



## Ohio Department of Commerce Processor Rules - Public Input Accepted

As one of three state government agencies responsible for developing, implementing and overseeing the state's Medical Marijuana Control Program, the Ohio Department of Commerce is tasked with developing rules that will govern the operation of medical marijuana processors in the state of Ohio. The primary focus of the rules is to develop a program that ensures the safety of the public and access to a safe medical product.

The draft rules presented to the Medical Marijuana Advisory Committee were developed after benchmarking with other states and talking with industry experts. The draft rules include flexibility to allow the program to respond to changes in demand.

The Department is accepting public input on the draft rules. The draft rules are available on the Medical Marijuana Control Program website, [medicalmarijuana.ohio.gov/rules](http://medicalmarijuana.ohio.gov/rules).

### How can I provide input?

Written comments will be accepted through close of business Feb. 10, 2017; comments submitted after the deadline will not be considered. All comments should be submitted via email to [MMCPRules@com.ohio.gov](mailto:MMCPRules@com.ohio.gov); please include "Processor Rules Public Input" in the subject line. Do not include attachments; they will not be reviewed.

When preparing your comments, be sure to:

- Explain your views as clearly as possible
- Describe any assumptions used
- Provide any technical information and/or data used to support your views
- Explain how you arrived at your estimate for potential burdens, benefits or costs
- Provide specific examples to illustrate your views
- Offer alternatives

### What if I have questions?

Questions on this rules package and the process for submitting comments may be forwarded by email to [MMCPRules@com.ohio.gov](mailto:MMCPRules@com.ohio.gov); please include "Question" in the subject line.

For more information, visit the Medical Marijuana Control Program website: [medicalmarijuana.ohio.gov](http://medicalmarijuana.ohio.gov).

## **3796 Ohio Medical Marijuana Control Program**

### **3796:3-1-01 Number of Processor provisional licenses**

- (A) Beginning September 8, 2018, the director of the department of commerce or the director's designee may issue up to 40 processor provisional licenses, with no more than 10 processor 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, the director or the director's designee, at his or her discretion, may issue additional provisional licenses for processors, if the patient population, demand for medical marijuana products and available approved forms support additional licenses.
- (C) In the event additional provisional licenses are deemed necessary, the department will follow the license application procedures outlined in rule [3796:3-1-02] of the Administrative Code.

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

- (A) The department shall provide advance notice to the public indicating the commencement date and time period for accepting applications. The director shall have the right to amend the notice prior to the deadline for submitting an application. The director shall publish such amended notice in the same manner as the original notice. The director shall also have the right to cancel a notice of open application prior to the award of a processor provisional license.
- (B) The provisional license application shall be submitted in accordance with Chapter 3796. of the Revised Code and this Chapter. The application will include instructions for completion and submission. An applicant for a processor provisional license shall submit, in accordance with the application instructions, the following:
  - (1) A non-refundable application fee as set forth in rule [3796:5-1] of the Administrative Code. Each application for a specific facility 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 processor, 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 processor will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and this Chapter, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and this Chapter;
  - (i) A location area map of the area surrounding the proposed processor 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 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.
- (3) An operations plan that establishes policies and procedures that the applicant will implement for the safe, secure, sustainable, and proper processing of medical marijuana, which, at a minimum, shall include:
- (a) Processing and extraction techniques;
  - (b) Experience with the processing of medical marijuana, agricultural, or horticultural products;
  - (c) A list of proposed medical marijuana products to be manufactured with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content;
  - (d) Facility plans and specifications, designating the areas in the facility where the extraction and processing activities will occur;
  - (e) The implementation of standards and guidelines for processing of plant material, refining of medical marijuana extracts, and manufacturing of medical marijuana products, including safety protocols and equipment; and

- (f) Facility staffing and employment matters, which, at minimum, shall include:
  - (i) Employee training standards for the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana conducted on an annual basis;
  - (ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols, conducted on an annual basis;
  - (iii) Employee training standards for the safe and sanitary execution of any applicable post-extraction refining protocols, conducted on an annual basis;
  - (iv) Employee training standards for the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter [3715] of the Administrative Code conducted on an annual basis; and
  - (v) Employee compliance with Chapter 3796. of the Revised Code and this Chapter;
- (4) A quality assurance plan that establishes policies and procedures for a safe, consistent supply of medical marijuana, which, at a minimum, shall include:
  - (a) Intended use and sourcing of extraction equipment and associated solvents for the extraction of medical marijuana, or, in the case of non-solvent extraction, the intended physical methods and equipment;
  - (b) Intended use and sourcing of all non-marijuana ingredients utilized in the manufacture of medical marijuana products, including methods to verify or ensure the safety and integrity of those ingredients, as well as their potential to be allergens or to contain allergens as a result of their specific manufacturing;
  - (c) Compliance with Chapter [3715] of the Administrative Code in the production of edible medical marijuana products, if applicable;
  - (d) Best practices for the packaging and labeling of medical marijuana, such that it maintains medicinal integrity for the expected shelf-life;
  - (e) Implementation and compliance with the inventory tracking system;
  - (f) An inventory control plan;
  - (g) Standards for the destruction of medical marijuana and disposal of waste; and
  - (h) Recall policies and procedures in the event of contamination, expiration, or other circumstances that render the medical marijuana unsafe or unfit for consumption, including at a minimum, identification of the products involved, notification to the dispensary 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 processor and protect facility personnel, which, at a minimum, shall include:
  - (a) Record keeping policies and procedures that will ensure the facility complies with rule [3796:3-2-08] of the Administrative Code;
  - (b) A security plan in accordance with rule [3796:3-2-05] of the Administrative Code;
  - (c) Transportation policies in accordance with rule [3796:5-3] of the Administrative Code; and
  - (d) A plot plan of the processing facility drawn to a reasonable scale that designates the different areas of operation, including, but not limited to, the marijuana extraction and production areas, with the mandatory access restrictions.

- (i) If the building is in existence at the time of the application, the applicant shall submit plans and specifications drawn to scale for the interior of the building. 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 processor with respect to which licensure is sought;
  - (b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
  - (c) Documentation acceptable to the department that the individual or entity filing the application has at least \$250,000 in liquid assets for a processor 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; and
  - (d) 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 five 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 for a processor license.

### **3796:3-1-03 Processor application review**

- (A) The department, an independent contractor selected by the department, or a combination of the two shall review the submitted applications as described in this Chapter and the application instructions. In order to receive consideration under paragraph (B) of this rule, an applicant shall:
  - (1) Demonstrate sufficient liquid capital pursuant to rule [3796:3-1-02] of the Administrative Code and an ability to meet the financial responsibility requirements under rule [3796:3-1-05] of the Administrative Code;
  - (2) Certify in writing at the time of application that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent or other person has not been:
    - (a) Convicted of a disqualifying offense, as defined in rule [3796:1] of the Administrative Code; or
    - (b) Issued a certificate to recommend or applied for certification under Chapter 4731.30 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 processor;
  - (5) Certify that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent, or other person who may significantly influence or control the activities of the processor does not have an ownership or investment interest, a compensation arrangement with, or share any corporate officers or employees with any of the following:
    - (a) A laboratory licensed under 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;
  - (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 or 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 processor 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 processor, 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 processor will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and this Chapter, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and this Chapter;
    - (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 approval to operate as a medical marijuana processing facility and evidence that the applicant's proposed location 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.

- (2) An operations plan, which shall include but not be limited to:
  - (a) Documentation of processing methods and standards that will provide a steady, uninterrupted supply of medical marijuana;
  - (b) Experience with the processing of medical marijuana;
  - (c) A list of proposed medical marijuana products to be manufactured with estimated cannabinoid profiles, if known, including varieties with high cannabidiol content; and
  - (d) Facility plans and specifications evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and this Chapter;
  - (e) Staffing and training guidelines, which shall include, but not be limited to:
    - (i) Employee training standards for the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana;
    - (ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols;
    - (iii) Employee training standards for the safe and sanitary execution of any applicable post-extraction refining protocols;
    - (iv) Employee training standards for the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter [3715] of the Administrative Code; and
    - (v) Employee compliance with Chapter 3796. of the Revised Code and this Chapter.
- (3) A quality assurance plan, which shall include but not be limited to:
  - (a) Intended use and sourcing of extraction equipment and associated solvents for the extraction of medical marijuana, or, in the case of non-solvent extraction, the intended methods and equipment, with details including, but not limited to, make and model of anticipated equipment, throughput capacity and secondary processing or clean-up strategies for extracts;
  - (b) Intended use and sourcing of all non-marijuana ingredients utilized in the manufacture of medical marijuana products, including methods to verify or ensure the safety and integrity of those ingredients, as well as their potential to be allergens or to contain allergens as a results of their specific manufacturing;
  - (c) Compliance with Chapter [3715] of the Administrative Code in the production of edible medical marijuana products, if applicable;
  - (d) Best practices for the packaging and labeling of medical marijuana, such that it maintains its medicinal integrity for the expected shelf-life;
  - (e) Implementation and compliance with the inventory tracking system;
  - (f) An inventory control plan;
  - (g) Standards for the destruction of medical marijuana and disposal of waste; and
  - (h) Recall policies and procedures in the event of contamination, expiration or other circumstances that render the medical marijuana unsafe or unfit for consumption, including at a minimum, identification of the products involved, notification to the dispensary 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, local law enforcement, and emergency response professionals;
  - (d) A plot plan of the processor facility drawn to a reasonable scale that designates the different areas of operation, including, but not limited to, the marijuana extraction and production areas, with the mandatory access restrictions; and
  - (e) Transportation policies and procedures, which includes the transportation of medical marijuana from a processor to a dispensary and from a processor to a testing laboratory in the state of Ohio, in accordance with rule [3796:5-3] 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 processor with respect to which licensure is sought;
  - (b) A cost breakdown of the applicant's anticipated costs in building the facility and implementing the policies and procedures submitted as part of the application and the source of funding for the associated costs;
  - (c) Documentation acceptable to the department that the individual or entity filing the application has secured at least \$250,000 in liquid assets for a processor provisional license 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 [3796:3-1-05] 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 five 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 medical marijuana processor.
- (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, as well as 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 use of

energy efficient lighting, use of alternative energy, the treatment of waste water and runoff, and scrubbing or treatment of exchanged air.

- (3) Employment Practices: The applicant may demonstrate a plan of action to 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 [3796:3-1-01] of the Administrative Code.

#### **3796:3-1-04 Processor provisional license award**

(A) A provisional license shall be issued to the 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 multiple provisional licenses will be issued for a processor, the additional provisional licenses, not to exceed 10 in each designated territory, 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 processor provisional license receive the same total score and only one provisional license remains to be issued, the department shall select the applicant that received the highest score in the operations plan category. In the event that the 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 [3796:3-1-03] 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 [3796:3-1-02] 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 processor provisional license or processor 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 processor. 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 processor.

**3796:3-1-05 Processor 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 processor 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 processor fails to ensure a consistent and uninterrupted supply of medical marijuana either:
    - (a) Pursuant to paragraph (A) of rule [3796:3-1-07] of the Administrative Code; or
    - (b) If under a director's order issued pursuant to paragraph (F) of rule [3796:3-1-07] of the Administrative Code, fails to comply with the order by the date upon which the order schedules the stay to be lifted;
  - (3) A processor engages in activities prohibited under rule [3796:3-2-07] of the Administrative Code; or
  - (4) A processor 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 \$750,000 for, 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 processor that established the account or a representative of the processor unless the processor or representative presents a statement issued by the department indicating that the account may be released; or
- (3) Providing a surety bond naming the processor as principal of the bond, upon terms approved by the department, in the amount of \$750,000 payable to the department in the event of circumstances outlined in paragraph (A) of this Chapter. 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 processor fails to file a new bond with the department in the required amount on or before the effective date of cancellation, the processor'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 processor to reduce the escrow or surety bond by \$250,000 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 processor remained fully operational without substantial interruption and was able to provide and maintain an uninterrupted supply of medical marijuana, in accordance with rule [3796:3-1-07], 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 a period of one year;
  - (b) A determination by the department that the processor remained fully operational without substantial interruption and was able to provide and maintain an uninterrupted supply of medical marijuana, in accordance with rule [3796:3-1-07], 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 processor remained fully operational without substantial interruption and was able to provide and maintain an uninterrupted supply of medical marijuana, in accordance with rule [3796:3-1-07], 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 processor 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.

**3796:3-1-06 Processor certificate of operation**

- (A) A provisional licensee is prohibited from operating as a licensed processor and performing any processing or manufacturing activities until a certificate of operation is issued by the department. The information and plan submitted by a provisional licensee shall become mandatory conditions that must be met before a certificate of operation can be awarded.
- (B) A provisional licensee shall have six months from the date they are notified of selection to obtain a certificate of operation. A certificate of operation shall be issued once all applicable inspections are passed and the provisional licensee demonstrates that it conforms to the specifications of the application, as well as the requirements imposed by law and rules. If a certificate of operation is issued, the provisional license becomes null and void.
- (C) The department shall not award a certificate of operation to a provisional licensee if the provisional licensee has not met all of the specifications in the application and passed all applicable inspections under rule [3796:3-3-01] of the Administrative Code within six months of written or electronic notification of the applicant's selection. If the provisional licensee fails to remedy the deficiencies in accordance with rule [3796:3-3-01] of the Administrative Code or otherwise satisfy the six-month time period established under paragraph (B) of this rule, the director, at his or her discretion, may extend the time period for the processor to obtain a certificate of operation or take action pursuant to rule [3796:5-6-01] of the Administrative Code.
- (D) The certificate of operation, along with any other certificate, business license or other authorization required to conduct production activities, shall be posted in a conspicuous place within the facility.

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

- (A) A processor shall ensure that a consistent supply of medical marijuana products is available to be sold to licensed dispensaries. Evidence of a consistent supply may be shown by:
- (1) Maintaining an inventory of at least [X GRAMS] of medical marijuana extract that is ready for immediate use in the manufacture of marijuana products; or
  - (2) Allowing no more than 30 days to elapse between shipments totaling at least one lot of medical marijuana products to any licensed dispensaries.
- (B) If the director believes a processor has failed to meet the requirements of paragraph (A) of this rule, the director may issue a notice of insufficient business activity to a licensed processor. The notice shall include the factual basis for the director's belief, including any appropriate supporting documentation.

- (C) Upon a notice issued pursuant to paragraph (B) of this rule, a licensed processor may respond with any evidence sufficient to prove that the processor has met, and continues to meet, the standards established by paragraph (A) of this rule.
- (D) If a processor fails to respond to a notice issued, or the director determines the evidence provided is insufficient to establish one of the conditions in paragraph (A) of this rule, the director shall move to revoke the processor certificate of operation pursuant to rule [3796:5-6-01] of the Administrative Code.
- (E) At any time prior to the issuance of a notice of insufficient business activity, a processor may petition the director to toll computation of the timeframes provided in paragraph (A) of this rule. Such a petition shall provide:
- (1) An explanation of the facts and circumstances that will not allow the processor to ensure a consistent supply of medical marijuana as required in paragraph (A) of this rule; and
  - (2) A plan for how and when the processor will be able to meet the requirement of paragraph (A) of this rule, with specific attention to how such a plan will allow the processor to meet the standards established in paragraph (A).
- (F) Upon receipt of a petition under paragraph (E) of this rule, the director may stay the requirement of paragraph (A) of this rule for a processor. A director's order staying the requirement of paragraph (A) of this rule shall state the date upon which the stay is lifted using information provided by the processor in accordance with paragraph (E)(2) of this rule.

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

- (A) A provisional license granted pursuant to this rule is nontransferable.
- (B) A certificate of operation shall be issued for the specific processor and location identified on the application, and is valid only for the owner, premises, and name designated on the certificate of operation and the location for which it is issued. A certificate of operation may only be transferred or assigned if the department determines that the proposed ownership or location change complies with 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 processor 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; and
    - (c) Demonstrate to the department that the person acquiring the interest meets the requirements under rules [3796:3-1-02] and [3796:3-1-03] of the Administrative Code and the processor will remain in compliance with its application for a processor provisional license, this Chapter, and Chapter 3796. of the Revised Code under the proposed ownership structure; and
    - (d) Submit a new application in accordance with rule [3796:3-1-02] of the Administrative Code if the transfer of ownership would result in a new controlling shareholder or shareholders outside of the current ownership structure approved by the department.

For purposes of calculating a controlling interest, the department will consider all transfers of ownership that occur in a given calendar year and calculate such transfers in the aggregate.

- (2) Upon a request for a change in location, a processor shall:
  - (a) Notify the department in writing of the proposed location change;
  - (b) 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 [3796:3-1-02] of the Administrative Code; and
  - (d) Demonstrate to the department that the new location meets the applicable requirements of rule [3796:3-1-02] of the Administrative Code and that the processor will remain in compliance with this Chapter and Chapter 3796. of the Revised Code at the new location.
- (C) A processor requesting a change in ownership or location shall submit the applicable fee under rule [3796:5-1] of the Administrative Code. A proposed change in ownership or request for a change in location shall not be effective until approved in writing by the department.
- (D) A processor receiving approval from the department for a change in location shall have 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 [3796:3-3-01] of the Administrative Code.
  - (2) No product or plant material may be transferred to or processed at the new location prior to the beginning date of the approved transition period.
  - (3) Any plant material, medical marijuana extract, or medical marijuana products remaining at the original location past the 90-day transition period shall be destroyed in accordance with rule [3796:3-2-03] of the Administrative Code.
  - (4) The processor shall notify the department in writing or by electronic transmission once the transfer of inventory is complete and production has begun at the new location.
- (E) Upon inspection and verification by the Department that the new location is in compliance with this rule and this Division, 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.

### **3796:3-1-09 Processor certificate of operation renewal**

- (A) Every processor certificate of operation issued by the department under this Chapter shall expire annually on the date it was issued. A renewal application for a processor, accompanied by the proper renewal fee established under this Chapter, 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 processor submits the corresponding renewal fee, the Department confirms that nothing warrants the denial of the renewal under rule [3796:5-6-01] of the Administrative Code, and the processor passes a full inspection, unless a full inspection was passed within three months before the renewal date.
- (C) If a renewal application is not filed prior to the expiration date of the certificate of operation, the certificate of operation shall be suspended for a maximum of 30 days, at which point it will be deemed expired if the processor has not successfully renewed the certificate of operation under paragraph (B) of this rule. Upon expiration of the certificate of operation, the processor shall not engage in any processing activities in furtherance of the business of processing medical marijuana. The department shall not renew the certificate of operation and the facility shall permanently cease its operations.

### **3796:3-1-10 Winding down**

- (A) If a processor decides to voluntarily surrender or not renew its certificate of operation and permanently discontinue business operations, the processor shall provide written notice to the department at least 90 days prior to the effective date of the closure. If the closure is the result of an eviction, the processor shall immediately notify the department of the eviction notice and the effective date of the notice. This notice shall be provided prior to the processor taking any steps to discontinue business operations.
- (B) A processor that notifies the department of its intent to voluntarily surrender or not renew its certificate of operation under paragraph (A) of this rule shall submit, within 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 manufacturing of medical marijuana products;
  - (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 processor was located.
- (C) The director shall approve or deny a processor'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.

### **3796:3-2 Processor Operations**

- (A) A processor shall establish, maintain, and comply with the policies and procedures contained in the operations plan submitted by the processor 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 plant material, medical marijuana extract, and medical marijuana products. 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 extraction area, with restricted access between the different areas based on access credentials assigned by the facility;
  - (2) Implement policies and procedures that provide best practices for safe, secure, and proper processing of medical marijuana, which includes restricted movement between the different production areas by personnel;
  - (3) Establish training and safety policies and procedures to ensure that any person involved in processing medical marijuana:
    - (a) Has been fully trained in the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana, with supporting documentation of the training;
    - (b) Has been fully trained in the safe use, handling, and storage of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols, with supporting documentation of the training;
    - (c) Has been fully trained in the safe and sanitary execution of any applicable post-extraction refining protocols;
    - (d) Has been fully trained in the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter [3715] of the Administrative Code; and
    - (e) Has direct access to applicable material safety data sheets and labels;
  - (4) Document the chain for all medical marijuana in the inventory tracking system;
  - (5) Establish sanitary operating procedures 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
  - (6) Maintain a facility with adequate lighting, ventilation, temperature, sanitation, equipment, and security for the processing of medical marijuana.
- (B) A processor may only use the methods, equipment, solvents, and gases set forth in this paragraph in the manufacture of medical marijuana products.
- (1) A processor using a hydrocarbon solvent-based extraction method shall do so in a spark-free and properly ventilated environment, and may use the following solvents, at a minimum of 99% purity, in a professional grade, closed-loop extraction system designed to recover the solvents:
    - (a) Propane;
    - (b) N-butane;
    - (c) Isobutane;
    - (d) Heptane; or
    - (e) Other solvents exhibiting minimal potential toxicity to humans with the approval of the department.

- (2) A processor using a carbon dioxide extraction method shall use food grade carbon dioxide at a minimum of 99% purity in a professional grade, closed-loop system in which each vessel is rated to a minimum pressure to accommodate the specific extraction protocol, including supercritical, liquid, and subcritical.
  - (3) A processor may use food grade glycerin, ethanol, and propylene glycol to manufacture medical marijuana tinctures.
  - (4) A processor may use non-solvent extraction methods involving the mechanical separation of cannabinoids from plant material to produce cannabinoid infused fats, including but not limited to dairy butter and vegetable oil, for use in the manufacture of edible medical marijuana products.
  - (5) A processor shall comply with all applicable OSHA regulations as well as any applicable fire, safety, and building codes pertaining to the use and storage of the equipment and solvents used in the manufacture of medical marijuana products.
- (C) The department may establish rules governing the use of any extraction methods not permitted in paragraph (B) of this rule, including any newly developed protocols or equipment. Until such time as rules are established, a processor shall not utilize any extraction methods not listed in paragraph (B) of this rule.
- (D) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods shall designate at least one individual to train and supervise employees in the use of extraction equipment and associated solvents who has earned, at minimum, a Bachelor's Degree in engineering or physical sciences from an accredited university, and who has at least 2 years of experience in the operation of the equipment being used in the facility or similar equipment.

### **3796:3-2-01 Processor quality assurance plan**

- (A) A processor shall submit, as part of the application process, and maintain a quality assurance and quality control plan for the processing 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 lots of medical marijuana products.
- (1) A processor shall submit any proposed changes to its plan to the department. The department shall review and approve or reject the proposed changes before the proposed changes can be made.
- (B) A processor shall maintain a facility in the following manner.
- (1) A processor shall keep all floors and benches free of debris, dust, and any other potential contaminants, and shall control rodents and other pests.
  - (2) A processor 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 processor shall keep its equipment in a clean, professional environment and maintain a cleaning and equipment maintenance log at the facility.
  - (4) The processor 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 processor. 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 processor shall implement policies and procedures related to receiving, inspecting, transporting, segregating, preparing, packaging, and storing plant material, medical marijuana extract, and medical marijuana products in accordance with adequate sanitation principles.

### **3796:3-2-02 Processor packaging and labeling**

- (A) A processor distributing medical marijuana to a dispensary shall meet the following requirements:
- (1) A processor shall place medical marijuana in a tamper-evident, opaque package approved by the department prior to distribution to a dispensary. Approved packaging shall maintain the integrity and stability of the medical marijuana.
  - (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 plant material was cultivated or the name and license number of the processor where the medical marijuana products were manufactured;
    - (b) The name and license number of the dispensary facility receiving the shipment;
    - (c) The product identifier;
    - (d) The registered name of the medical marijuana strain or medical marijuana product that was registered with the department;
    - (e) A unique batch or lot number as defined in paragraph (A) of rule [3796:1] of the Administrative Code that will match the medical marijuana or medical marijuana products with a batch or lot, in order to facilitate any warnings or recalls the department deems appropriate;
    - (f) The date of manufacture, final testing, and packaging;
    - (g) The total weight in grams of medical marijuana or medical marijuana products in each package;
    - (h) The name and license number of the independent testing laboratory that performed the required tests on the batch or lot from which the medical marijuana or medical marijuana products in the package were taken;
    - (i) The laboratory analysis and cannabinoid profile, including the percentage content by weight or total milligrams and milligrams per unit for:
      - (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 manufacture;
    - (k) If the product is edible, the following additional information:
      - (i) A list of all ingredients and all major food allergens as identified in [2 USC § 343];
      - (ii) A statement with the following language: “Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by 2 or more hours.”

- (l) If a marijuana extract was used in the manufacture of the product, a disclosure of the type of extraction process and any solvent, gas, or other chemical used in the extraction process or any other compound added to the extract; and
  - (m) 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) If a processor elects to or is required to determine portions for an edible, then the processor shall apply a universal symbol, as determined by the department, to each portion in accordance with the requirements of this Chapter. The size of the universal symbol marking shall be determined by the size of the portion instead of the overall product size, and shall not be less than ¼” by ¼”.
- (C) The label may contain the approval or certification logo of a third-party certifier of cultivation or manufacturing 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 processor 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.

### **3796:3-2-03 Processor waste disposal**

- (A) A licensed processor 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 processor'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 processor and submitted as part of the application process shall be sufficient to render the 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 processor. 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 waste;
  - (5) Soil or other growth media; or
  - (6) Other wastes approved by the department.
- (C) The disposal of medical marijuana or medical marijuana products shall be performed by a Type 1 key employee in the designated destruction area identified in the processor'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 approved solid waste used to render the medical marijuana waste unusable;
  - (4) The reasoning for and description of the disposal;
  - (5) The signature of the Type 1 employee overseeing the disposal of the medical marijuana;
  - (6) The batch number(s), volume, and weight of any medical marijuana extract or plant material being disposed of; and
  - (7) The lot number, registered product name, volume, weight, and unit count of any medical marijuana products being disposed of.
- (E) The disposal of other waste from the processor that does not include medical marijuana, including hazardous waste and liquid waste, shall be performed in a manner consistent with federal and state law.

**3796:3-2-04 Processor inventory control and storage**

- (A) A processor shall track and submit into the inventory tracking system any information the department determines necessary for maintaining and tracking medical marijuana extract and medical marijuana products.
- (1) Upon completion of each iteration of an approved extraction process, the processor shall securely attach a label to the container of medical marijuana extract that includes, at a minimum, the following information:
    - (a) The processor's name and license number;
    - (b) The batch number(s) of the batch(es) of plant material used in the extraction;
    - (c) The registered strain name(s) of the plant material used during the extraction;
    - (d) The batch number assigned to the batch of medical marijuana extract;
    - (e) The date of extraction; and
    - (f) The net weight and volume of medical marijuana extract.
  - (2) Upon completion of each iteration of an approved manufacturing process, the processor shall securely attach a label to the container of medical marijuana products that includes, at a minimum, the following information:
    - (a) The processor's name and license number;
    - (b) The registered product name;
    - (c) The batch number(s) of the batch(es) of medical marijuana extract used in the manufacturing process;
    - (d) The date of manufacture; and
    - (e) The net weight and unit count of medical marijuana products prepared or packaged for sale to a licensed dispensary.
- (B) Prior to commencing business, each processor shall establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of medical marijuana, medical marijuana extract, and medical marijuana products for traceability in the department's inventory tracking system, which shall enable the processor to detect any diversion, theft, or loss in a timely manner.
- (C) Upon commencing business, each processor 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 net weight of plant material;
    - (b) The net weight and volume of medical marijuana extract;
    - (c) The net weight and unit count of medical marijuana products prepared or packaged for sale to a dispensary;
    - (d) The results from a testing laboratory indicating the THC/CBD levels, if available; and
    - (e) The registered strain or product names and batch or lot numbers of plant material, medical marijuana extract, and medical marijuana products.
  - (3) The amount of medical marijuana and medical marijuana products sold since previous weekly inventory, which shall include:
    - (a) The date of sale;
    - (b) The name of the dispensary to which the medical marijuana and medical marijuana products were sold;

- (c) The lot number, strain or product name, and quantity sold.
  - (4) The date, quantity, and method of disposal of any plant material, medical marijuana extract, and medical marijuana products, if applicable;
  - (5) A summary of the inventory findings; and
  - (6) The name, signature and title of the Type 1 or Type 2 employees who conducted the inventory and oversaw the inventory.
- (D) On an annual basis and as a condition for renewal of a processor license, a processor shall conduct a physical, manual inventory of plant material, medical marijuana extract, and medical marijuana products on hand at the processor 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 processor 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 Chapter shall be maintained on the premises and made available to the department at all times.
- (F) A processor is authorized to store plant material, medical marijuana extract, and medical marijuana product inventory on the premises in a designated, enclosed, locked area identified in the processor'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, the department's designee, local law enforcement, or other federal, state, or local government officials from entering any area of a processor facility if necessary to perform their governmental duties.

**3796:3-2-05 Processor security**

- (A) The department shall determine the appropriate storage and security requirements for all processor facilities, and may require additional safeguards to ensure the security of medical marijuana. A processor shall comply with the security plan submitted as part of its processor provisional license application. At a minimum, the processor shall:
- (1) Install an adequate security alarm system around the perimeter of the facility to prevent and detect diversion, theft, or loss of medical marijuana, utilizing commercial grade equipment;
  - (2) Maintain or construct fencing and gates that surround the facility to prevent unauthorized entry to the facility or unauthorized access to waste disposal containers located outside the facility;
  - (3) Utilize a video surveillance recording system installed by a vendor that is approved by the department and that meets the standards required by the department to prevent and detect diversion, theft, or loss of medical marijuana;
  - (4) Maintain all security system equipment and video surveillance systems in a secure location so as to prevent theft, loss, destruction, or alterations;
    - (a) A processor shall limit access to surveillance areas to Type 1 key employees that are essential to surveillance operations, law enforcement agencies, security system service employees, the department, and others when approved by the department; and

- (b) A processor shall make available to the department, upon request, a current list of Type 1 key employees and contractors who have access to the surveillance room. A processor shall keep all on-site surveillance rooms locked and shall not use such rooms for any other functions.
  - (5) Keep all approved safes, vaults, or any other approved equipment or areas used for processing or storing of plant material, medical marijuana extract, and medical marijuana products securely locked and protected from unauthorized access;
  - (6) Ensure the outside perimeter of the facility is well-lit and in accordance with the processor's plan in its license application;
  - (7) Restrict access to any area within the facility containing plant material, medical marijuana extract, or medical marijuana products to all persons except licensed employees and agents or an individual permitted to access the facility under the supervision of a licensed employee or agent in accordance with the visitor authorization procedures set forth in 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 processor shall install a security alarm system and a video surveillance recording system under paragraph (A) of this rule. A security alarm system and video surveillance recording system shall, at a minimum, contain the following:
- (1) A system designed to detect motion and identify unauthorized access to the facility;
  - (2) Video cameras that capture the entire facility, including direct placement near the entrances, exits, and parking areas to capture a clear and certain identification of any person entering or exiting the facility, which shall be appropriate for the normal lighting conditions of the area under surveillance;
  - (3) Video cameras shall be directed at all approved safes, approved vaults, marijuana sales areas, and any other area where plant material, medical marijuana extract, or medical marijuana products are being processed, stored, or handled;
  - (4) The video surveillance recording system shall comply with the following minimum capabilities:
    - (a) Provide a direct feed and login capabilities to the department to allow for real-time access and monitoring of the facility via the live video surveillance recording system.
    - (b) A display monitor with a minimum screen size of 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 processor facility shall make available for immediate viewing by the department upon request and shall retain for at least 45 days. If a processor is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the processor that it is not necessary to retain the recording;
  - (6) 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 processor facility within five minutes of the failure, either by telephone, email, or text message; and
  - (10) The ability to comply with the security requirements of this rule for a period of at least 48 hours during a power outage.
- (C) In addition to the requirements listed in paragraph (B) of this rule, each processor shall have a back-up alarm system approved by the department that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.
- (D) A processor shall keep all security equipment in good-working order and the systems shall be inspected and all devices tested on an annual basis.

### **3796:3-2-06 Laboratory testing**

- (A) Prior to the sale of any medical marijuana product to a dispensary licensed under Chapter 3796. of the Revised Code, an employee of a licensed testing laboratory shall select a random sample from every lot of medical marijuana products at the facility that is of sufficient quantity to perform the required tests. 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) Cannabinoid potency including, at minimum:
    - (a) Delta-9-tetrahydrocannabinolic acid (THCA);
    - (b) Delta-9-tetrahydrocannabinol (THC);
    - (c) Cannabidiolic acid (CBDA); and
    - (d) Cannabidiol (CBD).
  - (3) If the medical marijuana extract used in the manufacture of the product was not previously tested by a licensed testing laboratory, the product sample shall also be analyzed for:
    - (a) Mycotoxins;
    - (b) Heavy metals, including, at a minimum, arsenic, cadmium, lead, and mercury;
    - (c) Pesticide and fertilizer residue; and
    - (d) Residual solvents.
- (B) Prior to the sale of any plant material to a dispensary licensed under Chapter 3796. of the Revised Code, a processor shall verify that the required laboratory tests have been performed on each batch of plant material pursuant to paragraph (A) of rule [3796:2-2-06] of the Administrative Code.
- (C) A licensed testing laboratory shall submit to the processor a certificate of analysis of every sample of medical marijuana tested by the laboratory in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code. A processor 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.

### **3796:3-2-07 Processor prohibited activities**

- (A) A licensed processor shall not sell medical marijuana in any form to a patient or caregiver.
- (B) A licensed processor shall not permit the consumption of medical marijuana in any form on the premises.
- (C) A licensed processor shall not process or manufacture a form of marijuana that is not permitted by section 3796.06 of the Revised Code or approved by the state of Ohio board of pharmacy pursuant to division (A)(6) of section 3796.06 of the Revised Code.

- (D) Pursuant to division (D)(1) of section 3796.06 of the Revised Code, a processor shall not manufacture medical marijuana products that exceed seventy percent (70%) THC content as defined in paragraph (A)(5) of rule 3796:1 of the Administrative Code.
- (E) A licensed processor shall not amend or otherwise change its approved operations plan, quality assurance plan, or manufacturing techniques, unless written approval is obtained from the department.
- (F) A licensed processor 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.
- (G) A licensed processor shall not directly or indirectly discriminate in price between different dispensary facilities that are purchasing a like, grade, strain, brand, and quality of medical marijuana, provided nothing herein shall prevent differentials which only make due allowance for differences in the cost of manufacture, sale, or delivery resulting from the differing methods or quantities in which such medical marijuana or medical marijuana products are sold or delivered to such dispensary facilities.

### **3796:3-2-08 Processor records and reporting requirements**

- (A) Each processor 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 medical marijuana, medical marijuana products, and waste in accordance with paragraph (E) of this rule and rule [3796:3-2-03] of the Administrative Code;
  - (2) Records related to the sale of medical marijuana in accordance with paragraph (D) of rule [3796:3-2-04] 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 [3796:3-2-05] 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 [3796:3-2-04] of the Administrative Code;
  - (7) Processing records, which at a minimum shall include:
    - (a) The form and types of medical marijuana maintained at the facility on a daily basis;
    - (b) Production records, including extraction, refining, manufacturing, packaging, and labeling;
  - (8) Financial records 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 processor 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 processor 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 processor;
  - (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 processor 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 processor;
  - (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 processor, if applicable; and
  - (4) Accounting and tax records related to the processor and all investors in the facility.
- (D) A processor shall maintain employee records, which shall include the following:
- (1) All records relating to the hiring of employees, including applications, interview notes, 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, and
  - (3) Documentation that each employee has been successfully trained in accordance with the operations plan submitted as part of the processor application and in compliance with paragraph (A)(3) of rule [3796:2] of the Administrative Code.
- (E) Medical marijuana production and disposal records may be stored at the facility and shall include all of the following:
- (1) The registered strain or product name, form, 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 medical marijuana sold, transported, or otherwise disposed of;
  - (5) The date and time of selling, transporting, or disposing of the medical marijuana; and

- (6) If the medical marijuana is destroyed, the processor shall maintain records in accordance with paragraph (D) of rule [3796:3-2-03] of the Administrative Code.

### **3796:3-3 Processor Enforcement**

#### **3796:3-3-01 Processor inspections**

- (A) The submission of an application that results in the issuance of a provisional license or certificate of operation for a processor irrevocably gives the department consent to conduct all inspections necessary to ensure compliance with the processor'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 processor's application, state 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 [3796:3-2-08] of the Administrative Code;
  - (2) Enter any room in the facility;
  - (3) Inspect facility vehicles;
  - (4) Review the policies and procedures of the processor, 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 process medical marijuana and manufacture medical marijuana products;
  - (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 products processed at the facility, chemicals and ingredients used in processing medical marijuana, any labels or containers for medical marijuana, or any raw packaged medical marijuana.
- (C) A pre-approval inspection of a processor that is required before the department issues a certificate of operation to a processor possessing a provisional license under rule [3796:3-1-06] shall occur at a mutually agreeable time. The department shall rely on the facility's application, Chapter 3796. of the Revised Code and this Chapter of the Administrative 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 [3796:3-1-06] of the Administrative Code, at which point the facility will be permitted to begin operations; or
  - (2) A written plan of correction request 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 [3796:3-1-06] 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 [3796:3-1-06] 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 processor must comply. Upon acceptance of the written plan of correction, the department and the processor will sign a mutually binding agreement defining the terms under which the processor will 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 processor 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 shall 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 processor to ensure compliance with the facility's application, state law, Chapter 3796. of the Revised Code and this Chapter of the Administrative Code in accordance with paragraph (A) of this rule. An inspection of a processor 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 processor 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 processor 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 processor 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. If the plan submitted is not acceptable to the department, the department may either direct the processor to resubmit a plan of

correction or the department may develop a directed plan of correction with which the processor must comply. Upon acceptance of the written plan of correction, the department and the processor will sign a mutually binding agreement defining 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 processor 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 shall 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.