

# Cultivator Rules

Ohio Department of Commerce





# Background

- The primary focus of the rules is to develop a program that ensures the safety of the public and access to a safe medical product.
- The draft rules presented to the Medical Marijuana Advisory Committee were developed after benchmarking with other states and talking with industry experts.



# Definitions

- The proposed rules includes a shared definitions section to help ensure consistent terminology in the different rule sections.
- Definitions specific to a particular component of the Medical Marijuana Control Program may be handled in that section of the rules.



# Provisional Licenses

- The Department may issue up to 12 Level I and 6 Level II provisional licenses prior to September 8, 2018.
  - Level I – permitted to operate a 15,000 square footage marijuana cultivation area.
  - Level II – permitted to operate a 1,600 square footage marijuana cultivation area.
- Director has discretion to issue additional provisional licenses after September 9, 2018, based on state's population and patient population.
- Limits persons to one cultivator license in Ohio.



# License Applications & Review

- Establishes a baseline for the application criteria, with specific standards and criteria in the application instructions.
- Application will cover many areas, but of significant importance will be an operations plan, security plan, quality assurance plan and financial plan.
- Sets forth the creation of a scoring rubric that will ensure an unbiased, impartial review of every application submitted.
- Establishes financial requirements that will allow for effective implementation of submitted application.

# Certificate of Operation Issuance & Renewal



- Issuance
  - Gives provisional licensees nine months from issuance to meet conditions in the application and rule and pass inspection for a certificate of operation.
  - Cultivator cannot grow until this is issued.
  - Includes a process if they don't pass inspection.
- Renewal
  - Outlines the process for renewal of a cultivator certificate of operation.
  - If not renewed before expiration, suspended for 30 days then revoked.



# Transfer of Ownership or Location

- Prohibits transfer of provisional licenses.
- Establishes grounds and process for a transfer of ownership or change in location of a cultivator.
  - Different process depending on % of ownership change.
- Develops process for change in location.



# Cultivator Operations

- Packaging and Labeling
- Inventory & Storage
- Security
- Quality Assurance
- Recording and Reporting
- Waste Disposal





# Packaging and Labeling

- Establishes requirements and standards for the packaging and labeling of medical marijuana that apply to cultivators.
  - Other standards may be set for processors and dispensaries.
- Provides the department with enforcement authority if anyone knowingly or intentionally alters or destroys a package or label.
- Prohibits the use of cartoons or graphics not approved by the department.



# Inventory Control & Storage

- Sets the requirements that need to be met for the seed-to-sale inventory tracking system, including information that will be necessary for plant tags.
- Outlines inventory control standards measures as well as reporting requirements.
- Requires a manual inventory of medical marijuana at the facility on an annual basis.



# Security

- Divides security into physical security (fences, lighting, locked doors, safes, etc.) and technology security (alarm system, video cameras, silent alarm, etc.).
- Sets standards for the video recording technology and alarm technology.
  - State will have the ability to access live camera feeds.
- Notifies the department and law enforcement of breaches in security.



# Quality Assurance Plan

- States that a quality assurance/quality control plan must be submitted as a part of a cultivator license application.
- Focuses on product consistency and safety for patients, which includes pesticide/fertilizer/fungicide usage and waste disposal from the facilities.
- Establishes facility cleanliness standards for the different areas of the facility, equipment and resources used to cultivate medical marijuana.



# Records and Reporting

- Creates a five year retention policy for books and most records of the cultivator.
- Requires record keeping of various types of records, including disposal, sales, transportation, test samples, security, inventory tracking, finances, and employee records.



# Waste Disposal

- Sets standards for the disposal of medical marijuana waste and what information must be recorded for all disposals.
  - Requires a disposal log and that the disposal occur on camera.
  - Level 1 key employee will oversee disposal.
- Requires disposal in accordance with federal and state law pertaining to other categories of waste.



# Inspections & Testing

- Establishes scope of inspections and the different inspections by the department, including:
  - Pre-approval inspection for issuance of certificate of operation, and
  - Compliance inspections conducted with or without notice.
- Requires that every batch of plant material be tested by a licensed testing laboratory in accordance with testing laboratory rules before being packaged and transported.



# Employee Identification Cards

- Requires every employee of cultivator, processor or testing laboratory to apply to the department prior to engaging in work with the entity.
- Designates two types of employees and a "key employee".
  - Type 1 – granted access to all areas of the cultivator facility, including security room and management areas.
    - Key Employee – one person designated as primary contact with the department.
  - Type 2 – granted access to all medical marijuana cultivation areas, but prohibited from entering security room, management areas, etc.





# Fee Schedules

- Establishes fees for applications, certificates of operations, renewals, lost/destroyed/stolen certificates and employee identification cards.
  - Renewal for IDs is every two years.
  - Renewal for certificate of operations is every year.
  - The proposed non-refundable fees for cultivators are as follows:
    - Application Fee: Level I - \$20,000; Level II - \$2,000
    - License Fee: Level I - \$180,000; Level II - \$18,000
    - License Renewal Fee: Level I - \$200,000; Level II - \$20,000
    - Employee ID Card Application - \$100
- \* Other fees may apply.



# Transportation

- Facility must maintain a transportation log and provide to receiving facility and department the day before transit.
- Require vehicle security standards and employee travel requirements.
- All medical marijuana shall be transported by the cultivator, excluding batch samples for laboratory testing, which could be transported by licensed laboratory employees.



# Loss and Theft Reporting

- Puts in place reporting requirements for suspected or actual loss, theft or diversion.
- Requires notice to the department and law enforcement within 24 hours and further investigation within 10 days of the notice.
  - Review video footage.
  - Seal all records/footage necessary to investigate.



# Facility Distance from Public Spaces

- Details how to measure the 500 ft. distance requirement from a school, church, public library, public playground, or public park in statute, which is defined as prohibited facility.
- The 500 ft. distance requirements aligns with O.R.C. 3796.
- Includes a provision that allows a cultivator to continue to operate if a prohibited facility moves within 500 feet of an existing cultivation facility.



# Enforcement

- Establishes the actions the department may take if a licensed entity commits a prohibited act, as defined in rule.
  - ORC establishes that suspension/revocation would be under Chapter 119
- Prohibited Acts
  - Lists the activities that would give rise to a sanction or other disciplinary measure.
  - Offers an extensive list that includes the activities listed in the Cole memo, as well as acts deemed not in the interest of public health, welfare and safety.



# Advertising

- Requires department approval of an advertisement before it is disseminated to the public.
- Prohibits specific content, as well as distribution mediums.
- Establishes restrictions on the placement and appearance of advertisements.
- Places restrictions on a cultivator's use of social media and web activity.



# Product Registration

- Requires cultivators to register every strain of medical marijuana cultivated at the facility.
- This is a one time fee.