



# Common Sense Initiative

Mike DeWine, Governor  
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## Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Commerce, Division of Cannabis Control

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Regulation/Package Title (a general description of the rules' substantive content):

Rule Package 5 – Renewals, Employee Badging, Transportation, Security, Inspections, Patient & Caregiver Registration

Rule Number(s): OAC 1301:18-3-09 (New), 1301:18-2-08 (New), 1301:18-3-02 (New), 1301:18-3-13 (New), 1301:18-3-17 (New), 1301:18-5-01 (New), 1301:18-5-02 (New), 1301:18-5-05 (New), 1301:18-6-01 (New), 1301:18-6-02 (New), 1301:18-6-04 (New), 1301:18-7-01 (New), 1301:18-8-07 (New), 1301:18-9-01 (New), 1301:18-9-06 (New), 1301:18-10-01 (New), 1301:18-10-02 (New), 1301:18-10-04 (New), 1301:18-10-06 (New), 1301:18-10-07 (New), 1301:18-10-08 (New), 1301:18-10-09 (New)

3796:2-1-02 (Rescind), 3796:2-1-03 (Rescind), 3796:2-1-04 (Rescind), 3796:2-1-06 (Rescind), 3796:2-1-07 (Rescind), 3796:2-1-08 (Rescind), 3796:2-1-10 (Rescind), 3796:2-1-11 (Rescind), 3796:2-2-05 (Rescind), 3796:3-1-02 (Rescind), 3796:3-1-03 (Rescind), 3796:3-1-06 (Rescind), 3796:3-1-07 (Rescind), 3796:3-1-08 (Rescind), 3796:3-1-09 (Rescind), 3796:3-1-10 (Rescind), 3796:3-2-05 (Rescind), 3796:4-1-02 (Rescind), 3796:4-1-06 (Rescind), 3796:4-1-08 (Rescind), 3796:5-2-01 (Rescind), 3796:5-2-02 (Rescind), 3796:5-2-03 (Rescind), 3796:5-3-01 (Rescind), 3796:6-2-07 (Rescind), 3796:7-2-01 (Rescind), 3796:7-2-03 (Rescind), 3796:7-2-07 (Rescind), 3796:7-2-08 (Rescind), 3796:7-2-10 (Rescind), 3796:7-2-11 (Rescind)

Date of Submission for CSI Review: 6/12/2024

Public Comment Period End Date: 6/26/2024

Rule Type/Number of Rules:

New/ 22 rules

No Change/      rules (FYR?     )

Amended/      rules (FYR?     )

Rescinded/ 31 rules (FYR? Y)

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The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

### **Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

### **Regulatory Intent**

2. Please briefly describe the draft regulation in plain language.

*Please include the key provisions of the regulation as well as any proposed amendments.*

O.A.C. 1301:18-3-09 EMPLOYEE BADGES (New)

- Establishes requirements for employees and owners of licensed cannabis facilities to obtain an employee badge via application to the Division. Requires these individuals to submit fingerprints for BCI and FBI background checks. Enrolls eligible individuals into “Rapback.”
- Allows an employee to maintain one badge for each license in the family of companies, rather than a badge for each individual license.

- Provides a provisional employee badge to streamline and expedite the hiring and onboarding process for new employees. An applicant for an employee badge may begin working in a licensed cannabis facility upon submission of 1) a complete and accurate application, 2) attestations that the employee does not have any offenses on their record that would disqualify them from obtaining employment, 3) evidence that the applicant has submitted fingerprints for both a BCI and FBI background check.

The licensed medical marijuana facility is responsible for conducting a thorough background evaluation to confirm the employee applicant does not have a disqualifying offense and is compliant with all program rules.

A provisional employee identification card is valid for 90 days.

#### O.A.C. 1301:18-2-08 CANNABIS ENTITY LICENSE RENEWALS (New)

- Cultivator and Processor facility licenses must be renewed annually. A compliance inspection is required once each renewal cycle.
- Testing Laboratory and Dispensary facility licenses must be renewed biannually. A compliance inspection is required once each renewal cycle.
- If a licensee fails to meet all license renewal requirements by the expiration date, the Certificate of Operation is suspended for a maximum of 30 days. If the licensee fails to meet all requirements during the suspension, the Certificate of Operation is revoked, requiring the licensee to permanently cease all operations.

#### O.A.C. 1301:18-3-02 CHANGE OF LOCATION (New)

- A licensee wishing to change facility location must receive prior approval from the Division. For a dispensary, the proposed location must be located within the same dispensary district as the existing location.

#### O.A.C. 1301:18-3-13 TRANSPORTATION OF CANNABIS TO ANOTHER LICENSE ENTITY (New)

- All licensees must maintain transportation policies that ensure property security protocols to mitigate the risk of theft, loss, or diversion.
- Only individuals with a badge certificate through the Division are permitted to transport cannabis. Individuals with a provisional badge or no badge at all are not permitted to transport cannabis.
- Transportation vehicles must be free of any marks, logos, brands, or illustrations.

#### O.A.C. 1301:18-3-17 DISCONTINUING BUSINESS (New)

- In the event a licensee seeks to permanently cease all business operations, notification must be made to the Division 90 days in advance of the closure. The licensee must wind down operations in accordance with a written closure plan submitted to the Division.

#### O.A.C. 1301:18-5-01 CULTIVATOR CERTIFICATE OF OPERATION (New)

- This rule provides the activities in which a cultivator licensee may engage.

O.A.C. 1301:18-5-02 CULTIVATOR UNINTERRUPTED SUPPLY OF CANNABIS (New)

- Cultivators must ensure a consistent supply of cannabis plant material is available for sale to consumers, which may be evidenced by not more than 120 days elapsing between harvests totaling at least 15 pounds and sale or transfer totaling at least 20 pounds for a level I cultivator and 10 pounds for a level II cultivator.
- Provides a pathway to temporarily toll these timelines upon approval by the Division.

O.A.C. 1301:18-5-05 CULTIVATOR MINIMUM SECURITY AND SURVEILLANCE REQUIREMENTS (New)

- Each cultivator must establish, maintain, and comply with written policies and procedures that ensure adequate security, surveillance, and control of the licensed premises that prevent diversion, theft, or loss and meet the minimum requirements outlined under this rule.

O.A.C. 1301:18-6-01 PROCESSOR CERTIFICATE OF OPERATION (New)

- This rule provides the activities in which a processor licensee may engage.

O.A.C. 1301:18-6-02 PROCESSOR UNINTERRUPTED SUPPLY OF CANNABIS (New)

- Processors must ensure a consistent supply of cannabis is available for sale to consumers, which may be evidenced by not more than 30 days elapsing between extracting or manufacturing at least 250 grams of extract or not more than 30 days elapsing between sale or transfer of at least one lot of cannabis products to a dispensary.
- Provides a pathway to temporarily toll these timelines upon approval by the Division.

O.A.C. 1301:18-6-04 PROCESSOR MINIMUM SECURITY AND SURVEILLANCE REQUIREMENTS (New)

- Each processor must establish, maintain, and comply with written policies and procedures that ensure adequate security, surveillance, and control of the licensed premises that prevent diversion, theft, or loss and meet the minimum requirements outlined under this rule.

O.A.C. 1301:18-7-01 TESTING LABORATORY CERTIFICATE OF OPERATION (New)

- This rule provides the activities in which a testing laboratory licensee may engage.

O.A.C. 1301:18-8-07 DISPENSARY PATIENT CONFIDENTIALITY (New)

- Requires each dispensary to ensure confidentiality of all records related to medical marijuana patient transactions, and specifies the circumstances under which patient records may be released.

O.A.C. 1301:18-9-01 CANNABIS FACILITY INSPECTIONS (New)

- Outlines the Division's authority to conduct inspections with or without notice provided to the licensee.
- Allows the Division to conduct inspections with other state agencies, such as the Department of Agriculture or State Fire Marshal, or local authorities.
- Requires inspections to be conducted prior to the issuance or renewal of a Certificate of Operation.

#### O.A.C. 1301:18-9-06 VARIANCES (New)

- Allows the Division to grant variances to rules if the requirement is not statutorily mandated, the variance is within the public interest, individuals will not be injured by the proposed variance, and the provision in the specific case is unreasonable or unnecessarily burdensome.

#### O.A.C. 1301:18-10-01 PROCEDURE FOR PATIENT REGISTRATION (New)

- Specifies the steps and information required for a medical marijuana patient to obtain or renew their patient registration, including information required to be submitted to the Medical Marijuana Patient & Caregiver Registry by the physician and the patient.

#### O.A.C. 1301:18-10-02 PROCEDURE FOR CAREGIVER REGISTRATION (New)

- Specifies the steps and information required for a caregiver of a medical marijuana patient to obtain or renew their caregiver registration, including information required to be submitted to the Medical Marijuana Patient & Caregiver Registry by the patient's physician and the caregiver.

#### O.A.C. 1301:18-10-04 PATIENT AND CAREGIVER NOTIFICATION REQUIREMENTS (New)

- Outlines scenarios in which a patient or caregiver must report information to the Division, including any changes to information outlined in their Registry profile or if their card has been used fraudulently. Patients must also notify the Division if their doctor has determined that they no longer have a condition qualifying them for the use of medical marijuana.

#### O.A.C. 1301:18-10-06 PATIENT AND CAREGIVER ENFORCEMENT (New)

- Allows the Division to impose sanctions on patients or caregivers who violate program rules.

#### O.A.C. 1301:18-10-07 PATIENT CONFIDENTIALITY AT ADJUDICATION HEARINGS (New)

- Adjudication hearings related to patient registration are closed to the public, and documents that contain patient-identifying information are confidential.

#### O.A.C. 1301:18-10-08 RELEASE OF PATIENT INFORMATION (New)

- Patient records are confidential and generally not subject to disclosure, except in limited circumstances.

O.A.C. 1301:18-10-09 SUSPENSION OF ACCESS TO PATIENT INFORMATION (New)

- Allows the Division to suspend access to the Medical Marijuana Patient & Caregiver Registry if the individual has violated confidentiality or other requirements.

The Division is also proposing to rescind several of the current medical marijuana rules under Chapter 3796 which the new rules under Chapter 1301 in this package will replace. Those include 3796 rules regarding license renewals, change of location, transportation, discontinuing business, uninterrupted supply of cannabis, cultivator and processor security and surveillance, procedures for patient and caregiver registration, patient and caregiver enforcement, and patient confidentiality. Other rule rescissions include Chapter 3796 rules regarding medical marijuana cultivator, processor, and testing laboratory provisional licensing.

**3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Authorized By: R.C. 3796.03, 3780.03, 3780.20

Amplifies: R.C. 3796.08, 3796.22, 3796.23, 3780.03, 3780.07, 3780.09, 3780.11, 3780.12, 3780.14, 3780.16, 3780.17, 3780.20, 3780.26

**4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

No

**5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

n/a

**6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

In November 2023, Ohio voters approved a citizen-initiated statute to legalize the use, possession, and sale of non-medical cannabis. The statute charges the Division of Cannabis Control with adopting rules to regulate the non-medical cannabis market.

The rules proposed in this package aim to ensure individual employees are badged with the Division and have a background check on file, ensuring no individuals with disqualifying conditions are employed by a cannabis facility.

The rules also address business-to-business transportation, procedures for discontinuing business, facility inspections, and minimum security and surveillance requirements. The public purpose for these regulations is to prevent theft, loss, or diversion and ensure that licensed facilities are operating in a secure manner.

Finally, the rules address the confidentiality of medical marijuana patient information and the circumstances under which it may be released.

**7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by compliance and the prevention of theft, loss, and diversion.

**8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No

**Development of the Regulation**

**9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The Division posted the proposed rules for early stakeholder feedback on its website and sent a direct email soliciting feedback to medical marijuana license holders from April 26, 2024 – May 10, 2024. The Division has also received stakeholder feedback during meetings, including group meetings with associations representing license holders.

**10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

Stakeholder feedback was utilized considerably to draft the rules. After sending those drafts out for early stakeholder outreach, the Division received a few comments to further improve the rule drafts.

One concern was raised regarding language in the transportation rule that would have required the transporter to maintain visibility at all times of all products contained within the vehicle. Stakeholders flagged this as having potential unintended consequences, with which the Division agreed and updated the requirement to require that the vehicle is attended.

Regarding security and surveillance, a concern was raised about language requiring “tamper-evident” cameras. The Division agreed that the appropriate requirement is cameras that deter tampering, which is also in line with the current requirements for medical marijuana licensees. Another concern was raised requiring licensees to test the equipment at least once per 30 calendar days. Licensees requested that the tests be required monthly, and the Division made that update.

Finally, a physician with a certificate to recommend medical marijuana flagged some concerns about document upload requirements in the patient and caregiver registration rules.



The Division agreed that the document upload referenced is not currently required and adjusted the rule to be consistent.

**11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

Other state cannabis markets and regulations were studied and identified best practices were used to help develop these rules. Additionally, the Division reviewed appropriate standards for surveillance cameras and equipment, and incorporated those where applicable, such as the required DPI on a still photo.

**12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

*Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

The Division is establishing standard-based, performance-based regulations, with the goal of allowing businesses the flexibility in how they meet the Division's standards set in the rules.

**13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The initiated statute approved by voters in O.R.C. 3780 places sole regulatory authority over the non-medical cannabis industry with the Division of Cannabis Control.

However, areas of overlap include inspections by other entities such as the State Fire Marshal or local fire department, the Division of Industrial Compliance, and the Department of Agriculture. The Division works closely with each of these entities to ensure there are no conflicts or unnecessary duplications in rules.

**14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

All licensees must comply with the Division's rules. The Division regularly issues industry guidance documents to communicate rule requirements and how to maintain compliance, emails those updates out to licensees, and posts them on the Division's website.

**Adverse Impact to Business**

**15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

- a. Identify the scope of the impacted business community, and
- b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.*



The impacted business community includes currently licensed medical marijuana entities who, pursuant to the initiated statute, are the first businesses eligible to operate in the non-medical market, as well as any other businesses who may become licensed in the future.

A license must be renewed prior to expiration. For cultivators and processors, renewal is required annually. For testing laboratories and dispensaries, renewal is required every other year. A renewal application and fee is required; however, the fee amount is not prescribed in this rule package. The application takes minimal time to complete, as the licensee should have all required information readily available, such as a list of owners and evidence of financial responsibility.

If a licensee fails to meet all renewal requirements, the license will be suspended for 30 days and if the licensee does not meet all renewal requirements in that time the license would be revoked.

The rules also permit the Division to inspect a licensed facility at any time and require an inspection prior to issuance or renewal of a Certificate of Operation. The amount of time an inspection would require for a licensee depends upon the nature of the inspection.

The Division may issue written deficiencies to a licensee, which would require them to submit a written plan of correction within 10 business days. The amount of time this takes depends upon the nature of the deficiency and how extensive the plan of correction needs to be.

The rules require an application and fee to request approval of a change of location. The application fee amount is not established in this rule package. A location change must follow the process detailed in the rule, including written transfer plans and mandatory inspections.

Cultivators and processors are required by the rules in this package to meet the Division's standards for security and surveillance, which include, at a minimum, things like an alarm system with point of entry alarms, motion detectors, and silent alarm, and a video surveillance system which must be accessible remotely in real time by the Division and all video must be stored for at least 45 days. The cost of these systems can vary depending on the size of the facility, and the vendor, software, and equipment the licensee has chosen.

A licensee who permanently ceases all operations must provide a written closure plan to the Division. The amount of time this takes to compile is dependent on the facility's operations and unique circumstances.

**16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).**

The rules proposed here are new pursuant to O.R.C. 3780; however, they will replace the rules adopted under O.R.C. 3796, which were specific to the regulation of the Medical Marijuana Control Program. The new rules apply to both medical and non-medical cannabis.

The proposed employee badging rule reduces some regulatory burdens by allowing an employee to maintain one badge for each license in a family of companies; rather than a badge for each individual license. Additionally, employee badging updates provide a provisional employee badge to streamline and expedite the hiring and onboarding process for new employees.

Additionally, testing laboratories will now be required to renew their license every two years, as opposed to the current annual requirement under O.A.C. 3796. This adjustment more closely aligns with standard laboratory reviews and provides sufficient time for the Division to conduct thorough renewal inspections.

**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The adverse impacts created by the proposed rules mostly include the report of information or certain expenditures. All of the rules associated with these impacts seek to balance fair regulations for business while protecting public health and safety.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

These rules are largely focused on public health and safety, and the requirements that must be met to ensure that priority are intended to create a level playing field for all licensees.

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

The DCC works diligently to ensure that all licensees understand all applications, forms, and compliance requirements. The Division does not fine licensees for simple paperwork violations, but does work with licensees who encounter challenges to ensure they have the information necessary to comply with all laws and rules.

**20. What resources are available to assist small businesses with compliance of the regulation?**

The DCC regularly issues guidance to licensees and posts those documents and other helpful information on its website: [www.com.ohio.gov/cannabiscontrol](http://www.com.ohio.gov/cannabiscontrol). Additionally, the DCC has a team of inspectors who work closely with all licensees to ensure they are able to achieve and maintain compliance with program regulations

# Ohio Division of Cannabis Control Rules Package 5

(All section numbers and citations subject to change)

**\*\*NEW\*\***

## Rules Applicable to All Cannabis Entities

### 1301:18-2-08 Cannabis Entity License Renewals

- **(A)** A certificate of operation issued pursuant to division 1301:18 of the Administrative Code shall expire as follows:
  - **(1)** Cultivators: annually on the date of issuance
  - **(2)** Processors: annually on the date of issuance
  - **(3)** Testing Laboratories: biennially on the date of issuance
  - **(4)** Dispensaries: biennially on the date of issuance
- **(B)** At least thirty calendar days prior to the expiration of its certificate of operation, each licensee shall:
  - **(1)** Submit the following in a manner prescribed by the division:
    - **(a)** A complete renewal application;
    - **(b)** Evidence of compliance with all applicable tax laws;
    - **(c)** The non-refundable renewal fee as outlined under [OAC fees]; and
  - **(2)** Pursuant to rule 1301:18-9-01 of the Administrative Code, pass a full inspection within each licensee's respective renewal period as outlined under paragraph (A) of this rule.
- **(C)** Upon receipt and completion of all requirements outlined under paragraph (B) of this rule, the division will review all associated materials.
  - **(1)** After confirmation that nothing warrants the denial of renewal pursuant to rule 1301:18-9-01, the division will grant the license renewal.
- **(D)** In the event a licensee fails to meet all requirements outlined under paragraph (B) of this rule prior to the expiration date of the certificate of operation, the certificate of operation shall be suspended for a maximum of thirty calendar days.
  - **(1)** In the event a licensee fails to meet all requirements under paragraph (B) during its mandatory suspension, the certificate of operation shall be deemed revoked.
  - **(2)** Upon revocation of a certificate of operation, the division shall not renew the certificate of operation.
    - **(a)** The licensee shall:
      - **(i)** Permanently cease all operations;
      - **(ii)** Not engage in any activities authorized under this chapter; and
      - **(iii)** Destroy the certificate of operation and all affiliated employee badges.

### 1301:18-3-02: Change of Location

- **(A)** A licensee shall not change the location of its licensed premises without prior approval from the division of cannabis control.
- **(B)** Prior to any proposed change, a licensee shall submit the following to the division:
  - **(1)** A complete and accurate application on a form prescribed by the division evidencing the following:

- **(a)** The proposed location of the licensed premises;
      - **(i)** For licensed dispensaries, any proposed location must be located within the same dispensary district as the existing location.
    - **(b)** The associated plans and specifications for the proposed location;
    - **(c)** Evidence the proposed location meets all applicable requirements under [OAC Operations rules];
    - **(d)** The licensee will remain in compliance with division 1301:18 of the Administrative Code at the proposed location;
    - **(e)** Any supporting documentation evidencing the requirements outlined under this paragraph; and
    - **(f)** The non-refundable change of location fee as outlined under [OAC fees].
  - **(2)** After review of the application for a change of location, the division may:
    - **(a)** Approve the application;
    - **(b)** Deny the application; or
    - **(c)** Advise the licensee in writing that the applicant failed to meet all application requirements.
  - **(3)** Upon receipt of written approval, the licensee may construct and prepare the new location.
- **(C)** Once the new location is fully constructed and prepared to commence all business, the licensee shall submit in a manner prescribed by the division a proposed transition plan outlining the following:
  - **(1)** A proposed procedure for the safe and secure transfer all inventory and other materials maintained at the original location to the proposed location within ninety calendar days as outlined under paragraph (E) of this rule;
  - **(2)** Confirmation that the licensee's transition plan will ensure proper security and surveillance of the original location and the proposed location during the transition period that mitigates the risk of theft, loss, and diversion; and
  - **(3)** Assurance the licensee will maintain ongoing compliance with all requirements outlined under these rules.
- **(D)** Upon receipt of a licensee's proposed transition plan, the division will:
  - **(1)** Review the proposed transition plan and advise of any necessary modifications; and
  - **(2)** Conduct a change of location inspection pursuant to rule 1301:18-9-01 of the Administrative Code.
- **(E)** Unless otherwise authorized by the division, the licensee shall have ninety calendar days from the date the licensee passes the change of location inspection pursuant to paragraph (D) of this rule to transfer all inventory.
  - **(1)** No inventory may be transferred prior to the beginning date of the approved transition period.
  - **(2)** Any cannabis remaining at the original location past the ninety-day transition period shall be destroyed in accordance with rule 1301:18-3-12 of the Administrative Code.
  - **(3)** The licensee shall notify the division once the transfer of inventory is complete and business may commence at the new location.
  - **(4)** Pursuant to rule 1301:18-9-01 of the Administrative Code, the division may conduct an inspection at the original location and the proposed location to ensure compliance with all requirements outlined under these rules.
- **(F)** After verification by the division that the new location is in full compliance with these rules, the division will issue a modified certificate of operation reflecting the new location.

- **(1)** The licensee shall not operate at the new location until the division approves and issues an amended certificate of operation outlining the new location.
- **(2)** A licensee's modified certificate of operation has the same expiration date as the previously issued license.
- **(G)** Upon receipt of the modified certificate of operation, the licensee may commence business.
  - **(1)** Unless otherwise authorized by the division, a licensee shall not operate in two locations pursuant to the same certificate of operation.

### **1301:18-3-09 Employee Badges**

- **(A) Employee Badge Required**
  - **(1)** Each licensee shall ensure all of the following associated individuals obtain an employee badge from the division of cannabis control prior to commencement of business:
    - **(a)** Any administrator or individual responsible for the daily operation of the facility;
    - **(b)** All owners, officers, and board members, of the licensee; and
    - **(c)** All employees and agents of the licensee.
  - **(2)** Each licensee shall ensure all associated individuals outlined under paragraph (A)(1) of this rule are appropriately designated as follows:
    - **(a) Responsible Party:**
      - **(i)** Prior to the issuance or renewal of a certificate of operation, each licensee shall designate at least one, but not more than three individuals to serve as the licensee's responsible party.
      - **(ii)** The designated responsible party will manage the facility's daily operations and ensure compliance with all standard operating procedures.
      - **(iii)** A responsible party is to be physically present at the licensed premises at least twenty hours per week and be immediately available to communicate with facility staff or the division during any operating hours when they are not physically present.
    - **(b) Owner or Officer:**
      - **(i)** Any and all owners, officers, and board members of the licensee.
    - **(c) Employee:**
      - **(i)** All other employees and agents of the licensee.
- **(B) Prior to petitioning the division for an employee badge, each licensee shall:**
  - **(1)** Complete a thorough background evaluation to confirm the applicant does not have a disqualifying offense, as defined by rule 1301:18-1-01 of the Administrative Code; and
  - **(2)** Submit a receipt or transaction number confirming that the applicant submitted the following to the Ohio bureau of criminal identification as required by sections 3780.08 and 3796.12 of the Revised Code:
    - **(a)** A complete and accurate application for:
      - **(i)** An Ohio bureau of criminal identification records check; and
      - **(ii)** A federal bureau of criminal identification records check.
    - **(b)** Two fingerprint impressions; and
    - **(c)** Clearly indicated that both records checks be sent directly to the division.

- **(C) Application for Employee Badge**
  - **(1)** Pursuant to the application process, each licensee shall submit the following to the division on behalf of the applicant:
    - **(a)** A complete and accurate application on a form prescribed by the division evidencing the following:
      - **(i)** The following applicant information:
        - **(A)** Full legal name;
        - **(B)** The applicant's intended employee designation, as outlined under paragraph (A)(2) of this rule;
        - **(C)** Telephone number that may be utilized during normal business hours;
        - **(D)** Electronic mail address; and
        - **(E)** Mailing address.
        - **(F)** All information provided must be in working order and readily available to receive voice messages, electronic messages, or other communication as applicable.
      - **(ii)** The applicant submitted fingerprint impressions to the Ohio bureau of criminal identification for an Ohio and federal bureau of criminal identification records checks;
      - **(iii)** The applicant does not have a disqualifying offense, as defined by rule 1301:18-1-01 of the Administrative Code;
      - **(iv)** A copy of the applicant's valid, unexpired government issued photographic identification evidencing that the applicant is at least twenty-one years of age;
      - **(v)** A clear, recognizable photographic headshot of the applicant, captured within the past six months of the date of submission;
      - **(vi)** The business name and license number for any associated cultivator, processor, testing laboratory, or dispensary at which the applicant seeks employment;
      - **(vii)** Individuals who have been a resident of the state of Ohio continuously for the past five years may apply for expedited renewal if the applicant consents for enrollment in the Ohio attorney general's retained applicant fingerprint database ("Rapback"), or other third-party database as determined by the division, that monitors publicly available databases for arrests and criminal convictions; and
      - **(viii)** The non-refundable application fee as outlined under [OAC fees].
- **(D) Provisional Employee Badge**
  - **(1)** Upon receipt of a complete application, the division will issue the applicant a provisional employee badge.
    - **(a)** Each licensee shall print the applicant's provisional employee badge and ensure the applicant maintains the card on their person while conducting any business within the scope of their employment.
    - **(b)** The applicant may then immediately commence business at the associated licensee.
    - **(c)** Unless otherwise authorized by this rule, an applicant's provisional employee badge expires ninety calendar days after the date of issuance.

- (2) A licensee may petition the division to extend an applicant's provisional employee badge for an additional ninety calendar days all of the following are met:
  - (a) The licensee submitted the extension request within ten business days of the provisional employee badge expiration;
  - (b) The licensee and applicant fulfilled all application requirements outlined under this rule; and
  - (c) Evidence that the licensee would suffer immediate irreparable harm should the extension be denied.
- **(E) Division review of application.**
  - (1) During the pendency of the provisional employee badge, the division will review the employee badge application and accompanying Ohio and federal criminal identification records checks.
  - (2) After review of the application, the division may:
    - (a) Approve the application and issue a badge certificate;
    - (b) Deny the application; or
    - (c) Advise the licensee in writing that the applicant failed to meet all application requirements.
  - (3) Each licensee shall print the applicant's employee badge certificate and ensure the individual maintains the card on their person while engaged in any activity within the scope of their employment.
    - (a) Each licensee shall ensure all employee badge certificates prevent unauthorized duplication of the badge.
  - (4) An employee badge certificate shall expire two years after the date of issuance.
- **(F) Deficiencies in applications.**
  - (1) Upon determination by the division that a licensed entity failed to meet all requirements of paragraph (C) of this rule, the division will notify the associated licensed entity in writing of all deficiencies contained within the application.
  - (2) Within ten business days of receipt of written notification from the division, the licensee shall ensure that all deficiencies outlined are alleviated and submit any further documentation requested by the division.
  - (3) Should a licensee fail to cure all application deficiencies, the application shall be deemed abandoned.
- **(G) Failure to Comply with Application Requirements.**
  - (1) Should a licensee fail to ensure all requirements of this rule are met, the division shall abandon the application and the licensee shall forfeit any non-refundable fee submitted to the division.
- **(H) Denial of application required.**
  - (1) The division shall deny an application for an employee badge pursuant to any of the following:
    - (a) The applicant was convicted of a disqualifying offense; or
    - (b) The applicant is not at least twenty-one years of age or older.
- **(I) Notification Requirements.**
  - (1) Each licensee shall notify the division of any of the following:
    - (a) Any employee badge that is lost, destroyed, stolen is to be immediately reported.
    - (b) Any modifications or changes to any information contained within their employee badge application within five business days of such change;



- (c) A change of a designated responsible party within ten calendar days of the effective date of the appointment of a new designated responsible party.
  - (2) An individual registered pursuant to this rule arrested for activities that, if convicted, would constitute a disqualifying offense as defined by 1301:18-1-01 shall immediately notify the division.
    - (a) If the associated licensed entity has knowledge of such arrest, it shall notify the division.
  - (3) In the event an individual is no longer employed or associated with a licensee, the licensee shall update all accompanying information provided to the division, within one business day and ensure that the employee badge certificate is returned and destroyed upon separation.
- (J) **Employee badge renewal.**
  - (1) Pursuant to the renewal process, the licensed entity shall submit the following to the division on behalf of the applicant prior to the badge's expiration:
    - (a) A complete and accurate renewal application in a manner prescribed by the division; and
    - (b) The non-refundable renewal fee as outlined under [OAC fee rule].
- (K) An individual whose employee badge was revoked, and any individual whose actions directly caused a license entity's license revocation, is precluded from applying for an employee identification for at least five years from the date of revocation or final judicial decision upon of an order of revocation.

#### **1301:18-3-13 Transportation of Cannabis to Another Licensed Entity**

- (A) Each licensee shall establish, maintain, and comply with written policies and procedures for the transportation of cannabis and ensure the following:
  - (1) Implementation of proper security protocols to mitigate the risk of diversion, theft, or loss and safety measures for possible emergency scenarios;
  - (2) Real-time knowledge of the location of all motor vehicles while in transit;
  - (3) Pursuant to the [OAC inventory control] the originating licensee transporting cannabis creates a transfer manifest within the state inventory tracking system and ensure all information contained within the transfer manifest is transmitted to the recipient entity and the division.
  - (4) All individuals transporting cannabis shall:
    - (a) Be registered pursuant to rule 1301:18-3-09 of the Administrative Code and issued a badge certificate;
    - (b) Maintain and display their registered badge during transportation;
    - (c) Ensure the transportation vehicle containing cannabis is attended to by at least one badged employee;
    - (d) Ensure delivery times vary and routes are randomized;
    - (e) Maintain a physical copy of the transfer manifest completed pursuant to paragraph (A)(3) of this rule for the duration of the transportation;
    - (f) Notify the originating cannabis entity when the delivery has reached the recipient entity and the delivery is completed; and
    - (g) Report the following:
      - (1) Any vehicle accident that occurs during the transportation to a person designated by the transporting cannabis entity to receive such reports within two hours after the accident occurs;

- **(2)** Any loss or theft of cannabis that occurs during the transportation of cannabis in accordance with rule [OAC theft rule] of the Administrative Code; and
  - **(3)** In the event of an emergency, immediately notify law enforcement through the 911 emergency system and to the cannabis entities, which will immediately notify the division, unless the notification is impractical under the circumstances.
- **(B)** The vehicle transporting the cannabis shall:
  - **(1)** Be registered in the state of Ohio and insured as required by the law;
  - **(2)** Store the cannabis in a locked, safe, and secure storage compartment affixed to the motor vehicle, or in a locked storage container that has a separate key or combination pad;
  - **(3)** Ensure all product is not visible from the outside of the vehicle;
  - **(4)** Have access to a secure form of communication with personnel at the cannabis entity and the ability to contact law enforcement through the 911 emergency system at all times that the vehicle contains cannabis, unless notification is impractical under the circumstances; and
  - **(5)** Not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership.

#### **1301:18-3-15: Discontinuing Business**

- **(A)** In the event a licensed entity permanently ceases all business operations, the licensed entity shall provide written notice to the division at least ninety calendar days prior to the effective date of the closure.
- **(B)** A licensed entity that intends to permanently cease all business operations under paragraph (A) of this rule shall submit a written closure plan to the division at least sixty calendar days prior to the effective date of the closure, and include, at a minimum, the following:
  - **(1)** The sale of cannabis inventory at market rate;
  - **(2)** The destruction of cannabis on hand at the facility on the effective date of the closure;
  - **(3)** The sale or removal of equipment and products ancillary to the business;
  - **(4)** The retention of all records required to be maintained in accordance with the applicable records retention schedules;
  - **(5)** The steps that will be taken to maintain compliance with these rules, and any other conditions required by the division until the approved closure date; and
  - **(6)** The closure and intended use of the premises in which the licensed entity was located.
- **(C)** Within thirty calendar days of receipt of a licensee's closure plan, the division will review the plan and may:
  - **(1)** Approve the plan;
  - **(2)** Deny the plan; or
  - **(3)** Advise the licensee in writing that additional information is needed for review.
- **(D)** Upon discontinuing business, the division shall not renew the certificate of operation.
  - **(1)** The licensee shall:
    - **(a)** Permanently cease all operations;
    - **(b)** Not engage in any activities authorized under this chapter; and
    - **(c)** Destroy the certificate of operation and all affiliated employee badges.
- **(E)** If the closure is the result of an eviction notice, the licensed entity shall immediately notify the division of the eviction notice and the effective date of the notice.

- (1) This notice shall be provided prior to the licensed entity taking any steps to wind down and discontinue business operations.

## **Cultivator Rules**

### **1301:18-5-01 Cultivator Certificate of Operation**

- (A) Unless otherwise authorized by the division of cannabis control, each cultivator shall not engage in any activity authorized under these rules until the division issues the cultivator a certificate of operation.
- (B) The division shall not issue a provisional cultivator a certificate of operation unless and until the cultivator meets all requirements outlined under division 1301:18 of the Administrative Code.
- (C) Each cultivator shall have twelve months from the date the cultivator is issued a provisional license pursuant to these rules to obtain a certificate of operation.
- (D) Upon receipt of its certificate of operation, a cultivator may engage in the following activities:
  - (1) Cultivate cannabis;
  - (2) Distribute, transfer, and sell cannabis to a cultivator, processor, or dispensary licensed pursuant to division 1301:18 of the Administrative Code; and
  - (3) Transfer cannabis for research and development or laboratory testing to a laboratory licensed pursuant to division 1301:18 of the Administrative Code.
- (E) A certificate of operation shall be issued to, and valid only for, the designated business entity, owners, and licensed premises specified within the cultivator's initial application for licensure pursuant to rule 1301:18-2-02.

### **1301:18-5-02 Cultivator Uninterrupted Supply of Cannabis**

- (A) Each cultivator shall conduct its daily business and cultivation activities in a manner that ensures a consistent supply of cannabis plant material is available for sale to customers.
  - (1) Evidence of a cultivator's consistent supply pursuant to this rule is shown by not more than one hundred twenty days elapsing between both of the following:
    - (a) Harvests totaling at least fifteen pounds of cannabis plant material; and
    - (b) Sale or transfer totaling at least twenty pounds of cannabis plant material for level I cultivators and ten pounds of cannabis plant material for level II cultivators.
- (B) A cultivator may petition the division to toll computation of the timeframes provided in paragraph (A) of this rule. Such a petition shall be in writing and provide:
  - (1) An explanation of the facts and circumstances that prevent the cultivator's compliance with paragraph (A) of this rule; and
  - (2) A written plan, outlined in specific detail with the cultivator's intended actions and projected timeline, to ensure the cultivator complies with this rule.
  - (3) Upon receipt of a petition under this paragraph, the division may stay the requirement of paragraph (A) of this rule for the cultivator. A division order staying the requirement of paragraph (A) of this rule will state the date upon which the stay is lifted.

### **1301:18-5-05: Cultivator Minimum Security and Surveillance Requirements**

- (A) Each cultivator shall establish, maintain, and comply with written policies and procedures that ensure adequate security, surveillance, and control of the licensed premises that prevent diversion, theft, or loss and meet the minimum requirements outlined under this rule.

- **(1)** Pursuant to rule [OAC cultivator operations] each cultivator shall petition the division prior to implementing any major modification to the facility's security procedures, systems, or equipment.
- **(B)** Prior to the commencement of business, each cultivator shall meet the following security and surveillance requirements that ensure compliance with all standards established by the division:
  - **(1)** Designate a secure, limited access area for all equipment maintained pursuant to this rule that is accessible only by authorized registered cultivator employees with foundational training in security and surveillance;
  - **(2)** Maintain or construct fencing to prevent unauthorized entry or access to waste disposal containers, disposal areas or compost areas located outside the facility;
  - **(3)** Install a security alarm system with commercial grade equipment that includes the following:
    - **(a)** An access alarm on all entry points and windows;
    - **(b)** Motion detectors that identify unauthorized access into the facility; and
    - **(c)** A silent alarm, which may be utilized during instances of duress that sends a pre-recorded voice message to the facility's designated security personnel and law enforcement, public safety, or emergency services requesting dispatch, which includes the capability to enter a designated code into an arming station to signal that the alarm user is being forced to turn off the system.
  - **(4)** Install a video surveillance system that complies with the following:
    - **(a)** Capable of electronic monitoring of the facility and real-time access by the division;
    - **(b)** Collects twenty-four-hour live video feed with motion-activated recording capabilities for all video cameras that record in at least fifteen frames per second;
    - **(c)** Archives and retains recordings for at least forty-five calendar days;
    - **(d)** Contains a display monitor with a minimum screen size of twelve inches;
    - **(e)** Exports still images in an industry standard format that guarantees authentication and prevents alteration of the recorded images;
    - **(f)** Produces clear color still photographs that are a minimum of 600 x 600 dpi from any camera image, live or recorded;
    - **(g)** Embeds a date and time stamp on all recordings; and
    - **(h)** Includes a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.
  - **(5)** Install unobstructed cameras in a manner that prevents tampering, captures the entirety of the licensed premises, and clearly identifies all individuals and activities within the surveilled area;
  - **(6)** Camera placement at all the following locations:
    - **(a)** All points of ingress and egress;
    - **(b)** All secure, limited access areas;
    - **(c)** Any area where cannabis is cultivated, harvested, stored, or handled;
    - **(d)** Any area that stores cannabis or facility inventory;
    - **(e)** The facility's cannabis destruction and disposal area; and
    - **(f)** All areas where sales proceeds are stored or transferred.
  - **(7)** Daily records of all registered employees' access to any secure, limited access areas;
  - **(8)** Develop emergency policies and procedures for securing all inventory and currency in the event of diversion, theft, or loss; and
  - **(9)** Any other requirements the division deems necessary to maintain proper security and surveillance and ensure public safety.

- **(C)** Each cultivator shall inspect and test all security and surveillance equipment at least once per month to ensure functionality.
  - **(1)** Pursuant to [OAC Records], each cultivator shall record and maintain of all security and surveillance equipment tests.
  - **(2)** Each cultivator shall immediately notify the division of any failure in the facility's security or surveillance system or equipment.
    - **(a)** Any necessary repair or replacement shall occur within twenty-four hours of identification.
  - **(3)** Each cultivator shall keep all security equipment in good-working order and the systems shall be inspected and all devices tested on an annual basis by a third party.
- **(D)** In the event a cultivator is made aware of any pending criminal, civil, or administrative investigations or legal proceedings for which a video recording may contain relevant information, the cultivator shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the cultivator that it is not necessary to retain the recording.

## **Processor Rules**

### **1301:18-6-01: Processor Certificate of Operation**

- **(A)** Unless otherwise authorized by the division of cannabis control, each processor is prohibited from engaging in any activity authorized under these rules until the division issues the processor a certificate of operation.
- **(B)** The division shall not issue a provisional processor a certificate of operation unless and until the processor meets all requirements outlined under division 1301:18 of the Administrative Code.
- **(C)** Each processor shall have twelve months from the date the processor is issued a provisional license pursuant to these rules to obtain a certificate of operation.
- **(D)** Upon receipt of its certificate of operation, a processor may engage in the following activities:
  - **(1)** Obtain cannabis from a cultivator, processor, or dispensary licensed pursuant to division 1301:18 of the Administrative Code;
  - **(2)** Process cannabis into a form authorized under [OAC forms rule];
  - **(3)** Distribute, transfer, and sell cannabis to a cultivator, processor, or other dispensary licensed pursuant to division 1301:18 of the Administrative Code; and
  - **(4)** Transfer cannabis for research and development or laboratory testing to a laboratory licensed pursuant to division 1301:18 of the Administrative Code.
- **(E)** A certificate of operation shall be issued to, and valid only for, the designated business entity, owners, and licensed premises specified within the processor's initial application for licensure pursuant to rule 1301:18-2-02.

### **1301:18-6-02: Processor Uninterrupted Supply of Cannabis**

- **(A)** Each processor shall conduct its daily business and manufacturing activities in a manner that ensures a consistent supply of cannabis is available for sale to customers.
  - **(1)** Evidence of a processor's consistent supply pursuant to this rule is shown by:
    - **(a)** Not more than thirty calendar days elapsing without extracting or manufacturing at least two hundred fifty grams of extract; or
    - **(b)** Not more than thirty calendar days elapsing between sale or transfer of at least one lot of cannabis products to a dispensary.

- **(B)** A processor may petition on a form prescribed by the division to toll computation of the timeframes provided in paragraph (A) of this rule and include the following:
  - **(1)** An explanation of the facts and circumstances that prevent the processor's compliance with paragraph (A) of this rule; and
  - **(2)** A written plan, outlined in specific detail with the processor's intended actions and projected timeline, to ensure the processor complies with this rule.
  - **(3)** Upon receipt of a petition under this paragraph, the division may stay the requirement of paragraph (A) of this rule for the processor. A division order staying the requirement of paragraph (A) of this rule will state the date upon which the stay is lifted.

#### **1301:18-6-04: Processor Minimum Security and Surveillance Requirements**

- **(A)** Each processor shall establish, maintain, and comply with written policies and procedures that ensure adequate security, surveillance, and control of the licensed premises that prevent diversion, theft, or loss and meet the minimum requirements outlined under this rule.
  - **(1)** Pursuant to rule [OAC processor operations] each processor shall petition the division prior to implementing any major modification to the facility's security procedures, systems, or equipment.
- **(B)** Prior to the commencement of business, each processor shall meet the following security and surveillance requirements that ensure compliance with all standards established by the division:
  - **(1)** Designate a secure, limited access area for all equipment maintained pursuant to this rule that is accessible only by authorized registered processor employees with foundational training in security and surveillance;
  - **(2)** Maintain or construct fencing to prevent unauthorized entry or access to waste disposal containers, disposal areas or compost areas located outside the facility.
  - **(3)** Install a security alarm system with commercial grade equipment that includes the following:
    - **(a)** An access alarm on all entry points and windows;
    - **(b)** Motion detectors that identify unauthorized access into the facility; and
    - **(c)** A silent alarm, which may be utilized during instances of duress that sends a pre-recorded voice message to the facility's designated security personnel and law enforcement, public safety, or emergency services requesting dispatch, which includes the capability to enter a designated code into an arming station to signal that the alarm user is being forced to turn off the system.
  - **(4)** Install a video surveillance system that complies with the following:
    - **(a)** Capable of electronic monitoring of the facility and real-time access by the division;
    - **(b)** Collects twenty-four-hour live video feed with motion-activated recording capabilities for all video cameras that record in at least fifteen frames per second;
    - **(c)** Archives and retains recordings for at least forty-five calendar days;
    - **(d)** Contains a display monitor with a minimum screen size of twelve inches;
    - **(e)** Exports still images in an industry standard format that guarantees authentication and prevents alteration of the recorded images;
    - **(f)** Produces clear color still photographs that are a minimum of 600 x 600 dpi from any camera image, live or recorded;
    - **(g)** Embeds a date and time stamp on all recordings; and
    - **(h)** Includes a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.

- (5) Install unobstructed cameras in a manner that prevents tampering, captures the entirety of the licensed premises, and clearly identifies all individuals and activities within the surveilled area;
- (6) Camera placement at all the following locations:
  - (a) All points of ingress and egress;
  - (b) All secure, limited access areas;
  - (c) Any area where cannabis is manufactured, processed, extracted, stored, or handled;
  - (d) Any area that stores cannabis or facility inventory;
  - (e) The facility's cannabis destruction and disposal area; and
  - (f) All areas where sales proceeds are stored or transferred.
- (7) Daily records of all registered employees' access to any secure, limited access areas;
- (8) Develop emergency policies and procedures for securing all inventory and currency in the event of diversion, theft, or loss;
- (9) Any other requirements the division deems necessary to maintain proper security and surveillance and ensure public safety.
- (C) Each processor shall inspect and test all security and surveillance equipment at least once per month to ensure functionality.
  - (1) Pursuant to [OAC Records], each processor shall record and maintain all security and surveillance equipment tests.
  - (2) Each processor shall immediately notify the division of any failure in the facility's security or surveillance system or equipment.
    - (a) Any necessary repair or replacement shall occur within twenty-four hours of identification.
  - (3) Each processor shall keep all security equipment in good-working order and the systems shall be inspected and all devices tested on an annual basis by a third party.
- (D) In the event a processor is made aware of any pending criminal, civil, or administrative investigations or legal proceedings for which a video recording may contain relevant information, the processor shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the processor that it is not necessary to retain the recording.

## **Testing Laboratory Rules**

### **1301:18-7-01: Testing Laboratory Certificate of Operation**

- (A) Unless otherwise authorized by the division of cannabis control, each testing laboratory shall not engage in any activity authorized under these rules until the division issues the testing laboratory a certificate of operation.
- (B) The division shall not issue a provisional testing laboratory a certificate of operation unless and until the testing laboratory meets all requirements outlined under division 1301:18 of the Administrative Code.
- (C) Each testing laboratory shall have twelve months from the date the testing laboratory is issued a provisional license pursuant to these rules to obtain a certificate of operation.
- (D) Upon receipt of its certificate of operation, a testing laboratory may engage in the following activities:
  - (1) Obtain cannabis from a cultivator, processor, or dispensary licensed under division 1301:18 of the Administrative Code for testing purposes only; and



- **(2)** Conduct laboratory testing, and development in accordance with division 1301:18 of the Administrative Code.
- **(E)** A certificate of operation shall be issued to, and valid only for, the designated business entity, owners, and licensed premises specified within the testing laboratory's initial application for licensure pursuant to rule 1301:18-2-02.

## **Dispensary Rules**

### **1301:18-8-07: Dispensary Patient Confidentiality**

- **(A)** Each dispensary shall ensure the confidentiality of all records related to patient transactions. Except as authorized under paragraph (B) of this rule, patient records may only be released via written authorization and consent by the patient.
  - **(1)** Any consent must be signed by the patient and dated.
    - **(a)** If a patient is unable to provide written consent, consent may only be provided by the patient's caregiver or legal guardian.
  - **(2)** Any consent for disclosure is valid until rescinded by the patient.
- **(B)** A dispensary may release patient records to the following individuals:
  - **(1)** The patient;
  - **(2)** The patient's designated caregiver;
  - **(3)** The certified physician who issued the recommendation to the patient;
  - **(4)** Certified or licensed health care personnel responsible for the care of the patient;
  - **(5)** Any person that the dispensary is legally required to release the information to, including upon issuance of a valid subpoena, court order, or other similar document only in a criminal matter or an equivalent juvenile matter;
  - **(6)** An agent who contracts with the dispensary as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for the privacy of individually identifiable health information;
  - **(7)** If applicable, an agent of a medical insurance company who provides insurance coverage for medical cannabis upon authorization and proof of insurance by the patient or proof by the insurance company for those medications requested; and
  - **(8)** The Ohio division of cannabis control.
- **(C)** In an emergency, a dispensary may disclose the recommendation information when it is deemed to be in the best interest of the patient.
  - **(1)** A dispensary employee that orally discloses patient information pursuant to an emergency must prepare a written statement outlining the following:
    - **(a)** The name of the dispensary employee who disclosed the information;
    - **(b)** The patient's name;
    - **(c)** The date and time of disclosure;
    - **(d)** The nature of the emergency; and
    - **(e)** The names of the individuals to whom the information was disclosed.

## Cannabis Entity Enforcement

### 1301:18-9-01: Cannabis Facility Inspections

- **(A)** The Ohio division of cannabis control may, at any time, with or without notice, conduct an inspection to ensure compliance with all representations made to the division, state and local law, Chapters 3780 and 3796. of the Revised Code, and the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code.
- **(B)** Notwithstanding the requirements of division 1301:18 of the Administrative Code, nothing shall prohibit the division of cannabis control, the division's designee, law enforcement, or other federal, state, or local government officials from entering any area of a cannabis entity's licensed premises if necessary to perform their governmental duties.
- **(C)** The submission of an application that results in the issuance of a provisional license or certificate of operation irrevocably gives the division of cannabis control consent to conduct all inspections necessary to ensure compliance with state and local law, Chapters 3780 and 3796. of the Revised Code, and the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code.
  - **(1)** The division of cannabis control may conduct the inspection independently, or may work with third parties, other divisions, state agencies, or local authorities, including the Ohio division of agriculture, the division of industrial compliance, and the division of state fire marshal, to ensure compliance with, state and local law, Chapters 3780 and 3796. of the Revised Code, and the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code.
  - **(2)** An inspection of a licensee may include, without limitation, investigation of standards for safety from fire on behalf of the division by the local fire protection agency.
    - (a) If a local fire protection agency is not available, the division of state fire marshal may conduct the inspection after the licensee pays the appropriate fee to the division of state fire marshal for such inspection.
- **(D)** Pursuant to an inspection, the division may do any of the following:
  - **(1)** Access and inspect:
    - **(a)** The licensed premises, including any off-site facilities;
    - **(b)** Any area within the licensed premises;
    - **(c)** Any secure, limited access area or other locked area of the licensed premises;
    - **(d)** Facility motor vehicles;
    - **(e)** All inventory; and
    - **(f)** All equipment, instruments, tools, containers, materials, machinery, or any other resource utilized at the licensed premises;
  - **(2)** Obtain samples for testing of any cannabis maintained at the facility, media used to grow cannabis, chemicals and ingredients used in any cultivation, manufacturing, and extracting process, any labels or containers for cannabis, or any raw packaged cannabis.
  - **(3)** Question and interview registered responsible parties, owners, officers, board members, and all other employees or agents of the licensee;
  - **(4)** Review any and all policies and procedures; and
  - **(5)** Make and obtain copies of any and all records pursuant to [OAC records].
- **(E)** Prior to the issuance or renewal of a certificate of operation or change of location each licensee must pass a pre-approval inspection to ensure the licensed premises comply with all of the following:
  - **(1)** All representations made to the division;

- **(2)** All specifications outlined in written policies and procedures as required by these rules;
- **(3)** All requirements outlined under Chapters 3780 and 3796. of the Revised Code, and the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code.
- **(4)** The pre-approval inspection will occur at a mutually agreeable time.
- **(5)** Upon the completion of the pre-approval inspection, the division may issue either of the following:
  - **(a)** A certificate of operation in accordance with this chapter; or
  - **(b)** A written statement listing the deficiencies identified during the inspection that must be remedied before a certificate of operation will be issued by the division.
- **(F)** Following an inspection conducted pursuant to this rule, the division will issue an inspection report that documents the following:
  - **(1)** The observations and findings of the inspections;
  - **(2)** The outcome of the inspection;
  - **(3)** Any suggestions for the licensee to take into consideration; and
  - **(4)** If applicable, a written statement listing the deficiencies identified during the inspection.
- **(G)** Deficiencies
  - **(1)** Upon receipt of a statement of deficiencies, the licensee shall develop a plan of correction for each deficiency and submit the plan in writing to the division for approval within ten business days after receipt of the statement of deficiencies, unless a written extension is issued by the division.
    - **(a)** The plan of correction must include specific requirements for corrective action that will be performed within thirty calendar days after the division's acceptance of the plan of correction
    - **(b)** If the plan of correction submitted is not acceptable to the division, the division may either direct the licensee to resubmit a plan of correction or the division may develop a directed plan of correction with which the licensee must comply.
  - **(2)** Upon acceptance of the written plan of correction, the licensee shall sign the plan of correction, binding the licensee to the terms under which the licensee may be issued a certificate of operation.
    - **(a)** If the licensee and the division are unable to come to terms on the written plan of correction, the division may take action in accordance with rule [OAC enforcement] of the Administrative Code.
  - **(3)** The division will re-inspect a licensee upon the completion of the written plan of correction.
    - **(a)** If the corrective measures meet the division's satisfaction, the division will issue a certificate of operation.
    - **(b)** If the corrective measures do not meet the requirements of the written plan of correction, the division may take action in accordance with rule [OAC enforcement] of the Administrative Code.
- **(H)** If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, risk to public health, or a violation of any representation made to the division, state and local law, Chapters 3780 and 3796. of the Revised Code, and the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code, the division may take any action authorized under rule [OAC Enforcement] of the Administrative Code.

- **(I)** To prevent destruction of evidence, diversion, or other threats to public safety, the division may order an administrative hold of cannabis or cannabis product or any books and records of any licensee. The division may assess the costs of an investigation, including travel and the time of any and all division employees, to a licensee.

#### **1301:18-9-06: Variances**

- **(A)** The division may grant variances from rules promulgated in accordance with chapters 3796 and 3780 of the Revised Code when:
  - **(1)** The applicable provision is not statutorily mandated;
  - **(2)** The proposed variance is within public interest;
  - **(3)** Individuals will not be injured by the proposed variance; and
  - **(4)** The applicable provision would, in the particular case, be unreasonable or unnecessarily burdensome.

## **Patients and Caregivers**

#### **1301:18-10-01 Procedure for Patient Registration**

- **(A)** An individual is mandated to register with the Ohio division of cannabis control in accordance with this rule prior to purchasing, possessing, or administering medical cannabis.
- **(B)** To qualify for placement on the registry, a prospective patient is to meet the following mandates:
  - **(1)** Establish and maintain a bona fide physician-patient relationship with a recommending physician;
  - **(2)** Receive a diagnosis or confirmation of a qualifying condition from the recommending physician;
  - **(3)** Submit a complete registration as outlined under paragraph (C) of this rule; and
  - **(4)** Unless otherwise provided pursuant to a reciprocal agreement under division (A) of section 3796.16 of the Revised Code, be an Ohio resident.
- **(C)** Registration Submission.
  - **(1)** The recommending physician shall submit the following, in a manner prescribed by the division, on behalf of the patient:
    - **(a)** All of the following patient information:
      - **(i)** For a patient who is eighteen years of age or older:
        - **(A)** Patient's full legal name;
        - **(B)** Residential address;
        - **(C)** Telephone number;
        - **(D)** Electronic mail address;
        - **(E)** Qualifying condition(s);
        - **(F)** The prospective patient's valid, unexpired government issued photographic identification number, evidencing that the individual is at least eighteen years of age; and
        - **(G)** The following patient attestations:
          - **(1)** The physician has explained to the individual the possible risks and benefits associated with the use of medical marijuana;
          - **(2)** The individual consents to treatment with medical marijuana; and

- **(3)** The individual agrees to comply with Chapters 2925., 3780, and 3796. of the Revised Code and this division.
    - **(ii)** For a patient who is a minor or an individual with a court-appointed legal guardian:
      - **(A)** In addition to the information outlined above:
        - **(1)** The prospective patient's parent or legal representative consent to treatment with medical marijuana; and
        - **(2)** A caregiver registration submission in accordance with rule 1301:18-10-02 of the Administrative Code.
    - **(iii)** Patients who become eighteen years of age during the time period in which their registration is valid may apply for a new registration either immediately or in accordance with the renewal process under paragraph (H) of this rule.
  - **(b)** The date the recommending physician issued the recommendation;
  - **(c)** Indication whether the recommendation is new or a renewal;
  - **(d)** The recommending physician's:
    - **(i)** Full legal name;
    - **(ii)** Drug enforcement administration physician identification number;
    - **(iii)** Medical license number issued by the state medical board;
    - **(iv)** Business address;
    - **(v)** Telephone number;
    - **(vi)** Electronic mail address;
    - **(vii)** And the following attestation(s) if applicable:
      - **(A)** An attestation in accordance with division (A)(2) of section 3796.08 of the Revised Code; and
      - **(B)** For a patient diagnosed with a terminal illness as defined under rule 1301:18-1-01 of the Administrative Code, the recommending physician shall execute and submit an attestation the patient has a terminal illness.
  - **(e)** Any other information the division mandates.
- **(D)** A complete patient registration submission must be received by the division within ninety calendar days of the date the recommending physician issued the recommendation.
  - **(1)** If a registration submission is determined to be inaccurate or incomplete, the division will send the patient notice of the deficiency.
  - **(2)** If the deficiency is not corrected within ninety calendar days from the date that the registration was submitted by a physician, the submission shall be considered a stale registration as defined by rule 1301:18-1-01 of the Administrative Code
- **(E)** Patient registrations are non-transferrable.
  - **(1)** Patients shall not permit another individual to use their patient registration.
  - **(2)** Before purchasing medical cannabis, patients must provide the dispensary employee the following:
    - **(a)** Their registry identification card; and
    - **(b)** A copy of the patient's valid, unexpired government issued photographic identification.
  - **(3)** Patients shall carry their registry identification with them whenever they are in possession of medical cannabis.

- **(F)** Except as authorized under rule 1301:18-10-02 of the Administrative Code, a patient may not designate more than two caregivers.
- **(G)** If a patient requests permission to change a caregiver before renewal, the patient is to do the following:
  - **(1)** Submit a change of caregiver request to the recommending physician, or, subject to the limitations under section 3796.08 of the Revised Code, the physician's delegate, who shall set forth the reasons the patient seeks to change caregivers and conform with the caregiver registration mandates under rule 1301:18-10-02 of the Administrative Code.
  - **(2)** The division will approve a new caregiver if the individual meets the mandates of Chapter 3796. of the Revised Code and this division.
- **(H)** A patient registration shall be valid from the date of issuance and expire one year later, on the last day of the month it was issued.
  - **(1)** At any time, a patient may voluntarily relinquish their patient medical cannabis registration by notifying the division in writing.
  - **(2)** The division will send a notification to each patient forty-five calendar days before the expiration date on the patient's registry identification card.
  - **(3)** Renewal submissions and required documentation may be submitted up to thirty calendar days before the registration will expire.
  - **(4)** Failure to renew a patient registration will result in an automatic expiration of the registration card.
  - **(5)** Patients shall dispose of all medical cannabis within seven calendar days of the expiration of their registration.

#### **1301:18-10-02 Procedure for Caregiver Registration**

- **(A)** An individual is mandated to register with the division in accordance with this rule prior to serving as a caregiver for a registered patient.
- **(B)** To qualify for placement on the registry, a prospective caregiver is mandated to:
  - **(1)** Be all of the following:
    - **(a)** A natural person;
    - **(b)** At least twenty-one years of age or older; and
    - **(c)** A resident of the state of Ohio.
    - **(d)** Notwithstanding the age limitation in paragraph (B)(1)(b) of this rule, the parent of a minor patient who is eighteen years of age or older and who otherwise meets the requirements of Chapter 3796. of the Revised Code and this division, may serve as the minor patient's caregiver.
  - **(2)** Not be outlined in one or more of the following databases:
    - **(a)** The internet-based database of department of rehabilitation and correction inmates established under section 5120.66 of the Revised Code; or
    - **(b)** The Ohio medicaid provider exclusion and suspension list found at: <http://medicaid.ohio.gov>.
  - **(3)** Identify a registered patient for whom the individual intends to serve as a caregiver; and
  - **(4)** Submit a complete caregiver registration outlined under paragraph (C) of this rule.
- **(C)** Registration Submission.
  - **(1)** The recommending physician is to submit the following, in a manner prescribed by the division, on behalf of the caregiver:
    - **(a)** The date the recommending physician issued the recommendation;

- **(b)** Indication whether the recommendation is new or a renewal;
- **(c)** The recommending physician's:
  - **(1)** Full legal name;
  - **(2)** Drug enforcement administration physician identification number;
  - **(3)** Medical license number issued by the state medical board;
  - **(4)** Business address;
  - **(5)** Telephone number; and
  - **(6)** Electronic mail address.
- **(d)** All of the following caregiver information:
  - **(1)** For a patient who is eighteen years of age or older:
    - **(a)** Patient's full name;
    - **(b)** Residential address;
    - **(c)** Telephone number;
    - **(d)** Electronic mail address; and
    - **(e)** The prospective caregiver's valid, unexpired government issued photographic identification number evidencing that the individual is at least twenty-one years of age;
    - **(f)** The following caregiver attestations:
      - **(i)** The physician has explained to the individual the possible risks and benefits associated with the use of medical cannabis;
      - **(ii)** The individual agrees to serve as the caregiver for the patient identified in the application;
      - **(iii)** The individual agrees to control the dosage and frequency of use of medical cannabis in accordance with the physician's recommendation; and
      - **(iv)** The individual agrees to comply with Chapters 2925. and 3796. of the Revised Code and this division.
  - **(2)** For a caregiver whose prospective patient is younger than eighteen years of age:
    - **(a)** In addition to the information outlined above:
      - **(i)** The prospective caregiver is the parent or legal representative of the individual under eighteen years of age; and
      - **(ii)** The parent or legal representative understands the information provided by the recommending physician and knowingly consent to use of medical cannabis by the individual under eighteen years of age.
    - **(e)** Any other information the division mandates.
- **(D)** A patient's recommending physician shall not serve as the patient's caregiver.
- **(E)** A registered caregivers may purchase, possess, and administer medical cannabis to any patient associated with the caregiver's registration.
  - **(1)** Before purchasing medical cannabis, caregivers must provide the dispensary employee the following:
    - **(a)** Their registry identification card; and
    - **(b)** A copy of the caregiver's valid, unexpired government issued photographic identification.



- **(2)** Caregivers shall carry their registry identification with them whenever they are in possession of medical cannabis.
- **(F)** Caregiver registrations are non-transferrable.
- **(G)** A caregiver shall not:
  - **(1)** Allow another individual to use their caregiver registration.
  - **(2)** Purchase medical cannabis without an associated active registered patient.
  - **(3)** Receive payment or other compensation for services provided as a caregiver other than reimbursement for reasonable expenses incurred in the provision of services as a caregiver.
    - **(a)** In the case of an employee of a hospice provider, nursing facility, or medical facility, or a visiting nurse, personal care attendant, or home health aide serving as a caregiver, the individual shall not receive payment or compensation above or beyond his or her regular wages.
  - **(4)** Except as outlined under this rule, serve as a caregiver for more than two registered patients.
    - **(a)** Upon a written request on a form in accordance with section 3796.04 of the Revised Code, the division may, in its discretion, permit an individual to serve as a caregiver for more than two patients, permit a patient to designate more than two caregivers, and permit an individual who is not a resident of the state of Ohio to serve as a caregiver pursuant to the following requirements:
      - **(i)** In order to avoid unnecessary hardship to the patient or patients;
      - **(ii)** Where the patients care is being provided in a hospice program licensed under Chapter 3712. of the Revised Code; or
      - **(iii)** Where the caregiver is simultaneously caring for multiple patients who reside in the same household as the caregiver.
      - **(iv)** Should a hospice provider wish to obtain an exception as outlined under this paragraph, it shall do the following:
        - **(A)** Register as caregivers all employees who will possess or administer medical cannabis in accordance with this rule; and
        - **(B)** Notify the division when a patient with an active medical cannabis registration issued by the division is admitted to hospice pursuant to rule 3701-19-20 of the Administrative Code.
- **(H)** A caregiver registration is valid from the date of issuance and expires one year later, on the last day of the month it was issued.
  - **(1)** At any time, a caregiver may voluntarily relinquish their caregiver medical cannabis registration by notifying the division in writing.
  - **(2)** The division will send a notification to each caregiver forty-five calendar days before the expiration date on the caregiver's registry identification card.
  - **(3)** Renewal submissions and necessary documentation may be submitted up to thirty calendar days before the expiration.
  - **(4)** Failure to renew a caregiver registration will result in an automatic expiration of the registration card.
  - **(5)** Caregivers shall dispose of all medical cannabis within seven calendar days of the expiration of their registration.

#### **1301:18-10-04 Patient and Caregiver Notification Requirements**

- **(A)** Unless otherwise required by this rule, a patient or caregiver is to notify the division of cannabis control of any changes of information outlined in their registration within thirty calendar days.
- **(B)** A patient or caregiver is to notify the division within ten calendar days of determination any of the following:
  - **(1)** The patient or caregiver's registry identification card has been used fraudulently.
  - **(2)** The patient or caregiver's registry was accessed without authorization.
  - **(3)** After notification pursuant to this section, the division may issue a new registry identification card with a new registry number.
- **(C)** A patient is to report to the division a conviction of any offense and/or any arrest or charges pending of a felony or misdemeanor offense under Chapter 2925. or 4729. of the Revised Code, or of an arrest or conviction in another jurisdiction that is substantially the same as a felony or misdemeanor offense under Chapter 2925. or 4729. of the Revised Code, within ten calendar days of the conviction or arrest.
- **(D)** A caregiver is to report to the division a violation of any state or federal law or rule, regardless of jurisdiction in which such acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration which do not need to be reported unless the offense involved operating vehicle under the influence of alcohol or a controlled substance.
- **(E)** Upon determination by a recommending physician that a patient no longer has a diagnosis of a qualifying condition, the following mandates apply:
  - **(1)** The patient or caregiver is to notify the division in writing within fourteen calendar days of such determination.
  - **(2)** If the patient seeks to maintain an active patient registration, request in writing, a hearing in accordance with Chapter 119. of the Revised Code, seeking authorization to maintain an active patient registration.
  - **(3)** If the caregiver seeks to maintain an active caregiver registration, request in writing, a hearing in accordance with Chapter 119. of the Revised Code, seeking authorization to maintain an active caregiver registration.
- **(F)** If a patient has a caregiver, that caregiver may provide any required notification to the division on behalf of the patient.
- **(G)** If a patient is deceased, the patient's caregiver, if applicable, legal representative, or recommending physician is to notify the division in writing. The division will deactivate a deceased patient's registration.

#### **1301:18-10-06 Patient and Caregiver Enforcement**

- **(A)** Upon determination that a patient or caregiver violated any mandates outlined under division 1301:18 of the Administrative Code, the division of cannabis control may impose any one or more of the following sanctions:
  - **(1)** Revoke, suspend, restrict, limit, or refuse to grant or renew a registration; or
  - **(2)** Reprimand or place the registrant on probation.
- **(B)** Pursuant to division (B)(3) of section 3796.14 of the Revised Code, if the division determines that there is clear and convincing evidence that the continued dispensing or furnishing medical cannabis to the patient or caregiver or administration of medical cannabis to or by a patient, presents a danger of immediate and serious harm to oneself or to others, the division may suspend a patient or caregiver registration without a hearing.

- (1) The division will follow the procedure for suspension without a prior hearing in section 119.07 of the Revised Code.
- (2) The suspension shall remain in effect, unless removed by the division, until the divisions final adjudication order becomes effective.
- (C) If a patient's registration is suspended or revoked, the patient or caregiver shall dispose of all medical cannabis dispensed for the benefit of that patient within seven calendar days of the expiration of their registration.

#### **1301:18-10-07 Patient Confidentiality at Adjudication Hearings**

- (A) Notwithstanding any provision to the contrary in Chapter 119. of the Revised Code, all adjudication hearings related to a patient registration shall be closed to the public, in accordance with division (B) of section 3796.08 of the Revised Code.
- (B) Documents that contain patient-identifying information are confidential. Patient-identifying information includes, but is not limited to:
  - (1) Patient's name;
  - (2) Patient's social security number;
  - (3) Patient's date of birth;
  - (4) Patient's driver's license number;
  - (5) Patient's home address, telephone number, email address, or any other contact information;
  - (6) Patient's registry card number and related information; and
  - (7) Any other information that can be used to identify a patient or is required to be confidential under state or federal law.
- (C) For all proceedings associated with an adjudication hearing, whether related to a patient registration or not:
  - (1) Any confidential document, as described in paragraph (B) of this rule, may be provided to a representative of record or to a witness during the adjudication hearing but shall not be disseminated to any other person unless the patient-identifying information is redacted.
  - (2) Any confidential documents as described in paragraph (B) of this rule that is presented as an exhibit, whether admitted or proffered, shall either have all patient-identifying information redacted or be sealed prior to being made part of the adjudication hearing record.
  - (3) Any portion of a transcript that contains patient-identifying information shall be sealed and made part of the adjudication hearing record. Sealed portions of transcripts shall only be provided to the parties or as otherwise necessary to conduct an adjudication hearing or related appeal pursuant to Chapter 119. of the Revised Code.
- (D) A patient may waive any of the provisions described in this rule.
- (E) Nothing in this rule prevents the dissemination of public records, as defined section 149.43 of the Revised Code, so long as they have been appropriately redacted to protect patient and other confidential information.

#### **1301:18-10-08 Release of Patient Information**

- (A) Pursuant to division (B) of section 3796.08 of the Revised Code and division (C) of section 4729.80 of the Revised Code, records related to registered patients are confidential and are not public records subject to disclosure under section 149.43 of the Revised Code.

- **(B)** Except as authorized under paragraph (C) of this rule, patient records may only be released via written authorization and consent by the patient.
  - **(1)** Any consent must be signed by the patient and dated.
    - **(a)** If a patient is unable to provide written consent, consent may only be provided by the patient's caregiver or legal guardian.
  - **(2)** Any consent for disclosure is valid until rescinded by the patient.
- **(C)** The division of cannabis control may provide information related to registered patients only as follows:
  - **(1)** The patient;
  - **(2)** The patient's designated caregiver;
  - **(3)** The certified physician who issued the recommendation to the patient;
  - **(4)** Certified or licensed health care personnel responsible for the care of the patient;
  - **(5)** Any state or local law enforcement agency conducting an investigation of a criminal violation of state or federal law;
  - **(6)** Any person that the division of cannabis control is legally required to, including upon issuance of a valid subpoena, court order, or other similar document only in a criminal matter or an equivalent juvenile matter; and
  - **(7)** A government entity responsible for the licensure, regulation, or discipline of health care professionals.
- **(D)** In an emergency, the division may disclose the registered patient information when it is deemed to be in the best interest of the patient.
- **(E)** Any person that receives patient information pursuant to this rule shall comply with the same requirements regarding confidentiality as those with which the division is mandated to comply, notwithstanding any conflicting provision of the Revised Code or agency procedure that applies when the agency is dealing with other information in its possession.

#### **1301:18-10-09 Suspension of Access to Patient Information**

- **(A)** Except as provided in paragraph (B) of this rule, after providing notice and affording an opportunity for a hearing in accordance with Chapter 119. of the Revised Code, the division of cannabis control may restrict a person from obtaining information from the registry established in accordance with section 3796.08 of the Revised Code if any of the following is the case:
  - **(1)** The person receives or releases registered patient information in violation of rule 1301:18-07-07 or 1301:18-10-08 of the Administrative Code or section 3796.08 of the Revised Code;
  - **(2)** The person's actions in another state would have constituted a violation of 1301:18-07-07 or 1301:18-10-08 of the Administrative Code or section 3796.08 of the Revised Code;
  - **(3)** The person fails to comply with rule 1301:18-08-07 or 1301:18-10-08 of the Administrative Code or section 3796.08 of the Revised Code, regardless of the jurisdiction in which the failure to comply occurred; and
  - **(4)** The person creates, by clear and convincing evidence, a threat to the security of information contained in the registry.
- **(B)** If the division determines that allegations regarding a person's actions warrant restricting the person from obtaining further information from the registry established by the division in accordance with section 3796.08 of the Revised Code without a prior hearing, the division may summarily impose the restriction.

- **(1)** The summary restriction will remain in effect, unless removed by the division, until the division's final adjudication order becomes effective.
- **(C)** The division will determine the extent to which the person is restricted from obtaining further information from the registry established by the division in accordance with section 3796.08 of the Revised Code.

**\*\*TO BE RESCINDED\*\***

**~~Rule 3796:2-1-02 | Cultivator provisional license application.~~**

~~(A) The department shall provide advance notice to the public indicating the commencement date and time period for accepting applications. The director shall have the right to amend the notice prior to the deadline for submitting an application. The director shall publish such amended notice in the same manner as the original notice. The director shall also have the right to cancel a notice of open application prior to the award of a cultivator provisional license.~~

~~(B) The provisional license application shall be submitted in accordance with Chapter 3796. of the Revised Code and this chapter. The application will include instructions for completion and submission. An applicant for a level I cultivator provisional license shall be prohibited from applying for a level II cultivator provisional license, and an applicant for a level II cultivator provisional license shall be prohibited from applying for a level I cultivator provisional license. An applicant for a level I or level II cultivator provisional license shall submit, in accordance with the application instructions, the following:~~

~~(1) A non-refundable application fee as set forth in rule 3796:5-1-01 of the Administrative Code;~~

~~(2) A business plan, which, at a minimum, shall include:~~

~~(a) The legal name of the applicant;~~

~~(b) The type of business organization of the applicant, such as an individual, corporation, partnership, limited liability company, association or cooperative, joint venture, or any other business organization;~~

~~(c) Confirmation that the applicant is registered with the secretary of state as the type of business submitted pursuant to paragraph (B)(2)(b) of this rule, a certificate of good standing issued by the secretary of state, and a copy of the applicable business documents governing the operations and administration of the business;~~

~~(d) The proposed physical address of the applicant's facility;~~

~~(e) An organizational chart of the company, including name, address, and date of birth of each principal officer, board member and any other individual associated with the cultivator, provided that all those individuals shall be at least twenty-one years of age;~~

~~(f) All persons subject to the criminal records checks shall submit both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of criminal investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;~~

~~(g) Any instance in which a business that any person associated with the applicant had managed or served on the board of the business and was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding;~~

~~(h) Evidence that the applicant owns the property on which the proposed cultivator will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the cultivator from operating pursuant to Chapter 3796. of the Revised Code and in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the cultivator from operating pursuant to Chapter 3796. of the Revised Code and in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;~~

~~(i) A location area map of the area surrounding the proposed cultivator that establishes the facility is at least five hundred feet from the boundaries of a parcel of real estate having~~

situated on it a prohibited facility, as measured under rule ~~3796:5-5-01~~ of the Administrative Code;

(j) For any instance in which an applicant or any person associated with the applicant is currently or was previously licensed or authorized in another state or jurisdiction to cultivate, produce, test, dispense, or otherwise deal in the distribution of marijuana in any form, the following:

- (i) A copy of each such licensing or authorizing document verifying licensure in that state or jurisdiction;
- (ii) A statement granting permission to contact the regulatory agency that granted the license, accompanied by the contact information, to confirm the information contained in the application; and
- (iii) If the license, authorization or application was ever warned, fined, denied, suspended, revoked or otherwise sanctioned, a copy of documentation so indicating, or a statement that the applicant was so licensed and was never sanctioned; and

(k) Documentation that the applicant is in compliance with applicable building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the applicant's proposed property is located, which are in effect at the time of the application, including but not limited to building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code and any applicable zoning considerations.

(3) An operations plan that establishes policies and procedures that the applicant will implement for the secure, safe, sustainable, and proper cultivation of medical marijuana, which, at a minimum, shall include:

- (a) Agricultural cultivation techniques;
- (b) Experience with the cultivation of medical marijuana or agricultural or horticultural products, operation of an agriculturally related business, or operation of a horticultural business;
- (c) A list of medical marijuana varieties proposed to be grown with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;
- (d) Facility specifications, including the cultivation environment, layout of the marijuana cultivation area (i.e. grow tables, tiered or stacked orientation, etc.) evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;
- (e) The implementation of standards and guidelines for cultivating, propagating, vegetating, flowering, and harvesting medical marijuana, including safety protocols and equipment; and
- (f) Facility staffing and employment matters, including employee training and employee compliance with Chapter 3796. of the Revised Code and in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code.

(4) A quality assurance plan that establishes policies and procedures for a safe, consistent supply of medical marijuana, which, at a minimum, shall include:

- (a) Intended use of pesticides, fertilizers, and other agricultural products or production control factors in the cultivation of medical marijuana;
- (b) Best practices for the packaging and labeling of medical marijuana;
- (c) Implementation and compliance with the inventory tracking system;
- (d) An inventory control plan;
- (e) Standards for the disposal of medical marijuana waste and other wastes; and



- (f) Recall policies and procedures in the event of contamination, expiration or other circumstances that render the medical marijuana unsafe or unfit for consumption, including, at a minimum, identification of the products involved, notification to the dispensary or others to whom the product was sold or otherwise distributed, and how the products will be disposed of if returned to or retrieved by the applicant;
- (5) A security plan that establishes policies and procedures to prevent theft, loss or diversion from a cultivator and protect facility personnel, which, at a minimum, shall include:
  - (a) Record keeping policies and procedures that will ensure the facility complies with rule ~~3796:2-2-08~~ of the Administrative Code;
  - (b) A security plan in accordance with rule ~~3796:2-2-05~~ of the Administrative Code;
  - (c) Transportation policies in accordance with rule ~~3796:5-3-01~~ of the Administrative Code; and
  - (d) A plot plan of the cultivation facility drawn to a reasonable scale that designates the different areas of operation, including the marijuana cultivation area, with the mandatory access restrictions.
    - (i) If the building is in existence at the time of the application, the applicant shall submit plans and specifications drawn to scale for the interior of the building.
    - (ii) If the building is not in existence at the time of application, the applicant shall submit a plot plan and a detailed drawing to scale of the interior and the architect's drawing of the building to be constructed.
- (6) A financial plan, which, at a minimum, shall include:
  - (a) The identity and ownership interest of every person, association, partnership, other entity, or corporation having a financial interest, direct or indirect, in the cultivator with respect to which licensure is sought;
  - (b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
  - (c) Documentation acceptable to the department that the individual or entity filing the application has at least five hundred thousand dollars in liquid assets for a level I cultivator provisional license and fifty thousand dollars in liquid assets for a level II cultivator provisional license, which are unencumbered and can be converted within thirty days after a request to liquidate such assets;
    - (i) Documentation acceptable to the department shall include, as evidence of compliance, a signed statement from an Ohio-licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
    - (ii) The documentation must be dated within thirty calendar days before the date that the application was submitted.
  - (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule ~~3796:2-1-05~~ of the Administrative Code; and
  - (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one per cent or greater in the applicant for the three years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.
- (7) Any other information requested in the application instructions that the department deems necessary to evaluate and determine the applicant's suitability to operate as a cultivator.

**Rule 3796:2-1-03 | Cultivator application review.**

(A) The department, an independent contractor selected by the department, or a combination of the two shall review the submitted applications as described in this chapter and the application instructions. In order to receive consideration under paragraph (B) of this rule, an applicant shall:

- (1) Demonstrate sufficient liquid capital pursuant to rule 3796:2-1-02 of the Administrative Code and an ability to meet the financial responsibility requirements under rule 3796:2-1-05 of the Administrative Code;
- (2) Certify in writing at the time of application that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person has not been:
  - (a) Convicted of a disqualifying offense, as defined in rule 3796:1-1-01 of the Administrative Code; or
  - (b) Issued a certificate to recommend or applied for certification under section 4731.30 of the Revised Code;
- (3) Verify that the proposed facility is not located within five hundred feet of a prohibited facility, which shall be measured in accordance with rule 3796:5-5-01 of the Administrative Code;
- (4) Certify that the local jurisdiction where the facility is proposed has not passed a moratorium or taken other action that would prohibit the applicant from operating as a medical marijuana cultivator;
- (5) Certify that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person who may significantly influence or control the activities of the cultivator does not have an ownership or investment interest, or compensation agreement with, or share any corporate officers or employees with any of the following:
  - (a) A laboratory licensed under Chapter 3796. of the Revised Code; or
  - (b) An applicant for a license to conduct laboratory testing under Chapter 3796. of the Revised Code;
- (6) Provide documentation sufficient to establish that the applicant is in compliance with the applicable tax laws of this state and any jurisdiction where the applicant operates and conducts business; and
- (7) Submit an application with the applicable fee under rule 3796:5-1-01 of the Administrative Code that does not contain information that misleads the department, misrepresents a material fact, or is received after the established application submission period established under paragraph (A) of rule 3796:2-1-02 of the Administrative Code.

(B) The applicants shall be ranked using an impartial and numerical process taking into account the criteria identified in rule 3796:2-1-02 of the Administrative Code, as developed by the department, an independent contractor selected by the department, or a combination of the two. The applicants will be ranked based on the following criteria, at a minimum:

- (1) A business plan, which, at a minimum, shall include:
  - (a) A proposed business model demonstrating a likelihood of success, a sufficient business ability, and experience on the part of the applicant;
  - (b) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the cultivator, provided that all those individuals shall be at least twenty-one years of age;
  - (c) Experience, which includes information on business licenses held by any person affiliated with the applicant, regardless if said license is active, revoked, suspended, or expired. If expired, applicant shall provide the grounds behind the expiration. The information provided

on business licenses shall include the type of license, the licensing agency, the date the license was obtained, and a summary of any negative actions taken against each license;

(d) Evidence that the applicant owns the property on which the proposed cultivator will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the cultivator from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the cultivator from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code; and

(e) Documentation that the applicant is in compliance with any local ordinances, rules, or regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application. Such documentation may include, but is not limited to, local building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code to construct the proposed facility, local approval to operate as a medical marijuana cultivation facility, and evidence that the applicant's proposed location is in compliance with local ordinances, rules, or regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of application.

(2) An operations plan, which shall include, but not be limited to, the following:

(a) Documentation of cultivation methods and standards that will provide a steady, uninterrupted supply of medical marijuana;

(b) Experience with the cultivation of medical marijuana, or agricultural or horticultural products, operation of an agriculturally related business, or operation of a horticultural business;

(c) A list of medical marijuana varieties proposed to be grown with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;

(d) Facility specifications, including the cultivation environment, layout of the marijuana cultivation area (i.e. grow tables, tiered or stacked orientation, et cetera.), evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code; and

(e) Staffing and training guidelines.

(3) A quality assurance plan, which shall include, but not be limited to, the following:

(a) Intended use of pesticides, fertilizers, and other agricultural products or production control factors in the cultivation of medical marijuana;

(b) Best practices for the packaging and labeling of medical marijuana;

(c) Implementation and compliance with the inventory tracking system;

(d) An inventory control plan;

(e) Standards for the destruction of medical marijuana and disposal of waste; and

(f) Recall policies and procedures in the event of contamination, expiration, or other circumstances that render the medical marijuana unsafe or unfit for consumption, including at a minimum, identification of the products involved, notification to the dispensary or others to whom the product was sold or otherwise distributed, and how the products will be disposed of if returned to or retrieved by the applicant;

(4) A security plan, which shall include, but not be limited to, the following:

(a) Policies and procedures to ensure a secure, safe facility to prevent theft, loss, or diversion and protect facility personnel;

- (b) Physical equipment used to monitor the facility and meet the security requirements under Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
  - (c) Emergency notification procedures with the department, law enforcement, and emergency response professionals;
  - (d) A plot plan of the cultivation facility drawn to a reasonable scale that designates the different areas of operation, including the marijuana cultivation area, with the mandatory access restrictions; and
  - (e) Transportation policies and procedures, which includes the transportation of medical marijuana from a cultivator to a processor or dispensary and from a cultivator to a testing laboratory in the state of Ohio, in accordance rule 3796:5-3-01 of the Administrative Code.
- (5) A financial plan, which, at a minimum, shall include the following:
- (a) The identity and ownership interest of every person, association, partnership, other entity, or corporation having a financial interest, direct or indirect, in the cultivator with respect to which licensure is sought;
  - (b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
  - (c) Documentation acceptable to the department that the individual or entity filing the application has secured at least five hundred thousand dollars in liquid assets for a level I cultivator provisional license and fifty thousand dollars in liquid assets for a level II cultivator provisional license, which are unencumbered and can be converted within thirty days after a request to liquidate such assets;
    - (i) Documentation acceptable to the department shall include, as evidence of compliance, a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
    - (ii) The documentation must be dated within thirty calendar days before the date the application was submitted.
  - (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:2-1-05 of the Administrative Code; and
  - (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level and in all jurisdictions in which an applicant has operated as a business, and for every person with a financial interest of one per cent or greater in the applicant for the three years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.
- (6) Any other information that the department deems necessary to evaluate and determine the applicant's suitability to operate as a cultivator.
- (C) In addition to the criteria established in paragraph (B) of this rule, the department may also consider the following when awarding a provisional license:
- (1) Principal place of business;
    - (a) The applicant must provide documentation establishing that its principal place of business is headquartered in Ohio. The applicant may also provide names, addresses, and verification of any persons associated with the applicant that have established residency in Ohio.
    - (b) The applicant may also provide a plan for generating Ohio-based jobs and economic development.
  - (2) Environmental plan;

(a) The applicant must demonstrate an environmental plan of action to minimize the carbon footprint, energy usage, environmental impact, and resource needs for the production of medical marijuana.

(b) The applicant may also describe any plans for the construction or use of a greenhouse cultivation facility, energy efficient lighting, use of alternative energy, the treatment of waste water and runoff, and scrubbing or treatment of exchanged air.

(3) Employment practices, which the applicant must demonstrate a plan of action to inform, hire, and educate minorities, women, veterans, disabled persons, and Ohio residents;

(4) Verification of economically disadvantaged groups; and

(a) The applicant must demonstrate the following:

(i) It is owned and controlled by a United States citizen who is a resident of this state and is a member of one of the economically disadvantaged groups set forth in division (C) of section ~~3796.09~~ of the Revised Code. As used in that section, "owned and controlled" means that at least fifty-one per cent of the business, including corporate stock if a corporation, is owned by persons who belong to one or more of the groups set forth in this rule, and that those owners have control over the management and day-to-day operations of the business and an interest in the capital, assets, and profits and losses of the business proportionate to their percentage of ownership; or

(ii) It is owned and controlled as a woman-owned business by a United States citizen who is a resident of this state. For purposes of this paragraph, "owned and controlled" has the same ownership and control requirements as listed in paragraph (C)(4)(a)(i) of this rule.

(5) Research plan, which the applicant must provide the department with a detailed proposal to conduct or facilitate a scientific study or studies related to the medicinal use of marijuana.

(D) The department may request additional information as part of the application review process from an applicant that otherwise meets all of the requirements under paragraph (A) of this rule. The applicant shall have thirty calendar days from the date the applicant receives the department's request to provide the information. If the applicant fails to provide the requested information within thirty calendar days, it will result in an abandoned application. An abandoned application shall not receive further consideration.

(E) An applicant forfeits all fees associated with an abandoned application. The department shall not be required to act on an abandoned application and the application may be destroyed by the department. An abandoned application will not prevent an applicant from applying for a provisional license in the future if the department issues additional provisional licenses pursuant to paragraph (B) of rule ~~3796:2-1-01~~ of the Administrative Code.

#### **Rule ~~3796:2-1-04~~ | Cultivator provisional license award.**

(A) A provisional license shall be issued to the level I and level II qualified applicants receiving at least the minimum required score in each category and the highest total score overall as compared to the other applicants.

(B) In the event that two or more qualified applicants for a cultivator provisional license received the same total score, and awarding a provisional license to all tied applicants would violate paragraph (A) of rule ~~3796:2-1-01~~ of the Administrative Code, the department shall select the applicant that received the highest score in the operations plan category. In the event that the same applicants received the same score in the operations plan category, the department shall select the applicant that received the highest score in the security plan category. If a tie score still remains, the tied applicants will be interviewed by an unbiased panel selected by the department.

(C) If no qualified applicants are found during the process described in rule ~~3796:2-1-03~~ of the Administrative Code, a provisional licensee fails to fulfill the conditions in the application, or a certificate of operation is revoked, the department may, at the discretion of the director, announce another period to submit applications in accordance with rule ~~3796:2-1-02~~ of the Administrative Code. If the department announces another application period, a qualified applicant that submitted an application during the previous application period, but was not issued a provisional license, may re-submit an application and the application fee under rule ~~3796:5-1-01~~ of the Administrative Code shall be waived.

(D) No person shall hold or be granted more than one cultivator provisional license or cultivator certificate of operation at any time. No person shall hold a financial interest in or be an owner, partner, officer, director, shareholder, member, or other person who may significantly influence or control the activities of more than one cultivator. No corporation, partnership, limited liability partnership, limited liability company, or other entity or subsidiary thereof shall hold a financial interest in or be an owner, principal officer, partner, shareholder, member, or other person who may significantly influence or control the activities of more than one cultivator.

**Rule ~~3796:2-1-06~~ | Cultivator certificate of operation.**

(A) A provisional licensee is prohibited from operating as a licensed cultivator and performing any cultivation or production activities until a certificate of operation is issued by the department. The information and plan submitted by a provisional licensee shall become mandatory conditions that must be met before a certificate of operation can be awarded.

(B) A provisional licensee shall have nine months from the date they are notified of selection for a provisional license to obtain a certificate of operation. A certificate of operation shall be issued once all applicable inspections are passed, a certificate of occupancy issued by the building department having jurisdiction for such use is obtained, and the provisional licensee demonstrates that it conforms to the specifications of the application, as well as the requirements imposed by law and rules. Cultivation activities shall not be agriculture for purposes of section ~~3781.061~~ of the Revised Code. If a certificate of operation is issued, the provisional license becomes null and void.

(C) The department shall not award a certificate of operation to a provisional licensee if the provisional licensee has not met all of the specifications in the application and passed all applicable inspections under rule ~~3796:2-3-01~~ of the Administrative Code within nine months of written or electronic notification of the applicant's selection for a provisional license. If the provisional licensee fails to remedy the deficiencies in accordance with rule ~~3796:2-3-01~~ of the Administrative Code or otherwise satisfy the nine month time period established under paragraph (B) of this rule, the director, at his or her discretion, may extend the time period for the cultivator to obtain a certificate of operation or take action pursuant to rule ~~3796:5-6-01~~ of the Administrative Code.

(D) In addition to entities authorized to purchase medical marijuana pursuant to Chapter 3796. of the Revised Code from a cultivator possessing a certificate of operation, medical marijuana may be sold to a laboratory licensed under Chapter 4729-13 of the Administrative Code, to possess dangerous drugs and controlled substances for scientific and clinical purposes.

(E) The certificate of operation, along with a copy of the current certificate of occupancy for the facility and any other certificate, business license, or other authorization required to conduct production activities, shall be posted in a conspicuous place within the facility and made available to the department and all fire code and building officials upon request.

**Rule ~~3796:2-1-07~~ | Uninterrupted supply of medical marijuana.**

(A) A cultivator shall ensure that a consistent supply of medical marijuana is available to be sold to licensed processors and dispensaries. Evidence of a consistent supply may be shown by:

(1) Not more than one hundred twenty days elapsing between harvests of at least fifteen pounds of medical marijuana; or

(2) Maintaining an inventory of at least twenty pounds of medical marijuana for level I cultivators and ten pounds of medical marijuana for level II cultivators that is ready for immediate sale.

(B) If the director believes a cultivator has failed to meet the requirements of paragraph (A) of this rule, the director may issue a notice of insufficient business activity to a licensed cultivator. The notice shall include the factual basis for the director's belief, including any appropriate supporting documentation.

(C) Upon a notice issued pursuant to paragraph (B) of this rule, a licensed cultivator may respond with any evidence sufficient to prove that the cultivator has met, and continues to meet, the standards established by paragraph (A) of this rule.

(D) If a cultivator fails to respond to a notice issued, or the director determines the evidence provided is insufficient to establish one of the conditions in paragraph (A) of this rule, the director shall move to revoke the cultivator's certificate of operation pursuant to rule 3796:5-6-01 of the Administrative Code.

(E) At any time prior to the issuance of a notice of insufficient business activity, a cultivator may petition the director to toll computation of the timeframes provided in paragraph (A) of this rule. Such a petition shall provide:

(1) An explanation of the facts and circumstances that will not allow the cultivator to ensure a consistent supply of medical marijuana as required in paragraph (A) of this rule; and

(2) A plan for how and when the cultivator will be able to meet the requirements of paragraph (A) of this rule, with specific attention to how such a plan will allow the cultivator to show the standards established in paragraph (A) of this rule.

(F) Upon receipt of a petition under paragraph (E) of this rule, the director may stay the requirement of paragraph (A) of this rule for a cultivator. A director's order staying the requirement of paragraph (A) of this rule shall state the date upon which the stay is lifted using information provided by the cultivator in accordance with paragraph (E)(2) of this rule.

#### **Rule 3796:2-1-08 | Cultivator transfer of ownership or location.**

(A) A provisional license issued pursuant to this chapter is nontransferable.

(B) A certificate of operation shall be issued for the specific cultivator and location identified on the application, and is valid only for the owner, premises and name designated on the certificate of operation and the location for which it is issued. A certificate of operation may only be transferred or assigned if the department determines that the proposed ownership or location change complies with the rules promulgated in accordance with Chapter 3796. of the Revised Code, Chapter 3796. of the Revised Code, and the following:

(1) Upon any request for a change in ownership, the cultivator shall:

(a) Notify the department in writing of the proposed ownership change;

(b) Facilitate the submission of both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of criminal investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;

(c) Demonstrate to the department that the person acquiring the interest meets the requirements under rules 3796:2-1-02 and 3796:2-1-03 of the Administrative Code, and the cultivator will remain in compliance with its application for a cultivator provisional license, the rules promulgated in accordance with Chapter 3796. of the Revised Code, and Chapter 3796. of the Revised Code under the proposed ownership structure; and

~~(d) Require the cultivator to re-submit an application in accordance with rule 3796:2-1-02 of the Administrative Code if the transfer of ownership would result in a new controlling shareholder or shareholders outside of the current ownership structure approved by the department. For purposes of calculating a controlling interest, the department will consider all transfers of ownership that occur in a given calendar year and calculate such transfers in the aggregate.~~

~~(2) Upon a request for a change in location, a cultivator shall:~~

~~(a) Notify the department in writing of the proposed location change;~~

~~(b) Submit plans and specifications for the new facility in accordance with rule 3796:2-1-02 of the Administrative Code; and~~

~~(c) Demonstrate to the department that the new location meets the applicable requirements of rule 3796:2-1-02 of the Administrative Code and that the cultivator will remain in compliance with the rules promulgated in accordance with Chapter 3796. of the Revised Code, and Chapter 3796. of the Revised Code, at the new location.~~

~~(C) A cultivator requesting a change in ownership or location shall submit the applicable fee under rule 3796:5-1-01 of the Administrative Code. A proposed change in ownership or request for a change in location shall not be effective until approved in writing by the department.~~

~~(D) A cultivator receiving approval from the department for a change in location shall have ninety days from the date of approval, unless an extension is granted at the discretion of the department, to transfer inventory and begin operations at the new location, subject to the following restrictions:~~

~~(1) The transition period shall not begin until the new location is ready to begin production and has passed an inspection by the department under rule 3796:2-3-01 of the Administrative Code;~~

~~(2) No product may be transferred to or cultivated at the new location prior to the beginning date of the approved transition period;~~

~~(3) Any medical marijuana remaining at the original location past the ninety-day transition period shall be destroyed in accordance with rule 3796:2-2-03 of the Administrative Code; and~~

~~(4) The cultivator shall notify the department in writing or by electronic transmission once the transfer of inventory is complete and production has begun at the new location.~~

~~(E) Upon inspection and verification by the department that the new location is in compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, the department shall issue a license modification reflecting the new location. The modified license shall have the same expiration date as the previously issued license.~~

#### **Rule 3796:2-1-10 | Cultivator certificate of operation renewal.**

~~(A) Every cultivator certificate of operation issued by the department under this chapter shall expire annually on the date it was issued. A renewal application for a cultivator, accompanied by the proper renewal fee established under rule 3796:5-1-01 of the Administrative Code, shall be filed with the department at least thirty days prior to the expiration date of the certificate of operation.~~

~~(B) The department shall grant a renewal application if the application is filed in a timely manner, the cultivator submits the corresponding renewal fee, the department confirms that nothing warrants the denial of the renewal under rule 3796:5-6-01 of the Administrative Code, and the cultivator passes a full inspection, unless a full inspection was passed within three months before the renewal date.~~

~~(C) If a renewal application is not filed prior to the expiration date of the certificate of operation, the certificate of operation shall be suspended for a maximum of thirty days, at which point it will be deemed expired if the cultivator has not successfully renewed the certificate of operation under paragraph (B) of this rule. Upon expiration of the certificate of operation, the cultivator shall not engage~~



in any cultivation activities in furtherance of the business of growing medical marijuana. The department shall not renew the certificate of operation and the facility shall permanently cease its operations.

**Rule 3796:2-1-11 | Winding down.**

(A) If a cultivator decides to voluntarily surrender or not renew its certificate of operation and permanently discontinue business operations, the cultivator shall provide written notice to the department at least ninety days prior to the effective date of the closure. If the closure is the result of an eviction notice, the cultivator shall immediately notify the department of the eviction notice and the effective date of the notice. This notice shall be provided prior to the cultivator taking any steps to wind down and discontinue business operations.

(B) A cultivator that notifies the department of its intent to voluntarily surrender or not renew its certificate of operation under paragraph (A) of this rule shall submit, within sixty days of the effective date, a written plan of closure for approval by the department. This plan shall include, at a minimum, the following:

- (1) The sale of medical marijuana inventory at market rate;
- (2) The destruction of medical marijuana on hand at the facility on the effective date of the closure;
- (3) The sale or removal of equipment and products ancillary to the cultivation of medical marijuana;
- (4) The retention of all records required to be maintained in accordance with the applicable records retention schedules;
- (5) The steps that will be taken to maintain compliance with Chapter 3796. of the Revised Code, the rules promulgated in accordance with Chapter 3796. of the Revised Code, and any other conditions required by the director until the approved closure date; and
- (6) The closure and intended use of the premises in which the cultivator was located.

(C) The director shall approve or deny a cultivator's plan of closure within thirty days of receipt. The director may request additional information if approval or denial of the plan cannot be determined based on the information provided.

**Rule 3796:2-2-05 | Cultivator security.**

(A) The department shall determine the appropriate storage and security requirements for all cultivator facilities, and may require additional safeguards to ensure the security of medical marijuana. A cultivator shall comply with the security plan submitted as part of its cultivator provisional license application. At a minimum, the cultivator shall do the following:

- (1) Install an adequate security alarm system around the perimeter of the facility to prevent and detect diversion, theft, or loss of medical marijuana utilizing commercial grade equipment;
- (2) Maintain or construct fencing to prevent unauthorized entry or access to waste disposal containers, disposal areas or compost areas located outside the facility;
- (3) Utilize a video surveillance recording system installed by a vendor that is approved by the department and meets the standards required by the department to prevent and detect diversion, theft or loss of medical marijuana;
- (4) Maintain all security system equipment and video surveillance systems in a secure location so as to prevent theft, loss, destruction or alterations;
  - (a) A cultivator shall limit access to surveillance areas to type 1 key employees that are essential to surveillance operations, law enforcement agencies, security system service employees, the department, and others when approved by the department.

(b) A cultivator shall make available to the department, upon request, a current list of type 1 key employees and contractors who have access to the surveillance rooms. A cultivator shall keep all on-site surveillance rooms locked and shall not use such rooms for any other functions.

(5) Keep all approved safes, approved vaults, or any other approved equipment or areas used for cultivating, harvesting, or storing of medical marijuana, securely locked and protected from unauthorized access to medical marijuana;

(6) Ensure the outside perimeter of the cultivator is well-lit and in accordance with the cultivator's plan in its license application;

(7) Restrict access to any area within a cultivator containing medical marijuana except registered employees and agents or an individual permitted to access the facility under the supervision of a registered employee or agent in accordance with the visitor authorization procedures set forth in this chapter;

(8) Limit the use of combination numbers, passwords, or electronic or biometric security systems to registered, authorized employees and prevent the sharing of any employee-specific access credentials; and

(9) Not allow keys to be left in the locks and not store or place keys or badges in a location accessible to persons other than registered, authorized employees.

(B) The cultivator shall install a security alarm system and a video surveillance recording system under paragraph (A) of this rule. A security alarm system and video surveillance recording system shall, at a minimum, contain the following:

(1) A system designed to detect motion and identify unauthorized access to the facility;

(2) Video cameras that capture the entire facility, including direct placement near the entrances, exits, and parking areas to capture a clear and certain identification of any person entering or exiting the facility, which shall be appropriate for the normal lighting conditions of the area under surveillance;

(3) Video cameras shall be directed at all approved safes, approved vaults, and any other area where medical marijuana is being cultivated, harvested, stored, or handled;

(4) The video surveillance recording system shall comply with the following minimum capabilities:

(a) Provide a direct feed and login capabilities to the department to allow for real-time access and monitoring of the facility via the live video surveillance recording system;

(b) A display monitor with a minimum screen size of twelve inches shall be connected to the electronic recording security system at all times;

(c) Installed in a manner that will prevent cameras from being readily obstructed, tampered with, or disabled;

(d) The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

(e) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture;

(f) Cameras installed outdoors and in low-light interior areas shall be day/night cameras with a minimum resolution of 600 lines per inch (analog) or D1 (IP) and a minimum light factor requirement of 0.7 LUX. The installation of additional lighting may be required to increase picture clarity and brightness. Cameras shall be calibrated and focused to maximize the quality of the recorded image;

(g) Allow for the exporting of still images in an industry standard image format, including .jpg, .bmp and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard

file format that can be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal;

(h) Security recordings shall provide an image resolution of at least D1, and the image frame rate shall be at least thirty frames per second during alarm or motion based recording; and

(i) Repair or replace any failed component of the video surveillance recording system within twenty four hours, unless notice is provided to the department and an extension is approved.

(5) Twenty four hour live feed with motion activated recording capabilities from all video cameras, which the cultivation facility shall make available for immediate viewing by the department upon request and shall retain the recordings for at least forty five days. If a cultivator is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the cultivator shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the cultivator that it is not necessary to retain the recording;

(6) Silent alarm, which can be utilized in the event of a holdup or other instances of duress, which notifies law enforcement;

(7) Panic alarm, which means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;

(8) Automatic voice dialer, which means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio, or other communication system, to a law enforcement, public safety, or emergency services agency requesting dispatch;

(9) Failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the cultivation facility within five minutes of the failure, either by telephone, email, or text message; and

(10) The ability to comply with the security requirements of this rule for a period of at least forty-eight hours during a power outage.

(C) In addition to the requirements listed in paragraph (B) of this rule, each cultivator shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(D) A cultivator shall keep all security equipment in good working order and the systems shall be inspected and all devices tested on an annual basis by a third party.

#### **Rule 3796:3-1-02 | Processor provisional license application.**

(A) The department shall provide advance notice to the public indicating the commencement date and time period for accepting applications. The director shall have the right to amend the notice prior to the deadline for submitting an application. The director shall publish such amended notice in the same manner as the original notice. The director shall also have the right to cancel a notice of open application prior to the award of a processor provisional license.

(B) The provisional license application shall be submitted in accordance with Chapter 3796. of the Revised Code and this chapter. The application will include instructions for completion and submission. An applicant for a processor provisional license shall submit, in accordance with the application instructions, the following:

(1) A non-refundable application fee as set forth in rule 3796:5-1-01 of the Administrative Code;

(2) A business plan, which, at a minimum, shall include:

(a) The legal name of the applicant;

- (b) The type of business organization of the applicant, such as individual, corporation, partnership, limited liability company, association or cooperative, joint venture, or any other business organization;
- (c) Confirmation that the applicant is registered with the secretary of state as the type of business submitted pursuant to paragraph (B)(2)(b) of this rule, a certificate of good standing issued by the secretary of state, and a copy of the applicable business documents governing the operations and administration of the business;
- (d) The proposed physical address of the applicants facility;
- (e) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the processor, provided that all those individuals shall be at least twenty-one years of age;
- (f) Experience with the manufacture of medical marijuana, agricultural, or horticultural products;
- (g) All persons subject to the criminal records checks shall submit both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of criminal investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;
- (h) Any instance in which a business that any person associated with the applicant had managed or served on the board of the business and was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding;
- (i) Evidence that the applicant owns the property on which the proposed processor will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
- (j) A location area map of the area surrounding the proposed processor that establishes the facility is at least five hundred feet from the boundaries of a parcel of real estate having situated on it a prohibited facility, as measured under rule 3796:5-5-01 of the Administrative Code;
- (k) For any instance in which an applicant or any person associated with the applicant is currently or was previously licensed or authorized in another state or jurisdiction to cultivate, produce, test, dispense, or otherwise deal in the distribution of medical marijuana in any form, the following:
  - (i) A copy of each such licensing or authorizing document verifying licensure in that state or jurisdiction;
  - (ii) A statement granting permission to contact the regulatory agency that granted the license, accompanied by the contact information, to confirm the information contained in the application; and
  - (iii) If the license, authorization, or application was ever warned, fined, denied, suspended, revoked, or otherwise sanctioned, a copy of documentation so indicating, or a statement that the applicant was so licensed and was never sanctioned; and
- (l) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with all building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application, including but not limited

to building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code and any applicable zoning considerations.

(3) An operations plan that establishes policies and procedures that the applicant will implement for the safe, secure, sustainable, and proper processing of medical marijuana, which, at a minimum, shall include:

- (a) Processing and extraction techniques;
- (b) A list of medical marijuana products proposed to be manufactured with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;
- (c) Facility specifications, designating the areas in the facility where the extraction and processing activities will occur, and evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;
- (d) The implementation of standards and guidelines for processing of plant material, refining of medical marijuana extracts, and manufacturing of medical marijuana products, including safety protocols and equipment; and
- (e) Facility staffing and employment matters, which, at minimum, shall include:
  - (i) Employee training standards for the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana conducted on an annual basis;
  - (ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols, conducted on an annual basis;
  - (iii) Employee training standards for the safe and sanitary execution of any applicable post-extraction refining protocols, conducted on an annual basis;
  - (iv) Employee training standards for the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter 901:3-1 of the Administrative Code conducted on an annual basis; and
  - (v) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;

(4) A quality assurance plan that establishes policies and procedures for a safe, consistent supply of medical marijuana, which, at a minimum, shall include:

- (a) Intended use and sourcing of extraction equipment and associated solvents for the extraction of medical marijuana, or, in the case of non-solvent extraction, the intended physical methods and equipment;
- (b) Intended use and sourcing of all non-marijuana ingredients utilized in the manufacture of medical marijuana products, including methods to verify or ensure the safety and integrity of those ingredients, as well as their potential to be allergens or to contain allergens as a result of their specific manufacturing;
- (c) Compliance with Chapter 901:3-1 of the Administrative Code in the production of edible medical marijuana products;
- (d) Best practices for the packaging and labeling of medical marijuana, such that it maintains medicinal integrity for the expected shelf life;
- (e) Implementation and compliance with the inventory tracking system;
- (f) An inventory control plan;
- (g) Standards for the disposal of medical marijuana waste and other wastes; and
- (h) Recall policies and procedures in the event of contamination, expiration, or other circumstances that render the medical marijuana unsafe or unfit for consumption, including at

a minimum, identification of the products involved, notification to the dispensary or others to whom the product was sold or otherwise distributed, and how the products will be disposed of if returned to or retrieved by the applicant.

(5) A security plan that establishes policies and procedures to prevent theft, loss, or diversion from a processor and protect facility personnel, which, at a minimum, shall include:

(a) Record keeping policies and procedures that will ensure the facility complies with rule ~~3796:3-2-08~~ of the Administrative Code;

(b) A security plan in accordance with rule ~~3796:3-2-05~~ of the Administrative Code;

(c) Transportation policies in accordance with rule ~~3796:5-3-01~~ of the Administrative Code;

and

(d) A plot plan of the processing facility drawn to a reasonable scale that designates the different areas of operation, including, but not limited to, the marijuana extraction and production areas, with the mandatory access restrictions.

(i) If the building is in existence at the time of the application, the applicant shall submit plans and specifications drawn to scale for the interior of the building.

(ii) If the building is not in existence at the time of application, the applicant shall submit a plot plan and a detailed drawing to scale of the interior and the architect's drawing of the building to be constructed.

(6) A financial plan, which, at a minimum, shall include:

(a) The identity and ownership interest of every person, association, partnership, other entity, or corporation having a financial interest, direct or indirect, in the processor with respect to which licensure is sought;

(b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;

(c) Documentation acceptable to the department that the individual or entity filing the application has sufficient liquid assets for a processor provisional license, which are unencumbered and can be converted within thirty days after a request to liquidate such assets. Documentation acceptable to the department includes a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application. The documentation must be dated within thirty calendar days before the date the application was submitted. The following shall be considered sufficient liquid assets:

(i) Two hundred fifty thousand dollars for a processor provisional license; or

(ii) One hundred thousand dollars for a processor provisional license, if at the time of application, the applicant has previously been issued a cultivator provisional license or cultivator certificate of operation and the processor will be located in the cultivators existing facility;

(d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule ~~3796:3-1-05~~ of the Administrative Code; and

(e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one percent or greater in the applicant for the five years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.

(7) Any other information requested in the application instructions that the department deems necessary to evaluate and determine the applicants suitability to operate as a processor.

**Rule 3796:3-1-03 | Processor application review.**

(A) The department, an independent contractor selected by the department, or a combination of the two shall review the submitted applications as described in this chapter and the application instructions. In order to receive consideration under paragraph (B) of this rule, an applicant shall:

- (1) Demonstrate sufficient liquid capital pursuant to rule ~~3796:3-1-02~~ of the Administrative Code and an ability to meet the financial responsibility requirements under rule ~~3796:3-1-05~~ of the Administrative Code;
- (2) Certify in writing at the time of application that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person who may significantly influence or control the activities of the processor has not been:
  - (a) Convicted of a disqualifying offense, as defined in rule ~~3796:1-1-01~~ of the Administrative Code; or
  - (b) Issued a certificate to recommend or applied for certification under section ~~4731.30~~ of the Revised Code;
- (3) Verify that the proposed facility is not located within five hundred feet from a prohibited facility, which shall be measured in accordance with rule ~~3796:5-5-01~~ of the Administrative Code;
- (4) Certify that the local jurisdiction where the facility is proposed has not passed a moratorium or taken other action that would prohibit the applicant from operating as a medical marijuana processor;
- (5) Certify that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person who may significantly influence or control the activities of the processor does not have an ownership or investment interest, a compensation arrangement with, or share any corporate officers or employees with any of the following:
  - (a) A laboratory licensed under Chapter 3796. of the Revised Code; or
  - (b) An applicant for a license to conduct laboratory testing under Chapter 3796. of the Revised Code;
- (6) Provide documentation sufficient to establish that the applicant is in compliance with the applicable tax laws of this state and any jurisdiction where the applicant operates and conducts business;
- (7) Submit an application with the applicable fee under rule ~~3796:5-1-01~~ of the Administrative Code during the established application submission period established under paragraph (A) of rule ~~3796:3-1-02~~ of the Administrative Code. The application shall be submitted in accordance with the application instructions and forms issued by the department. The department may remove an application from consideration for any of the following:
  - (a) Failure or refusal to submit information required under rule ~~3796:3-1-02~~ of the Administrative Code or requested by the department during the application submission or review process;
  - (b) Inclusion of information in the application that misleads the department, misrepresents a material fact, or fails to disclose a material fact to the department;
  - (c) Submission of an application that is in violation of the application instructions issued by the department, or includes forms issued by the department that have been altered.

(B) The applicants shall be ranked using an impartial and numerical process taking into account the criteria identified in rule ~~3796:3-1-02~~ of the Administrative Code, as developed by the department, an

independent contractor selected by the department, or a combination of the two. The applicants will be ranked based on the following criteria, at a minimum:

- (1) A business plan, which, at a minimum, shall include:
  - (a) A proposed business model demonstrating a likelihood of success, a sufficient business ability, and experience on the part of the applicant;
  - (b) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the processor, provided that all those individuals shall be at least twenty-one years of age;
  - (c) Experience, which includes information on business licenses held by any person affiliated with the applicants, regardless if said license is active, revoked, suspended, or expired. If expired, applicant shall provide the grounds behind the expiration. The information provided on business licenses shall include the type of license, the licensing agency, the date the license was obtained, and a summary of any negative actions taken against each license.
  - (d) Evidence that the applicant owns the property on which the proposed processor will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code; and
  - (e) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with any local ordinances, rules or regulations adopted by the locality in which the applicants property is located, which are in effect at the time of the application. Such documentation may include, but is not limited to, local building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code to construct the proposed facility, local approval to operate as a medical marijuana processing facility, and evidence that the applicants proposed location is in compliance with any other local ordinances, rules or regulations adopted by the locality in which the applicants property is located, which are in effect at the time of the application.
- (2) An operations plan, which shall include but not be limited to:
  - (a) Documentation of processing and extraction methods, techniques, and standards that will provide a steady, uninterrupted supply of medical marijuana;
  - (b) A list of proposed medical marijuana products to be manufactured with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;
  - (c) Facility specifications, designating the areas in the facility where the extraction and processing activities will occur, and evidencing that the applicant will comply with the requirements of Chapter 3796. Of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;
  - (d) The implementation of standards and guidelines for processing of plant material, refining of medical marijuana extracts, and manufacturing of medical marijuana products, including safety protocols and equipment; and
  - (e) Facility staffing and employment matters, which shall include, but not be limited to:
    - (i) Employee training standards for the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana;



- (ii) Employee training standards for the safe use, handling, storage, and disposal of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols;
  - (iii) Employee training standards for the safe and sanitary execution of any applicable post-extraction refining protocols;
  - (iv) Employee training standards for the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter 901:3-1 of the Administrative Code; and
  - (v) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code.
- (3) A quality assurance plan, which shall include but not be limited to:
- (a) Intended use and sourcing of extraction equipment and associated solvents for the extraction of medical marijuana, or, in the case of non-solvent extraction, the intended methods and equipment, with details including, but not limited to, make and model of anticipated equipment, throughput capacity, and secondary processing or clean-up strategies for extracts;
  - (b) Intended use and sourcing of all non-marijuana ingredients utilized in the manufacture of medical marijuana products, including methods to verify or ensure the safety and integrity of those ingredients, as well as their potential to be allergens or to contain allergens as a result of their specific manufacturing;
  - (c) Compliance with Chapter 901:3-1 of the Administrative Code in the production of edible medical marijuana products;
  - (d) Best practices for the packaging and labeling of medical marijuana, such that it maintains its medicinal integrity for the expected shelf life;
  - (e) Implementation and compliance with the inventory tracking system;
  - (f) An inventory control plan;
  - (g) Standards for the destruction of medical marijuana and disposal of waste; and
  - (h) Recall policies and procedures in the event of contamination, expiration, or other circumstances that render the medical marijuana unsafe or unfit for consumption, including at a minimum, identification of the products involved, notification to the dispensary or others to whom the product was sold or otherwise distributed, and how the products will be disposed of if returned to or retrieved by the applicant.
- (4) A security plan, which shall include but not be limited to:
- (a) Policies and procedures to ensure a secure, safe facility to prevent theft, loss, or diversion and protect facility personnel;
  - (b) Physical equipment used to monitor the facility and meet the security requirements under Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
  - (c) Emergency notification procedures with the department, law enforcement, and emergency response professionals;
  - (d) A plot plan of the processor facility drawn to a reasonable scale that designates the different areas of operation, including the marijuana extraction and production areas, with the mandatory access restrictions; and
  - (e) Transportation policies and procedures, which includes the transportation of medical marijuana from a processor to a dispensary and from a processor to a testing laboratory in the state of Ohio, in accordance with rule 3796:5-3-01 of the Administrative Code.
- (5) A financial plan, which, at a minimum, shall include:

- (a) The identity and ownership interest of every person, association, partnership, other entity, or corporation having a financial interest, direct or indirect, in the processor with respect to which licensure is sought;
  - (b) A cost breakdown of the applicants anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
  - (c) Documentation acceptable to the department that the individual or entity filing the application has secured sufficient liquid assets as required in rule 3796:3-1-02 of the Administrative Code for a processor provisional license that are unencumbered and can be converted within thirty days after a request to liquidate such assets.
    - (i) Documentation acceptable to the department shall include, as evidence of compliance, a signed statement from an Ohio-licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
    - (ii) The documentation must be dated within thirty calendar days before the date the application was submitted.
  - (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:3-1-05 of the Administrative Code; and
  - (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one per cent or greater in the applicant for the five years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.
- (6) Any other information that the department deems necessary to evaluate and determine the applicant's suitability to operate as a medical marijuana processor.
- (C) In addition to the criteria established in paragraph (B) of this rule, the department may also consider the following when awarding a provisional license:
- (1) Principal place of business;
    - (a) The applicant must provide documentation establishing that its principal place of business is headquartered in Ohio. The applicant may also provide the names, addresses, and verification of any persons associated with the applicant that have established residency in Ohio.
    - (b) The applicant may also provide a plan for generating Ohio-based jobs and economic development.
  - (2) Environmental plan;
    - (a) The applicant must demonstrate an environmental plan of action to minimize the carbon footprint, energy usage, environmental impact, and resource needs for the processing and manufacture of medical marijuana.
    - (b) The applicant must describe any plans for the use of energy efficient lighting, use of alternative energy, the treatment of waste water and runoff, and scrubbing or treatment of exchanged air.
  - (3) Employment practices, in which the applicant must demonstrate a plan of action to inform, hire, and educate minorities, women, veterans, disabled persons, and Ohio residents;
  - (4) Verification of economically disadvantaged groups; and
    - (a) The applicant must demonstrate the following:
      - (i) It is owned and controlled by a United States citizen who is a resident of this state and is a member of one of the economically disadvantaged groups set forth in division (C) of section 3796.09 of the Revised Code. As used in this section, "owned and controlled"

means that at least fifty-one percent of the business, including corporate stock if a corporation, is owned by persons who belong to one or more of the groups set forth in this rule, and that those owners have control over the management and day-to-day operations of the business and an interest in the capital, assets, and profits and losses of the business proportionate to their percentage of ownership; or

(ii) It is owned and controlled as a woman-owned business by a United States citizen who is a resident of this state. For purpose of the paragraph, "owned and controlled" has the same ownership and control requirements as listed in paragraph (C)(4)(a)(i) of this rule.

(5) Research plan, in which the applicant must provide the department with a detailed proposal to conduct or facilitate a scientific study or studies related to the medicinal use of marijuana.

(D) The department may request additional information as part of the application review process from an applicant that otherwise meets all of the requirements under paragraph (A) of this rule. The applicant shall have thirty calendar days from the date the applicant receives the department's request to provide the information. If the applicant fails to provide the requested information within thirty calendar days, it will result in an abandoned application. An abandoned application shall not receive further consideration.

(E) An applicant forfeits all fees associated with an abandoned application. The department shall not be required to act on an abandoned application and the application may be destroyed by the department. An abandoned application will not prevent an applicant from applying for a provisional license in the future if the department issues additional provisional licenses pursuant to paragraph (B) of rule ~~3796:3-1-01~~ of the Administrative Code.

#### **Rule ~~3796:3-1-06~~ | Processor certificate of operation.**

(A) A provisional licensee is prohibited from operating as a licensed processor and performing any processing or manufacturing activities until a certificate of operation is issued by the department. The information and plan submitted by a provisional licensee shall become mandatory conditions that must be met before a certificate of operation can be awarded.

(B) A provisional licensee shall have six months from the date they are notified of selection for a provisional license to obtain a certificate of operation. A certificate of operation shall be issued once all applicable inspections are passed, a certificate of occupancy issued by the building department having jurisdiction for such use is obtained, and the provisional licensee demonstrates that it conforms to the specifications of the application, as well as the requirements imposed by law and rules. If a certificate of operation is issued, the provisional license becomes null and void.

(C) The department shall not award a certificate of operation to a provisional licensee if the provisional licensee has not met all of the specifications in the application and passed all applicable inspections under rule ~~3796:3-3-01~~ of the Administrative Code within six months of written or electronic notification of the applicant's selection for a provisional license. If the provisional licensee fails to remedy the deficiencies in accordance with rule ~~3796:3-3-01~~ of the Administrative Code or otherwise satisfy the six-month time period established under paragraph (B) of this rule, the director, at his or her discretion, may extend the time period for the processor to obtain a certificate of operation or take action pursuant to rule ~~3796:5-6-01~~ of the Administrative Code.

(D) In addition to entities authorized to purchase medical marijuana pursuant to Chapter 3796 of the Revised Code from a processor possessing a certificate of operation, medical marijuana may be sold to a laboratory licensed under Chapter 4729-13 of the Administrative Code, to possess dangerous drugs and controlled substances for scientific and clinical purposes.

(E) The certificate of operation, a copy of the current certificate of occupancy for the facility, and any other certificate, business license, or other authorization required to conduct production activities, shall

be posted in a conspicuous place within the facility and made available to the department and all fire code officials upon request.

**Rule 3796:3-1-07 | Uninterrupted supply of medical marijuana.**

(A) A processor shall ensure that a consistent supply of medical marijuana is available to be sold to licensed dispensaries. Evidence of a consistent supply may be shown by:

(1) Not more than thirty days elapsing between shipments totaling at least one lot of medical marijuana products, as defined in rule 3796:1-1-01 of the Administrative Code, to any licensed dispensaries.; or

(2) Maintaining an inventory of at least five hundred grams of medical marijuana extract that is ready for immediate use in the manufacture of marijuana products.

(B) If the director believes a processor has failed to meet the requirements of paragraph (A) of this rule, the director may issue a notice of insufficient business activity to a licensed processor. The notice shall include the factual basis for the director's belief, including any appropriate supporting documentation.

(C) Upon a notice issued pursuant to paragraph (B) of this rule, a licensed processor may respond with any evidence sufficient to prove that the processor has met, and continues to meet, the standards established by paragraph (A) of this rule.

(D) If a processor fails to respond to a notice issued, or the director determines the evidence provided is insufficient to establish one of the conditions in paragraph (A) of this rule, the director shall move to revoke the processor certificate of operation pursuant to rule 3796:5-6-01 of the Administrative Code.

(E) At any time prior to the issuance of a notice of insufficient business activity, a processor may petition the director to toll computation of the timeframes provided in paragraph (A) of this rule. Such a petition shall provide the following:

(1) An explanation of the facts and circumstances that will not allow the processor to ensure a consistent supply of medical marijuana as required in paragraph (A) of this rule; and

(2) A plan for how and when the processor will be able to meet the requirement of paragraph (A) of this rule, with specific attention to how such a plan will allow the processor to meet the standards established in paragraph (A) of this rule.

(F) Upon receipt of a petition under paragraph (E) of this rule, the director may stay the requirement of paragraph (A) of this rule for a processor. A director's order staying the requirement of paragraph (A) of this rule shall state the date upon which the stay is lifted using information provided by the processor in accordance with paragraph (E)(2) of this rule.

**Rule 3796:3-1-08 | Processor transfer of ownership or location.**

(A) A provisional license granted pursuant to this rule is nontransferable.

(B) A certificate of operation shall be issued for the specific processor and location identified on the application, and is valid only for the owner, premises, and name designated on the certificate of operation and the location for which it is issued. A certificate of operation may only be transferred or assigned if the department determines that the proposed ownership or location change complies with Chapter 3796. of the Revised Code, the rules promulgated in accordance with Chapter 3796. of the Revised Code, and the following:

(1) Upon any request for a change in ownership, the processor shall:

(a) Notify the department in writing of the proposed ownership change;

(b) Facilitate the submission of both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of criminal investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;

- (c) Demonstrate to the department that the person acquiring the interest meets the requirements under rules 3796:3-1-02 and 3796:3-1-03 of the Administrative Code and the processor will remain in compliance with its application for a processor provisional license, Chapter 3796. of the Revised Code, and the rules promulgated in accordance with Chapter 3796. of the Revised Code, under the proposed ownership structure; and
  - (d) Submit a new application in accordance with rule 3796:3-1-02 of the Administrative Code if the transfer of ownership would result in a new controlling shareholder or shareholders outside of the current ownership structure approved by the department. For purposes of calculating a controlling interest, the department will consider all transfers of ownership that occur in a given calendar year and calculate such transfers in the aggregate.
- (2) Upon a request for a change in location, a processor shall:
- (a) Notify the department in writing of the proposed location change;
  - (b) Submit plans and specifications for the new facility in accordance with rule 3796:3-1-02 of the Administrative Code; and
  - (c) Demonstrate to the department that the new location meets the applicable requirements of rule 3796:3-1-02 of the Administrative Code and that the processor will remain in compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code at the new location.
- (C) A processor requesting a change in ownership or location shall submit the applicable fee under rule 3796:5-1-01 of the Administrative Code. A proposed change in ownership or request for a change in location shall not be effective until approved in writing by the department.
- (D) A processor receiving approval from the department for a change in location shall have ninety days from the date of approval, unless an extension is granted at the discretion of the department, to transfer inventory and begin operations at the new location, subject to the following restrictions:
- (1) The transition period shall not begin until the new location is ready to begin production and has passed an inspection by the department under rule 3796:3-3-01 of the Administrative Code.
  - (2) No product or plant material may be transferred to or processed at the new location prior to the beginning date of the approved transition period.
  - (3) Any plant material, medical marijuana extract, or medical marijuana products remaining at the original location past the ninety-day transition period shall be destroyed in accordance with rule 3796:3-2-03 of the Administrative Code.
  - (4) The processor shall notify the department in writing or by electronic transmission once the transfer of inventory is complete and production has begun at the new location.
- (E) Upon inspection and verification by the department that the new location is in compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, the department shall issue a license modification reflecting the new location. The modified license shall have the same expiration date as the previously issued license.

**Rule 3796:3-1-09 | Processor certificate of operation renewal.**

- (A) Every processor certificate of operation issued by the department under this chapter shall expire annually on the date it was issued. A renewal application for a processor, accompanied by the proper renewal fee established under rule 3796:5-1-01 of the Administrative Code, shall be filed with the department at least thirty days prior to the expiration date of the certificate of operation.
- (B) The department shall grant a renewal application if the application is filed in a timely manner, the processor submits the corresponding renewal fee, the department confirms that nothing warrants the denial of the renewal under rule 3796:5-6-01 of the Administrative Code, and the processor passes a full inspection, unless a full inspection was passed within three months before the renewal date.

(C) If a renewal application is not filed prior to the expiration date of the certificate of operation, the certificate of operation shall be suspended for a maximum of thirty days, at which point it will be deemed expired if the processor has not successfully renewed the certificate of operation under paragraph (B) of this rule. Upon expiration of the certificate of operation, the processor shall not engage in any processing activities in furtherance of the business of manufacturing medical marijuana products. The department shall not renew the certificate of operation and the facility shall permanently cease its operations.

**Rule 3796:3-1-10 | Winding down.**

(A) If a processor decides to voluntarily surrender or not renew its certificate of operation and permanently discontinue business operations, the processor shall provide written notice to the department at least ninety days prior to the effective date of the closure. If the closure is the result of an eviction, the processor shall immediately notify the department of the eviction notice and the effective date of the notice. This notice shall be provided prior to the processor taking any steps to discontinue business operations.

(B) A processor that notifies the department of its intent to voluntarily surrender or not renew its certificate of operation under paragraph (A) of this rule shall submit, within sixty days of the effective date, a written plan of closure for approval by the department. This plan shall include, at a minimum:

- (1) The sale of medical marijuana inventory at market rate;
- (2) The destruction of medical marijuana on hand at the facility on the effective date of the closure;
- (3) The sale or removal of equipment and products ancillary to the manufacturing of medical marijuana products;
- (4) The removal or disposal of any solvents or other chemicals used in the manufacture of medical marijuana products, which shall be carried out in accordance with all applicable local, state, and federal laws;
- (5) The retention of all records required to be maintained in accordance with the applicable records retention schedules;
- (6) The steps that will be taken to maintain compliance with Chapter 3796. of the Revised Code, the rules promulgated in accordance with Chapter 3796. of the Revised Code, and any other conditions required by the director until the approved closure date; and
- (7) The closure and intended use of the premises in which the processor was located.

(C) The director shall approve or deny a processors plan of closure within thirty days of receipt. The director may request additional information if approval or denial of the plan cannot be determined based on the information provided.

**Rule 3796:3-2-05 | Processor security.**

(A) The department shall determine the appropriate storage and security requirements for all processor facilities, and may require additional safeguards to ensure the security of medical marijuana. A processor shall comply with the security plan submitted as part of its processor provisional license application. At a minimum, the processor shall:

- (1) Install an adequate security alarm system around the perimeter of the facility to prevent and detect diversion, theft, or loss of medical marijuana, utilizing commercial grade equipment;
- (2) Maintain or construct fencing and gates that surround the facility to prevent unauthorized entry to the facility or unauthorized access to waste disposal containers located outside the facility;

- (3) Utilize a video surveillance recording system installed by a vendor that is approved by the department and that meets the standards required by the department to prevent and detect diversion, theft, or loss of medical marijuana;
  - (4) Maintain all security system equipment and video surveillance systems in a secure location so as to prevent theft, loss, destruction, or alterations:
    - (a) A processor shall limit access to surveillance areas to type 1 key employees that are essential to surveillance operations, law enforcement agencies, security system service employees, the department, and others when approved by the department; and
    - (b) A processor shall make available to the department, upon request, a current list of type 1 key employees and contractors who have access to the surveillance room. A processor shall keep all on-site surveillance rooms locked and shall not use such rooms for any other functions.
  - (5) Keep all approved safes, vaults, or any other approved equipment or areas used for processing or storing of plant material, medical marijuana extract, and medical marijuana products securely locked and protected from unauthorized access;
  - (6) Ensure the outside perimeter of the facility is well lit and in accordance with the processors plan in its license application;
  - (7) Restrict access to any area within the facility containing plant material, medical marijuana extract, or medical marijuana products to all persons except licensed employees and agents or an individual permitted to access the facility under the supervision of a licensed employee or agent in accordance with the visitor authorization procedures set forth in rule 3796:5-2-01 of the Administrative Code;
  - (8) Limit the use of combination numbers, passwords, or electronic or biometric security systems to licensed, authorized employees, and prevent the sharing of any employee specific access credentials; and
  - (9) Not allow keys to be left in the locks and not store or place keys or badges in a location accessible to persons other than licensed, authorized employees.
- (B) The processor shall install a security alarm system and a video surveillance recording system under paragraph (A) of this rule. A security alarm system and video surveillance recording system shall, at a minimum, contain the following:
- (1) A system designed to detect motion and identify unauthorized access to the facility;
  - (2) Video cameras that capture the entire facility, including direct placement near the entrances, exits, and parking areas to capture a clear and certain identification of any person entering or exiting the facility, which shall be appropriate for the normal lighting conditions of the area under surveillance;
  - (3) Video cameras shall be directed at all approved safes, approved vaults, marijuana sales areas, and any other area where plant material, medical marijuana extract, or medical marijuana products are being processed, stored, or handled;
  - (4) The video surveillance recording system shall comply with the following minimum capabilities:
    - (a) Provide a direct feed and login capabilities to the department to allow for real time access and monitoring of the facility via the live video surveillance recording system.
    - (b) A display monitor with a minimum screen size of twelve inches shall be connected to the electronic recording security system at all times.
    - (c) Installed in a manner that will prevent cameras from being readily obstructed, tampered with, or disabled.
    - (d) The ability to immediately produce a clear color still photo that is a minimum of ninety-six hundred dpi from any camera image, live or recorded.

- (e) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture.
  - (f) Cameras installed outdoors and in low light interior areas shall be day/night cameras with a minimum resolution of six hundred lines per inch (analog) or D1 (IP) and a minimum light factor requirement of 0.7 LUX. The installation of additional lighting may be required to increase picture clarity and brightness. Cameras shall be calibrated and focused to maximize the quality of the recorded image.
  - (g) Allow for the exporting of still images in an industry standard image format, including .jpg, .bmp and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal.
  - (h) Security recordings shall provide an image resolution of at least D1, and the image frame rate shall be at least three frames per second during alarm or motion based recording.
  - (i) Repair or replace any failed component of the video surveillance recording system within twenty four hours, unless notice is provided to the department and an extension is approved.
- (5) Twenty four hour live feed with motion activated recording capabilities from all video cameras, which the processor facility shall make available for immediate viewing by the department upon request and shall retain the recordings for at least forty five days. If a processor is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the processor that it is not necessary to retain the recording;
- (6) Silent alarm, which can be utilized in the event of a holdup or other instances of duress, which notifies law enforcement;
- (7) Panic alarm, which for purposes of this subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;
- (8) Automatic voice dialer, which for purposes of this subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;
- (9) A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor facility within five minutes of the failure, either by telephone, email, or text message; and
- (10) The ability to comply with the security requirements of this rule for a period of at least forty eight hours during a power outage.
- (C) In addition to the requirements listed in paragraph (B) of this rule, each processor shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.
- (D) A processor shall keep all security equipment in good working order and the systems shall be inspected and all devices tested on an annual basis.

**Rule 3796:4-1-02 | Testing laboratory provisional license application.**



(A) The department shall provide advance notice to the public indicating the commencement date and time period for accepting applications. The director shall have the right to amend the notice prior to the deadline for submitting an application. The director shall publish such amended notice in the same manner as the original notice. The director shall also have the right to cancel a notice of open application prior to the award of a testing laboratory provisional license.

(B) The provisional license application shall be submitted in accordance with Chapter 3796. of the Revised Code and this division. The application will include instructions for completion and submission. An applicant for a testing laboratory provisional license shall submit, in accordance with the application instructions, the following:

(1) A non-refundable application fee as set forth in rule 3796:5-1-01 of the Administrative Code.

(2) A business plan, which, at a minimum, shall include:

(a) The legal name of the applicant;

(b) The type of business organization of the applicant, such as individual, corporation, partnership, limited liability company, association, cooperative, joint venture, or any other business organization;

(c) Confirmation that the applicant is registered with the secretary of state as the type of business submitted pursuant to paragraph (B)(2)(b) of this rule, a certificate of good standing issued by the secretary of state, and a copy of the applicable business documents governing the operations and administration of the business;

(d) The proposed physical address of the applicants facility;

(e) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the testing laboratory, provided that all those individuals shall be at least twenty one years of age;

(f) Experience with the analytical testing of medical marijuana or other agricultural, horticultural, or pharmaceutical products;

(g) All persons subject to the criminal records checks shall submit both an Ohio bureau of criminal identification and investigation criminal records check and a federal bureau of criminal investigation criminal records check pursuant to division (B) of section 3796.12 of the Revised Code;

(h) Any instance in which a business that any person associated with the applicant had managed or served on the board of the business and was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding;

(i) Evidence that the applicant owns the property on which the proposed testing laboratory will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;

(j) A location area map of the area surrounding the proposed testing laboratory that establishes the facility is at least five hundred feet from the boundaries of a parcel of real estate having situated on it a prohibited facility, as measured under rule 3796:5-5-01 of the Administrative Code;

(k) For any instance in which an applicant or any person associated with the applicant is currently or was previously licensed or authorized in another state or jurisdiction to cultivate, produce, test, dispense, or otherwise deal in the distribution of medical marijuana in any form, the following:

- (i) A copy of each such licensing or authorizing document verifying licensure in that state or jurisdiction;
  - (ii) A statement granting permission to contact the regulatory agency that granted the license, accompanied by the contact information, to confirm the information contained in the application; and
  - (iii) If the license, authorization, or application was ever warned, fined, denied, suspended, revoked, or otherwise sanctioned, a copy of documentation so indicating, or a statement that the applicant was so licensed and was never sanctioned; and
  - (l) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with all building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the applicants property is located, which are in effect at the time of the application, including but not limited to building department approval demonstrating compliance with rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code and any applicable zoning considerations.
- (3) An operations plan that establishes policies and procedures in accordance with the requirements of ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories," that the applicant will implement for the secure and proper analytical testing of medical marijuana, which, at a minimum, shall include:
- (a) Laboratory analysis techniques, including specific instrumentation and protocols necessary to perform the tests required by this division;
  - (b) The implementation of standards and methods for conducting testing laboratory analysis of medical marijuana and medical marijuana products that will allow the applicant to obtain accreditation to the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard within two years of issuance of a provisional license;
  - (c) A list of proposed analytical services to be offered;
  - (d) Facility specifications, designating the areas in the facility where analytical testing will occur, and evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;
  - (e) Facility staffing and employment matters, which, at a minimum, shall include:
    - (i) Employee training standards for the safe operation and maintenance of any and all instrumentation that will be used in the analytical testing of medical marijuana conducted on an annual basis;
    - (ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used in the analytical testing of medical marijuana, in accordance with OSHA protocols, conducted on an annual basis; and
    - (iii) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
  - (f) Compliance with the inventory tracking system implemented by the department; and
  - (g) Policies and procedures for the disposal of medical marijuana waste and other wastes that ensure medical marijuana waste is rendered unusable.
- (4) A security plan that establishes policies and procedures to prevent theft, loss, or diversion from a testing laboratory and protect facility personnel, which, at a minimum, shall include:
- (a) Record keeping policies and procedures that will ensure the facility complies with rule 3796:4-2-06 of the Administrative Code;
  - (b) A security plan in accordance with rule 3796:4-2-07 of the Administrative Code;

- ~~(c) Transportation policies in accordance with rule 3796:4-2-10 of the Administrative Code; and~~
- ~~(d) A plot plan of the laboratory facility drawn to a reasonable scale that designates the different areas of operation, with mandatory access restrictions.~~
  - ~~(i) If the building is in existence at the time of the application, the applicant shall submit plans and specifications drawn to scale for the interior of the building.~~
  - ~~(ii) If the building is not in existence at the time of application, the applicant shall submit a plot plan and a detailed drawing to scale of the interior and the architect's drawing of the building to be constructed.~~
- ~~(5) A financial plan, which, at a minimum, shall include:~~
  - ~~(a) The identity and ownership interest of every person, association, partnership, other entity or corporation having a financial interest, direct or indirect, in the testing laboratory with respect to which licensure is sought;~~
  - ~~(b) A cost breakdown of the applicants anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;~~
  - ~~(c) Documentation acceptable to the department that the individual or entity filing the application has at least two hundred fifty thousand dollars in liquid assets for a testing laboratory provisional license, which are unencumbered and can be converted within thirty days after a request to liquidate such assets;~~
    - ~~(i) Documentation acceptable to the department includes a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.~~
    - ~~(ii) The documentation must be dated within thirty calendar days before the date the application was submitted;~~
  - ~~(d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code; and~~
  - ~~(e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one per cent or greater in the applicant for the five years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.~~
- ~~(6) Any other information requested in the application instructions that the department deems necessary to evaluate and determine the applicant's suitability for a testing laboratory license.~~

**~~Rule 3796:4-1-06 | Testing laboratory certificate of operation.~~**

- ~~(A) A provisional licensee is prohibited from operating as a licensed testing laboratory and performing any analytical testing activities until a certificate of operation is issued by the department. The information and plan submitted by a provisional licensee shall become mandatory conditions that must be met before a certificate of operation can be awarded.~~
- ~~(B) A provisional licensee shall have six months from the date they are notified of selection to obtain a certificate of operation. A certificate of operation shall be issued once all applicable inspections are passed and the provisional licensee demonstrates that it conforms to the specifications of the application, as well as the requirements imposed by law and rules. If a certificate of operation is issued, the provisional license becomes null and void.~~

(C) The department shall not award a certificate of operation to a provisional licensee if the provisional licensee has not met all of the specifications in the application and passed all applicable inspections under rule ~~3796:4-3-01~~ of the Administrative Code within six months of written or electronic notification of the applicants selection. If the provisional licensee fails to remedy the deficiencies in accordance with rule ~~3796:4-3-01~~ of the Administrative Code or otherwise satisfy the six month time period established under paragraph (B) of this rule, the director, at his or her discretion, may extend the time period for the testing laboratory to obtain a certificate of operation or take action pursuant to rule ~~3796:5-6-01~~ of the Administrative Code.

(D) The certificate of operation, along with a copy of the current certificate of occupancy for the facility and any other certificate, business license, or other authorization required to conduct testing activities, shall be posted in a conspicuous place within the facility and made available to the department and all fire code and building officials upon request.

#### **Rule ~~3796:4-1-08~~ | Testing laboratory certificate of operation renewal.**

(A) Every testing laboratory certificate of operation issued by the department under this chapter shall expire annually on the date it was issued. A renewal application for a testing laboratory, accompanied by the proper renewal fee established under rule ~~3796:5-1-01~~ of the Administrative Code, shall be filed with the department at least thirty days prior to the expiration date of the certificate of operation.

(B) The department shall grant a renewal application if the application is filed in a timely manner, the testing laboratory submits the corresponding renewal fee, the department confirms that nothing warrants the denial of the renewal under rule ~~3796:5-6-01~~ of the Administrative Code, and the testing laboratory passes a full inspection, unless a full inspection was passed within three months before the renewal date.

(C) If a renewal application is not filed prior to the expiration date of the certificate of operation, the certificate of operation shall be suspended for a maximum of thirty days, at which point it will be deemed expired if the testing laboratory has not successfully renewed the certificate of operation under paragraph (B) of this rule. Upon expiration of the certificate of operation, the testing laboratory shall not engage in any testing activities in furtherance of the business of the testing of medical marijuana. The department shall not renew the certificate of operation and the facility shall permanently cease its operations.

(D) If a testing laboratory fails to achieve accreditation to the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard within two years of the issuance of a provisional license, the certificate of operation may not be renewed, at the discretion of the department. If a testing laboratory fails to maintain accreditation to the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard, including suspension by the accrediting body or failure on the part of the laboratory to renew accreditation, the certificate of operation may not be renewed, at the discretion of the department.

#### **Rule ~~3796:5-2-01~~ | Employee identification cards.**

(A) Every owner, principal officer, board member, employee, administrator, agent, or other person who may significantly influence or control the activities of a cultivator, processor, or testing laboratory must apply to the department for an employee identification card.

(1) The cultivator, processor, or testing laboratory with which a person listed under paragraph (A) of this rule is seeking employment shall submit the following information:

(a) A completed application;

- (b) A copy of the applicant's valid driver's license or state issued identification card establishing that the individual is at least twenty one years of age;
  - (c) A recognizable headshot photograph of the applicant taken no more than six months before the date of application;
  - (d) The name of the cultivator, processor, or testing laboratory that the applicant seeks to work for or otherwise be associated with;
  - (e) The application fee; and
  - (f) Any additional information requested by the department in the application.
- (2) An individual on whose behalf an application is submitted under this chapter or is issued an employee identification card under this chapter shall notify the department of any changes to the information provided on the application no later than five business days after such change.
- (B) Upon receipt of an application and verification of the information specified in paragraph (A) of this rule, the department shall do the following:
- (1) Approve or deny the application within thirty days after receipt;
  - (2) Issue an identification card that shall expire two years after the date of issuance; and
  - (3) Enter in its record system the name and any other identifying information on the cultivator, processor, or testing laboratory where the individual is employed.
- (C) An employee identification card issued by the department shall contain, at a minimum, the following:
- (1) The name of the cardholder;
  - (2) The license number of the cultivator, processor, or testing laboratory employing the cardholder;
  - (3) The date of issuance and expiration;
  - (4) A random ten digit alphanumeric identification number with at least four numbers and four letters that is unique to the holder and assigned by the department; and
  - (5) A photograph of the cardholder that was provided as part of the application.
- (D) No person shall begin working at a cultivator, processor, or testing laboratory prior to receiving his or her employee identification card. A cardholder must keep his or her employee identification card visible at all times when on the property of a cultivator, processor, or testing laboratory and during the transportation of medical marijuana to another cultivator, processor, or testing laboratory. Any employee identification card that is lost, destroyed, or stolen shall be reported to the department immediately upon discovery of the loss, destruction, or theft, and the department may require a similar report to law enforcement. A cardholder that reports his or her employee identification card as lost, destroyed, or stolen shall apply for a replacement card with the department and pay a replacement employee identification card fee as specified in rule 3796:5-1-01 of the Administrative Code.
- (E) A cardholder is not subject to prosecution, search, or penalty in any manner, and will not be denied any right or privilege, including, but not limited to, civil penalty or disciplinary action by a business licensing board or entity, for working at a cultivator, processor, or testing laboratory and performing the actions permitted under Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code.
- (F) An employee identification card remains the property of the department and the department may order the return or seizure of an employee identification card if the registration is revoked or expires. The employee identification card shall be immediately returned to the cultivator, processor, or testing laboratory upon termination or completion of services provided.
- (1) Following the revocation or expiration of an employee identification card, the cultivator, processor, or testing laboratory shall do the following:
    - (a) Notify the department of the circumstances around the termination or expiration within one business day in a manner determined by the department;

(b) Ensure the employee identification card is returned to the cultivator, processor, or testing laboratory; and

(c) Return the employee identification card to the department within fifteen calendar days of the employee's termination or completion of services.

(2) The department shall revoke an employee identification card upon receiving notification that the individual is no longer associated with the cultivator, processor, or testing laboratory. If the employee identification card is not returned within thirty days of the termination, the department may take action under rule 3796:5-6-01 of the Administrative Code.

(G) An individual arrested for activities that, if convicted, would constitute a disqualifying offense shall immediately notify the department. If an employer has knowledge of such arrest, the employer shall notify the department.

(H) A cultivator, processor, or testing laboratory shall designate the level of access granted to an applicant for an employee identification card. A cultivator, processor, or testing laboratory may choose to implement additional access restrictions, but at a minimum, the access levels shall be designated as follows:

(1) A type 1 designation is an owner, administrator, or individual that has control and management over the day-to-day activities that significantly impact the operations of the cultivator, processor, or testing laboratory. Type 1 access permits the cardholder to enter every area of the medical marijuana entity facility. A cultivator, processor, or testing laboratory shall designate one and may designate up to three type 1 cardholders as a key employee. A key employee shall be responsible for all activities at the facility and will serve as the point of contact for the facility with the department.

(2) A type 2 designation is a board member, officer, employee, or agent permitted to enter the production and non-production areas of the facility designated in the facility plans and specifications submitted by a cultivator, processor, or testing laboratory under rule 3796:2-1-02 of the Administrative Code. A type 2 cardholder shall not be permitted to access the areas containing the vault, security equipment, and other equipment related to the facility's surveillance operations.

(I) A person that is not a holder of a valid employee identification card of a cultivator, processor, or testing laboratory is prohibited from accessing a facility, unless they receive authorization and obtain a visitor identification badge from the cultivator, processor, or testing laboratory. To obtain a visitor identification badge, the visitor must provide a valid, government issued identification with a photograph.

(1) A person who obtains a visitor identification badge must do the following:

(a) Be escorted and monitored by an assigned registered employee of the facility at all times he or she is on the premises and has access to medical marijuana;

(b) Visibly display his or her visitor identification badge at all times he or she is on the premises; and

(c) Return the visitor identification badge upon leaving the premises.

(2) A cultivator, processor, or testing laboratory shall maintain a visitor log, which includes the name of the visitor, the date and time of arrival and departure, the assigned registered employee of the facility, and the purpose of the visit. The cultivator, processor, or testing laboratory shall make its visitor log available to the department upon request.

(3) Notwithstanding the requirements of paragraph (I) of this rule, employees of the department, law enforcement, emergency medical personnel, in the event of an emergency, or other federal, state of Ohio, or local government officials may enter a cultivator, processor, or testing laboratory if necessary to perform their official duties.

**Rule 3796:5-2-02 | Criminal records check.**

(A) Pursuant to division (B)(1) of section ~~3796.12~~ of the Revised Code, any person required to perform a criminal records check must submit fingerprint impressions to the Ohio bureau of criminal identification and investigation for a criminal records check of the applicant.

(B) Pursuant to section ~~3796.13~~ of the Revised Code, prospective employees for a medical marijuana entity licensed by the department must submit fingerprint impressions to the Ohio bureau of criminal identification and investigation for a criminal records check of the applicant.

(C) A person required to submit a criminal records check under paragraph (A) or (B) of this rule shall submit both a bureau of criminal identification and investigation criminal records check and a federal bureau of investigation criminal records check.

(D) The Ohio bureau of criminal identification and investigation shall send results of the bureau of criminal identification and investigation and the federal bureau of investigation criminal records checks performed under this rule directly to the department. The department requires that the criminal records check does the following:

(1) Be based on electronic fingerprint impressions that are submitted directly to the bureau of criminal identification and investigation from a "WebCheck" provider agency. The department may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only if readable electronic fingerprint impressions cannot be obtained, or if submission of ink impressions is otherwise authorized by the bureau of criminal identification and investigation.

(2) Results will only be considered valid if the fingerprint impressions were obtained within the previous twelve months.

(E) After the department receives the results from both required criminal records checks, the licensing process will proceed.

**Rule 3796:5-2-03 | Denial of an employee identification card.**

(A) The department shall deny an application for an employee identification card if any of the following conditions exist:

(1) The applicant has been convicted of a disqualifying offense;

(2) The applicant is not twenty-one years of age;

(3) The application failed to include any of the required application materials stated in paragraph (A) of rule ~~3796:5-2-01~~ of the Administrative Code; or

(4) The applicant has had an application for drug enforcement administration registration or any application for a license from a licensing agency under Chapter ~~4776~~ of the Revised Code, denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

(B) The department may deny an application for an employee identification card if the department determines, upon review of all relevant materials, that the applicant lacks the character or fitness necessary to be employed within the medical marijuana industry. An employee that reports a concern about compliance with or suspected violations of any state or federal regulation, including Chapter ~~3796~~ of the Revised Code and the rules promulgated in accordance with Chapter ~~3796~~ of the Revised Code, shall not be cause for revoking or denying an employee identification card. The department shall provide written justification of its decision to deny the applicant for an employee identification card to both the applicant and the entity who applied on the applicant's behalf. The department's decision under this rule shall be subject to Chapter ~~119~~ of the Revised Code.

(C) An applicant who has his or her employee identification card revoked or suspended due to his or her employer's revocation or suspension of a provisional license or certification of operation shall not be prohibited from obtaining an employee identification card for another licensed medical marijuana entity, if the suspension or revocation of the provisional license or certificate of operation was a result of the applicant reporting an incident or violation of any state or federal law, including Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code.

**Rule 3796:5-3-01 | Transportation of medical marijuana and medical marijuana products.**

(A) Prior to transporting any medical marijuana, regardless of form, a medical marijuana entity licensed by the department shall maintain a transportation log, in writing, that contains the following information:

- (1) The names and addresses of the medical marijuana entities sending and receiving the shipment;
- (2) The names and registration numbers of the registered employees transporting the medical marijuana or the products containing medical marijuana;
- (3) The license plate number and vehicle type that will transport the shipment;
- (4) The time of departure and estimated time of arrival;
- (5) The specific delivery route, which includes street names and distances; and
- (6) The total weight of the shipment and a description of each individual package that is part of the shipment, and the total number of individual packages.

(B) The medical marijuana entity transporting medical marijuana under paragraph (A) of this rule shall transmit a copy of the transportation log to the medical marijuana entity that will receive the products and to the department before the close of business the day prior to transport. The medical marijuana entity shall enter the information required in the inventory tracking system in accordance with section 3796.07 of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code. The transportation log shall be made available to law enforcement agencies upon request. A medical marijuana entity shall maintain all transportation logs in accordance with the record keeping requirements established under the rules promulgated in accordance with Chapter 3796. of the Revised Code, and make them available at the request of the department.

(C) The vehicle transporting the medical marijuana or any product containing medical marijuana shall meet the following requirements:

- (1) Be insured as required by law;
- (2) Store the medical marijuana and any product containing medical marijuana in a locked, safe, and secure storage compartment that is part of the motor vehicle, or in a locked storage container that has a separate key or combination pad;
- (3) Ensure any medical marijuana or product containing medical marijuana is not visible from the outside of the vehicle;
- (4) Be staffed with a minimum of two employees registered with the department, with at least one employee remaining with the vehicle at all times that the vehicle contains medical marijuana;
- (5) Have access to a secure form of communication with personnel at the medical marijuana entity and the ability to contact law enforcement through the 911 emergency system at all times that the vehicle contains medical marijuana, unless notification is impractical under the circumstances; and
- (6) Not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership.

(D) Any vehicle transporting medical marijuana or any product containing medical marijuana shall travel directly from the sending medical marijuana entity to the receiving medical marijuana entity and shall not make any stops in between except to other medical marijuana entities listed on the transportation log, to refuel the vehicle, or to notify the medical marijuana entities, the department and law



enforcement in the event of an emergency. In the event of an emergency, the employees will report the emergency immediately to law enforcement through the 911 emergency system and to the medical marijuana entities, which will immediately notify the department, unless the notification is impractical under the circumstances.

(E) A registered employee transporting medical marijuana shall do the following:

- (1) Display his or her department issued employee identification card at all times when transporting or delivering medical marijuana and shall produce it for the department or department's authorized representative or law enforcement official upon request;
- (2) Ensure delivery times vary and routes are randomized;
- (3) Report any vehicle accident that occurs during the transportation to a person designated by the transporting medical marijuana entity to receive such reports within two hours after the accident occurs;
- (4) Report any loss or theft of medical marijuana that occurs during the transportation of medical marijuana in accordance with rule 3796:5-4-01 of the Administrative Code;
- (5) Carry a copy of the transportation log completed pursuant to paragraph (A) of this rule for the duration of the trip; and
- (6) Notify the medical marijuana entity when the delivery has been completed.

**Rule 3796:6-2-07 | Licensing of medical marijuana dispensary associated key employees and dispensary key employees.**

(A) An applicant for a dispensary associated key employee or key employee license shall:

- (1) Comply with all requirements set forth in Chapter 3796. of the Revised Code and the rules adopted thereunder;
- (2) Comply with the criminal records check requirements in this rule;
- (3) Be twenty-one years of age or older; and
- (4) Submit a complete application, in a manner determined by the board, that includes all the following:

- (a) The name and license number of the dispensary employing the applicant;
- (b) A copy of the applicant's unexpired driver's license, identification card issued by the Ohio bureau of motor vehicles (BMV) or the equivalent issued by another state, or United States passport or United States passport card, or other identification approved by the board of pharmacy;
- (c) An acknowledgment that the applicant has not been convicted of a disqualifying offense in any jurisdiction;
- (d) The required fee; and
- (e) Any additional information or documentation required by the state board of pharmacy.

(B) Any person applying for an initial associated key employee license shall pay the required fee no later than thirty days after the award of a provisional dispensary license to the provisional dispensary applicant to which the person is associated.

(C) Pursuant to division (B)(1) of section 3796.12 of the Revised Code, dispensary associated key employee and dispensary key employee applicants must submit fingerprint impressions to the bureau of criminal investigation (BCI) for a criminal records check of the applicant.

(D) Pursuant to division (B)(2) of section 3796.12 of the Revised Code, the person subject to the criminal records check shall submit both a BCI criminal records check and a federal bureau of investigation (FBI) criminal records check.

(E) BCI shall send the results of the BCI and FBI criminal records checks directly to the state board of pharmacy. The state board of pharmacy requires that the criminal records check:

(1) Be based on electronic fingerprint impressions that are submitted directly to BCI from a "WebCheck" provider agency located in Ohio. The state board of pharmacy may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only if readable electronic fingerprint impressions cannot be obtained, or if submission of ink impressions is otherwise authorized by BCI.

(2) Results will only be considered valid if the fingerprint impressions were obtained within the twelve month period immediately preceding the application date.

(F) If a dispensary associated key employee or key employee license has expired, the applicant shall submit to a criminal records check that meets the criteria prescribed in this rule.

(G) Every applicant for a dispensary associated key employee license shall comply with Chapter 3796. of the Revised Code and this division and be included on the dispensary license application or renewal application. A dispensary wishing to add a dispensary associated key employee who is not included in the dispensary license application or renewal application, or who did not submit with the dispensary application the required items under this rule, shall apply for a change of ownership pursuant to rule 3796:6-2-12 of the Administrative Code and remit the required fee.

(H) Applicants acting in compliance with this rule who meet the requirements of Chapter 3796. of the Revised Code and this division, who do not have a conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense, and who remit the required fee shall be issued the applicable dispensary associated key or dispensary key employee license. Any license issued pursuant to this rule shall be effective from the date the license is issued until the expiration date of the first day of July of each odd numbered year. Initial licenses issued on or after the first day of April of each odd numbered year shall receive an expiration date of the first day of July of the next odd numbered year.

(I) Except as authorized under paragraph (B) of rule 3796:6-2-09 of the Administrative Code, dispensary associated key employee and dispensary key employee licenses are non transferable and shall expire upon the occurrence of any of the following conditions:

(1) At the conclusion of the biennial term indicated on the dispensary associated key employee or key employee's license;

(2) When the associated key employee or the key employee is no longer employed by the licensed dispensary identified on the employee's application; or

(3) When the licensed dispensary ceases to maintain its certificate of operation.

(J) A renewal application for an associated key employee or key employee license shall be submitted no later than the expiration date listed on the employee's biennial license. Renewal applications shall be accepted no earlier than ninety days prior to the expiration date on a date determined by the board's director of licensing.

(K) A dispensary associated key employee or dispensary key employee shall submit a renewal application in a manner determined by the board, that includes all of the following:

(1) An acknowledgement that the applicant does not have a conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense;

(2) The required fee; and

(3) Any additional information or documentation required by the state board of pharmacy.

(L) A dispensary associated key employee or dispensary key employee license is valid until the expiration indicated on the employee's biennial license. A license that is not renewed by the expiration date is expired.

(M) A dispensary associated key employee or dispensary key employee who fails to renew their license in accordance with this rule is prohibited from engaging in the activities authorized by Chapter 3796. of the Revised Code and agency 3796 of the Administrative Code.

~~(N) A dispensary associated key employee or dispensary key employee with an expired license may apply to reinstate their license in accordance with this rule.~~

~~(O) If any information contained in the application or accompanying documents changes after being submitted to the state board of pharmacy, the applicant shall immediately notify the state board of pharmacy in writing and provide corrected information within fourteen days of the change.~~

**~~Rule 3796:7-2-01 | Procedure for patient registration.~~**

~~(A) Before medical marijuana may be dispensed to or for, possessed by or for, or administered by or for a prospective patient, the prospective patient must be placed on the registry established by the state board of pharmacy in accordance with section 3796.08 of the Revised Code.~~

~~(B) To qualify for placement on the registry, a prospective patient must:~~

- ~~(1) Establish and maintain a bona fide physician-patient relationship with a recommending physician who shall submit a complete patient registration submission;~~
- ~~(2) Receive a diagnosis or confirmation of a qualifying condition from the recommending physician;~~
- ~~(3) Consent to treatment with medical marijuana. If the patient is a minor or individual with a court-appointed legal guardian, the prospective patients parent or legal representative shall consent to treatment with medical marijuana;~~
- ~~(4) Remit to the state board of pharmacy the required fee; and~~
- ~~(5) Unless otherwise provided pursuant to a reciprocal agreement under division (A) of section 3796.16 of the Revised Code, be an Ohio resident.~~

~~(C) A physician with whom a prospective patient has a bona fide physician-patient relationship, or, subject to the limitations under section 3796.08 of the Revised Code, the physicians delegate, shall submit the patient registration. For a registration submission, related to a patient who is eighteen years of age or older, to be considered complete, a completed recommendation from a physician, applicable patient registration fee, and the following items must be submitted to the state board of pharmacy in a manner suitable to the board:~~

- ~~(1) Patient's full name, residential address, telephone number, date of birth, electronic mail address, and qualifying condition(s);~~
- ~~(2) Patients government issued identification number (such as drivers license number). Patients and caregivers must present a recommending physician with an unexpired drivers license, other identification issued by the Ohio bureau of motor vehicles (BMV) or other identification proving Ohio residency as approved by the board of pharmacy;~~
- ~~(3) Recommending physicians full name (first name and last name);~~
- ~~(4) Drug enforcement administration physician identification number and medical license number issued by the state medical board;~~
- ~~(5) Date recommendation was issued by the recommending physician;~~
- ~~(6) Recommending physicians business address, telephone number, and email address;~~
- ~~(7) Indication whether the recommendation is new or a renewal;~~
- ~~(8) The following patient attestations:~~
  - ~~(a) The physician has explained to the individual the possible risks and benefits associated with the use of medical marijuana;~~
  - ~~(b) The individual consents to treatment with medical marijuana; and~~
  - ~~(c) The individual agrees to comply with Chapters 2925. and 3796. of the Revised Code and this division.~~
- ~~(9) An attestation from the recommending physician in accordance with division (A)(2) of section 3796.08 of the Revised Code; and~~
- ~~(10) Such other information as the state board of pharmacy may reasonably require.~~

(D) If a prospective patient is younger than eighteen years of age or has a court appointed legal guardian, a patient registration submission must be accompanied by a caregiver registration submission in accordance with rule 3796:7-2-03 of the Administrative Code, before it will be considered complete. Patients who become eighteen years of age during the time period in which their registration is valid may apply for a new registration either immediately or in accordance with the renewal process under paragraph (K) of this rule. A submission from a patient that includes all information found in paragraph (C) of this rule, shall be considered complete.

(E) A complete patient registration submission must be received by the state board of pharmacy within ninety calendar days of the date on which the recommendation was created by the prospective patients recommending physician. Failure to comply with this requirement will void the recommendation and the persons registration shall be deemed abandoned.

(F) To qualify for registration as a patient diagnosed with a terminal illness, the prospective patients registration submission shall include with the registration submission, an attestation specifying that the patient has a terminal illness, submitted by the patients recommending physician.

(G) If a registration submission is determined to be inaccurate or incomplete, the state board of pharmacy shall send the prospective patient notice of the deficiency. If the deficiency is not corrected within ninety calendar days from the date that the registration was submitted by a physician, the submission shall be considered abandoned.

(H) Prospective patients must provide proof of Ohio residency to their recommending physician or the physicians delegate during the physicians initiation of the registration submission process. Proof of Ohio residency shall include one of the following:

- (1) The prospective patients unexpired Ohio drivers license;
- (2) The prospective patients unexpired Ohio identification card issued by the Ohio bureau of motor vehicles (BMV); or
- (3) Any other identification proving residency as approved by the board of pharmacy.

(I) A patient registration shall be valid from the date of issuance and expire one year later, on the last day of the month it was issued.

(J) The state board of pharmacy shall send a notification to each patient forty five calendar days before the expiration date on the patients registry identification card.

(K) To maintain a valid patient registration, a patient must annually renew, before the expiration date stated on the patients registry identification, a patient registration, in accordance with this rule. Renewal submissions, fees, and required documentation may be submitted up to thirty calendar days before the registration will expire. Failure to renew a patient registration will result in an automatic expiration of the registration card.

#### **Rule 3796:7-2-03 | Procedure for caregiver registration.**

(A) Caregivers who are registered in accordance with section 3796.08 of the Revised Code may possess medical marijuana and administer it to patients with whom the caregivers registration is associated.

(B) An individual who meets the caregiver eligibility requirements under rule 3796:7-2-02 of the Administrative Code may be registered as a caregiver if the following are submitted to the state board of pharmacy in a manner suitable to the board:

- (1) Identification of a patient who is registered or attempting to register as a patient pursuant to rule 3796:7-2-01 of the Administrative Code and for whom the individual intends to serve as a caregiver;
- (2) Completed caregiver registration submission in accordance with paragraph (C) of this rule; and
- (3) Required fee.

(C) The recommending physician with whom the patient or prospective patient has a bona fide physician-patient relationship, or the physician's delegate, shall submit the caregiver registration. For a registration submission to be considered complete, the applicable caregiver registration fee and the following items must be submitted to the state board of pharmacy in a manner suitable to the board:

- (1) Caregivers full name, caregiver residential address, caregiver telephone number, caregiver date of birth, caregiver electronic mail address;
- (2) Caregivers government issued identification number and proof of Ohio residency, unless approved pursuant to paragraph (F) of rule 3796:7-2-02 of the Administrative Code;
- (3) Associated patient name;
- (4) Associated patient registration number issued by the state board of pharmacy, if available;
- (5) Recommending physicians full name (first name and last name);
- (6) Drug enforcement administration physician identification number;
- (7) Recommending physicians medical license number issued by the state medical board;
- (8) Date recommendation was issued by the recommending physician;
- (9) Recommending physicians business address, telephone number, and email address;
- (10) Indication whether the recommendation is new or a renewal;
- (11) Such other information as the state board of pharmacy may reasonably require.

(D) All prospective caregivers shall attest to the following:

- (1) The physician has explained to the caregiver the possible risks and benefits associated with the use of medical marijuana;
- (2) The individual agrees to serve as the caregiver for the patient identified on their registry submission;
- (3) The individual agrees to control the dosage and frequency of the use of medical marijuana in accordance with any instruction for use provided by the physician; and
- (4) The individual agrees to comply with Chapters 2925. and 3796. of the Revised Code and this division.

(E) A prospective caregiver for a patient younger than eighteen years of age shall be:

- (1) An Ohio resident, unless authorized pursuant to a reciprocity agreement established pursuant to section 3796.16 of the Revised Code;
- (2) The patient's parent or legal representative; and
- (3) Shall attest in accordance with paragraph (D) of this rule and to the following:
  - (a) That the prospective caregiver is the parent or legal representative of the individual under eighteen years of age; and
  - (b) The parent or legal representative understands the information provided by the physician and knowingly consents to the use of medical marijuana by the individual under eighteen years of age.

(F) To be eligible for an exception under paragraph (F)(2) of rule 3796:7-2-02 of the Administrative Code, a hospice provider shall:

- (1) Register as caregivers all employees who will possess or administer medical marijuana in accordance with this rule; and
- (2) Notify the state board of pharmacy when a patient with an active medical marijuana registration issued by the board is admitted to hospice pursuant to rule 3701-19-20 of the Administrative Code.

(G) A caregiver registration shall be valid from the date of issuance and expire one year later, on the last day of the month it was issued.

(H) The state board of pharmacy shall send a notification to each caregiver forty-five calendar days before the expiration date on the caregivers registry identification card.

(I) To maintain a valid caregiver registration, a caregiver must annually renew, before the expiration date stated on the caregivers registry identification, a caregiver registration submission, in accordance with this rule. Renewal applications, fees, and required documentation may be submitted up to thirty calendar days before the caregiver registration will expire.

**Rule 3796:7-2-07 | Duty to report.**

(A) A patient or caregiver must notify the state board of pharmacy within ten calendar days of learning that the patient or caregivers registry identification card has been used fraudulently. After notification of the fraudulent use of a registry identification card, the state board of pharmacy may issue a new registry identification card with a new registry number.

(B) A patient or caregiver must notify the state board of pharmacy within ten calendar days of learning that the patient or caregivers registry was accessed without authorization. After notification of the unauthorized access, the state board of pharmacy may issue a new registry identification card with a new registry number.

(C) A patient or caregiver must notify the state board of pharmacy, in a manner suitable to the board, of any change in the information, other than a change in qualifying condition, previously provided to the board in accordance with rule 3796:7-2-01 of the Administrative Code not later than thirty calendar days after such change.

(D) If a patient is deceased, the patients caregiver, if any, or a legal representative of the patient shall notify the state board of pharmacy. A deceased patient's registration shall be deactivated at the request of the patient's:

(1) Caregiver or legal representative; or

(2) Recommending physician.

(E) A patient shall report to the state board of pharmacy a conviction of any offense and/or any arrest or charges pending of a felony or misdemeanor offense under Chapter 2925. or 4729. of the Revised Code, or of an arrest or conviction in another jurisdiction that is substantially the same as a felony or misdemeanor offense under Chapter 2925. or 4729. of the Revised Code, within ten calendar days of the conviction or arrest.

(F) A caregiver shall report to the state board of pharmacy a violation of any state or federal law or rule, regardless of jurisdiction in which such acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration which do not need to be reported unless the offense involved operating vehicle under the influence of alcohol or a controlled substance. Acts in accordance to Chapter 3796. of the Revised Code and this division that constitute a violation of federal law shall not be reported.

(G) If a patient has a caregiver, that caregiver may provide any required notification to the state board of pharmacy on behalf of the patient using the same forms and process in accordance with section 3796.04 of the Revised Code.

**Rule 3796:7-2-08 | Grounds for discipline.**

(A) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may revoke or impose any one or more of the following sanctions on a patient or caregiver if the board finds the individual engaged in any of the conduct set forth in paragraph (B) of this rule:

(1) Revoke, suspend, restrict, limit, or refuse to grant or renew a registration; or

(2) Reprimand or place the registrant on probation, or refuse to grant an identification card.

(B) The board may impose the sanctions listed in paragraph (A) of this rule if the board finds:

- (1) The patient or caregiver applicant or registrant fails to meet the requirements set forth in Chapter 3796. of the Revised Code or this division;
- (2) Any information provided to the state board of pharmacy by the patient or caregiver was false or misleading;
- (3) The prospective patients or caregivers registration submission has been previously revoked;
- (4) The prospective patient or caregiver has had a patient or caregiver registration previously suspended or denied;
- (5) The applicant is a prospective caregiver who is already registered to serve as a caregiver for two patients;
- (6) The caregivers sole patient has had their patient registration suspended, revoked, or inactivated and the caregiver has not voluntarily relinquished their caregiver registration;
- (7) The prospective caregiver is attempting to register to serve as a caregiver for a patient whose registration has been denied or suspended;
- (8) The patient obtained more than a ninety-day supply of medical marijuana in a ninety-day period. A ninety-day supply includes the aggregate amount of medical marijuana obtained by a patient and all of the patients caregivers;
- (9) The caregiver obtained more than a ninety-day supply of marijuana in a ninety-day period on behalf of a single patient;
- (10) The patient is no longer diagnosed with a qualifying condition and the patient or caregiver did not voluntarily relinquish the patients registration;
- (11) The patient or caregiver failed to report any changes in any information related to the patient or caregiver, other than a change in medical condition, required to be provided under rule 3796:7-2-01 of the Administrative Code, within thirty calendar days;
- (12) The patient or caregiver failed to report knowledge of conduct in violation of the medical marijuana control program;
- (13) The patient or caregiver used or maintained medical marijuana in a manner that put others at risk or failed to take reasonable precautions to avoid putting others at risk;
- (14) The patient or caregiver sold marijuana to any other person, including other patients or caregivers;
- (15) The patient or caregiver allowed another to use the patient or caregivers registration identification card;
- (16) The patient or caregivers medical marijuana registration was accessed by a person without authorization and the patient or caregiver did not notify the state board of pharmacy within seven days of learning that the registry was accessed without authorization;
- (17) The patient consumed medical marijuana using a method of administration that is not permitted under Chapter 3796. of the Revised Code or this division;
- (18) A caregiver administered medical marijuana to a patient using a method of administration that is not permitted under Chapter 3796. of the Revised Code or this division;
- (19) The patient or caregiver allowed medical marijuana to be consumed in a place where consumption is prohibited under Chapter 3796. of the Revised Code or this division;
- (20) The patient or caregiver tampered, falsified, altered, modified or allowed another person to tamper, falsify, alter or modify, a patient or caregiver registry identification card;
- (21) The patient operated a vehicle, streetcar, trackless trolley, watercraft, or aircraft under the influence of medical marijuana;
- (22) The patient or caregiver grew or cultivated medical marijuana contrary to paragraph (B) of rule 3796:7-2-05 of the Administrative Code;

- (23) The patient or caregiver knowingly misrepresented any fact or circumstances related to the medical use of marijuana to the state board of pharmacy, law enforcement, recommending physician, or a dispensary employee;
- (24) The patient or caregivers medical marijuana registry identification card has been fraudulently used and the patient or caregiver did not notify the state board of pharmacy within ten calendar days of learning that the card was fraudulently used;
- (25) The patient or caregiver violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 2925., 3715., 3719., 3796., or 4729. of the Revised Code, or of any rule adopted by the board under those provisions; or
- (26) The patient or caregiver violated any state or federal law or rule, regardless of jurisdiction in which acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration. Acts in accordance with Chapter 3796. of the Revised Code and this division that constitute a violation of federal law shall not be considered as grounds for discipline.

**~~Rule 3796:7-2-10 | Confidentiality of patient identifying information at adjudication hearings.~~**

- (A) Notwithstanding any provision to the contrary in Chapter 119. of the Revised Code, all adjudication hearings related to a patient registration shall be closed to the public, in accordance with division (B) of section ~~3796.08~~ of the Revised Code.
- (B) Documents that contain patient-identifying information are confidential. Patient-identifying information includes, but is not limited to:
  - (1) Patient's name;
  - (2) Patient's social security number;
  - (3) Patient's date of birth;
  - (4) Patient's driver's license number;
  - (5) Patient's home address, telephone number, email address, or any other contact information;
  - (6) Patient's registry card number and related information;
  - (7) Any other information that can be used to identify a patient or is required to be confidential under state or federal law.
- (C) For all proceedings associated with an adjudication hearing, whether related to a patient registration or not:
  - (1) Any confidential document, as described in paragraph (B) of this rule, may be provided to a representative of record or to a witness during the adjudication hearing but shall not be disseminated to any other person unless the patient identifying information is redacted.
  - (2) Any confidential documents as described in paragraph (B) of this rule that is presented as an exhibit, whether admitted or proffered, shall either have all patient-identifying information redacted or be sealed prior to being made part of the adjudication hearing record.
  - (3) Any portion of a transcript that contains patient-identifying information shall be sealed and made part of the adjudication hearing record. Sealed portions of transcripts shall only be provided to the parties or as otherwise necessary to conduct an adjudication hearing or related appeal pursuant to Chapter 119. of the Revised Code.
- (D) A patient may waive any of the provisions described in this rule.
- (E) Nothing in this rule prevents the dissemination of public records, as defined section ~~149.43~~ of the Revised Code, so long as they have been appropriately redacted to protect patient and other confidential information.



**Rule 3796:7-2-11 | Release of registered patient information maintained by the state board of pharmacy.**

~~(A) Pursuant to division (B) of section 3796.08 of the Revised Code and division (C) of section 4729.80 of the Revised Code, records related to registered patients are confidential and are not public records subject to disclosure under section 149.43 of the Revised Code. The state board of pharmacy is authorized or required to provide information related to registered patients only as follows:~~

- ~~(1) The patient or that patient's designated caregiver;~~
- ~~(2) The certified physician who issued the recommendation to the patient;~~
- ~~(3) Certified or licensed health care personnel who is responsible for the care of the patient;~~
- ~~(4) Any state or local law enforcement agency conducting an investigation of a criminal violation of state or federal law;~~
- ~~(5) Any person that the state board of pharmacy is legally required to, including upon issuance of a valid subpoena, court order, or other similar document only in a criminal matter or an equivalent juvenile matter;~~
- ~~(6) A government entity responsible for the licensure, regulation, or discipline of health care professionals;~~
- ~~(7) Any person, other than those listed in paragraphs (A)(1) to (A)(6) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient is unable to deliver written consent, in which case, written consent must be provided by the patient's caregiver or legal guardian.~~
  - ~~(a) Any consent must be signed by the patient or caregiver and dated.~~
  - ~~(b) Any consent for disclosure is valid until rescinded by the patient or caregiver.~~
  - ~~(c) In an emergency, the state board of pharmacy may disclose the registered patient information when it is deemed to be in the best interest of the patient.~~

~~(B) Any person that receives patient information pursuant to paragraphs (A)(4) to (A)(6) of this rule shall comply with the same requirements regarding confidentiality as those with which the state board of pharmacy must comply, notwithstanding any conflicting provision of the Revised Code or agency procedure that applies when the agency is dealing with other information in its possession.~~