

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

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

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

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

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

(a) The legal name of the applicant;

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

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

(d) The proposed physical address of the 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 twenty-one years of age;

(f) Experience with the manufacture of medical marijuana, agricultural, or horticultural products;

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

- (h) Any instance in which a business that any person associated with the applicant had managed or served on the board of the business and was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding;
- (i) Evidence that the applicant owns the property on which the proposed processor will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the processor from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
- (j) A location area map of the area surrounding the proposed processor that establishes the facility is at least five hundred feet from the boundaries of a parcel of real estate having situated on it a prohibited facility, as measured under rule 3796:5-5-01 of the Administrative Code;
- (k) For any instance in which an applicant or any person associated with the applicant is currently or was previously licensed or authorized in another state or jurisdiction to cultivate, produce, test, dispense, or otherwise deal in the distribution of medical marijuana in any form, the following:

  - (i) A copy of each such licensing or authorizing document verifying licensure in that state or jurisdiction;
  - (ii) A statement granting permission to contact the regulatory agency that granted the license, accompanied by the contact information, to confirm the information contained in the application; and
  - (iii) If the license, authorization, or application was ever warned, fined, denied, suspended, revoked, or otherwise sanctioned, a copy of documentation so indicating, or a statement that the applicant was so licensed and was never sanctioned; and
- (l) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with all building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the applicant's property is located, which are in effect at the time of the application, including but not limited to building department approval demonstrating compliance with rules adopted by the board of building standards

pursuant to Chapters 3781. and 3791. of the Revised Code and any applicable zoning considerations.

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

(a) Processing and extraction techniques;

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

(c) Facility specifications, designating the areas in the facility where the extraction and processing activities will occur, and evidencing that the applicant will comply with the requirements of Chapter 3796. Of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;

(d) The implementation of standards and guidelines for processing of plant material, refining of medical marijuana extracts, and manufacturing of medical marijuana products, including safety protocols and equipment; and

(e) Facility staffing and employment matters, which, at minimum, shall include:

(i) Employee training standards for the safe operation and maintenance of any and all equipment that will be used for processing medical marijuana conducted on an annual basis;

(ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used for processing medical marijuana, in accordance with OSHA protocols, conducted on an annual basis;

(iii) Employee training standards for the safe and sanitary execution of any applicable post-extraction refining protocols, conducted on an annual basis;

(iv) Employee training standards for the safe and sanitary execution of any applicable manufacturing processes, including any applicable food safety standards under Chapter 901:3-1 of the Administrative Code conducted on an annual basis; and

(v) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the

Revised Code:

- (4) A quality assurance plan that establishes policies and procedures for a safe, consistent supply of medical marijuana, which, at a minimum, shall include:
- (a) Intended use and sourcing of extraction equipment and associated solvents for the extraction of medical marijuana, or, in the case of non-solvent extraction, the intended physical methods and equipment;
  - (b) Intended use and sourcing of all non-marijuana ingredients utilized in the manufacture of medical marijuana products, including methods to verify or ensure the safety and integrity of those ingredients, as well as their potential to be allergens or to contain allergens as a result of their specific manufacturing;
  - (c) Compliance with Chapter 901:3-1 of the Administrative Code in the production of edible medical marijuana products;
  - (d) Best practices for the packaging and labeling of medical marijuana, such that it maintains medicinal integrity for the expected shelf-life;
  - (e) Implementation and compliance with the inventory tracking system;
  - (f) An inventory control plan;
  - (g) Standards for the disposal of medical marijuana waste and other wastes; and
  - (h) Recall policies and procedures in the event of contamination, expiration, or other circumstances that render the medical marijuana unsafe or unfit for consumption, including at a minimum, identification of the products involved, notification to the dispensary or others to whom the product was sold or otherwise distributed, and how the products will be disposed of if returned to or retrieved by the applicant.
- (5) A security plan that establishes policies and procedures to prevent theft, loss, or diversion from a processor and protect facility personnel, which, at a minimum, shall include:
- (a) Record keeping policies and procedures that will ensure the facility complies with rule 3796:3-2-08 of the Administrative Code;
  - (b) A security plan in accordance with rule 3796:3-2-05 of the Administrative Code;
  - (c) Transportation policies in accordance with rule 3796:5-3-01 of the Administrative Code; and

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

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

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

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

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

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

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

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

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

- (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:3-1-05 of the Administrative Code; and
- (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one percent or greater in the applicant for the five years before the filing of the application, unless the department determines that documentation should be submitted for all individuals and entities.
- (7) Any other information requested in the application instructions that the department deems necessary to evaluate and determine the applicant's suitability to operate as a processor.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	R.C. 3796.03
Rule Amplifies:	R.C. 3796.03, R.C. 3796.09