

3796:4-1-03

**Testing laboratory 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 3796:4-1-02 of the Administrative Code and an ability to meet the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code;

(2) Certify in writing at the time of application that an owner or prospective owner, officer or prospective officer, board member or prospective board member, administrator or prospective administrator, employee or prospective employee, agent or other person has not been:

(a) Convicted of a disqualifying offense, as defined in rule 3796:1-1-01 of the Administrative Code; or

(b) Issued a certificate to recommend or applied for certification under section 4731.30 of the Revised Code;

(3) Verify that the proposed facility is not located within five hundred feet from a prohibited facility, which shall be measured in accordance with rule 3796:5-5-01 of the Administrative Code;

(4) Certify that the local jurisdiction where the facility is proposed has not passed a moratorium or taken other action that would prohibit the applicant from operating as a medical marijuana testing laboratory;

(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 testing laboratory does not have a direct or indirect financial interest in, or serve as an owner, officer, board member, administrator, employee, agent, or other person who may significantly influence or control the activities of any of the following:

(a) A cultivator, processor, or dispensary licensed under Chapter 3796. of the Revised Code;

(b) An applicant for a cultivator, processor, or dispensary license;

(6) Provide documentation sufficient to establish that the applicant is in compliance with the applicable tax laws of this state and any jurisdiction where the applicant operates and conducts business;

(7) Submit an application with the applicable fee under rule 3796:5-1-01 of the

Administrative Code during the established application submission period established under paragraph (A) of rule 3796:4-1-02 of the Administrative Code. The application shall be submitted in accordance with the application instructions and forms issued by the department. The department may remove an application from consideration for any of the following:

- (a) Failure or refusal to submit information required under rule 3796:4-1-02 of the Administrative Code or requested by the department during the application submission or review process;
- (b) Inclusion of information in the application that misleads the department, misrepresents a material fact, or fails to disclose a material fact to the department;
- (c) Submission of an application that is in violation of the application instructions issued by the department, or includes forms issued by the department that have been altered.

(B) The applicants shall be evaluated using an impartial and numerical process taking into account the criteria identified in rule 3796:4-1-02 of the Administrative Code, as developed by the department, an independent contractor selected by the department, or a combination of the two. The applicants will be evaluated based on the following criteria, at a minimum:

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

- (a) A proposed business model demonstrating a likelihood of success, a sufficient business ability and experience on the part of the applicant;
- (b) An organizational chart of the company, including name, address, and date of birth of each principal officer and board member of the testing laboratory, provided that all those individuals shall be at least twenty-one years of age;
- (c) Experience with the analytical testing of medical marijuana or other agricultural, horticultural, or pharmaceutical products, 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. The information provided on business licenses shall include the type of license, the licensing agency, the date the license was obtained, and a summary of any negative actions taken against each license.
- (d) Evidence that the applicant owns the property on which the proposed testing laboratory will be located, has executed a lease for the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the

Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code, or has secured the ability to purchase or lease the property that does not contain any use restrictions that would otherwise prevent the testing laboratory from operating pursuant to Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;

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

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

(a) Laboratory analysis techniques, including specific instrumentation and protocols necessary to perform the tests required by this division;

(b) The implementation of standards and methods for conducting testing laboratory analysis of medical marijuana and medical marijuana products that will allow the applicant to obtain accreditation to the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard within two years of issuance of a provisional license;

(c) A list of proposed analytical services to be offered;

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

(e) Facility staffing and employment matters, which shall include, but not be limited to:

(i) Employee training standards for the safe operation and maintenance of any and all instrumentation that will be used in the testing of medical marijuana;

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

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

(f) Compliance with the inventory tracking system implemented by the department; and

(g) Policies and procedures for the destruction and disposal of medical marijuana waste and other wastes that ensure medical marijuana waste is rendered unusable.

(3) A security plan, which shall include but not be limited to:

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

(b) Physical equipment used to monitor the facility and meet the security requirements under Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;

(c) Emergency notification procedures with the department, local law enforcement, and emergency response professionals;

(d) A plot plan of the laboratory facility drawn to a reasonable scale that designates the different areas of operation, with the mandatory access restrictions; and

(e) Transportation policies and procedures, which includes the transportation of medical marijuana from a cultivator or processor licensed by the department to the proposed testing laboratory in the state of Ohio, in accordance with rule 3796:4-2-10 of the Administrative Code.

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

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

(b) A cost breakdown of the 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 two hundred fifty thousand dollars in liquid assets for a testing laboratory provisional license are unencumbered and can be converted within thirty days after a request to liquidate such assets:
- (i) Documentation acceptable to the department includes a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
  - (ii) The documentation must be dated within thirty calendar days before the date the application was submitted.
- (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code; and
- (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one 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.
- (5) Any other information that the department deems necessary to evaluate and determine the applicant's suitability to operate as a medical marijuana testing laboratory.
- (C) In addition to the criteria established in paragraph (B) of this rule, the department may also consider the following when awarding a provisional license:
- (1) Principal place of business:
    - (a) The applicant must provide documentation establishing that its principal place of business is headquartered in Ohio. The applicant may also provide the names, addresses, and verification of any persons associated with the applicant that have established residency in Ohio.
    - (b) The applicant may also provide a plan for generating Ohio-based jobs and economic development.
  - (2) Employment practices, in which the applicant must demonstrate a plan of action to inform, hire, and educate minorities, women, veterans, disabled persons,

and Ohio residents:

(3) Verification of economically disadvantaged groups; and

(a) The applicant must demonstrate the following:

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

(ii) It is owned and controlled as a woman-owned business by a United States citizen who is a resident of this state. For purpose of the paragraph, "owned and controlled" has the same ownership and control requirements as listed in paragraph (C)(3)(a)(i) of this rule.

(4) Research plan, in which the applicant must provide the department with a detailed proposal to conduct or facilitate a scientific study or studies related to the medicinal use of marijuana. Such a proposal shall address any applicable regulatory restrictions and compliance therewith.

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

(E) An applicant forfeits all fees associated with an abandoned application. The department shall not be required to act on an abandoned application and the application may be destroyed by the department. An abandoned application will not prevent an applicant from applying for a provisional license in the future if the department issues additional provisional licenses pursuant to rule 3796:4-1-01 of the Administrative Code.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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