CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Department of Commerce

Regulation/Package Title: Medical Marijuana Control Program Cultivator Rules

Rule Number(s): 3796:1-1-01; 3796:2-1-01; 3796:2-1-02; 3796:2-1-03; 3796:2-1-04; 3796:2-1-05; 3796:2-1-06; 3796:2-1-07; 3796:2-1-08; 3796:2-1-09; 3796:2-1-10; 3796:2-1-11; 3796:2-2-01; 3796:2-2-02; 3796:2-2-03; 3796:2-2-04; 3796:2-2-05; 3796:2-2-06; 3796:2-2-07; 3796:2-2-08; 3796:2-3-01; 3796:5-1-01; 3796:5-2-01; 3796:5-2-02; 3796:5-2-03; 3796:5-3-01; 3796:5-4-01; 3796:5-5-01; 3796:5-6-01; 3796:5-6-02; 3796:5-6-03; 3796:5-7-01; 3796:5-8-01;

Date: January 10, 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 cultivators.

- Rule 3796:1-1-01 provides a list of definitions that make up the Program. These definitions apply to all rules promulgated in OAC 3796, including those promulgated by the Board of Pharmacy. Included in the definitions is a list of disqualifying offenses for the Program.
- Rule 3796:2-1-01 addresses the number of cultivator 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 3796:2-1-02 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 3796:2-1-03 covers the application review process and establishes the parameters of a scoring rubric that will be used to ensure a fair and unbiased review of the applications submitted for cultivator licenses. 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 3796:2-1-04 details the procedures for awarding and accepting a provisional license. This rule prevents a person or business from holding more than one cultivator license in the State, which includes a financial interest in a licensee.
- Rule 3796:2-1-05 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 $750,000 for Level I cultivators and $75,000 for Level II cultivators, or (c) an escrow account in the amount of $750,000 for Level I cultivators and $75,000 for Level II cultivators. This rule also establishes benchmarks that, if met, reduce the dollar amount of the bond or escrow account.

- Rule 3796:2-1-06 addresses the time period for a provisional licensee to get up and running (9 months) and the issuance of a certificate of operation, which allows a cultivator to start growing medical marijuana. It also allows a provisional licensee to request an extension to obtain this certificate if the circumstance permit it.
- Rule 3796:2-1-07 places a requirement on cultivators to meet an uninterrupted supply standard to ensure adequate supply and make sure licensee are operating. The standard is different for Level I and Level II cultivators, and there is a process if they are unable to meet this standard to toll the time period or for the director to take action, at his or her discretion.
- Rule 3796:2-1-08 prohibits a cultivator provisional licensee from transferring its license to another person and establishes a process that a cultivator 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. This rule also covers change in location for a cultivator within the same designated territory.
- Rule 3796:2-1-09 permits a cultivator to expand its marijuana cultivation area from the original space (up to 25,000 square feet permitted for Level I and 3,000 square feet permitted for Level II) by way of an approved build out not to exceed the initial limits for Level I and Level II cultivators, resulting in a maximum marijuana cultivation area for 50,000 square feet for Level I and 6,000 square feet for Level II. This rule covers the plan for expansion and gives the director discretion to authorize a second build out of up to an additional 25,000 square feet for Level I cultivators and 3,000 square feet for Level II cultivators, if necessary to meet patient demand and other factors in rule, resulting in a maximum marijuana cultivation area of 75,000 square feet for Level I and 9,000 square feet for Level II.
- Rule 3796:2-1-10 covers the renewal of a cultivator's certificate of operation and the process to renew, which includes a $200,000 renewal fee for Level I cultivators and $20,000 renewal fee for Level II cultivators. Fee amounts are established in 3796:5-1. A failure to renew 30 days past renewal date will result in the certificate being revoked.
- Rule 3796:2-1-11 addresses the winding down of a cultivator facility, if the cultivator voluntarily chooses to exit the industry without a transfer in ownership or the cultivator is evicted from the facility. This rule includes a plan of closure that must be submitted and approved by the Department.
- Rule 3796:2-2-01 details the components of a quality assurance plan and establishes standards with which cultivators must comply to ensure product consistency and patient safety. This rule includes limits on pesticide and fertilizer usage, equipment cleanliness,

facility sanitation and other quality assurance considerations. This rule also includes language around the cultivator's operations plan that will help them comply with the various requirements imposed by law and rule, including cleanliness and sanitary environment standards.

- Rule 3796:2-2-02 sets forth packaging and labeling requirements for cultivators and plant-only processors that package and transport plant material to processors and/or dispensaries. This rule includes the required content and laboratory analysis found on the label or container that contains the medical marijuana. This rule also allows cultivators to send sample containers to processors and dispensaries for patients to smell and analyze prior to a sale.
- Rule 3796:2-2-03 addresses the different ways a cultivator can dispose of medical marijuana waste and non-medical marijuana waste, including rendering it unusable in a locked dumpster or composting the waste on-site for future use on-site. 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 3796:2-2-04 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 cultivation 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 3796:2-2-05 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 3796:2-2-06 lists the testing requirements depending on the intended use of the plant material. If the plant material is being shipped directly to a dispensary for patient administration, a much stricter lab analysis is required. If the plant material is being sent to a processor to be refined and extracted, then the product will undergo subsequent tests and the analysis for this material will be reduced. The industry will impose its own set of requirements. Testing laboratory standards will be detailed in future rules.

- Rule 3796:2-2-07 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 3796:2-2-08 lists the various records and reporting requirements, including inventory records, sales records, transportation records, security records, testing lab records, cultivation records, employee records, and enforcement records. The record retention period is five years and allows a cultivator to maintain its own, independent electronic system for records, but this is not required. This rule further breaks down each record listed above.
- Rule 3796:2-3-01 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 an annual inspection of the facility. The rule outlines a process that will allow a cultivator 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.
- Rule 3796:5-1-01 states the various fees for medical marijuana entities licensed by the Department. This fee schedule includes employee identification cards and covers the fees for applications, certificate of operations, license renewals and other fees based on the circumstances. These fees are based on a review of other states' programs and the need to fully fund the operations of the Program.
- Rule 3796:5-2-01 addresses required employee identification cards and includes the application process, issuance of the ID card, employee designations for facility access purposes, and the revocation of a card and/or entity license that employs the person.
- Rule 3796:5-2-02 describes the criminal background check process required under O.R.C. 3796.
- Rule 3796:5-2-03 lists the reasons or events that will trigger a denial of an employee identification card. This rule also provides protection to an employee that reports a violation at the facility.
- Rule 3796:5-3-01 establishes transportation requirements for medical marijuana, including transportation logs, vehicle requirements and employee requirements for transporting medical marijuana.
- Rule 3796:5-4-01 covers reporting and responsibilities if a theft or diversion of medical marijuana occurs at a facility. This rule includes reporting timelines and information that must be provided to the Department.

- Rule 3796:5-5-01 defines the measurement of medical marijuana facilities from a prohibited facility, as defined in rule based on O.R.C. 3796. This rule also establishes that facilities in existing prior to a prohibited facility coming within 500 feet are grandfathered in.
- Rule 3796:5-6-01 provides an overview and scope of the enforcement rules for these medical marijuana entities. This rule also defines the enforcement powers made available to the Department in the event of a prohibited act under rule 3796:5-6-02.
- Rule 3796:5-6-02 breaks down prohibited activities that may trigger an enforcement action. This rule also encourages agency cooperation between the agency stakeholders under Ohio's Medical Marijuana Control Program.
- Rule 3796:5-6-03 states the outcome of a revoked or suspended license and acknowledges the 119 process with respect to licensing.
- Rule 3796:5-7-01 lists the permitted and prohibited advertising activities with respect to form and substance. This rule also permits a medical marijuana entity licensed by the department to seek Department approval of an advertisement prior to its use for a small advertising fee. The rule also addresses social media and web-based advertising considerations.
- Rule 3796:5-8-01 handles product registration and designates a two-step process involving the Pharmacy Board and the assignment of the required product identifier, including a product registration fee paid to Pharmacy.

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 cultivation 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 75 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 75 responses during the rule comment period. In general, the majority of the feedback received can be categorized into the following areas:

   - The number of provisional licenses issued for Level I and Level II cultivators.
   - The Program's ability to scale operations and meet patient demand, including the square footage limitation and lack of an ability to expand grow capacity absent additional licenses.
   - The financial constraints and barriers to entry for potential applicants, including the licensing fee amounts and financial responsibility requirements that must be met by Level I and Level II cultivators.
   - The impact on the environment and cultivation practices that increase the quality and safety of medical marijuana (i.e. use of pesticides and fertilizers during cultivation).
   - The packaging requirements and expiration of medical marijuana.

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:

- **Number of Licenses** – The Department increased the number of Level II cultivator provisional licenses that the Department may issue before September 8, 2018, from six to 12. This is consistent with the number of Level I cultivator provisional licenses available to be issued before the effective date and would allow the Department to provide additional grow capacity if necessary.
- **Marijuana Cultivation Area Increase** – The Department increased the square footage of grow capacity for both Level I and Level II cultivator licenses. Level I cultivators are now permitted to maintain a marijuana cultivation area of 25,000 square feet, up from 15,000 square feet in the initial rules draft. Level II cultivators are now permitted to maintain a marijuana cultivation area of 3,000 square feet, up from 1,600 square feet in the initial rules draft.
- **Marijuana Cultivation Area Expansion** – Beginning September 9, 2018, a cultivator may, at the discretion of the director and approval by the Department, perform an expansion of its marijuana cultivation area of (1) up to 25,000 square feet for Level I cultivators, for a total square footage marijuana cultivation area of 50,000, and (2) up to 3,000 square feet for Level II cultivators, for a total square footage marijuana cultivation area of 6,000. The director may also, at his or her discretion, and based on patient population, approve a subsequent expansion of (1) up to 25,000 additional square feet for Level I cultivators, for a total square footage marijuana cultivation area of 75,000, and (2) up to 3,000 additional square feet for Level II cultivators, for a total square footage marijuana cultivation area of 9,000.
- **Adjusted Financial Responsibility Requirements** – The department reduced the level of surety bond coverage or escrow account balance from $2,000,000 to $750,000 for Level I cultivators and $200,000 to $75,000 for Level II cultivators and included performance triggers that will reduce the amount by $250,000 and $75,000, respectively, for each performance measure achieved, until an escrow/surety bond requirement is no longer present. The Department added an insurance required for coverage related to general liability and products liability to protect patients and licensees from potential liabilities.
- **Pesticide and Fertilizer Usage** – The Department worked with the Department of Agriculture to revise the rules around pesticide and fertilizer usage on medical marijuana. Cultivators are now permitted to apply approved pesticides and/or fertilizers for the first 21 days in the flowering stage. In exchange, every batch must undergo testing for pesticides and fertilizers before it can be packaged and transported. The Department also removed the applicator license required based on the public's feedback and Agriculture's guidance.

- **Environmental and Similar Considerations –** Based on changes to the draft rules, cultivators are now permitted to compost waste from the facility for use at the facility if they meet the requirements in the proposed rules. Additionally, the rules provide a mechanism for cultivators to market their products as meeting different standards in the industry geared towards product quality and safety (i.e. third party organic certifiers, etc.).

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:

- **Unlimited grow capacity** – To avoid the complications of excess supply that other states that recently implemented a medical program are experiencing, the Department decided that a modest increase to the square footage capacity with additional expansion capabilities was appropriate in lieu of unlimited grow capacity. This will allow Ohio to attract top industry experts to enter the market and compete, which will help control price and supply with reasonable controls.
- **Square footage supply control method** – Other states tie production to the number of registered patients or establish canopy limits. The Department received feedback and guidance on the positives and negatives of both supply control measures and determined that a square footage limitation was the best option available to Ohio. This model allows licensees to tweak their cultivation practices and make changes to production that will meet demand without interfering or revisiting the supply control method, other than the expansion of a cultivator's marijuana cultivation area. This supply control measure provides the greatest flexibility for these businesses and helps the Department from a compliance and enforcement standpoint.
- **Unlimited Cultivator 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 decisions to add two levels of cultivator licenses, limit the production capacities for both level of licenses and implement a license issuance process based on patient population and demand will introduce new licensees and provide many opportunities for businesses and individuals to become involved in the industry.

A summary of the comments received by the Department can be found in Attachment 1, and a summary of the changes made to the cultivator rules can be found in Attachment 2.

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 a cultivation 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. Facilities may also petition for expansion of growing space if they provide a consistent supply and maximize the use of the permitted marijuana cultivation area.

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 cultivator provisional licenses, cultivator certificates of operation and employee identification cards. The rules require the development of impartial, unbiased scoring rubrics to evaluate applicants and implement a consistent set of requirements that will result in highly qualified and capable businesses receiving licenses in Ohio. 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 cultivators of medical marijuana. "Cultivator", as used in Chapter 3796. of the Revised Code, means an entity that has been issued a certificate of operation by the Department to grow, harvest, package and transport medical marijuana as permitted under Chapter 3796. of the Revised Code. Cultivators will be the sole entity responsible for the legal growing 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 $20,000 for Level I cultivator applications and $2,000 for Level II cultivator applications. Applicants that are issued a provisional license have nine months to pass a pre-operation inspection and become operational. The license fees will be $180,000 for Level I cultivators and $18,000 for Level II cultivators. Renewal fees will be $200,000 for Level I cultivators and $20,000 for Level II cultivators. Additionally, there is an optional designation for cultivators to be licensed as a plant-only processor, allowing them to perform the limited function of packaging plant material for distribution to licensed dispensaries. The cost associated with this designation is $5,000 for Level I cultivators and $500 for Level II cultivators.

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 cultivation 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 cultivation 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 cultivating 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 cultivator 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.

The Department offers a Level II cultivator license that will likely be a better fit for small businesses. Since the operation is smaller and won't require as many employees, it is likely that these facilities will be considered small businesses and provides for a reduced license fee structure and lower financial responsibility requirements. The rules are intended to create a level playing field for all market participants, regardless of size.

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.gov
The Department's office is located at: 77 S. High St., Columbus, OH 43215