

3796:4-1-02

Testing laboratory provisional license application.

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

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

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

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

(a) The legal name of the applicant;

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

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

(d) The proposed physical address of the 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 testing laboratory, provided that all those individuals shall be at least twenty-one years of age;

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

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

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

 - (i) A copy of each such licensing or authorizing document verifying licensure in that state or jurisdiction;
 - (ii) A statement granting permission to contact the regulatory agency that granted the license, accompanied by the contact information, to confirm the information contained in the application; and
 - (iii) If the license, authorization, or application was ever warned, fined, denied, suspended, revoked, or otherwise sanctioned, a copy of documentation so indicating, or a statement that the applicant was so licensed and was never sanctioned; and
- (l) Documentation that the applicant is currently in compliance, or will be in compliance prior to the issuance of a certificate of operation, with all building, fire, safety, and zoning statutes, local ordinances, and rules and regulations adopted by the locality in which the 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 in accordance with the requirements of ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories," that the applicant will implement for the secure and proper analytical testing of medical marijuana, which, at a minimum, shall include:
- (a) Laboratory analysis techniques, including specific instrumentation and protocols necessary to perform the tests required by this division;
 - (b) The implementation of standards and methods for conducting testing laboratory analysis of medical marijuana and medical marijuana products that will allow the applicant to obtain accreditation to the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard within two years of issuance of a provisional license;
 - (c) A list of proposed analytical services to be offered;
 - (d) Facility specifications, designating the areas in the facility where analytical testing will occur, and evidencing that the applicant will comply with the requirements of Chapter 3796. of the Revised Code and will operate in accordance with the rules promulgated pursuant to Chapter 3796. of the Revised Code;
 - (e) Facility staffing and employment matters, which, at a minimum, shall include:
 - (i) Employee training standards for the safe operation and maintenance of any and all instrumentation that will be used in the analytical testing of medical marijuana conducted on an annual basis;
 - (ii) Employee training standards for the safe use, handling, storage and disposal of any and all chemicals that will be used in the analytical testing of medical marijuana, in accordance with OSHA protocols, conducted on an annual basis; and
 - (iii) Employee compliance with Chapter 3796. of the Revised Code and the rules promulgated in accordance with Chapter 3796. of the Revised Code;
 - (f) Compliance with the inventory tracking system implemented by the department; and

- (g) Policies and procedures for the disposal of medical marijuana waste and other wastes that ensure medical marijuana waste is rendered unusable.
- (4) A security plan that establishes policies and procedures to prevent theft, loss, or diversion from a testing laboratory and protect facility personnel, which, at a minimum, shall include:
- (a) Record keeping policies and procedures that will ensure the facility complies with rule 3796:4-2-06 of the Administrative Code;
- (b) A security plan in accordance with rule 3796:4-2-07 of the Administrative Code;
- (c) Transportation policies in accordance with rule 3796:4-2-10 of the Administrative Code; and
- (d) A plot plan of the laboratory facility drawn to a reasonable scale that designates the different areas of operation, with mandatory access restrictions.
- (i) If the building is in existence at the time of the application, the applicant shall submit plans and specifications drawn to scale for the interior of the building.
- (ii) If the building is not in existence at the time of application, the applicant shall submit a plot plan and a detailed drawing to scale of the interior and the architect's drawing of the building to be constructed.
- (5) A financial plan, which, at a minimum, shall include:
- (a) The identity and ownership interest of every person, association, partnership, other entity or corporation having a financial interest, direct or indirect, in the testing laboratory with respect to which licensure is sought;
- (b) A cost breakdown of the 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 two hundred fifty thousand dollars in liquid assets for a testing laboratory provisional license, which are unencumbered and can be converted within thirty days after a request to liquidate such assets;

- (i) Documentation acceptable to the department includes a signed statement from an Ohio licensed certified public accountant attesting to proof of the required amount of liquid assets under the control of an owner or the entity applying, if such a statement is available at the time of application.
- (ii) The documentation must be dated within thirty calendar days before the date the application was submitted;
- (d) Information verifying that the applicant will be able to conform to the financial responsibility requirements under rule 3796:4-1-05 of the Administrative Code; and
- (e) A record of tax payments in the form of tax summary pages for individuals and businesses at the state and federal level in this state and in all jurisdictions in which an applicant has operated as a business and for every person with a financial interest of one 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.
- (6) Any other information requested in the application instructions that the department deems necessary to evaluate and determine the applicant's suitability for a testing laboratory license.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

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