5/4/2017

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 testing laboratory operations under Ohio's Medical Marijuana Control Program.

Comments on the proposed rules will be accepted until close of business on May 19, 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 Testing Laboratory Rules

Rule Number(s): 3796:4-1-01; 3796:4-1-02; 3796:4-1-03; 3796:4-1-04; 3796:4-1-05; 3796:4-1-06; 3796:4-1-07; 3796:4-1-08; 3796:4-1-09; 3796:4-2-01; 3796:4-2-02; 3796:4-2-03; 3796:4-2-04; 3796:4-2-05; 3796:4-2-06; 3796:4-2-07; 3796:4-2-08; 3796:4-2-09; 3796:4-2-10; 3796:4-3-01;

Date: May 4, 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, processors, 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 testing laboratories.

- Rule 3796:4-1-01 addresses the number of testing laboratories licenses to be issued.
- Rule 3796:4-1-02 establishes the application submission process and the criteria that will be evaluated in the application, including a business plan, operations plan, security plan, financial plan, and any other information deemed necessary by the Department.
- Rule 3796:4-1-03 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 3796:4-1-04 details the procedures for issuing a provisional license. This rule prevents a person or business from holding more than one testing laboratory license in the State, which includes a financial interest in a licensee.
- Rule 3796:4-1-05 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 $75,000, or (c) an escrow account in the amount of $75,000. This rule also establishes benchmarks that, if met, reduce the dollar amount of the bond or escrow account.
- Rule 3796:4-1-06 addresses the time period for a provisional licensee to get up and running (6 months) and the issuance of a certificate of operation.
- Rule 3796:4-1-07 prohibits a testing laboratory provisional licensee from transferring its license to another person and establishes a process that a testing laboratory 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 3796:4-1-08 covers the renewal of a testing laboratory's certificate of operation and the process to renew, which includes a $20,000 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 3796:4-1-09 covers the winding down of a testing laboratory's operation including dates for submission of a plan for closure, destruction of medical marijuana, sale or removal of equipment, retention of records, and removal of chemicals or solvents.

- Rule 3796:4-2-10 outlines the manner in which medical marijuana testing laboratories must transport medical marijuana samples obtained from cultivators or processors.
- Rule 3796:4-2-01 details testing laboratory operations and establishes standards with which testing laboratories must comply to ensure testing consistency and safety. This rule also contains rules on equipment cleanliness, facility sanitation and other quality assurance considerations. This rule requires the employment of a scientific director and indicates which methods of analysis are permitted.
- Rule 3796:4-2-02 details testing laboratory accreditation requirements and third party proficiency testing programs. This provision permits the Director to fine, suspend, or revoke the testing laboratory certificate of operation if the provisions of this rule are not met.
- Rule 3796:4-2-03 addresses sample procurement for testing laboratories including obtaining samples from cultivators and processors. This rule also provides guidance as to what the testing laboratory should test samples for.
- Rule 3796:4-2-04 establishes analysis requirements including tests for pesticides, fertilizers, heavy metals, other contaminants, and cannabinoid potency. This rule provides direction on the minimum sample size required for testing.
- Rule 3796:4-2-05 lists the testing laboratory reporting requirements including content and general format.
- Rule 3796:4-2-06 lists the methods and procedures to follow for proper disposal of testing laboratory waste.
- Rule 3796:4-2-07 covers the security requirements for testing laboratories. This includes requirements for a surveillance system as well as restricted access to parts of the facility in which medical marijuana is contained.
- Rule 3796:4-2-08 lists the activities testing laboratories are prohibited from conducting. These include prohibition on the cultivation and processing of medical marijuana, sharing facilities with a processor or cultivator, maintaining excessive quantities of medical marijuana, and other requirements ensuring the integrity of the testing.
- Rule 3796:4-2-09 establishes the record keeping requirements for testing laboratories. This section requires retention of records for five years.
- Rule 3796:4-3-01 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 testing laboratories 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 testing laboratory facilities.

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

   The success of the 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. Four comment submissions were received. The Department received feedback from 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 four public comments on the testing laboratory rules. Three comments were concerned that higher education laboratories would not participate in the program. These comments address the H.B. 523 Section 5 requirement limiting licensure to testing laboratories of public institutions of higher education, located in Ohio, with the capability to conduct testing as required by R.C. 3796 for one year from the date the Department accepts applications for licensure. The Department is not able to adjust this requirement as the comments suggested due to the text of H.B. 523.

   The remaining comment indicated that the requirements for microbiological testing are not specific enough. The Department elected not to adjust the requirements as the Department feels they are adequate to ensure patient protection.

   The Department also received recommended changes from industry stakeholders since the initial release of the testing laboratory rules draft. These recommended changes all related to procedural aspects of ISO/IEC 17025 accreditation and the validation of alternative methods as part of ISO/IEC 17025 accreditation. The recommended changes also focused on the administration of proficiency testing in the State of Ohio. The Department made some changes to the following rules to make this subject matter more clear and consistent: 3796:4-1-02(B)(3), 3796:4-2-01(A)(6), 3796:4-2-01(C)(2), 3796:4-2-02(A) and 3796:4-2-02(G).

   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.

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 Ohio 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 testing laboratory provisional licenses and testing laboratory certificates of operation. The regulations also establish and communicate the process for the issuance of licenses, 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 testing laboratories of medical marijuana. "Testing Laboratory", means an independent laboratory located in Ohio that has been issued a certificate of operation by the Department to have custody and use of controlled substances for scientific and medical purposes and for purposes of instruction, research, or analysis. Testing laboratories will be the sole entities responsible for the qualitative analysis 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 $2,000 for Testing Laboratories. Applicants that are issued a provisional license have six months to pass a pre-operation inspection and become operational. The license fees will be $18,000 for testing laboratories. Renewal fees will be $20,000 for testing laboratories.

There will be additional fees associated with the registration of employees and corresponding issuance of identification cards, 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 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 testing laboratory 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 licensed cultivator or processor to a testing laboratory. 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 testing laboratory 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