4/7/2017

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the Department of Commerce, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the impacted public to provide input on the following rules.

**New Rules**

- These rules govern processor operations under Ohio's Medical Marijuana Control Program.

Comments on the proposed rules will be accepted until close of business on April 21, 2017. Please send all comments to the following email address:

**MMCPRules@com.state.oh.us**

In addition, please copy your comments to:

**CSIPublicComments@governor.ohio.gov**

Continue on to the next page for the BIA.

# CSI - Ohio
The Common Sense Initiative

## Business Impact Analysis

**Agency Name:** Department of Commerce

**Regulation/Package Title:** Medical Marijuana Control Program Processor Rules

**Rule Number(s):** 3796:3-1-01; 3796:3-1-02; 3796:3-1-03; 3796:3-1-04; 3796:3-1-05; 3796:3-1-06; 3796:3-1-07; 3796:3-1-08; 3796:3-1-09; 3796:3-1-10; 3796:3-2-01; 3796:3-2-02; 3796:3-2-03; 3796:3-2-04; 3796:3-2-05; 3796:3-2-06; 3796:3-2-07; 3796:3-2-08; 3796:3-3-01;

**Date:** April 6, 2017

**Rule Type:** New

**The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.**

### Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   **Please include the key provisions of the regulation as well as any proposed amendments.**

   The responsibilities under Chapter 3796 of the Revised Code are divided up between multiple agencies under Ohio's Medical Marijuana Program ("Program"), including the Ohio Department of Commerce ("Department"), Ohio Board of Pharmacy and the State Medical Board of Ohio. The Program was established by House Bill 523 of the 131st General Assembly. The Department is responsible for the administration, implementation and enforcement of cultivators, processor and testing laboratories under the Program. In addition to these responsibilities, the Department is also statutorily responsible for establishing a

"seed-to-sale" electronic system that tracks medical marijuana from the beginning stages until sale to a registered patient. This Business Impact Analysis addresses rules that apply to medical marijuana processors.

- Rule 3796:3-1-01 addresses the number of processor licenses issued (a) prior to the effective date of the Program, which is September 8, 2018, and (b) after the effective date of the program, based on population and patient population.
- Rule 3796:3-1-02 establishes the application submission process and the criteria that will be evaluated in the application, including a business plan, operations plan, quality assurance plan, security plan, financial plan, and any other information deemed necessary by the Department.
- Rule 3796:3-1-03 covers the application review. This rule also establishes certain requirements that must be met for an application to receive consideration and identifies bonus criteria to consider during the review process.
- Rule 3796:3-1-04 details the procedures for issuing a provisional license. This rule prevents a person or business from holding more than one processor license in the State, which includes a financial interest in a licensee.
- Rule 3796:3-1-05 sets forth the financial responsibility requirements that must be met in order for a provisional licensee to receive a certificate of operation. These requirements include (a) general liability and products liability insurance coverage with limits determined by the Department, and (b) a surety bond in the amount of $250,000, or (c) an escrow account in the amount of $250,000. This rule also establishes benchmarks that, if met, reduce the dollar amount of the bond or escrow account.
- Rule 3796:3-1-06 addresses the time period for a provisional licensee to get up and running (6 months) and the issuance of a certificate of operation. It also allows the director, at his or her discretion, to extend the time period for the processor to obtain a certificate of operation.
- Rule 3796:3-1-07 places a requirement on processors to meet an uninterrupted supply standard to ensure adequate supply and make sure the licensee is operating. This rule creates a process if the licensee is unable to meet this standard.
- Rule 3796:3-1-08 prohibits a processor provisional licensee from transferring its license to another person and establishes a process that a processor must follow if there is a change in location or transfer in ownership once a certificate of operation is obtained. If the controlling interest changes, a new application is required and must be approved by the Department.

- Rule 3796:3-1-09 covers the renewal of a processor's certificate of operation and the process to renew, which includes a $100,000 renewal fee. Fee amounts are established in 3796:5-1-01. A failure to renew 30 days past renewal date will result in the certificate being revoked.
- Rule 3796:3-1-10 addresses the winding down of a processor facility, if the processor voluntarily chooses to exit the industry without a transfer in ownership or the processor is evicted from the facility. This rule includes a plan of closure that must be submitted and approved by the Department.
- Rule 3796:3-2-01 details the components of processor operations and quality assurance plans and establishes standards with which processors must comply to ensure product consistency and patient safety. This rule includes limits on the methods, equipment, solvents and gases utilized in the manufacture of medical marijuana. This rule also contains rules on equipment cleanliness, facility sanitation and other quality assurance considerations. This rule also establishes how a processor obtains plant material from a cultivator or a dispensary.
- Rule 3796:3-2-02 sets forth packaging and labeling requirements for processors. This rule establishes a universal symbol for edible medical marijuana. This rule also allows processors to send samples to dispensaries for patients to smell and analyze prior to a sale.
- Rule 3796:3-2-03 addresses the different ways a processor can dispose of medical marijuana waste and non-medical marijuana waste, including rendering it unusable in a locked dumpster. The rule lists the material that can be mixed with the waste to render it unusable pursuant to the rule. It also requires that a Level I key employee oversee all waste disposal and destruction documented in a destruction log maintained by the facility and submitted to the Department.
- Rule 3796:3-2-04 establishes processes and procedures for inventory control and the information that enters the seed-to-sale system. This includes a weekly inventory based on sales and destruction, as well as processing at the facility. This rule also requires an annual, manual inventory to ensure the seed-to-sale system properly tracks inventory and facility operations.
- Rule 3796:3-2-05 highlights the facility security measures, ranging from locked access areas to technology requirements. The facility requirements are covered under paragraph (A) and the technology security requirements fall under (B). The technology security is a big component of the security plan and requires a video surveillance system and alarm system that allows the Department to live access the cameras in the facility and monitor the operations.

- Rule 3796:3-2-06 lists the testing requirements prior to sale of any medical marijuana product to a dispensary. Testing laboratory standards will be detailed in future rules.
- Rule 3796:3-2-07 covers the prohibited activities found in statute and pulled from other states with comparable programs and that is separate from the "prohibited acts" under the enforcement rules.
- Rule 3796:3-2-08 lists the various records and reporting requirements, including inventory records, sales records, transportation records, security records, testing lab records, processing records, employee records, and enforcement records. The record retention period is five years and allows a processor to maintain its own, independent electronic system for records, but this is not required. This rule further breaks down each record listed above.
- Rule 3796:3-3-01 establishes the scope of the Department's inspections, both during a pre-operation inspection that is required for the issuance of a certificate of operation, and subsequent inspections of the facility. The rule outlines a process that will allow a processor to remedy any shortcomings or compliance issue before action is taken by the Department under the enforcement section of the rules. It also requires inspection reports.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   Chapters 119 and 3796 of the Revised Code are the authorizing statutes for these rules.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

   No, these rules do not implement a federal requirement.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Not applicable.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   These rules help ensure that patients will receive a safe and consistent medical marijuana product and establishes a process that must be followed to provide adequate safety and security measures for processor facilities.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of this program will be measured by the availability of safe medical marijuana for patients with qualified conditions at a reasonable price. Ohio's Program is designed to be conservative, yet flexible in nature, which will help ensure patient safety and limit threats of diversion/theft and involvement of criminal enterprises.

## Development of the Regulation

**7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

The Department solicited comments from the general public and the Medical Marijuana Advisory Committee. Over 19 comment submissions were received. The Department received feedback from many different groups and stakeholders with an interest in the Program, including Ohio citizens, Ohio businesses, advocacy groups, and industry associations formed in this state and outside of Ohio.

**8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

The Department received over 19 responses during the rule comment period. In general, the majority of the feedback received can be categorized into the following areas:

- The 24-hour access to security systems was too burdensome and should be altered to allow recordings to be triggered by motion/activity.
- General questions or comments about the Medical Marijuana Control Program such as requesting the time period for applications and comments on home cultivation.
- The financial constraints and barriers to entry for potential applicants, including the licensing fee amounts and financial responsibility requirements that must be met by.
- Concerns over use of a universal symbol on very small products and other packaging and labeling requirements.
- Requests for an Ohio residency requirement.
- Requests to expand the number of processors beyond 40, though at least one comment expressed that 40 was the correct number.
- Solventless extracts should not be limited to only those that are infused into a carrier oil or fat.

Based on the public's feedback, guidance from an industry consultant and discussions between the stakeholders responsible for the MMCP, the following changes were made to the draft rules:

- **Solventless extracts** – 3796:3-2-01 was changed to remove references to oils and fats. Expanded language regarding non-solvent extraction methods and the sourcing of non-marijuana ingredients used in the manufacture of medical marijuana products.
- **Packaging & Labeling -** Language added/modified to ensure processor compliance with packaging and labeling rules promulgated by Board of Pharmacy.
- **Motion sensor recording only** – This suggestion was incorporated into 3796:3-2-05(B)(1).
- **Financial responsibility** – Surety bond and escrow amounts reduced to $250,000. Liquid capital requirements were reduced to $100,000 for processors that are commonly-owned and co-located with a cultivator.
- **Number of licenses** - The number of provisional licenses that may be issued prior to September 9, 2018 remains at 40. However, as was the case with medical marijuana cultivators, the designated geographic territories have been removed.
- **Plant material acquisition** - Provision added to allow expired plant material to be acquired from dispensaries and extracted for use in the manufacture of medical marijuana products.

The Department reviewed every comment submitted to the MMCP rules address. The Department determined that it was in the best interest of the Program to not make certain changes to the rules draft. Some examples include the following:

- **Increased Processor Licenses** – The Department listened to the different concerns related to a limited number of licenses. The Department acknowledges that the proposed structure will provide applicants with experience, knowledge and ability with these licenses, but that is in line with the responsibilities of a medical program: ensuring a consistent, safe medical product for registered patients that need relief. The rules have been drafted to allow for the Department to add licenses should demand in Ohio warrant it. Additionally, at least one comment fully supported limiting licenses to 40.
- **Ohio Residency Requirement** – There is a provision in 3796:3-1-03(C)(1) that permits the Department to consider whether the applicant is an Ohio business.

A summary of the comments received by the Department can be found in Attachment 1.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

   Rules were developed after benchmarking with other states and talking with industry experts, including an expert consultant.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    There are no alternative regulations or specific provisions within the regulation to be considered.

11. **Did the Agency specifically consider a performance-based regulation? Please explain.**

    Performance-based regulation was considered for these rules. For example, the application criteria were developed as a merit-based system, where applicants will have to demonstrate their knowledge and abilities in this specific field to be considered for a license. Additionally, the regulations include language that allows medical marijuana entities to phase-out bonding and escrow requirements as these entities meet performance thresholds and provide a consistent supply of medical marijuana.

12. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    This is a new industry, so there are no existing rules to duplicate.

13. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    The Department established standards and procedures that apply to every entity that will be licensed by the Department under the Program. The proposed rules set forth a consistent process for the issuance of processor provisional licenses, processor certificates of operation and employee identification cards. The regulations also establish and communicate the process for the issuance of licenses and employee identification cards, which speaks to the predictability of the Program's operations.

## Adverse Impact to Business

14. **Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**
    a. **Identify the scope of the impacted business community;**

These rules regulate processors of medical marijuana. “Processor”, means an entity that has been issued a certificate of operation by the department to manufacture medical marijuana products. Processors will be the sole entity responsible for the legal processing of marijuana in the state of Ohio.

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

The Department has established both application and licensing fee schedules for medical marijuana entities regulated by the Department under rule 3796:5-1-01 of the Administrative Code. Application fees will be $10,000 for processors. Applicants that are issued a provisional license have six months to pass a pre-operation inspection and become operational. The license fees will be $90,000 for processors. Renewal fees will be $100,000 for processors.

There will be additional fees associated with the registration of employees and corresponding issuance of identification cards, as well as fees for product registration, both of which will be $100 per instance. Total cost will be highly variable based on the number of employees and number of products that a given entity will need to register. Employees will also be required to undergo a background check.

With respect to fines, the Department has the authority under rule 3796:5-6-01 to issue fines for violations of the rules chapter and Chapter 3796 of the Revised Code of up to $50,000 per violation.

Costs for compliance fall into several categories, not all of which can be accurately estimated due to the fact that this is an emerging industry, and thus the data does not currently exist. There will be costs associated with compliance with rules regarding laboratory testing of medical marijuana, as well as for waste removal, but there is currently no industry-wide accepted standard by which an estimate can be generated. These costs will vary based on the prerogative of the firms providing the services. Similarly, there will be costs of compliance associated with security requirements, which will be variable based on vendor and equipment used.

Costs associated with employee time for compliance may be incurred throughout the inspection process, as inspectors will be escorted by an employee while inside the processor facilities. There will also be an employee time cost associated with the transportation requirements, which state that two employees are required to be present while transporting medical marijuana from a processor facility to a processor or

dispensary. Additionally, businesses will incur employee time costs associated with preparing the application for licensure, formulation of standard operating procedures that ensure compliance with the proposed rules, and performing required record keeping duties.

**c. Quantify the expected adverse impact from the regulation.**

Each entity licensed with the Department will be required to comply with these new regulations to ensure the public health and safety within establishments processing medical marijuana.

The Department does not have data to provide a quantified potential impact for the reasonable compliance costs associated with compliance with the rules, beyond the fees established in rule.

While the ultimate adverse impact for a violation of the Department's rules could be a fine, suspension, revocation, or rejection of an entity's license, the Department intends to work to assist and educate all of these entities to avoid such repercussions.

**15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The regulation of medical marijuana is brand new to Ohio. These rules are designed to provide a balanced, transparent, and accountable method of allowing individuals and entities to obtain and maintain processor licenses. The regulatory intent of the rules justifies the adverse impact because the manufacturing and sale of medical marijuana is a unique industry that requires strict regulation for the health, safety, and protection of the public. The State has a compelling interest in promoting safe and temperate use of medical marijuana while avoiding risks such as diversion and theft of medical marijuana.

## Regulatory Flexibility

**16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

No.

**17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

While the Department takes great effort to ensure that applicants submit correct documentation, ORC 119.14 is not applicable to these rules as there is no penalty associated with the paperwork necessary pursuant to these rules.

18. **What resources are available to assist small businesses with compliance of the regulation?**

The Department can be contacted via multiple sources:
The Program website: http://medicalmarijuana.ohio.gov
The Department's office is located at: 77 S. High St., Columbus, OH 43215