
- After September 8, 2018, licensees may request approval from the Department of Commerce to increase their space up to two times (50,000 sq. feet for Level I and 6,000 sq. feet for Level II for their first expansion, and 75,000 sq. feet for Level I and 9,000 sq. feet for Level II for their second expansion).

# Medical Marijuana Control Program

## Regulations for Cultivators

### Cultivator (cont'd)...

- Application must include:
  - Application fee (\$20,000 for Level I; \$2,000 for Level II)
  - Business plan (legal name of applicant, type of business (i.e. partnership, LLC, etc.), documentation that applicant is in compliance with local regulations)
  - Operations plan (cultivation techniques, list of medical marijuana varieties proposed, facility specifications, facility staffing, etc.)
  - Quality assurance plan (intended use of pesticides, best practices for packaging and labelling, etc.)
  - Security plan (recording keeping practices, transportation policies, and additional security features)
  - Financial plan (identity and ownership of every person with a financial interest and tax summary for each person with 1% interest or greater, cost breakdown, documentation indicating application has at least \$500,000 (Level I, Level II requires \$50,000) in liquid assets)
- Applications are scored and provisional licenses granted to cultivators that at least meet the minimum requirements and have the highest overall score
  - In event of a tie, license is awarded to cultivator with highest operations score, and then highest security score.
- If granted a provisional license, then the cultivator must pay the licensing fee and provide a surety bond before a certificate of operation is issued
  - \$750,000 for Level I cultivators; \$75,000 for Level II cultivators payable to the Department of Commerce.
- Applications for cultivation licenses are available on the State's website. Applications for small cultivation sites (Level II) are due June 5-June 16, 2017. Level I applications (large cultivation sites) are due June 19-June 30, 2017.



# Medical Marijuana Control Program

## Tentative Regulations - Processor

### Processor

- Public comment closed on February 10, 2017, regulations have now been submitted to CSI.
- Rules drafted by Department of Commerce
- Up to 40 provisional licenses may be issued prior to September 8, 2018, with no more than 10 in any one designated territory. After September 9, 2019, additional licenses may be issued based on patient demand.
- Territories have not yet been determined.
- Application process
  - Application fee (\$10,000)
  - Business plan (legal name of applicant, type of business (i.e. partnership, LLC, etc., submission to a criminal background check, etc., documentation that applicant is in compliance with local regulations)
  - Operations plan (processing techniques, list of medical marijuana products to be manufactured, facility specifications, facility staffing, etc.)
  - Quality assurance plan (intended use and sourcing of equipment and solvents used for extraction, best practices for packaging and labelling, inventory control plan, recall policies.)
  - Security plan (recording keeping practices, transportation policies, and additional security features)
  - Financial plan (identity and ownership of every person with a financial interest and tax summary for each person with 1% interest or greater, cost breakdown, documentation indicating application has specific amount in liquid assets (\$500,000 for Level I; \$50,000 for Level II)
- Applications are scored (rubric has not yet been released) and provisional licenses granted to processor in each of the 40 designated territories that at least meet the minimum requirements and have the highest overall score.
- Applicants granted a provisional license must pay an additional \$90,000 fee. \$100,000 annual renewal fee.
- Licensed processors must provide a surety bond of \$750,000
- Licensees have six months from issuance of provisional license to meet conditions in the application and rule and pass inspection for a certificate of operation.
- Products must be lab tested before packaging and distribution.

# Medical Marijuana Control Program

## Tentative Regulations - Dispensary

### Dispensary

- Public comment closed January 13, 2017. Have now been submitted to CSI.
- Rules written by Board of Pharmacy.
- Current rules permitted up to 60 provisional licenses issued prior to September 8, 2018.
- Initial rules ensured at least one dispensary 25 miles away from any potential patient.
- Each dispensary must have a Clinical Director who is a licensed pharmacist or licensed prescriber.



# Medical Marijuana Control Program

## Tentative Regulations - Dispensary

### Dispensary (cont'd)

- Application:
  - State Board of Pharmacy will provide notice of a request for applications. Request will include scoring procedure, information on obtaining an application, acceptable methods for submission, preferred geographic distribution of sites, and additional required information.
    - Application period will open 45 business days after the request is posted, and will remain open for 10 business days.
  - Application must include:
    - Name of dispensary as reflected in Article of Incorporation and copy of the Articles;
    - Type of business organization;
    - Physical address where dispensary will be located;
    - Proposed hours of operation;
    - Proof that the applicant controls (through leasehold interest) all real property where medical marijuana will be dispensed;
    - Evidence that the dispensary is compliant with all local regulations;
    - Financial plan;
      - Financial capacity of the applicant or evidence that investors have committed money to use of the applicant
      - Liquid assets to cover the expenses and costs of the first year of operation
    - Operations plan
    - Documentation showing the size of the proposed dispensary will include space for a dispensary department, waiting room, restrict access area, and patient care areas.
    - Business plan that include inventory control plans

# Medical Marijuana Control Program

## Tentative Regulations - Dispensary

### Dispensary (cont'd)

- Application will be evaluated based on (but not limited to):
  - Character and fitness of applicant
  - Location of proposed dispensary
  - Applicants ability to show ability to deter and detect theft or loss
  - Extent to which applicant's backers have an interest in another licensee, registrant, or applicant.
- Facility must begin operations with 180 days of receipt of provisional license.
- Licensed dispensary must provide surety bond of \$50,000.
- \$80,000 licensing fee due every two years
- Dispensaries must report dispensing information to online system in real-time.
- All employees must be licensed with the Board of Pharmacy



# Medical Marijuana Control Program

## Tentative Regulations - Patient/Caregiver

### Patient/Caregiver

- Public comment closed February 10, 2017. Have been submitted to CSI.
- Regulations drafted by the Board of Pharmacy.
- Each registered patient may also have up to two registered caregivers (caregiver must be **at least 21 years old**) who may purchase medical marijuana on patient's behalf.
  - Patients under 18 must have a parent or legal representative serve as their caregiver.
  - Patients must have a bona fide relationship with recommending physician, have a qualifying diagnosis, consent to treatment with marijuana, submit required fees, and be an Ohio resident (with a few limited exceptions).
- Electronic registration process for patients and caregivers.
- Registering costs \$50 per patient and \$25 per caregiver.
- Patients and caregivers will receive a physical card to present to dispensary before purchasing medical marijuana.
- Patients or caregivers may purchase a portion of their 90-day supply, but no patient shall receive more than their 90-day supply in a 90-day period.



# Medical Marijuana Control Program

## Tentative Regulations - Form and Method

### Form and Method

- Drafted by Board of Pharmacy
- Individuals may petition the Board of Pharmacy to add a new form or method of consuming medical marijuana. Petition should include:
  - Scientific evidence capable of reproduction and information about adverse effects;
  - Opinion from an expert;
  - Extent to which the form is accepted in the medical community; and
  - Benefits to approving the form.
- All medical marijuana must be packaged in a child resistant container. Products attractive to children are prohibited:
  - Products with cartoon characters or other characters appealing to children, products resembling commercially available candy.
- Prohibits flavors in oils for vaping other than menthol and flavors that mimic strain flavors.
- Vaporizing is prohibited for patients under 18.
- 90-day supply:



Form	90-Day Supply
Tier I plant material: 0 – 23% THC	6 ounces of plant material
Tier II plant material: 23.1 - 35% 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

# Medical Marijuana Control Program

## Tentative Regulations - Testing

### Testing

- Drafted by Department of Commerce
- Department may issue provisional licenses to laboratories affiliated with institutions of higher learning after the rules become effective. Department may begin issuing provisional licenses to private laboratories one year after that date.
- Application process
  - Application fee (\$2,000)
  - Business plan (legal name of applicant, type of business (i.e. partnership, LLC, etc., submission to a criminal background check, etc., documentation that applicant is in compliance with local regulations)
  - Operations plan (lab analysis techniques, experience with medical marijuana or other agricultural testing, implementation of standards and guidelines for conducting lab analysis, facility and staffing plan , etc.)
  - Security plan (plan to prevent theft and loss, transportation policies, and additional security features)
  - Financial plan (identity and ownership of every person involved, cost breakdown, documentation indicating application has at least \$250,000 in liquid assets)
- Applications are scored on the above categories, as well as principal place of business, employment practices, and research plan.
- Testing facilities granted a provisional license must pay an additional \$18,000 fee. Annual renewal fee is \$20,000.
- Licensed testing facilities must provide a surety bond of \$750,000
- Testing facilities must have a Scientific Director.
- Department may require proficiency testing or other third-party validation.



# Medical Marijuana Control Program

## Tentative Regulations - Additional provisions

Additional provisions for cultivators, processors, and testing facilities:  
(All written by Dept. of Commerce and submitted to JCARR)

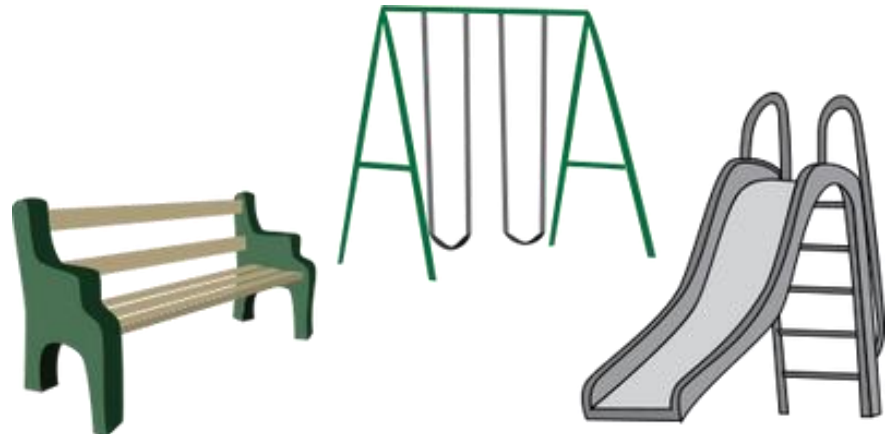
- Every owner, operator, officer, board member, and employee must have an employee identification card issued by the Department of Commerce.
- All employees subject to criminal background check.
- Must maintain a transportation log, vehicles must be insured and unmarked.
- Must submit advertisements to the Department of Commerce for approval.
  - May not advertise on a billboard, a radio, or TV advertisement, on leaflets distributed in public places, on a vehicle, left on private property without consent of the property owner, on any handheld or portable sign. Advertisements may not include cartoons, suggest that the advertisement has been endorsed by the State, advertise in a manner inconsistent with medicinal use.

**For more information about the regulations and to sign up  
for e-mail updates, visit:**

<http://www.medicalmarijuana.ohio.gov/>

# Local Regulation

- Municipal legislative authority **may pass legislation that prohibits** (or limits the number of) cultivators, processors, or retail dispensaries within the municipality.
- Municipal legislative authority **may not** pass legislation that limits research related to marijuana conducted at a state university, academic medical center, or private research and development organization as part of a research protocol approved by an institutional review board or equivalent entity.
- Municipalities **may not** prohibit the use of medical marijuana within their borders.
  - Patients may not be criminally prosecuted for:
    - (1) Obtaining, using, or possessing medical marijuana;
    - (2) Possessing certain marijuana paraphernalia.
  - Criminal ordinances may require amendment to conform to new state law.
- Dispensaries **must** be at least 500 feet from any church, public school, public library, public park, or public playground. Each municipality where a medical marijuana entity is proposed must sign a form indicating that the entity will be at least 500 feet from the above organizations. This form must be submitted with the entity's application
- Each municipality where a medical marijuana entity is propose must also sign a form indicating that the medical marijuana entity complies with the municipality's zoning. This form must be submitted with the entity's application.
- Possible additional zoning restrictions include:
  - Number of establishments
  - Signage
  - Security
  - Guards, safes, cameras, lighting, etc...
  - Operations
  - Use on Premises
  - Hours





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