

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the Department of Commerce, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the impacted public to provide input on the following rules.

Comments on the proposed rules will be accepted until **close of business on January 27, 2017**. Please send all comments to the following email address:

MMCPRules@com.state.oh.us

In addition, please copy your comments to:

CSIPublicComments@governor.ohio.gov

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Department of Commerce

Regulation/Package Title: Medical Marijuana Control Program Cultivator Rules

Rule Number(s): 3796:1; 3796:2-1-01; 3796:2-1-02; 3796:2-1-03; 3796:2-1-04; 3796:2-1-05;
3796:2-1-06; 3796:2-1-07; 3796:2-1-08; 3796:2-1-09; 3796:2-1-10; 3796:2-1-11; 3796:2-2-01;
3796:2-2-02; 3796:2-2-03; 3796:2-2-04; 3796:2-2-05; 3796:2-2-06; 3796:2-2-07; 3796:2-2-08;
3796:2-3-01; 3796:5-1; 3796:5-2-01; 3796:5-2-02; 3796:5-2-03; 3796:5-3; 3796:5-4; 3796:5-5;
3796:5-6; 3796:5-6-01; 3796:5-6-02; 3796:5-6-03; 3796:5-7; 3796:5-8; 3796:5-9

Date: January 10, 2017

Rule Type: New

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

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

The responsibilities under Chapter 3796 of the Revised Code are divided up between multiple agencies under Ohio’s Medical Marijuana Program (“Program”), including the Ohio Department of Commerce (“Department”), Ohio Board of Pharmacy and the State Medical Board of Ohio. The Program was established by House Bill 523 of the 131st General

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

Assembly. The Department is responsible for the administration, implementation and enforcement of cultivators, processor and testing laboratories under the Program. In addition to these responsibilities, the Department is also statutorily responsible for establishing a “seed-to-sale” electronic system that tracks medical marijuana from the beginning stages until sale to a registered patient. This Business Impact Analysis addresses rules that apply to medical marijuana cultivators.

- Rule 3796:1 provides a list of definitions that make up the Program. These definitions apply to all rules promulgated in OAC 3796, including those promulgated by the Board of Pharmacy. Included in the definitions is a list of disqualifying offenses for the Program.
- Rule 3796:2-1-01 addresses the number of cultivator licenses issued (a) prior to the effective date of the Program, which is September 8, 2018, and (b) after the effective date of the program, based on population and patient population.
- Rule 3796:2-1-02 establishes the application submission process and the criteria that will be evaluated in the application, including a business plan, operations plan, quality assurance plan, security plan, financial plan, and any other information deemed necessary by the Department.
- Rule 3796:2-1-03 covers the application review process and establishes the parameters of a scoring rubric that will be used to ensure a fair and unbiased review of the applications submitted for cultivator licenses. This rule also establishes certain requirements that must be met for an application to receive consideration and identifies bonus criteria to consider during the review process.
- Rule 3796:2-1-04 details the procedures for awarding and accepting a provisional license. This rule prevents a person or business from holding more than one cultivator license in the State, which includes a financial interest in a licensee.
- Rule 3796:2-1-05 sets forth the financial responsibility requirements that must be met in order for a provisional licensee to receive a certificate of operation. These requirements include (a) general liability and products liability insurance coverage with limits determined by the Department, and (b) a surety bond in the amount of \$1,500,000 for Level I cultivators and \$150,000 for Level II cultivators, or (c) an escrow account in the amount of \$1,500,000 for Level I cultivators and \$150,000 for Level II cultivators. This rule also establishes benchmarks that, if met, reduce the dollar amount of the bond or escrow account.

- Rule 3796:2-1-06 addresses the time period for a provisional licensee to get up and running (9 months) and the issuance of a certificate of operation, which allows a cultivator to start growing medical marijuana. It also allows a provisional licensee to request an extension to obtain this certificate if the circumstance permit it.
- Rule 3796:2-1-07 places a requirement on cultivators to meet an uninterrupted supply standard to ensure adequate supply and make sure licensee are operating. The standard is different for Level I and Level II cultivators, and there is a process if they are unable to meet this standard to toll the time period or for the director to take action, at his or her discretion.
- Rule 3796:2-1-08 prohibits a cultivator provisional licensee from transferring its license to another person and establishes a process that a cultivator must follow if there is a change in ownership or transfer in ownership once a certificate of operation is obtained. If the controlling interest changes, a new application is required and must be approved by the Department. This rule also covers change in location for a cultivator within the same designated territory.
- Rule 3796:2-1-09 permits a cultivator to expand its marijuana cultivation area from the original space (up to 25,000 square feet permitted for Level I and 3,000 square feet permitted for Level II) by way of an approved build out not to exceed the initial limits for Level I and Level II cultivators, resulting in a maximum marijuana cultivation area for 50,000 square feet for Level I and 6,000 square feet for Level II. This rule covers the plan for expansion and gives the director discretion to authorize a second build out of up to an additional 25,000 square feet for Level I cultivators and 3,000 square feet for Level II cultivators, if necessary to meet patient demand and other factors in rule, resulting in a maximum marijuana cultivation area of 75,000 square feet for Level I and 9,000 square feet for Level II.
- Rule 3796:2-1-10 covers the renewal of a cultivator's certificate of operation and the process to renew, which includes a \$200,000 renewal fee for Level I cultivators and \$20,000 renewal fee for Level II cultivators. Fee amounts are established in 3796:5-1. A failure to renew 30 days past renewal date will result in the certificate being revoked.
- Rule 3796:2-1-11 addresses the winding down of a cultivator facility, if the cultivator voluntarily chooses to exit the industry without a transfer in ownership or the cultivator is evicted from the facility. This rule includes a plan of closure that must be submitted and approved by the Department.
- Rule 3796:2-2-01 details the components of a quality assurance plan and establishes standards with which cultivators must comply to ensure product consistency and patient

safety. This rule includes limits on pesticide and fertilizer usage, equipment cleanliness, facility sanitation and other quality assurance considerations.

- Rule 3796:2-2-02 sets forth packaging and labeling requirements for cultivators and plant-only processors that package and transport plant material to processors and/or dispensaries. This rule includes the required content and laboratory analysis found on the label or container that contains the medical marijuana. This rule also allows cultivators to send sample containers to processors and dispensaries for patients to smell and analyze prior to a sale.
- Rule 3796:2-2-03 addresses the different ways a cultivator can dispose of medical marijuana waste and non-medical marijuana waste, including rendering it unusable in a locked dumpster or composting the waste on-site for future use on-site. The rule lists the material that can be mixed with the waste to render it unusable pursuant to the rule. It also requires that a Level I key employee oversee all waste disposal and destruction documented in a destruction log maintained by the facility and submitted to the Department.
- Rule 3796:2-2-04 establishes processes and procedures for inventory control and the information that enters the seed-to-sale system. This includes a weekly inventory based on sales and destruction, as well as cultivation at the facility. This rule also requires an annual, manual inventory to ensure the seed-to-sale system properly tracks inventory and facility operations.
- Rule 3796:2-2-05 highlights the facility security measures, ranging from locked access areas to technology requirements. The facility requirements are covered under paragraph (A) and the technology security requirements fall under (B). The technology security is a big component of the security plan and requires a video surveillance system and alarm system that allows the Department to live access the cameras in the facility and monitor the operations.
- Rule 3796:2-2-06 lists the testing requirements depending on the intended use of the plant material. If the plant material is being shipped directly to a dispensary for patient administration, a much stricter lab analysis is required. If the plant material is being sent to a processor to be refined and extracted, then the product will undergo subsequent tests and the analysis for this material will be reduced. The industry will impose its own set of requirements. Testing laboratory standards will be detailed in future rules.
- Rule 3796:2-2-07 covers the prohibited activities found in statute and pulled from other states with comparable programs and that is separate from the “prohibited acts” under the enforcement rules.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

- Rule 3796:2-2-08 lists the various records and reporting requirements, including inventory records, sales records, transportation records, security records, testing lab records, cultivation records, employee records, and enforcement records. The record retention period is five years and allows a cultivator to maintain its own, independent electronic system for records, but this is not required. This rule further breaks down each record listed above.
- Rule 3796:2-3-01 establishes the scope of the Department's inspections, both during a pre-operation inspection that is required for the issuance of a certificate of operation, and an annual inspection of the facility. The rule outlines a process that will allow a cultivator to remedy any shortcomings or compliance issue before action is taken by the Department under the enforcement section of the rules. It also requires inspection reports.
- Rule 3796:5-1 states the various fees for medical marijuana entities licensed by the Department. This fee schedule includes employee identification cards and covers the fees for applications, certificate of operations, license renewals and other fees based on the circumstances. These fees are based on a review of other states' programs and the need to fully fund the operations of the Program.
- Rule 3796:5-2-01 addresses required employee identification cards and includes the application process, issuance of the ID card, employee designations for facility access purposes, and the revocation of a card and/or entity license that employs the person.
- Rule 3796:5-2-02 describes the criminal background check process required under O.R.C. 3796.
- Rule 3796:5-2-03 lists the reasons or events that will trigger a denial of an employee identification card. This rule also provides protection to an employee that reports a violation at the facility.
- Rule 3796:5-3 establishes transportation requirements for medical marijuana, including transportation logs, vehicle requirements and employee requirements for transporting medical marijuana.
- Rule 3796:5-4 covers reporting and responsibilities if a theft or diversion of medical marijuana occurs at a facility. This rule includes reporting timelines and information that must be provided to the Department.
- Rule 3796:5-5 defines the measurement of medical marijuana facilities from a prohibited facility, as defined in rule based on O.R.C. 3796. This rule also establishes that facilities in existing prior to a prohibited facility coming within 500 feet are grandfathered in.

- Rule 3796:5-6 provides an overview and scope of the enforcement rules for these medical marijuana licensees.
- Rule 3796:5-6-01 defines the enforcement powers made available to the Department in the event of a prohibited act under rule 3796:5-6-02.
- Rule 3796:5-6-02 breaks down prohibited activities that may trigger an enforcement action.
- Rule 3796:5-6-03 states the outcome of a revoked or suspended license and acknowledges the 119 process with respect to licensing.
- Rule 3796:5-7 lists the permitted and prohibited advertising activities with respect to form and substance. This rule also required Department approval prior to use and an advertising fee. The rule also addresses social media and web-based advertising considerations.
- Rule 3796:5-8 handles product registration and designates a two-step process involving the Pharmacy Board and the assignment of the required product identifier, including a product registration fee paid to Pharmacy.
- Rule 3796:5-9 encourages agency cooperation between the agency stakeholders under Ohio's Medical Marijuana Control Program.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Chapters 119 and 3796 of the Revised Code are the authorizing statutes for these rules.

3. 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?

No, these rules do not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. 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)?

These rules help ensure that patients will receive a safe and consistent medical marijuana product and establishes a process that must be followed to provide adequate safety and security measures for cultivation facilities.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

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

The success of this program will be measured by the availability of safe medical marijuana for patients with qualified conditions at a reasonable price. Ohio's Program is designed to be conservative, yet flexible in nature, which will help ensure patient safety and limit threats of diversion/theft and involvement of criminal enterprises.

Development of the Regulation

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

The Department solicited comments from the general public and the Medical Marijuana Advisory Committee. Over 75 comment submissions were received. The Department received feedback from many different groups and stakeholders with an interest in the Program, including Ohio citizens, Ohio businesses, advocacy groups, and industry associations formed in this state and outside of Ohio.

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

The Department received over 75 responses during the rule comment period. In general, the majority of the feedback received can be categorized into the following areas:

- The number of provisional licenses issued for Level I and Level II cultivators.
- The Program's ability to scale operations and meet patient demand, including the square footage limitation and lack of an ability to expand grow capacity absent additional licenses.
- The financial constraints and barriers to entry for potential applicants, including the licensing fee amounts and financial responsibility requirements that must be met by Level I and Level II cultivators.
- The impact on the environment and cultivation practices that increase the quality and safety of medical marijuana (i.e. use of pesticides and fertilizers during cultivation).
- The packaging requirements and expiration of medical marijuana.

Based on the public's feedback, guidance from an industry consultant and discussions between the stakeholders responsible for the MMCP, the following changes were made to the draft rules:

- **Number of Licenses** – The Department increased the number of Level II cultivator provisional licenses that the Department may issue before September 8, 2018, from

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

- six to 12. This is consistent with the number of Level I cultivator provisional licenses available to be issued before the effective date and would allow the Department to provide additional grow capacity if necessary.
- **Marijuana Cultivation Area Increase** – The Department increased the square footage of grow capacity for both Level I and Level II cultivator licenses. Level I cultivators are now permitted to maintain a marijuana cultivation area of 25,000 square feet, up from 15,000 square feet in the initial rules draft. Level II cultivators are now permitted to maintain a marijuana cultivation area of 3,000 square feet, up from 1,600 square feet in the initial rules draft.
 - **Marijuana Cultivation Area Expansion** – Beginning September 9, 2018, a cultivator may, at the discretion of the director and approval by the Department, perform an expansion of its marijuana cultivation area of (1) up to 25,000 square feet for Level I cultivators, for a total square footage marijuana cultivation area of 50,000, and (2) up to 3,000 square feet for Level II cultivators, for a total square footage marijuana cultivation area of 6,000. The director may also, at his or her discretion, and based on patient population, approve a subsequent expansion of (1) up to 25,000 additional square feet for Level I cultivators, for a total square footage marijuana cultivation area of 75,000, and (2) up to 3,000 additional square feet for Level II cultivators, for a total square footage marijuana cultivation area of 9,000.
 - **Adjusted Financial Responsibility Requirements** – The department reduced the level of surety bond coverage or escrow account balance from \$2,000,000 to \$1,500,000 for Level I cultivators and \$200,000 to \$150,000 for Level II cultivators and included performance triggers that will reduce the amount by \$500,000 and \$50,000, respectively, for each performance measure achieved, until an escrow/surety bond requirement is no longer present. The Department added an insurance required for coverage related to general liability and products liability to protect patients and licensees from potential liabilities.
 - **Pesticide and Fertilizer Usage** – The Department worked with the Department of Agriculture to revise the rules around pesticide and fertilizer usage on medical marijuana. Cultivators are now permitted to apply approved pesticides and/or fertilizers for the first 21 days in the flowering stage. In exchange, every batch must undergo testing for pesticides and fertilizers before it can be packaged and transported. The Department also removed the applicator license required based on the public’s feedback and Agriculture’s guidance.
 - **Environmental and Similar Considerations** – Based on changes to the draft rules, cultivators are now permitted to compost waste from the facility for use at the facility if they meet the requirements in the proposed rules. Additionally, the rules provide a mechanism for cultivators to market their products as meeting different standards in the industry geared towards product quality and safety (i.e. third party organic certifiers, etc.).

The Department reviewed every comment submitted to the MMCP rules address. The Department determined that it was in the best interest of the Program to not make certain changes to the rules draft. Some examples include the following:

- **Unlimited grow capacity** – To avoid the complications of excess supply that other states that recently implemented a medical program are experiencing, the Department decided that a modest increase to the square footage capacity with additional expansion capabilities was appropriate in lieu of unlimited grow capacity. This will allow Ohio to attract top industry experts to enter the market and compete, which will help control price and supply with reasonable controls.
- **Square footage supply control method** – Other states tie production to the number of registered patients or establish canopy limits. The Department received feedback and guidance on the positives and negatives of both supply control measures and determined that a square footage limitation was the best option available to Ohio. This model allows licensees to tweak their cultivation practices and make changes to production that will meet demand without interfering or revisiting the supply control method, other than the expansion of a cultivator’s marijuana cultivation area. This supply control measure provides the greatest flexibility for these businesses and helps the Department from a compliance and enforcement standpoint.
- **Unlimited Cultivator Licenses** – The Department listened to the different concerns related to a limited number of licenses. The Department acknowledges that the proposed structure will provide applicants with experience, knowledge and ability with these licenses, but that is in line with the responsibilities of a medical program: ensuring a consistent, safe medical product for registered patients that need relief. The decisions to add two levels of cultivator licenses, limit the production capacities for both level of licenses and implement a license issuance process based on patient population and demand will introduce new licensees and provide many opportunities for businesses and individuals to become involved in the industry.

A summary of the comments received by the Department can be found in Attachment 1, and a summary of the changes made to the cultivator rules can be found in Attachment 2.

9. 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?

Rules were developed after benchmarking with other states and talking with industry experts, including a cultivation expert consultant.

10. 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?

There are no alternative regulations or specific provisions within the regulation to be considered.

11. Did the Agency specifically consider a performance-based regulation? Please explain.

Performance-based regulation was considered for these rules. For example, the application criteria were developed as a merit-based system, where applicants will have to demonstrate their knowledge and abilities in this specific field to be considered for a license. Additionally, the regulations include language that allows medical marijuana entities to phase-out bonding and escrow requirements as these entities meet performance thresholds and provide a consistent supply of medical marijuana. Facilities may also petition for expansion of growing space if they provide a consistent supply and maximize the use of the permitted marijuana cultivation area.

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

This is a new industry, so there are no existing rules to duplicate.

13. 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.

The Department established standards and procedures that apply to every entity that will be licensed by the Department under the Program. The proposed rules set forth a consistent process for the issuance of cultivator provisional licenses, cultivator certificates of operation and employee identification cards. The rules require the development of impartial, unbiased scoring rubrics to evaluate applicants and implement a consistent set of requirements that will result in highly qualified and capable businesses receiving licenses in Ohio. The regulations also establish and communicate the process for the issuance of licenses and employee identification cards, which speaks to the predictability of the Program's operations.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

These rules regulate cultivators of medical marijuana. "Cultivator", as used in Chapter 3796. of the Revised Code, means an entity that has been issued a certificate

of operation by the Department to grow, harvest, package and transport medical marijuana as permitted under Chapter 3796. of the Revised Code. Cultivators will be the sole entity responsible for the legal growing of marijuana in the state of Ohio.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

The Department has established a licensing fee schedule for medical marijuana entities regulated by the Department under rule 3796:5-1 of the Administrative Code. With respect to fines, the Department has the authority under rule 3796:5-6 to issue fines for violations of the rules chapter and Chapter 3796 of the Revised Code of up to \$50,000 per violation. Applicants that are issued a provisional license have nine months to pass a pre-operation inspection and become operational.

c. Quantify the expected adverse impact from the regulation.

Each entity licensed with the Department will be required to comply with these new regulations to ensure the public health and safety within establishments cultivating medical marijuana.

The Department does not have data to provide a quantified potential impact for the reasonable compliance costs associated with compliance with the rules, beyond the fees established in rule.

While the ultimate adverse impact for a violation of the Department's rules could be a fine, suspension, revocation, or rejection of an entity's license, the Department intends to work to assist and educate all of these entities to avoid such repercussions.

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

The regulation of medical marijuana is brand new to Ohio. These rules are designed to provide a balanced, transparent, and accountable method of allowing individuals and entities to obtain and maintain cultivator licenses. The regulatory intent of the rules justifies the adverse impact because the manufacturing and sale of medical marijuana is a unique industry that requires strict regulation for the health, safety, and protection of the public. The State has a compelling interest in promoting safe and temperate use of medical marijuana while avoiding risks such as diversion and theft of medical marijuana.

Regulatory Flexibility

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

The Department offers a Level II cultivator license that will likely be a better fit for small businesses. Since the operation is smaller and won't require as many employees, it is likely that these facilities will be considered small businesses and provides for a reduced license fee structure and lower financial responsibility requirements. The rules are intended to create a level playing field for all market participants, regardless of size.

17. 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?

While the Department takes great effort to ensure that applicants submit correct documentation, ORC 119.14 is not applicable to these rules as there is no penalty associated with the paperwork necessary pursuant to these rules.

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

The Department can be contacted via multiple sources:

The Program website: <http://medicalmarijuana.gov>

The Department's office is located at: 77 S. High St., Columbus, OH 43215

3796 Ohio Medical Marijuana Control Program

3796:1 Definitions

(A) As used in this Chapter:

- (1) “Abandoned application” means an application for a medical marijuana entity, patient or caregiver where the applicant fails to meet the minimum requirements in order to receive consideration, or is otherwise deemed abandoned pursuant to this chapter.
- (2) “Adulterated medical marijuana” means marijuana as defined by division (A)(1) of section 3796.01 of the Revised Code in which any of the following applies:
 - (a) A substance has been mixed or packed with the medical marijuana so as to reduce the quality or strength or the substance has been substituted wholly or in part for the marijuana;
 - (b) It consists, in whole or in part, of any filthy, putrid, or decomposed substance, including mold, mildew, and other contaminants;
 - (c) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or
 - (d) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- (3) “Batch” means:
 - (a) All of the plant material of the same variety of medical marijuana not to exceed 15 pounds of manicured, dried flowers or buds or 25 pounds of plant material, excluding flowers and buds, that have been:
 - (i) Grown, harvested, and processed together; and
 - (ii) Exposed to the same conditions throughout cultivation.
 - (b) Any amount of medical marijuana extract resulting from a single iteration of a specified extraction process, using the same batch or batches of plant material, as defined in paragraph (A)(3)(a) of this rule.
- (4) “Batch number” means a unique numeric or alphanumeric identifier assigned prior to testing to allow for inventory tracking and traceability.
- (5) “Bona fide physician-patient relationship” shall have the same meaning as used in the rule promulgated by the state medical board of Ohio under section 4731.301 of the Revised Code.
- (6) “Certificate of operation” means a license authorizing a medical marijuana entity to begin operating pursuant to Chapter 3796. of the Revised Code.
- (7) “Clone” means a non-flowering plant cut from a mother plant that is no taller than eight inches and is capable of developing into a new plant.
- (8) “Cultivate” means to grow, harvest, package and transport medical marijuana pursuant to Chapter 3796. of the Revised Code.
- (9) “Cultivator”, as used in Chapter 3796. of the Revised Code, means an entity that has been issued a certificate of operation by the department to grow, harvest, package and transport medical marijuana as permitted under Chapter 3796. of the Revised Code.
- (10) “Department” means the Ohio department of commerce.

- (11) “Designated caregiver” or “caregiver” means the individual designated by a registered patient in a registry application and who holds an active caregiver identification card.
- (12) “Designated territory” means a specific region within the state, as determined by the program.
- (13) “Director” means the director of the Ohio department of commerce.
- (14) “Dispensary”, as used in Chapter 3796. of the Revised Code, means an entity licensed pursuant to sections 3796.04 and 3796.10 of the Revised Code and any rules promulgated thereunder to sell medical marijuana to qualifying patients and caregivers.
- (15) “Dispense” means the delivery of medical marijuana to a patient or the patient’s registered caregiver that is packaged in a suitable container appropriately labeled for subsequent administration to or use by a patient who has an active patient registration with the state of Ohio board of pharmacy, authorizing them to receive medical marijuana.
- (16) “Disqualifying offense” means:
 - (a) A conviction or plea of guilty, including conspiracy to commit, attempt to commit, or aiding and abetting another in committing, the following:
 - (i) Any offense set forth in chapters 2925, 3719, or 4729 of the Revised Code, the violation of which constitutes a felony or misdemeanor of the first degree;
 - (ii) Any theft offense set forth under division (K) in section 2913.01 of the Revised Code, the violation of which constitutes a felony;
 - (iii) Any violation for which a penalty was imposed under section 3715.99 of the Revised Code;
 - (iv) A crime of moral turpitude as defined in section 4776.10 of the Revised Code; or
 - (v) A violation of any former law of this state, any existing or former law of another state, any existing or former law applicable in a military court or Indian tribal court, or any existing or former law of any nation other than the United States that is or was substantially equivalent to any of the offenses listed in paragraphs (i) through (iv).
 - (b) Any first degree misdemeanor offense listed in paragraphs (a)(i) through (v) will not automatically disqualify an applicant from licensure if the applicant was convicted of or pleaded guilty to the offense more than five years before the date the application for licensure is filed.
 - (c) Notwithstanding divisions (a) or (b) of this section, no misdemeanor offense, including misdemeanors of the first degree, related to marijuana possession, marijuana trafficking, illegal cultivation of marijuana, illegal use or possession of drug paraphernalia or marijuana drug paraphernalia, or other marijuana related crimes shall be considered a disqualifying offense.
- (17) “Employee identification card” means a badge issued by the department to an applicant in accordance with rule 3796:5-2-1 of the Administrative Code.
- (18) “Expired” means medical marijuana that is beyond:
 - (a) The date specified by the cultivator in its labeling for plant material, not to exceed one calendar year from its harvest date;
 - (b) The date specified by the processor in its labeling for medical marijuana products, not to exceed one calendar year from its production date; or
 - (c) Fourteen days of the opening of its processor-originated package by a dispensary employee.

- (19) "Financial interest" means any actual or future right to ownership, investment or compensation arrangement with another person, either directly or indirectly, through business, investment, spouse, parent, or child, in a medical marijuana entity. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national securities exchange or over-the-counter market in the United States, provided the investment securities held by the person and the person's spouse, parent, or child, in the aggregate, do not exceed one percent ownership in the medical marijuana entity.
- (20) "Flowering stage" means the stage of cultivation where and when a marijuana plant is cultivated to produce plant material for medical marijuana products. This includes mature plants which are identified by:
- (a) If greater than two stigmas are visible at each internode of the plant, or
 - (b) If the marijuana plant is in an area that has been intentionally deprived of light for a period of time intended to produce flower buds and induce maturation, from the exact moment the light deprivation has started to occur and for the remainder of the marijuana plant growth cycle in such area.
- (21) "Inventory tracking system" means the electronic database referenced in section 3796.07 of the Revised Code used to monitor medical marijuana.
- (22) "Label" means a display of printed information on the immediate container or affixed to the container of any product containing medical marijuana.
- (23) "Law enforcement" means a police department, office of a sheriff, state highway patrol, a county prosecuting attorney, or a federal, state, or local governing body that enforces criminal law and that has employees that have statutory power of arrest.
- (24) "Level I cultivator" means a cultivator that is permitted to operate up to 25,000 square footage of space designated as the marijuana cultivation area in the application, unless a request for expansion is approved by the director of the department under rule 3796:2-1-09 of the Administrative Code.
- (25) "Level II cultivator" means a cultivator that is permitted to operate up to 3,000 square footage of space designated as the marijuana cultivation area in the application, unless a request for expansion is approved by the director of the department under rule 3796:2-1-09 of the Administrative Code.
- (26) "Lot" means any amount of medical marijuana products of the same exact type produced using the same ingredients, extraction methods, standard operating procedures, and batches of plant material or marijuana extract.
- (27) "Lot number" means a unique numeric or alphanumeric identifier assigned prior to testing to allow for inventory tracking and traceability.
- (28) "Manufacture" means the process of converting harvested plant material into marijuana extract by physical or chemical means for use as an ingredient in a medical marijuana product.
- (29) "Marijuana cultivation area" means the boundaries of the enclosed areas in which medical marijuana is cultivated during the vegetative stage and flowering stage of the cultivation process. For purposes of calculating the marijuana cultivation area square footage, enclosed areas used solely for the storage and maintenance of mother plants, clones, or seedlings shall not be included.
- (30) "Medical marijuana" has the same meaning as defined in division (A)(2) of section 3796.01 of the Revised Code.

- (31) “Medical marijuana entity” means a licensed medical marijuana cultivator, processor, dispensary, or testing laboratory.
- (32) “Medical marijuana extract” means a substance obtained by separating cannabinoids from any part of the marijuana plant by physical or chemical means, so as to deliver a product with a cannabinoid concentration greater than the raw plant material from which it is derived, intended to be refined for use as an ingredient in a medical marijuana product and not for administration to a registered patient.
- (33) “Medical marijuana product” means a product that contains cannabinoids that have been extracted from plant material or the resin therefrom by physical or chemical means and is intended for administration to a registered patient, including but not limited to oils, tinctures, edibles, patches, and other forms approved under division (A)(6) of section 3796.06 of the Revised Code. Medical marijuana products shall have a THC content of not more than seventy percent.
- (34) “Medical purpose” means the acquisition, administration, delivery, possession, transfer, transportation, or use of medical marijuana to treat or alleviate a registered patient's qualifying medical condition or symptoms associated with the patient's qualifying medical condition.
- (35) “Mother plant” means a marijuana plant that is cultivated or maintained for the purpose of generating clones, and that will not be used to produce plant material for sale to a processor or dispensary.
- (36) “Person” includes, but is not limited to, a natural person, sole proprietorship, partnership, joint venture, limited liability partnership or company, corporation, association, agency, business, and not-for-profit organization.
- (37) “Physician” means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.
- (38) “Plant material” means the leaves, stems, buds, and flowers of the marijuana plant, and does not include seedlings, seeds, clones, stalks, or roots of the plant or the weight of any non-marijuana ingredients combined with marijuana.
- (39) “Plant-only processor” means a cultivator, as defined in paragraph (A)(9) of this rule, that has received a license from the department for the limited purposes of packaging, selling, and delivering finished plant material directly to a licensed dispensary for sale to a patient or caregiver.
- (40) “Processor”, as used in Chapter 3796. of the Revised Code, means an entity that has been issued a certificate of operation by the department to manufacture medical marijuana products.
- (41) “Product identifier” means the unique number assigned by the Ohio board of pharmacy for each dose and quantity of a registered product created by a cultivator or processor to allow for inventory and traceability.
- (42) “Program” means the Ohio Medical Marijuana Control Program.
- (43) “Prohibited facility” means any school, church, public library, public playground, or public park, as defined in section 3796.30 of the Revised Code.
- (44) “Provisional license” means a temporary license issued to a medical marijuana entity that establishes the conditions that must be met by the medical marijuana entity before the entity is issued a certificate of operation.
- (45) “Provisional licensee” means an applicant issued a provisional license to operate as a medical marijuana entity upon the issuance of a certificate of operation.

- (46) “Qualified applicant” means an applicant for a medical marijuana entity license that receives at least the minimum score in every category outlined in the scoring rubric developed by the department.
- (47) “Recommending physician” means a physician, as defined by division (A)(5) of section 3796.01 of the Revised Code, that holds a valid certificate to recommend medical marijuana issued by the state medical board of Ohio under section 4731.30 of the Revised Code.
- (48) “Registered patient,” or “patient” as used in Chapter 3796. of the Revised Code, means an Ohio resident who has applied to the state of Ohio board of pharmacy pursuant to section 3796.08 of the Revised Code and who holds an active patient identification card. This also includes residents of states with which reciprocity is established pursuant to section 3796.16 of the Revised Code and otherwise satisfy the requirements to use medical marijuana.
- (49) “Testing laboratory” means an independent laboratory located in Ohio that has been issued a certificate of operation by the department to have custody and use of controlled substances for scientific and medical purposes and for purposes of instruction, research, or analysis.
- (50) “Tetrahydrocannabinol content” or “THC content” means the sum of the amount of delta-9-tetrahydrocannabinol (THC) and eighty-seven point seven (87.7%) percent of the amount of delta-9-tetrahydrocannabinolic acid (THCA) present in the product or plant material.
- (51) “Unique plant identifier” means a numeric or alphanumeric sequence, as determined by the department, that is assigned to an individual plant when a plant reaches 12 inches in height or is transplanted from a cloning medium or apparatus into a growth medium or apparatus intended for the vegetative or flowering stages of the growth cycle, whichever occurs sooner, to allow for inventory and traceability in the inventory tracking system.
- (52) “Vegetative stage” means the stage of cultivation where and when a marijuana plant is propagated to produce additional marijuana plants or reach a sufficient size for production. This includes "seedlings", "clones", "mothers," and other immature marijuana plants identified by:
 - (a) Having no more than two stigmas visible at each internode of the marijuana plant and if the marijuana plant is in an area that has not been intentionally deprived of light for a period of time intended to produce flower buds and induce maturation, or
 - (b) Any marijuana plant that is cultivated solely for the purpose of propagating clones and is never used to produce any medical marijuana.

3796:2 Medical Marijuana Cultivators

3796:2-1 Licensing of Medical Marijuana Cultivators

3796:2-1-01 Number of cultivator provisional licenses

- (A) Until September 8, 2018, the director of the department of commerce or the director’s designee may issue up to 12 Level I and 12 Level II cultivator provisional licenses, with no more than three Level I and three Level II cultivator provisional licenses being issued in any one

designated territory, in consideration of the ranking of the applicants in accordance with the criteria listed in section 3796.09 of the Revised Code and this chapter.

- (B) Beginning September 9, 2018 and in accordance with section 3796.05 of the Revised Code, the director or the director's designee may issue additional provisional licenses for cultivators in a designated territory, if the population of this state and the number of patients seeking to use medical marijuana support additional licenses, at the discretion of the director.
- (C) In the event additional provisional licenses are deemed necessary, the department will follow the application procedures outlined in rule 3796:2-1-02 of the Administrative Code.

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 in any designated territory, and an applicant for a Level II cultivator provisional license shall be prohibited from applying for a Level I cultivator provisional license in any designated territory. An applicant for a Level I or Level II 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 of the Administrative Code. Each application for a particular designated territory shall be a separate application requiring a separate fee;
 - (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 applicant's facility;
 - (e) 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 21 years of age;
 - (f) All persons subject to the criminal records checks shall submit both a BCI&I 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 this chapter and 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 this chapter and 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 500 feet from the boundaries of a parcel of real estate having situated on it a prohibited facility, as measured under rule 3796:5-5 of the Administrative Code;
 - (j) If currently or 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/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 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, operating an agriculturally related business, or operating a horticultural business;
 - (c) A list of proposed medical marijuana varieties proposed to be grown with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;
 - (d) Facility plans and specifications, including the 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 this chapter and section 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 this chapter and 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 organization 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 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. 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, producer backer, 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 \$500,000 in liquid assets for a Level I cultivator provisional license and \$50,000 in liquid assets for a Level II cultivator provisional license, which are unencumbered and can be converted within 30 days after a request to liquidate such assets;

- (i) Documentation acceptable to the department includes a signed statement from an Ohio Licensed CPA attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying. The statement must be dated within 30 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 this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest in the applicant for the three years before the filing of the application.
- (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.

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 of the Administrative Code; or
 - (b) Certified or applied for certification under Chapter 4731. of the Revised Code;
 - (3) Verify that the proposed facility is not located within 500 feet from a prohibited facility, which shall be measured in accordance with rule 3796:5-5 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, a compensation arrangement with, or share any corporate officers or employees with any of the following:
 - (a) A laboratory licensed under this chapter;
 - (b) An applicant for a license to conduct laboratory testing;
 - (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 of the Administrative Code that does not contain information that misleads the department, misrepresents a material fact, or is received after the established 14-day submission period.

(B) The applicants shall be ranked using an impartial and numerical scoring rubric developed by the department, an independent contractor selected by the department, or a combination of the two. The department may revisit the scoring rubric and make changes that are necessary to evaluate the suitability of an applicant for a cultivator, processor, or testing laboratory license. At a minimum, the scoring rubric shall include the following weighted criteria:

(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 21 years of age;
- (c) Experience, which includes information on licenses held by any person affiliated with the applicants, regardless if said license is active or expired. If expired, applicant shall provide the grounds behind the expiration.
- (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 this chapter and 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 this chapter and Chapter 3796. of the Revised Code;
- (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.
 - (i) 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 the application.

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

- (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, operating an agriculturally related business, or operating a horticultural business;
- (c) A list of proposed medical marijuana varieties proposed to be grown with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;
- (d) Facility plans and specifications, including the 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 this chapter and section 3796. of the Revised Code;
and
- (e) Staffing and training guidelines.
- (3) A quality assurance plan, which shall include but not be limited to:
- (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 organization 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 this chapter;
 - (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 with rule 3796:5-3 of the Administrative Code.
- (5) A financial plan, which, at a minimum, shall include:
- (a) The identity and ownership interest of every person, association, producer backer, 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 \$500,000 in liquid assets for a Level I cultivator provisional license and \$50,000 in liquid assets for a Level II cultivator provisional license, which are unencumbered and can be converted within 30 days after a request to liquidate such assets;
 - (i) Documentation acceptable to the department includes a signed statement from an Ohio Licensed CPA attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying. The statement must be dated within 30 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 this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest in the applicant for the three years before the filing of the application.
 - (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 weighted 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: The applicant must provide documentation establishing that its principal place of business is headquartered in Ohio. The names, addresses, and verification of any persons associated with the applicant that have established residency in Ohio. The applicant may also provide a plan for generating Ohio-based jobs and economic development.
 - (2) Environmental Plan: The applicant may demonstrate an environmental plan of action to minimize the carbon footprint, energy usage, environmental impact, and resource needs for the production of medical marijuana. The applicant may 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: The applicant may demonstrate a plan of action to inform, hire, and educate minorities, women, veterans, disabled persons, and Ohio residents.
 - (4) Verification of Economically Disadvantaged Groups: The applicant must demonstrate that:
 - (a) 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 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
 - (b) 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 subparagraph (a) above.
 - (5) Research Plan: The applicant may 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 30 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 30 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.

3796:2-1-04 Cultivator provisional license award

(A) A provisional license shall be issued to the Level I and Level II qualified applicant receiving at least the minimum required score in each category and the highest total score overall as compared to the other applicants within a designated territory where a provisional license is being issued. In any designated territory where it is determined that more than one provisional license will be issued for a particular level of cultivator, the additional provisional license shall be issued to the qualified applicant receiving at least the minimum required score in each category and the next highest score overall as compared to the other applicants within that designated territory. If an applicant receives the highest score in more than one designated territory, the applicant shall choose the designated territory in which it will be issued a provisional license.

(B) In the event that two or more qualified applicants for a cultivator provisional license receive the same total score, the department shall select the applicant that received the highest score in the operations plan category. In the event that the same two 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, a certificate of operation is revoked in a designated territory, or no license is issued or active in a particular designated territory for any other reason, the department may, at the discretion of the director, announce another period to submit an application for that designated territory in accordance with rule 3796:2-1-02 of the Administrative Code. If the department announces another application period for that designated territory, 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 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, or member 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, or member of more than one cultivator.

3796:2-1-05 Cultivator financial responsibility.

- (A) A provisional licensee shall provide evidence of financial responsibility before a certificate of operation can be issued, which may be payable to the department if:
- (1) A cultivator fails to adhere to the security plan approved by the department or otherwise operates the facility in a manner that allows for or results in theft, loss, or diversion of medical marijuana;
 - (2) A cultivator engages in activities prohibited under rule 3796:2-2-07 of the Administrative Code; or
 - (3) A cultivator has its certification of operation revoked resulting from activities prohibited under rule 3796:5-6-02 of the Administrative Code.
- (B) Evidence of financial responsibility shall be provided by:
- (1) Providing and maintaining at all times and at its own expense any insurance coverage and terms of insurance required and approved by the department prior to the issuance of a certificate of operation; and
 - (2) Establishing and maintaining an escrow account in a chartered financial institution in Ohio in the amount of \$1,500,000 for Level I cultivators and \$150,000 for Level II cultivators, with escrow terms, approved by the department, that it shall be payable to the department in the event of circumstances outlined in paragraph (A) of this rule. A financial institution may not return money in an escrow or surety account to the cultivator that established the account or a representative of the cultivator unless the cultivator or representative presents a statement issued by the department indicating that the account may be released; or
 - (3) Providing a surety bond naming the cultivator as principal of the bond, upon terms approved by the department, in the amount of \$1,500,000 for Level I cultivators and \$150,000 for Level II cultivators payable to the department in the event of circumstances outlined in paragraph (A) of this rule. Bond terms include:
 - (a) The business name and registration number on the bond must correspond exactly with the business name and registration number in the department's records.
 - (b) A copy of the bond must be received by the department before a certificate of operation is issued.
 - (c) The bond shall not be canceled by a surety on less than 30 days' notice in writing to the department. If a bond is canceled and the cultivator fails to file a new bond with the department in the required amount on or before the effective date of cancellation, the cultivator's license shall be revoked. The total and aggregate liability of the surety on the bond is limited to the amount specified on the bond.
 - (4) The department shall permit a cultivator to reduce the escrow or surety bond by \$500,000 for Level I cultivators and \$50,000 for Level II cultivators upon the successful achievement of each of the following milestones, resulting in a potential elimination of the escrow account or surety bond:
 - (a) A determination by the department that the cultivator remained fully operational without substantial interruption and was able to provide and maintain an uninterrupted supply of medical marijuana, in accordance with rule 3796:2-1-07 of the Administrative Code, and demonstrates an ability to comply with the requirements of this chapter and Chapter 3796. of the Revised Code, as determined by the department, for a period of one year;

- (b) A determination by the department that the cultivator remained fully operational without substantial interruption and was able to provide and maintain an uninterrupted supply of medical marijuana, in accordance with rule 3796:2-1-07, and demonstrates an ability to comply with the requirements of this chapter and Chapter 3796. of the Revised Code, as determined by the department, for two consecutive years; and
 - (c) A determination by the department that the cultivator remained fully operational without substantial interruption and was able to provide and maintain an uninterrupted supply of medical marijuana, in accordance with rule 3796:2-1-07, and demonstrates an ability to comply with the requirements of this chapter and Chapter 3796. of the Revised Code, as determined by the department, for three consecutive years.
- (5) A cultivator will not be held in default should the failure to comply be the direct result of an event or effect that cannot be reasonably anticipated or controlled, such as an act of God or nature and not the result of a lack of good faith effort.

(C) The required insurance policy and surety bond shall be written by an insurance company formed, licensed or eligible, and authorized or approved to write such insurance in the state of Ohio under Title 39 of the Revised Code.

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 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 3796:2-3-01 of the Administrative Code within nine months of written or electronic notification of the applicant's selection. 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) 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 officials upon request.

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 and 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 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 license 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 requirement 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).
- (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.

3796:2-1-08 Cultivator 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 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 this chapter, Chapter 3796. of the Revised Code, and the following requirements under this rule.

- (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 a BCI&I 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, this chapter 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) Verify that the new location is situated in the same designated territory as the current location;
 - (c) Submit plans and specifications for the new facility in accordance with rule 3796:2-1-02 of the Administrative Code; and
 - (d) 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 this chapter 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 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 90 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 90-day transition period shall be destroyed in accordance with rule 3796:2-2-03 of the Administrative Code.
- (4) The cultivation center 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 this chapter, 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.

3796:2-1-09 Cultivator marijuana cultivation area expansion

- (A) Beginning September 9, 2018, the director or the director's designee, at his or her discretion, may approve a marijuana cultivation area expansion of an existing cultivator's facility, such that the approval of a proposed initial expansion shall not result in a total marijuana cultivation area that exceeds 50,000 square feet for Level I cultivators and 6,000 square feet for Level II cultivators, based on cultivator compliance with licensure requirements and other factors related to the Program. The director, at his or her discretion, may approve a subsequent expansion of an existing facility's marijuana cultivation area of up to 25,000 square feet for Level I cultivators and 3,000 square feet for Level II cultivators, based on cultivator compliance with licensure requirements, if the population of the state, number of patients seeking to use medical marijuana, and data from the inventory tracking system regarding patient recommendations and patient usage of medical marijuana support such expansion. In the event the director or the director's designee approves both expansions of a facility's marijuana cultivation area, the marijuana cultivation area shall not exceed 75,000 square feet for Level I cultivators and 9,000 square feet for Level II cultivators.
- (B) A cultivator seeking to expand its marijuana cultivation area shall submit an expansion plan, which, at a minimum, shall:
- (1) Include plans and specifications for the expansion or alteration in accordance with rule 3796:2-1-02 of the Administrative Code that demonstrate compliance with the requirements of the rules adopted by the board of building standards pursuant to Chapters 3781. and 3791. of the Revised Code and the rules adopted by the state fire marshal pursuant to Sections 3737.82 and 3737.86 of the Revised Code;
 - (2) Propose a timeline for completion of the proposed expansion, which, if approved, will become a mandatory condition;
 - (3) Demonstrate a history of compliance with Chapter 3796. of the Revised Code and this chapter, which includes a history of enforcement actions and sanctions issued by the department or law enforcement against the cultivator;
 - (4) Provide supporting documentation that cultivator has consistently met the cultivation requirements under rule 3796:2-1-07 of the Administrative Code; and
 - (5) Demonstrate to the department that the proposed expansion meets the applicable requirements of rule 3796:2-1-02 of the Administrative Code and that the cultivator will remain in compliance with this chapter and Chapter 3796. of the Revised Code, if the expansion is permitted.
- (C) Upon the department's receipt of a request for expansion, that department shall have a reasonable time to review and approve or deny a request for expansion. If approved, the cultivator will be bound to the terms in the request for expansion and must pass an inspection pursuant to rule 3796:2-3-01 of the Administrative Code prior to cultivating medical marijuana in the expanded marijuana cultivation area. A cultivator's failure to comply with the approved

request for expansion may result in the revocation of the department's approval or additional sanctions under rule 3796:5-6 of the Administrative Code. A cultivator shall not submit a request for expansion more than once during any twelve month period.

- (D) If the director or the director's designee determines that additional cultivation capacity is necessary to meet the demand for medical marijuana based on the population of this state, number of patients seeking to use medical marijuana, and data from the inventory tracking system regarding patient recommendations and patient usage of medical marijuana, the director may request expansion plans from existing cultivators in accordance with paragraphs (B) and (C) of this 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 of the Administrative Code, shall be filed with the department at least 30 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 30 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.

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 90 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 60 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 the 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, this chapter, 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 30 days of receipt. The director may request additional information if approval or denial of the plan cannot be determined based on the information provided.

3796:2-2 Cultivator Operations

- (A) A cultivator shall establish, maintain, and comply with the policies and procedures contained in the operations plan submitted by the cultivator as part of the application that was approved by the department. The operations plan shall include policies and procedures for the production, storage, inventory, and transportation of medical marijuana. At a minimum, a facility's operations plan shall accomplish the following:
- (1) Designate areas in the facility that are compartmentalized based on function, such as the marijuana cultivation area, with restricted access between the different areas of the facility;
 - (2) Implement policies and procedures that provide best practices for secure and proper cultivation of medical marijuana, which includes restricted movement between the different production areas by personnel based on access credentials assigned by the facility;
 - (3) Document the chain for all medical marijuana in the inventory tracking system;
 - (4) Establish a standard for the facility to be maintained in a clean and orderly condition, which includes free from infestation by rodents, insects birds and other animals of any kind; and
 - (5) Maintain a facility with adequate lighting, ventilation, temperature, sanitation, equipment and security for the safe and consistent cultivation of medical marijuana.

3796:2-2-01 Cultivator quality assurance plan

- (A) A cultivator shall submit, as part of the application process, and maintain a quality assurance and quality control plan for the cultivation of medical marijuana in its facility. The purpose of the plan is to ensure a safe, consistent product supply and minimize the deviation in quality of the production batches of medical marijuana.
- (1) A cultivator shall submit any proposed changes to its plan to the department 60 days before the effective date of the proposed changes. The department shall have 30 days to review and approve or reject the proposed changes.

(B) Pesticide and Fertilizer Usage

- (1) The department, with assistance from Ohio's department of agriculture, shall maintain an approved list of permitted pesticides, fertilizers, chemicals and plant growth regulators. The department shall make this list with the label type, active ingredients, and concentration of the approved pesticides, fertilizers, chemicals, and plant growth regulators available electronically.
- (2) The pesticides must be registered with the Ohio department of agriculture and either:
 - (a) Registered with the United States Environmental Protection Agency under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 - 136y (2012); or
 - (b) Exempt from registration under [40 C.F.R. 152.25\(f\)](#) and the active and inert ingredients of the pesticide product are authorized for use on crops or plants intended for human consumption by the United States Environmental Protection Agency.
- (3) Any specialty fertilizer, as defined in division (Q) of section 905.31 of the Revised Code, must be registered with the Ohio department of agriculture pursuant to section 905.33 of the Revised Code.
- (4) No application of pesticides or fertilizers shall be made after the twenty-first day following when a plant is moved into the flowering stage of growth, unless otherwise permitted on the department's approved list.
- (5) All individuals applying pesticides or fertilizers shall adhere to the use requirements of the label and shall employ all personal protective equipment.
- (6) The cultivator shall comply with all posting requirements of the standard protection language stated on the label.
- (7) A record of all pesticide or fertilizer applications shall be maintained by the cultivator for at least five years and shall be made available to the department upon request. The application record shall include the following information:
 - (a) Date and time of application;
 - (b) Stage of cultivation process;
 - (c) Date when the plants in the application area were moved to the flowering stage, if applicable;
 - (d) United States Environmental Protection Agency Registration Number, if applicable;
 - (e) Analysis of the fertilizer applied;
 - (f) Application site (the site shall be identified by the location legend maintained by the cultivator);
 - (g) Name of the product being applied;
 - (h) Amount applied;
 - (i) Unique plant identifier or other information that identifies which plants received the application;
 - (j) Size of the application area;
 - (k) Name of individual making the application; and
 - (l) Section for comments or special conditions related to the application.
- (8) Disposal of all unused pesticide or fertilizer products shall be performed in compliance with all state and federal laws and regulations, which require compliance with all directions on the product label.

(9) The use of a pesticide or fertilizer by a cultivator that is inconsistent with the product's label or in violation of paragraph (B) of this rule may result in action being taken by the department pursuant to rule 3796:5-6-01 of the Administrative Code.

(C) A cultivator shall maintain a facility in the following manner:

- (1) A cultivator shall keep all floors and benches free of debris, dust, and any other potential contaminants, remove dead and unusable plant parts from the marijuana cultivation area, and control rodents and other non-plant related pests.
- (2) A cultivator shall use chemicals, cleaning solutions, and other sanitizing agents approved for use around vegetables, fruit, or medicinal plants and shall store them in a manner that protects against contamination.
- (3) A cultivator shall keep its equipment in a clean, professional environment and maintain a cleaning and equipment maintenance log at the facility.
- (4) The cultivator shall have its scales, balances, or other weight and/or mass measuring devices routinely calibrated using National Institute of Standards and Technology (NIST)-traceable reference weights, at least once each calendar year.
- (5) The water supply shall be derived from a source that is a regulated water system and shall meet the needs of the cultivator. A private water supply shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water.
- (6) A cultivator shall implement policies and procedures related to receiving, inspecting, transporting, segregating, preparing, packaging, and storing medical marijuana in accordance with adequate sanitation principles.

3796:2-2-02 Cultivator and plant only processor packaging and labeling

(A) A cultivator distributing plant material to a processor shall meet the following requirements:

- (1) A cultivator shall place plant material in a tamper-evident, opaque package approved by the department prior to distributing plant material to a processor. Approved packaging shall maintain the integrity and stability of the plant material.
- (2) A label shall be affixed to every package and state in legible English:
 - (a) The name and license number of the cultivator where the packaged material was cultivated and harvested;
 - (b) The name and license number of the processor facility receiving the shipment;
 - (c) The product identifier;
 - (d) The registered name of the medical marijuana that was registered with the department;
 - (e) A unique identification number that will match the medical marijuana with a batch and batch number to facilitate any warnings or recalls the department deems appropriate;
 - (f) The date of harvest, final testing, and packaging;
 - (g) The total weight in grams of plant material in each package;
 - (h) The identification of the independent testing laboratory;
 - (i) The laboratory analysis, profile and a list of all active ingredients, including the percentage content by weight for the following cannabinoids, at a minimum:
 - (i) Delta 9-tetrahydrocannabinol (THC);
 - (ii) Delta 9-tetrahydrocannabinolic acid (THCA);
 - (iii) cannabidiol (CBD); and
 - (iv) cannabidiolic acid (CBDA);

- (j) The expiration date, which shall not exceed one calendar year from the date of harvest; and
 - (k) A statement with the following language: “This product is for medical use and not for resale or transfer to another person. This product may have intoxicating effects and may be habit-forming. This product may be unlawful outside the State of Ohio.”
- (B) A cultivator with a plant only processor license distributing plant material to a dispensary shall meet the following requirements:
- (1) A cultivator shall place plant material in a child-proof, tamper-evident, opaque package approved by the department prior to distributing plant material to a dispensary. Approved packaging shall maintain the integrity and stability of the plant material.
 - (2) A label shall be affixed to every package and state in legible English:
 - (a) The name and license number of the cultivator where the packaged material was cultivated and harvested;
 - (b) The name and license number of the dispensary receiving the shipment;
 - (c) The product identifier;
 - (d) The registered name of the medical marijuana that was registered with the department;
 - (e) A unique identification number that will match the medical marijuana with a batch and batch number to facilitate any warnings or recalls the department deems appropriate;
 - (f) The date of harvest, final testing and packaging;
 - (g) The total weight in grams of plant material in each package;
 - (h) The identification of the independent testing laboratory;
 - (i) The laboratory analysis, profile, and a list of all active ingredients, including the percentage content by weight for the following cannabinoids, at a minimum:
 - (i) Delta 9-tetrahydrocannabinol (THC);
 - (ii) Delta 9-tetrahydrocannabinolic acid (THCA);
 - (iii)Cannabidiol (CBD); and
 - (iv)Cannabidiolic acid (CBDA);
 - (j) The expiration date, which shall not exceed one calendar year from the date of harvest; and
 - (k) A statement with the following language: “This product is for medical use and not for resale or transfer to another person. This product may have intoxicating effects and may be habit-forming. This product may be unlawful outside the State of Ohio.”
- (C) A label may contain the approval or certification logo of a third-party certifier of cultivation practices whose protocols have been reviewed and approved by the department.
- (D) A label shall not contain:
- (1) Any false or misleading statement or design;
 - (2) Depictions of the product, cartoons, or images that are not registered with the department, which includes any insignia related to a governmental entity;
 - (3) Any sum totals of cannabinoids or terpenes, except as defined in paragraph (A)(50) of rule 3796:1 of the Administrative Code; or
 - (4) Any information that would violate paragraph (E) of rule 3796:5-7 of the Administrative Code.

- (E) A cultivator may provide a dispensary free samples of plant material sold at the dispensary. A free sample shall be packaged in a sample jar protected by a plastic or metal mesh screen to allow patients and caregivers to smell the plant material before purchase. A sample jar may not contain more than three grams of a particular strain of plant material. The sample jar and the plant material within may not be sold to a patient or caregiver and shall be destroyed by the dispensary after use by the dispensary. The dispensary shall document the destruction of every free sample in accordance with the rules established pursuant to Chapter 3796. of the Revised Code.
- (F) It is prohibited for anyone to knowingly or intentionally alter, obliterate, or otherwise destroy any container or label attached to an approved container. In the event a container or label is altered, obliterated, or otherwise destroyed, the department may act in accordance with rule 3796:5-6-01 of the Administrative Code.

3796:2-2-03 Cultivator waste disposal

- (A) A licensed cultivator shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded or deteriorated medical marijuana waste in the following manner:
- (1) By disposal executed in accordance with the cultivator's disposal plan under the supervision of a Type 1 employee and in such a manner as to render the medical marijuana waste unusable; or
 - (2) By surrender without compensation of such medical marijuana to the director or the director's designee, at the director's discretion.
- (B) The disposal procedures established by the cultivator and submitted as part of the application process shall be sufficient to render medical marijuana waste unusable. Medical marijuana waste that is rendered unusable shall be discarded into a locked dumpster or other approved, locked container for removal from the facility by a waste removal company selected by the cultivator, or may be composted in a secured area at the cultivation site for future use at the facility. Medical marijuana waste shall be rendered unusable by grinding and incorporating the medical marijuana waste with one or more of the non-consumable, solid wastes listed below, such that the resulting mixture is at least 51% non-marijuana waste:
- (1) Paper waste;
 - (2) Cardboard waste;
 - (3) Food waste;
 - (4) Yard or garden waste;
 - (5) Grease or other compostable oil waste;
 - (6) Bokashi, or other compost activators;
 - (7) Soil or other used growth media; or
 - (8) Other wastes approved by the department.
- (C) The disposal of medical marijuana shall be performed by a Type 1 key employee in the designated destruction area identified in the cultivator's plans and specifications submitted to the department. The disposal shall be performed under video surveillance from the time the

destruction begins to when it is placed in a locked dumpster or other approved, locked container and removed from the facility.

- (D) The Type 1 key employee overseeing the disposal of medical marijuana shall maintain and make available in accordance with this chapter a separate record of every disposal indicating:
- (1) The date and time of disposal;
 - (2) The manner of disposal;
 - (3) The volume and weight of the approved solid waste media used to render the medical marijuana unusable;
 - (4) The unique identification codes associated with the medical marijuana scheduled for destruction;
 - (5) The reasoning for and description of the disposal;
 - (6) The signature of the Type 1 employee overseeing the disposal of the medical marijuana; and
 - (7) If the medical marijuana waste for disposal contains plant material that was prepared for sale to a dispensary or processor, the batch number, strain, volume, and weight of the plant material being disposed of.
- (E) The disposal of other waste from the cultivator that does not include medical marijuana, including hazardous waste and liquid waste, shall be performed in a manner consistent with federal and state law.

3796:2-2-04 Cultivator inventory control and storage

- (A) A cultivator shall track and submit into the inventory tracking system any information the department determines necessary for maintaining and tracking medical marijuana. When a plant reaches 12 inches in height or is transplanted from a cloning medium or apparatus into a growth medium or apparatus intended for the vegetative or flowering stages of the growth cycle, whichever occurs sooner, the cultivator shall securely attach a tag to the plant or the plant's container that includes, at a minimum, the following information:
- (1) The cultivator's name and license number;
 - (2) The registered name of the strain;
 - (3) The unique plant identifier; and
 - (4) General information regarding the plant that is used for traceability.
- (B) Prior to commencing business, each cultivator shall:
- (1) Conduct an initial comprehensive inventory of all medical marijuana at the cultivator. If the cultivator commences business with no medical marijuana on hand, the cultivator shall record this fact as the initial inventory; and
 - (2) Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana for traceability in the department's inventory tracking system, which shall enable the cultivator to detect any diversion, theft, or loss in a timely manner.
- (C) Upon commencing business, each cultivator shall prepare a weekly inventory of medical marijuana at the facility, which shall include, at a minimum:

- (1) The date of the inventory;
- (2) The amount of medical marijuana on hand, which shall include:
 - (a) The total count of plants, whether in the flowering, vegetative, or clone phase of growth and organized by room in which the plants are being grown;
 - (b) The batch number, weight, and strain name associated with each batch at the cultivator's facility that has been quarantined for testing or ready for sale to a processor or dispensary; and
 - (c) The total number of plants and every unique plant identifier that have been harvested, but are not yet associated with a batch.
- (3) The amount of medical marijuana sold since previous weekly inventory, which shall include:
 - (a) The date of sale;
 - (b) The license number and name of the processor or dispensary to which the medical marijuana was sold; and
 - (c) The batch number, registered product name and quantity of medical marijuana sold.
- (4) The date, quantity, and method of disposal of medical marijuana, if applicable;
- (5) A summary of the inventory findings; and
- (6) The name, signature, and title of the employees who conducted the inventory and oversaw the inventory.

(D) On an annual basis and as a condition for renewal of a cultivator license, a key employee shall conduct a physical, manual inventory of the medical marijuana on hand at the cultivator and compare the findings to an annual inventory report generated using the inventory tracking system. If any discrepancies are discovered outside of loss standard to the industry due to moisture loss and handling, the key employee shall report such findings to the department in accordance with rule 3796:5-4 of the Administrative Code.

(E) All inventories, procedures and other documents required by this rule shall be maintained on the premises and made available to the department at all times.

(F) A cultivator is authorized to store medical marijuana inventory on the premises in a designated, enclosed, locked facility identified in the cultivator's plans and specifications submitted to the department and accessible only by authorized individuals. Notwithstanding the requirements of this chapter, nothing shall prohibit members of the department, a department's designee, law enforcement, or other federal, state, or local government officials from entering any area of a cultivator if necessary to perform their governmental duties.

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:

- (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; and
 - (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 room. 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 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 this chapter.
 - (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 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, marijuana sales areas 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 12 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 three frames per second during alarm or motion based recording.
 - (i) Repair and/or replace any failed component of the video surveillance recording system within 24 hours, unless notice is provided to the department and an extension is approved.
- (5) Twenty-four hour recordings from all video cameras, which the cultivation facility shall make available for immediate viewing by the department upon request and shall retain for at least 45 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 manager that it is not necessary to retain the recording;
- (6) A 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 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 48 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 annual basis.

3796:2-2-06 Laboratory testing

- (A) An employee of a licensed testing laboratory shall select a random sample of adequate weight from every batch of medical marijuana cultivated at the facility that is sufficient to perform the required tests, prior to packaging any plant material intended to be sold to a patient or caregiver through a dispensary licensed under Chapter 3796. of the Revised Code. Every sample shall be tested by a licensed testing laboratory in accordance with the testing standards established for testing laboratories in the rules promulgated pursuant to Chapter 3796. of the Revised Code. At a minimum, a testing laboratory shall test every sample for:
 - (1) Microbial contaminants;
 - (2) Mycotoxins;
 - (3) Heavy metals, including, at a minimum, arsenic, cadmium, lead, and mercury;
 - (4) Pesticide and fertilizer residue; and
 - (5) Cannabinoid potency including, at a minimum:
 - (a) Delta-9-tetrahydrocannabinolic acid (THCA);
 - (b) Delta-9-tetrahydrocannabinol (THC);
 - (c) Cannabidiolic acid (CBDA); and
 - (d) Cannabidiol (CBD).
- (B) An employee of a licensed testing laboratory shall select a random sample of adequate weight from every batch of medical marijuana cultivated at the facility that is sufficient to perform the required tests prior to packaging any plant material that shall be used in the manufacture of medical marijuana products by a processor licensed under Chapter 3796. of the Revised Code. Every sample shall be tested by a licensed testing laboratory in accordance with the testing standards established for testing laboratories in the rules promulgated pursuant to Chapter 3796. of the Revised Code. At a minimum, a testing laboratory shall test every sample for:
 - (1) Pesticide and fertilizer residue; and
 - (2) Cannabinoid potency including, at a minimum:
 - (a) Delta-9-tetrahydrocannabinolic acid (THCA);
 - (b) Delta-9-tetrahydrocannabinol (THC);
 - (c) Cannabidiolic acid (CBDA); and
 - (d) Cannabidiol (CBD).
- (C) A licensed testing laboratory shall submit to the cultivator an analysis of every sample of medical marijuana tested by the laboratory in accordance with the rules established pursuant to Chapter 3796. of the Revised Code. A cultivator shall not sell or otherwise distribute

medical marijuana unless the medical marijuana meets the standards set forth by the department and the package or label contains the analysis from a licensed testing laboratory.

3796:2-2-07 Cultivator prohibited activities

- (A) A cultivator shall not sell medical marijuana in any form to a patient or caregiver.
- (B) A cultivator shall not permit the consumption of medical marijuana in any form on the premises.
- (C) A cultivator shall not grow a prohibited form of marijuana not registered and approved by the state of Ohio board of pharmacy pursuant to section 3796.061 of the Revised Code.
- (D) A cultivator shall not produce or maintain medical marijuana in excess of the quantity required for normal, efficient operation based on patient population and consumption reported in the inventory tracking system.
- (E) A cultivator shall not amend or otherwise change its approved operations plan, quality assurance plan, or cultivation or production techniques, unless written approval is obtained from the department.
- (F) A cultivator shall not change the use or occupancy of the facility unless the department is notified of and provides prior written approval of such changes.
- (G) Pursuant to division (D)(1) of section 3796.06 of the Revised Code, a cultivator shall not sell plant material that exceeds thirty-five percent (35%) THC content, as defined in paragraph (A)(50) of rule 3796:1 of the Administrative Code.
- (H) A licensed cultivator shall not directly or indirectly discriminate in price between different processor or dispensary facilities that are purchasing a like, grade, strain, brand, quality, and quantity of marijuana. Nothing herein shall prevent price differentials based on differences in the cost of manufacture, sale, or delivery resulting from the differing methods or quantities in which the medical marijuana is sold or delivered.

3796:2-2-08 Cultivator records and reporting requirements

- (A) Each cultivator shall keep and maintain upon the licensed premises for a five-year period true, complete, legible and current books and records. All required records must be made available for inspection if requested by the department. The following records shall be maintained:
 - (1) Records relating to the disposal of marijuana, medical marijuana products, and waste in accordance with paragraph (E) of this rule and rule 3796:2-2-03 of the Administrative Code;
 - (2) Records related to the sale of medical marijuana in accordance with paragraph (C) of rule 3796:2-2-04 of the Administrative Code;
 - (3) Transportation records in accordance with rule 3796:5-3 of the Administrative Code;

- (4) Records of all samples sent to an independent testing lab and the quality assurance test results;
- (5) Security records in accordance with paragraph (B) of rule 3796:2-2-05 of the Administrative Code;
- (6) Inventory tracking records and inventory records maintained in the inventory tracking system, as well as records maintained by the facility outside the inventory tracking system, in accordance with rule 3796:2-2-04 of the Administrative Code;
- (7) Cultivation records, which at a minimum shall include:
 - (a) The form and types of medical marijuana maintained at the cultivator on a daily basis;
 - (b) Soil amendment, fertilizers, pesticides, or other chemicals applied to the growing medium or plants or used in the process of growing medical marijuana in accordance with paragraph (B) of rule 3796:2-2-01 of the Administrative Code; and
 - (c) Production records, including planting, harvest and curing, weighing, and packaging and labeling.
- (8) Financial records retained at a location determined by the cultivator in accordance with paragraph (C) of this rule;
- (9) Employee records in accordance with paragraph (D) of this rule; and
- (10) Records of any theft, loss, or other unaccountability of any medical marijuana as described in rule 3796:5-4 of the Administrative Code.

(B) A cultivator may use an electronic system for the storage and retrieval of records required by this chapter or other records relating to medical marijuana. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this rule. A cultivator shall use a system that:

- (1) Guarantees the confidentiality of the information stored in the system;
- (2) Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the cultivator;
- (3) Is capable of placing a litigation hold or enforcing a records retention hold for purposes of conducting an investigation or pursuant to ongoing litigation; and
- (4) Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

(C) A cultivator shall maintain financial records, which shall include the following:

- (1) Records that clearly reflect all financial transactions and the financial condition of the business, including contracts for services performed or received that relate to the cultivator;
- (2) Purchase invoices, bills of lading, manifests, sales records, copies of bills of sale, and any supporting documents, including the items and/or services purchased, from whom the items were purchased, and the date of purchase;
- (3) Bank statements and canceled checks for all accounts relating to the cultivation center, if applicable; and
- (4) Accounting and tax records related to the cultivator and all investors in the facility.

(D) A cultivator shall maintain employee records, which shall include the following:

- (1) All records relating to the hiring of employees, including applications, documentation of verification of references, and any other related materials;

- (2) An employee log that includes the following information for every current and former employee:
 - (a) Employee name, address, phone number and emergency contact information;
 - (b) Registration number and access credential designation;
 - (c) Date of hire and date of separation from employment, if applicable, and the reason for the separation;
 - (d) All training, education, and disciplinary records; and
 - (e) Salary and wages paid to each employee, and any executive compensation, bonus, benefit, or item of value paid to any individual affiliated with any medical marijuana entity, including members of a non-profit corporation, if any.

(E) Medical marijuana production and disposal records may be stored at the facility and shall include all of the following:

- (1) The registered product name, strain and quantity of marijuana involved;
- (2) The date of production or removal from production;
- (3) The reason for removal from production, if applicable;
- (4) A record of all marijuana sold, transported, or otherwise disposed of;
- (5) The date and time of selling, transporting, or disposing of the marijuana; and
- (6) If the medical marijuana is destroyed, the cultivator shall maintain records in accordance with paragraph (D) of rule 3796:2-2-03 of the Administrative Code.

3796:2-3 Cultivator Enforcement

3796:2-3-01 Cultivator inspections

- (A) The submission of an application that results in the issuance of a provisional license or certificate of operation for a cultivator irrevocably gives the department consent to conduct all inspections necessary to ensure compliance with the cultivator's application, state law, Chapter 3796. of the Revised Code and this chapter. The department may conduct the inspection independently, or may work with other departments, state agencies, or local authorities, including the Department of Agriculture, the Division of Industrial Compliance, and the State Fire Marshal, to ensure compliance with the cultivator's application, state and local law, Chapter 3796. of the Revised Code, and this chapter.
- (B) An inspector conducting an inspection pursuant to this section shall be accompanied by a Type 1 key employee during the inspection. The inspector may:
 - (1) Review and make copies of all records maintained in accordance with rule 3796:2-2-08 of the Administrative Code;
 - (2) Enter any area in the facility, with a key employee's assistance if unaccompanied access to an area could compromise production integrity or interrupt a dark cycle during the flowering stage;
 - (3) Inspect facility vehicles;
 - (4) Review the policies and procedures of the cultivator, including methods of operating;
 - (5) Survey the premises and any off-site facilities;
 - (6) Inspect all equipment, instruments, tools, materials, machinery, or any other resource used to cultivate medical marijuana;

- (7) Request access to locked areas in the facility;
- (8) Question licensed employees at the location; and
- (9) Obtain samples for testing of any medical marijuana cultivated at the facility, media used to grow medical marijuana, chemicals and ingredients used in the cultivation process, any labels or containers for marijuana, or any raw packaged medical marijuana;

(C) A pre-approval inspection that is required before the department issues a certificate of operation to a cultivator possessing a provisional license under rule 3796:2-1-06 shall occur at a mutually agreeable time. The department shall rely on the facility's application, this chapter and Chapter 3796. of the Revised Code, to facilitate the inspection and ensure compliance of the facility. Upon the completion of the pre-approval inspection, the department may issue:

- (1) A certificate of operation in accordance with rule 3796:2-1-06 of the Administrative Code, at which point the facility will be permitted to begin operations; or
- (2) A written plan of correction listing the deficiencies identified during the inspection that must be remedied before a certificate of operation will be issued by the department.
 - (a) Upon receipt of a request for a written plan of correction, the medical marijuana licensee shall develop a plan of correction for each deficiency and submit the plan to the department for approval within 10 business days after receipt of the statement of deficiencies and request for a plan, unless a written extension is issued by the department.
 - (b) The plan of correction must include specific requirements for corrective action that will be performed within (i) 30 calendar days after the department's acceptance of the plan of correction, or (ii) the remaining time period under paragraph (B) of rule 3796:2-1-06 of the Administrative Code, whichever is greater.
 - (c) If the plan submitted is not acceptable to the department or would prevent the facility from obtaining a certificate of operation in accordance with rule 3796:2-1-06 of the Administrative Code, the department may either direct the medical marijuana licensee to resubmit a plan of correction or the department may develop a directed plan of correction with which the cultivator must comply. Upon acceptance of the written plan of correction, the cultivator shall sign the plan of correction, binding the cultivator to the terms under which the cultivator may be issued a certificate of operation. If the parties are unable to come to terms on the written plan of correction, the department may take any action permitted under rule 3796:5-6-01 of the Administrative Code.
 - (d) The department shall re-inspect a cultivator upon the completion of the written plan of correction. If the corrective measures meet the department's satisfaction, the department shall issue a certificate of operation. If the corrective measures do not meet the requirements of the written plan of correction, the department may take action in accordance with rule 3796:5-6-01 of the Administrative Code.

(D) The department may, at any time it determines an inspection is needed, with or without notice, conduct an inspection of a cultivator to ensure compliance with the facility's application, state law, this chapter and Chapter 3796. of the Revised Code, in accordance with paragraph (A) of this rule. An inspection of a cultivator may include, without limitation, investigation of standards for safety from fire on behalf of the department by the local fire protection agency. If a local fire protection agency is not available, the State Fire Marshal may conduct the

inspection after the medical marijuana cultivator pays the appropriate fee to the State Fire Marshal for such inspection.

- (E) Following an inspection conducted pursuant to paragraph (C) of this rule, the department shall issue an inspection report that documents the following:
- (1) The observations and findings of the inspection;
 - (2) The outcome of the inspection;
 - (3) Any suggestions for the cultivator to take into consideration; and
 - (4) If applicable, a demand for corrective actions in the form of a written plan of correction.
 - (a) Upon receipt of a request for a written plan of correction, the medical marijuana licensee shall develop a plan of correction for each deficiency and submit the plan to the department for approval within 10 business days after receipt of the statement of deficiencies and request for a plan, unless a written extension is issued by the department.
 - (b) The plan of correction must include specific requirements for corrective action that will be performed within 30 calendar days of the department's acceptance of the plan. If the plan submitted is not acceptable to the department, the department may either direct the medical marijuana licensee to resubmit a plan of correction or the department may develop a directed plan of correction with which the cultivator must comply. Upon acceptance of the written plan of correction, the cultivator shall sign the plan of correction, binding the cultivator to the terms agreed upon by the parties. If the parties are unable to come to terms on the written plan of correction, the department may take any action permitted under rule 3796:5-6-01 of the Administrative Code.
 - (c) The department shall re-inspect a cultivator upon the completion of the written plan of correction. If the corrective measures meet the department's satisfaction, the department shall indicate such on the inspection report and conclude the inspection. If the corrective measures do not meet the requirements of the written plan of correction, the department may take action in accordance with rule 3796:5-6-01 of the Administrative Code.
- (F) If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, risk to public health, or the occurrence of a prohibited activities under rule 3796:5-6-02 of the Administrative Code, the department may take immediate action authorized under rule 3796:5-6-01 of the Administrative Code.
- (G) To prevent destruction of evidence, diversion, or other threats to public safety, the department may order an administrative hold of medical marijuana or medical marijuana product or any books and records of any licensee. The department may assess the costs of an investigation, including travel and the time of any and all employees, to a licensee.

3796:3 Medical Marijuana Processors

3796:4 Medical Marijuana Testing Laboratories

3796:5 General Provisions

3796:5-1 Fee schedules

- (A) An applicant for a license issued by the department or an applicant seeking employment with a licensee shall submit the following non-refundable application fees with the corresponding application:
- (1) Cultivator application: Level I – \$20,000; Level II – \$2,000
 - (2) Processor application: \$10,000
 - (3) Testing laboratory application: \$2,000
 - (4) Employee identification card application: \$100
- (B) An applicant that is awarded a provisional license by the department shall submit the following non-refundable fees at the time a certificate of operation is issued:
- (1) Cultivator license: Level I – \$180,000; Level II – \$18,000
 - (2) Processor license: \$90,000
 - (3) Testing laboratory license: \$18,000
- (C) A cultivator, processor, or testing laboratory awarded a certificate of operation by the department shall renew on an annual basis from the date the certificate of operation is issued and shall submit the following non-refundable fees:
- (1) Cultivator license: Level I – \$200,000; Level II – \$20,000
 - (2) Processor license: \$100,000
 - (3) Testing laboratory license: \$20,000
- (D) An employee that is issued an identification card shall renew every two years from the date of issuance and shall submit the following non-refundable fees:
- (1) Employee identification card: \$100
- (E) A cultivator, processor, or testing laboratory that is issued a certificate of operation shall submit the following non-refundable processing fee for a change in ownership or transfer to a new location:
- (1) Cultivator license: \$1,000
 - (2) Processor license: \$1,000
 - (3) Testing laboratory license: \$1,000
- (F) A cultivator, processor, or testing laboratory that is issued a certificate of operation or a person possessing an employee identification card that is lost, stolen, destroyed, or otherwise misplaced shall submit the following replacement fees:
- (1) Cultivator license: \$100
 - (2) Processor license: \$100
 - (3) Testing laboratory license: \$100
 - (4) Employee identification card: \$10
- (G) A cultivator that is issued a plant only processor license shall submit the following fee at the time the license is approved and on an annual basis from the date of the license being granted:

- (1) Level I cultivator: \$5,000
- (2) Level II cultivator: \$500

- (H) A cultivator or processor shall register each medical marijuana product with the department and pay a one-time registration fee of \$100 per product name.
- (I) A cultivator, processor, or testing laboratory shall submit every advertisement for approval prior to disseminating the advertisement with a fee of \$100 for every advertisement.
- (J) Any fees due and payable to the department of commerce shall be submitted in the form of a certified check or money order payable to the "Treasurer, State of Ohio," or by such other means as approved by the program.

3796:5-2-01 Employee identification cards

- (A) Every owner, principal officer, board member, employee, administrator, agent, or other person employed by 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 21 years of age;
 - (c) A copy of the applicant's social security card;
 - (d) A recognizable headshot photo of the applicant taken no more than six months before the date of the application;
 - (e) A document verifying the applicant's principal place of residence that contains the full mailing address, such as a bank statement, cancelled check, insurance policy, etc.;
 - (f) The name of the cultivator, processor, or testing laboratory that the applicant seeks to work for, invest in, or otherwise be associated with;
 - (g) A sworn statement that the applicant has not been convicted of a disqualifying offense as defined in rule 3796:1 of the Administrative Code;
 - (h) Verification that the applicant's background checks have been conducted and the applicant has not been convicted of a disqualifying offense;
 - (i) The application fee; and
 - (j) 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:
 - (1) Approve or deny the application within 30 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 works.
- (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 10 digit alphanumeric identification number with at least 4 numbers and 4 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 specified in rule 3796:5-1 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 this chapter and 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:
 - (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's identification card is returned to the cultivator, processor, or testing laboratory; and
 - (c) Return the employee's identification card to the department within 15 calendar days of his or her 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 30 days of the

termination, the department may take action under rule 3796:5-6 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) Type 1: 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 and 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) Type 2: 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 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 photo.
 - (1) A person who obtains a visitor identification badge:
 - (a) Must be escorted and monitored by an assigned licensed employee of the facility at all times he or she is on the premises and has access to medical marijuana;
 - (b) Must visibly display his or her visitor identification badge at all times he or she is on the premises; and
 - (c) Must 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 licensed 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 paragraphs (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.

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 bureau of criminal identification and investigation (BCI&I) 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 bureau of criminal identification and investigation (BCI&I) for a criminal records check of the applicant.
- (C) A person required to submit a criminal records check under paragraphs (A) or (B) of this rule shall submit both a BCI&I criminal records check and a federal bureau of investigation (FBI) criminal records check.
- (D) BCI&I shall send the results of the BCI&I and FBI criminal records checks performed under this rule directly to the department. The department requires that the criminal records check:
 - (1) Be based on electronic fingerprint impressions that are submitted directly to BCI&I from a “WebCheck” provider agency located in Ohio. 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 BCI&I.
 - (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.

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 21 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 this chapter and 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 an ID 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 had his or her employee identification card revoked or suspended due to his or her employer's revocation or suspension of a provisional license or certificate 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 this chapter and Chapter 3796. of the Revised Code.

3796:5-3 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:
- (1) The names and addresses of the medical marijuana entities sending and receiving the shipment;
 - (2) The names and registration numbers of the licensed 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;
 - (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 seed-to-sale system in accordance with section 3796.07 of the Revised Code and the requirements in this chapter. 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 this chapter and make them available at the request of the department.
- (C) The vehicle transporting the medical marijuana or any product containing medical marijuana shall:
- (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 licensed 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; 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.
- (E) A licensed employee transporting medical marijuana shall:
- (1) Display his or her department issued 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 2 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 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;
 - (6) Notify the medical marijuana entity when the delivery has been completed.

3796:5-4 Medical marijuana entity loss, theft, and emergency reporting

- (A) If a medical marijuana entity licensed by the department has reason to believe that an actual loss, theft, or diversion of medical marijuana has occurred, the medical marijuana entity shall notify immediately the department and law enforcement. A key employee of the medical marijuana entity licensed by the department shall provide the notice by submitting a signed statement that details the estimated time, location, and circumstances of the event, including an accurate inventory of the quantity and type of medical marijuana unaccounted for due to diversion or theft. The notice shall be provided no later than 24 hours after discovery of the event.

- (B) Within 10 days of a report submitted under paragraph (A) of this rule, a medical marijuana entity licensed by the department shall:
- (1) Review and secure video surveillance footage during the time of the suspected theft or diversion,
 - (2) Submit a report that contains the following information:
 - (a) The names and identification numbers of every employee at the facility at the time of the theft or diversion;
 - (b) The internal measures taken to locate the cause of the loss, theft, or diversion;
 - (c) The total quantity and type of medical marijuana stolen or otherwise diverted following a subsequent audit of the facilities actual inventory compared to the inventory reported by the inventory tracking system; and
 - (3) Submit to the department a revised plan to secure the facility's inventory and measures that will be taken to prevent future loss, theft, or diversion.
 - (4) Identify all records at the facility and potential evidence outside the facility, including video surveillance footage, that will be sealed and prevented from being destroyed until a full investigation is conducted by the department and law enforcement, if deemed necessary.
- (C) A medical marijuana entity licensed by the department shall notify the department within 24 hours and submit a written report within 10 days if there is:
- (1) An alarm activation or other event that requires response by public safety personnel occurs;
 - (2) A breach of security; or
 - (3) The failure of the security alarm system due to a loss of electrical support or mechanical malfunction.
- (D) A medical marijuana entity shall notify the department of any fire or other hazardous materials related incident or any incident requiring an emergency response to the licensed premise within twenty-four hours after the discovery of the incident.
- (E) A medical marijuana entity licensed by the department shall maintain and shall make available all documentation related to an occurrence that is reportable pursuant to paragraphs (A) through (C) of this rule.

3796:5-5 Medical marijuana entity distance from public spaces

- (A) In establishing the distance between a medical marijuana entity and a prohibited facility, the distance shall be measured linearly and shall be the shortest distance between the closest point of the property lines of the medical marijuana entity and the prohibited facility.
- (B) If a proposed expansion of a licensed medical marijuana entity would result in the medical marijuana entity being located 500 feet or less from a prohibited facility at the closest point of the property lines of the medical marijuana entity and the prohibited facility, the department shall deny the request for expansion.
- (C) If a proposed relocation plan of a licensed medical marijuana entity results in the medical marijuana entity being located 500 feet or less from a prohibited facility at the closest point of

the property lines of the medical marijuana entity and the prohibited facility, the department shall deny the request for relocation.

- (D) If a medical marijuana entity has been issued a provisional license or a certificate of operation prior to when a prohibited facility becomes established and is located 500 feet or less at the closest point of the property lines of the medical marijuana entity and the prohibited facility, the medical marijuana entity shall be permitted to continue operating at that location, provided that the medical marijuana entity:
- (1) Notifies the department;
 - (2) Submits the existing security plan to the department for a determination as to the adequacy of the existing security measures; and
 - (3) Agrees to implement additional, reasonable measures to prevent access and make the surrounding areas safe as deemed necessary by the department.

3796:5-6 Enforcement of medical marijuana entities

- (A) These regulations establish standards for the oversight and enforcement of the cultivation, processing and testing of medical marijuana. These regulations also establish legal standards for the denial, suspension or revocation of licenses issued by the department under Chapter 3796. of the Revised Code. If any portion of the rules is found to be invalid, the remaining portion of the rules shall remain in force and effect.

3796:5-6-01 Enforcement powers

- (A) Whenever it appears to the department that a medical marijuana entity issued a provisional license or certificate of operation by the department or a person possessing an employee identification card issued by the department has engaged in, is engaged in, or is about to engage in any act or practice declared to be prohibited by Chapter 3796. of the Revised Code or rules promulgated thereunder, or when the department believes that it is necessary for the program's administration, implementation and enforcement, the department may:
- (1) Investigate activities which are, or are suspected to be, prohibited and charge an investigation assessment;
 - (2) Serve all summonses, subpoenas, administrative orders, notices, or other processes concerning the enforcement of laws regulating medical marijuana and medical marijuana products;
 - (3) Issue either administrative subpoenas ad testificandum or subpoenas duces tecum, or both, to compel the testimony of witnesses or the production of any books and records, in paper or electronic format, to be served by personal service or by certified mail, return receipt requested;
 - (a) If the subpoena is returned because of inability to deliver, or if no return is received within thirty days of the date of mailing, the subpoena may be served by ordinary mail. If no return of ordinary mail is received within thirty days after the date of mailing, service shall be deemed to have been made. If the subpoena is returned because of inability to deliver, the department may designate a person or persons to effect either personal or residence service upon the witness.

- (b) The person designated to effect personal or residence service under this paragraph may be the sheriff of the county in which the witness resides or may be found or may be any other duly designated person.
 - (c) The fees and mileage of the person serving the subpoena shall be the same as those allowed by the courts of common pleas in criminal cases, and shall be paid from the funds of the department.
 - (4) Inspect, examine, or investigate any premises or vehicle where medical marijuana or medical marijuana products are grown, stored, cultivated, transported, processed, or tested, and any books and records in any way connected with any such activity;
 - (5) Require any cultivator, processor, or testing laboratory, or other person, upon demand, to permit an inspection of premises or vehicle during business hours or at any time of apparent operation, marijuana equipment, and marijuana accessories, or books and records; and, to permit the testing of or examination of medical marijuana or medical marijuana products;
 - (6) Suspend, suspend without prior hearing, revoke, or refuse to renew a license issued under Chapter 3796. of the Revised Code or any rules thereunder;
 - (7) Refuse to issue a provisional license or certificate of operation;
 - (8) Issue a Cease and Desist Order;
 - (9) Impose a civil penalty in an amount not to exceed \$50,000 for each violation, for any violation of this chapter or Chapter 3796. of the Revised Code;
 - (10) Place conditions on an applicant, license or licensee; and
 - (11) Exercise any other power or duty authorized by Chapter 3796. of the Revised Code or any rules issued thereunder.
- (B) A cultivator, processor, or testing laboratory whose certificate of operation has been suspended shall not sell, offer for sale, transport, or conduct any operations outside the facility related to medical marijuana. Employees of the facility may enter the premises of the facility for the necessary care and maintenance of the premises and any marijuana and marijuana products. The removal of medical marijuana from a cultivator, processor, or testing laboratory is strictly prohibited during an active suspension under this chapter.
- (C) The revocation of a provisional license or certificate of operation shall immediately terminate the employee identification cards of persons employed by the facility. A cultivator, processor, or testing laboratory whose certificate of operation has been revoked shall close the facility and prohibit anyone from entering the facility, other than employees with the department, law enforcement, or other individuals carrying out official duties related to the revocation of the certificate of operation.
- (D) Information obtained by the department shall be kept confidential and only disclosed to department employees, law enforcement, and persons deemed by the department to have a valid reason for access. Unauthorized disclosure shall be cause for discipline, including dismissal, if disclosure was by a department employee; and shall be grounds for disciplinary action against a cultivator, processor, or testing laboratory or any employee.
- (E) Department employees will not serve as expert witnesses in private litigation. In addition, the department may move to quash any subpoena that seeks fact testimony from department employees in private litigation. The department may certify as to the status of any person as a

licensee or licensed employee of a licensee. Such certification shall be admissible in any court as prima-facie evidence as to the status of the person.

3796:5-6-02 Prohibited activities

- (A) Any of the following shall be considered threats to the public health, welfare, or safety and shall be sufficient cause for a provisional license, certificate of operation, or employee identification card of a cultivator, processor, or testing laboratory, or any combination thereof, or employee to be denied, suspended with or without a hearing, revoked, fined, have conditions placed upon such license, or subject to other actions authorized under paragraph (A) of rule 3796:5-6-01 of the Administrative Code, or any combination of such actions necessary to ensure the program's administration, implementation and enforcement:
- (1) The distribution of marijuana to minors has occurred;
 - (2) Revenue from the sale of marijuana has gone to criminal enterprises;
 - (3) Medical marijuana has been diverted across state lines in a manner prohibited by either state;
 - (4) Trafficking of illegal drugs or illegal activities has occurred on the premises;
 - (5) Illegal or unauthorized possession or use of a firearm at a facility;
 - (6) Driving while drugged or otherwise intoxicated;
 - (7) Drug or alcohol abuse;
 - (8) Permitting the cultivation of medical marijuana in a facility outside the designated marijuana cultivation area;
 - (9) Failure to comply with a subpoena issued by the department;
 - (10) Acceptance of medical marijuana from a source other than a cultivator or processor licensed by the department, unless by a licensed testing laboratory pursuant to the rules promulgated for testing laboratories;
 - (11) Failure to maintain effective controls and security measures designed to ensure compliance with the law or protect the facility, employees, and medical marijuana;
 - (12) Knowing material misstatements or omissions in the inventory tracking system, where, in the exercise of reasonable diligence, the person should have obtained such knowledge prior to the misstatement or omission;
 - (13) A finding by the department that the medical marijuana entity, after having the license suspended or subject to mandatory corrections under rule 3796:2-3-01 of the Administrative Code, has violated the terms of the suspension or failed to perform the mandatory corrections;
 - (14) Operational failures that endanger public health, create a likelihood of contamination or diversion, or a pattern of deviation of standard operating procedures;
 - (15) Aiding or assisting another person in violating any provision of this chapter or Chapter 3796. of the Revised Code;
 - (16) Permitting another person to use the licensee's license;
 - (17) Cultivating, processing, transporting, or testing medical marijuana in violation of this chapter or Chapter 3796. of the Revised Code;
 - (18) Failure to cooperate or give information to the department, law enforcement authorities or any other enforcement agency upon any matter arising out of conduct at any cultivator, processor or testing laboratory; or

(19) Discontinuance of business for more than 90 days, unless the director or the director's designee approves an extension of such period for good cause shown, upon a written request.

(B) Any of the following shall be considered threats to public health, welfare, or safety and shall be sufficient cause for a provisional license, certificate of operation, or employee identification card of a cultivator, processor, or testing laboratory, or any combination thereof, or employee to be denied, suspended with or without a hearing, revoked, fined, have conditions placed upon such license, or any combination of such actions necessary to ensure the program's administration, implementation and enforcement:

(1) False or misleading statements in or involving a license application;

(2) Any civil or disciplinary action is taken, or has been taken, against any persons relating to a professional license;

(3) Failure to continuously escort an otherwise unauthorized person within an area designated by the facility as a controlled access area, unless that person is an investigator or employee of the department, authorities from local licensing authority or any state or law enforcement agency;

(4) Failure to promptly inform the department of any change of address or other material information contained in the application;

(5) Discipline, including, but not limited to, denial, suspension or revocation of a license, by any state or any territory of the United States or any foreign jurisdiction ;

(6) Failure to report to the department within 14 days of any adverse final action taken against a license in any state or any territory of the United States or any foreign jurisdiction, any governmental agency, any law enforcement agency or any court;

(7) Failure to respond to a written request for information by the department within 10 business days;

(8) Failure to keep accurate records in accordance with rule 3796:2-2-08 of the Administrative Code;

(9) Operating in a manner inconsistent with the public health, safety and welfare standards of the local governmental authority;

(10) A fraudulent or deceptive practice, transaction, representation or omission to the public, law enforcement or a representative of the department, regardless whether anyone relied on such practice, transaction, representation or omission;

(11) A finding by the department of a substantial discrepancy in a department inspection of any records and the subject matter of any records that are required under rule 3796:2-2-08 of the Administrative Code;

(12) Allowing medical marijuana, or medical marijuana byproduct or scrap, to be used or disposed of in a manner not consistent with this chapter or Chapter 3796. of the Revised Code; or

(13) Failure to maintain good business repute.

(a) For purposes of this rule and making a determination of a failure to maintain good business repute, the department shall consider if the person has engaged in any conduct which would reflect on the reputation for honesty, integrity, and competence in business and personal dealings of the person. These would include, but not limited to, if the person has been determined to have engaged in forgery, embezzlement, nondisclosure, incomplete disclosure, misstatement of material facts, and manipulative

or deceptive practices, or if the person has established a reputation for honesty, integrity, and competence.

3796:5-6-03 General enforcement

- (A) No person whose license has been revoked, nor any person affiliated with such revoked licensee, may make an application for any cultivator, processor, or testing laboratory license for at least five years from the date of such revocation or final judicial decision upon appeal of an order of revocation.
- (B) If a license is voluntarily surrendered or is not renewed, the department shall not be prohibited from imposing other penalties permitted by Chapter 3796. of the Revised Code, or any rules adopted pursuant thereto, on any such license or licensee.
- (C) Adjudicatory hearings will be conducted pursuant to Chapter 119. of the Revised Code. Sanctions describe under rule 3796:5-6-01 of the Administrative Code are not mutually exclusive and may be imposed in any combination.

3796:5-7 Advertising

- (A) For purposes of this rule, “advertisement” means any written or verbal statement, illustration, or depiction created to induce sales through a combination of letters, pictures, objects, lighting effects, illustrations, or other similar means. An “advertisement” includes brochures, promotional and other marketing materials. An advertisement with a high likelihood of reaching persons under the age of 18 is prohibited.
- (B) A cultivator, processor, or testing laboratory shall not use a name, logo, sign, or other advertisement unless the name, logo sign, or other advertisement has been approved by the department and the applicable advertisement fee has been paid. Materials submitted to the department for approval shall include, but are not limited to:
 - (1) A brief description of the format, medium, and length of the distribution;
 - (2) A verification that an actual patient is not being used on the advertisement;
 - (3) Verification that an official translation of a foreign language advertisement is accurate;
 - (4) Annotated references to support statements related to effectiveness of treatment; and
 - (5) A final copy of the advertisement, including a video where applicable, in a format acceptable to the department.
- (C) After the department has reviewed the proposed advertisement, the department may:
 - (1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the advertisement would be false or misleading without such a disclosure;
 - (2) Make recommendations with respect to changes that are necessary to protect the public health, safety and welfare; or
 - (3) Prohibit the use of the advertisement.

- (D) No cultivator, processor, or testing laboratory shall place or maintain, or cause to be placed or maintained, an advertisement of medical marijuana or medical marijuana products, including paraphernalia, in any form or through any medium:
- (1) Within five hundred feet of the perimeter of a prohibited facility, a game arcade where admission is not restricted to persons aged twenty-one years or older, or a business where the placement of the advertisement targets or is attractive to children, as determined by the department;
 - (2) On a billboard;
 - (3) On or in a public transit vehicle or public transit shelter; or
 - (4) On or in a publicly-owned or operated property.
- (E) An advertisement for a cultivator, processor, or testing laboratory, regardless of the medium, shall not:
- (1) Include any image bearing a resemblance to a cartoon character, fictional character whose target audience is children or youth, or pop culture icon;
 - (2) Market, distribute, offer, sell, license, or cause to be marketed, distributed, offered, sold, or licensed, any apparel or other merchandise related to the sale of marijuana, to an individual under eighteen years of age;
 - (3) Suggest or otherwise indicate that the product or entity in the advertisement has been approved or endorsed by the department, the state of Ohio or any person or entity associated with the state of Ohio;
 - (4) Encourage the use of medical marijuana for a condition other than a qualifying medical condition; or
 - (5) Contain any statement, design, representation, picture, or illustration that is:
 - (a) False or misleading;
 - (b) Disparaging to a competitor's products;
 - (c) Obscene or indecent; or
 - (d) Related to the safety or efficacy of marijuana, unless supported by substantial evidence or substantial clinical data.
- (F) A cultivator, processor, or testing laboratory may develop a website or otherwise establish a web presence advertising the name, business address, contact information, and services provided by a cultivator, processor, or testing laboratory. A cultivator, processor, or testing laboratory operating a website shall require age affirmation by the user before access to the website is granted. A cultivator, processor, or testing laboratory that establishes any type of web presence shall not:
- (1) Allow for direct engagement between consumers or user-generated content or reviews;
 - (2) Provide a medium for website users to transmit website content to individuals under the age of eighteen;
 - (3) Target a consumer group with a high likelihood of reaching individuals under the age of eighteen;
 - (4) Display or otherwise post content that has not been approved by the department;
 - (5) Transact business or otherwise facilitate a sales transaction to consumers or businesses; or
 - (6) Maintain a web presence that would otherwise violate rule 3796:5-7 of the Administrative Code.

- (G) A cultivator, processor, or testing laboratory shall not:
- (1) Display external signage larger than sixteen inches in height by eighteen inches in width;
 - (2) Illuminate a sign advertising a medical marijuana product or strain at any time;
 - (3) Advertise medical marijuana brand names or utilize graphics related to medical marijuana on the exterior of the building in which the cultivator, processor, or testing laboratory is operating; and
 - (4) Display medical marijuana, medical marijuana products, or medical marijuana paraphernalia that is visible from the exterior of the facility.

(H) This rule, as it pertains to advertisements, does not apply to a noncommercial message.

3796:5-8 Product registration

- (A) Every medical marijuana strain and every medical marijuana product shall be registered with the department and assigned a product identifier by the state board of pharmacy before it may be sold to a dispensary or dispensed to a patient or caregiver. Before a product is eligible for the assignment of a product identifier, in accordance with rules promulgated by the state board of pharmacy, the product shall be registered with the department.
- (B) Each registration application shall include the proposed label, and any other items deemed necessary by the department or in accordance with rules promulgated by the state board of pharmacy. A separate registration is required for each package size and dose of a particular strain or product before the strain or product may be offered for sale. A variation in ingredients shall constitute a new product and require a separate product registration and product identifier.

3796:5-9 Interagency cooperation

- (A) Whenever the department of commerce revokes or suspends a medical marijuana entity license, it shall notify the state of Ohio board of pharmacy, the state medical board of Ohio, law enforcement, and county sheriff's office whose jurisdiction includes the location of the medical marijuana entity.

3796:6 Medical Marijuana Dispensaries

3796:7 Patients and Caregivers