



Processor 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 consistent with previously presented cultivator rules.
- The draft rules presented were developed after benchmarking with other states and talking with industry experts.

Processor Provisional Licenses

3796:3-1-01



- The Department may issue up to 40 provisional licenses prior to September 8, 2018, with no more than 10 in any designated territory.
- The Director has discretion to issue additional provisional licenses after September 9, 2018, based on patient population, demand for medical marijuana products, and approval of new forms of administration by Board of Pharmacy (under ORC 3796.06(A)(6)).
- Limits persons to one processor license in Ohio.

License Application, Review, and Award

3796:3-1-02, 3796:3-1-03, 3796:3-1-04



- 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, quality assurance plan, and financial plan.
- Sets forth the creation of a scoring rubric that will ensure an unbiased, impartial review of every application submitted.

Processor Financial Responsibility

3796:3-1-05



- Establishes insurance requirements for processors.
- Processors must maintain either:
 - \$750,000 escrow account, or
 - \$750,000 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.

Certificate of Operation Issuance & Renewal 3796:3-1-06 & 3796:3-1-09



- Issuance (3796:3-1-06)
 - Gives provisional licensees six months from issuance to meet conditions in the application and rule and pass inspection for a certificate of operation.
 - Processor may not begin plant material procurement or product manufacturing operations until this is issued.
 - Includes a process if a processor does not pass inspection.
- Renewal (3796:3-1-09)
 - Outlines the process for renewal of a processor certificate of operation.
 - If not renewed before expiration, suspended for 30 days then revoked.

Uninterrupted Supply

3796:3-1-07



- Establishes production controls to ensure that processors are manufacturing and providing an uninterrupted supply to the market.
- Prevents licensees from holding a license on an inactive facility.
- Sets forth petition process in the event that a processor is unable to meet supply requirements for reasons including lack of availability of starting materials.

Transfer of Ownership or Location

3796:3-1-08



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

Discontinuation of Business

3796:3-1-10



- “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 inventory, processing equipment, and chemicals.
 - Plan must be approved by director or director’s designee.

Processor Operations

3796:3-2



- Requires compliance with these rules and with the approved operations plan submitted as part of application.
- Establishes permitted extraction techniques, including allowed solvents, in accordance with methods that can be used to manufacture statutorily permitted forms.
- Sets education and experience requirement for supervisory staff who will monitor the use of extraction equipment.

Quality Assurance

3796:3-2-01



- Requires compliance with rules and with QA plan submitted as part of the application.
- Establishes requirements for the clean and sanitary maintenance of a processing facility.
 - The Department continues to work with agencies regulating similar activities.

Packaging & Labeling

3796:3-2-02



- Sets requirements for what information must be included on a product label.
- Includes additional requirements and statements for edible products and products that have been infused with medical marijuana extract.
 - Disclosure of possible allergens.
 - Disclosure of extraction technique and any solvents used.
- Prohibits use of cartoons, pop culture icons, and unregistered images.
- Prohibits sum totals of cannabinoids or terpenes from being displayed (other than THC content as defined in 3796-1(A)).

Waste Disposal

3796:3-2-03



- Establishes requirements for the manner in which waste 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.

Inventory Control & Storage

3796:3-2-04



- Sets requirements for the information that must be tracked in the inventory control system.
- Requires ongoing inventory controls, weekly inventory, and annual, manual inventory reconciliation as a condition for license renewal.
- Allows department to access inventory records at any time.

Security

3796:3-2-05



- Mirrors security requirements for cultivators
- Divides security into physical security (fences, lighting, locked doors, safes, etc.) and technology security (alarm system, video cameras, silent alarm, etc.).
- Sets standards for the video recording technology and alarm technology.
 - State will have the ability to access live camera feeds.
- Notifies the department and law enforcement of breaches in security.

Laboratory Testing

3796:3-2-06



- Allows flexibility to test medical marijuana extract for potency and contaminants before the extract is used in the manufacture of a medical marijuana product.
- Requires processors packaging plant material on behalf of a cultivator to verify that tests have been performed prior to packaging.
- All final products must be tested prior to distribution to dispensaries.

Prohibited Activities

3796:3-2-07



- Prohibits the following:
 - Sale from processors to patients/caregivers.
 - On-premises consumption of any form of medical marijuana.
 - Manufacture of forms not permitted by statute or approved by Pharmacy.
 - Manufacture of products that exceed 70% THC content.
 - Changes to operations plan, QA plan, or manufacturing techniques without approval.
 - Stockpiling of medical marijuana or medical marijuana products.
 - Price discrimination between dispensaries for like quantity and grade of products.

Records & Reporting

3796:3-2-08



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

Enforcement & Inspections

3796:3-3



- 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).
- Allows for joint inspections with other state agencies, if necessary based on the circumstances.



Miscellaneous

- Fees:
 - Processor application: \$10,000
 - License fee: \$90,000
 - Renewal fee: \$100,000
- Advertising: same requirements as cultivators regarding department approval and registration fee.
- Product registration: same procedure and fee for processors to register products as for cultivators to register strains.