



Testing Laboratory Rules

Medical Marijuana Control Program

Ohio Department of Commerce



Background

- 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.
- License application and award process differs from cultivators and processors with the inclusion of provisions for laboratories affiliated with public institutions of higher learning.
- The draft rules presented were developed after benchmarking with other states and consulting with industry experts.

Provisional Licenses

3796:4-1-01



- The Department may issue provisional licenses to conduct testing to public institutions of higher learning in Ohio.
- The Department may issue licenses to laboratories unaffiliated with public institutions of higher learning beginning one year after submissions of applications begin for licensure under ORC 3796.09.

License Application

3796:4-1-02



- Establishes a baseline for the application criteria, with specific standards and criteria to be listed in the application instructions.
- Application will cover several areas, including operations plan, security plan, and financial plan.
- The quality assurance component removed from application and addressed in rule, specifically certification and proficiency testing.

Application Review and Award

3796:4-1-03, 3796:4-1-04



- Sets forth the creation of a scoring rubric that will ensure an unbiased, impartial review of every application submitted.
- Identical process to those established for cultivators and processors.
- Limits persons to one testing laboratory license in Ohio.

Certificate of Operation Issuance & Renewal

3796:4-1-06 & 3796:4-1-08



- Issuance (3796:4-1-06)
 - Gives provisional licensees six months from issuance to meet conditions in the application and rule and pass inspection for a certificate of operation.
 - Laboratory may not begin operations until this is issued.
 - Includes a process if a testing laboratory does not pass inspection.
- Renewal (3796:4-1-08)
 - Outlines the process for renewal of a testing laboratory certificate of operation.
 - If not renewed before expiration, suspended for 30 days then revoked.

Financial Responsibility

3796:4-1-05



- Establishes insurance requirements for testing laboratories.
- Testing laboratories must maintain either:
 - \$75,000 escrow account, or
 - \$75,000 surety bond.
- Outlines circumstances under which escrow or bond may be paid to the Department.
- Establishes compliance-based method to reduce or eliminate the escrow or bond amount.

Transfer of Ownership or Location

3796:4-1-07



- Prohibits transfer of provisional licenses.
- Establishes grounds and process for a transfer of ownership or change in location of a testing laboratory.
 - Different process depending on percentage of ownership change.
- Develops process for change in location.

Discontinuation of Business

3796:4-1-09



- “Winding down” provision establishes protocol for voluntary surrender or non-renewal of certificate of operation.
 - Notification must be made to department.
 - Plan must be established for the sale, disposal, or other removal of medical marijuana sample inventory, analytical instruments, and chemicals.
 - Plan must be approved by director or director’s designee.

Testing Laboratory Operations

3796:4-2-01



- Requires compliance with these rules and with the approved operations plan submitted as part of application.
- Requires employment of a scientific director, who will be responsible for supervision and training of staff and for ensuring quality practices.
- Requires adoption of best available analytical methodologies for medical marijuana testing.
- Requires compliance with inventory tracking system (seed-to-sale).

Proficiency Testing, Certification, and Accreditation

3796:4-2-02



- Laboratories have two years from issuance of a provisional license to become certified and accredited to ISO 17025 standard.
 - Includes process by which a laboratory may petition the Department for an extension of time, subject to Director approval.
- Allows Department to require proficiency testing and third-party validation of analytical methods, at the discretion of the Director.
- Intended to ensure that laboratories are capable of delivering the most accurate results, in the interest of patient safety.

Sample Procurement

3796:4-2-03



- Requires that samples be collected randomly from batches of harvested plant material or lots of finished medical marijuana products.
- Allows for testing of medical marijuana extract for contaminants prior to use as an ingredient in a medical marijuana product.
- Allows testing laboratories to perform R&D analyses, in order to facilitate development of novel strains and improved cultivation techniques.

Analysis Requirements

3796:4-2-04



- Establishes testing requirements and flexible testing options based on product type, extraction method, and destination.
- Sets analytical sample size at the following:
 - 0.5% of total batch weight for harvested plant material or medical marijuana extract.
 - 1 randomly selected unit for each lot of medical marijuana products.
- Establishes “pass/fail” standards, and mandates that “failing” batches or lots be destroyed by the cultivator or processor providing the sample.
 - Exception for plant material with respect to microbiological contaminants that can be extracted and re-tested as extract/product.

Reporting Requirements

3796:4-2-05



- Requires submission of certificate of analysis for each batch tested to be submitted to the department electronically.
- Establishes what shall, may, and shall not be included on a certificate of analysis.
 - Allows laboratories to report quantitative analyses beyond the minimum requirements for any cannabinoids or terpenes for which they are able to obtain a standard for comparison.

Waste Disposal

3796:4-2-06



- Establishes requirements for the manner in which waste or excess medical marijuana not used during analysis may be destroyed, including the tracking of batches of material and lots of material and products.
- Requires that disposal of non-marijuana waste be in compliance with applicable state and federal laws.

Security

3796:4-2-07



- Mirrors security requirements for cultivators and processors.
- Divides security into physical security (lighting, locked doors, etc.) and technology security (alarm system, video cameras, silent alarm, etc.).
- Sets standards for the video recording technology and alarm technology.
 - State will have 24-hour access to live camera feeds and equipment must allow for motion-activated recording capabilities.
- Notifies the department and law enforcement of breaches in security.

Prohibited Activities

3796:4-2-08



- Prohibits the following:
 - Cultivation, processing, manufacturing, or sale of medical marijuana,
 - Consumption on premises,
 - Sharing a facility with a cultivator, processor, or dispensary,
 - Alteration of test results, non-random sampling, biased sample preparation,
 - Storage or transportation of medical marijuana in excess of what is required to conduct require analyses,
 - Ownership or other interest in cultivator or processor,
 - Ownership by physician certified to recommend medical marijuana, and
 - Analysis of medical marijuana that has not been obtained from licensed cultivator or processor.

Records & Reporting

3796:4-2-09



- Establishes record requirements and 5-year records retention period for:
 - Analysis,
 - Transportation,
 - Destruction,
 - Security,
 - Employee matters (including training documentation),
 - Financial records, and
 - Theft/loss.

Enforcement

3796:4-3-01



- Establishes the actions the department may take if a licensed entity commits a prohibited act, as defined in rule.
 - ORC establishes that suspension/revocation would be under Chapter 119.
- Sets protocol for inspections (same as for cultivators and processors)
- Allows for joint inspections with other state agencies, if necessary based on the circumstances



Miscellaneous

- Fees:
 - Testing laboratory application fee: \$2,000.
 - License fee: \$18,000.
 - Renewal fee: \$20,000.