CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Commerce

Regulation/Package Title: Medical Marijuana Control Program

Rule Number(s): 3796:2-1-06; 3796:2-2-03; 3796:3-2-03; 3796:4-2-06; 3796:5-2-01; 3796:5-6-01; and 3796:5-6-04 (New)

Date: March 8, 2019

Rule Type:

- ☑ New
- ☑ Amended
- ☐ 5-Year Review
- ☐ Rescinded

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 rules implementing Ohio's Medical Marijuana Control Program (MMCP) were adopted in 2016. Since that time, applications for all license types under the program – cultivators, processors, testing laboratories, and dispensaries – have been developed, submitted, scored,

and licenses have been awarded. Many licensees in this new industry have become operational, and the first sales under Ohio's MMCP took place on January 16, 2019.

The rules in this package are proposed for amendment to fix targeted issues that have been identified through implementation of the program. This package was purposely limited, and it is the intention of Commerce to conduct, along with stakeholders, a more broad-based review of all its MMCP rules at a later date to address less time-sensitive issues. Many of the proposed amendments, as described below, reduce costs and unnecessary regulatory burdens.

- 3796:2-1-06 (Amended): This rule outlines requirements for a medical marijuana cultivation facility to obtain a certificate of operation. The proposed amendment clarifies that cultivation facilities are not eligible for the agricultural exemption from Ohio's building code. This codifies existing practice, but removes confusion among licensees and ensures that these facilities will be subject to all appropriate protections of the building code, including fire safety requirements.
- 3796:2-2-03, 3796:3-2-03, and 3796:4-2-06 (Amended): These rules outline requirements for cultivators, processors, and testing labs to dispose of medical marijuana waste material. The proposed amendment removes an option that could have required the Department to take possession of and destroy medical marijuana waste material. This function belongs with the licensee, which has the necessary protocols and tracking tools, and the state does not have the appropriate resources or safeguards to take possession of this material. The proposed amendments also remove the requirement that only Type 1 key employees can dispose of product. Each facility is limited to three such employees, so this restriction is both burdensome and unnecessary, as any employee who meets the criteria to be a Type 1 employee should be authorized to perform this function.
- 3796:5-2-01 (Amended): Every employee of a licensed medical marijuana facility is required to be licensed by the state, and this rule outlines requirements for obtaining the necessary employee identification cards. The proposed amendments remove unnecessary requirements from the list of materials to be submitted, including social security cards, proof of residence, and duplicative submissions related to criminal background checks.
- 3796:5-6-01 (Amended): This rule relates to the Department's enforcement authority over licensees, and currently includes language that makes information received by the Department confidential, and subjects employees and licensees to potential disciplinary action for disclosing this information. However, most of the information received by the Department is subject to public records law, and handling of both confidential information and public records law is addressed by existing law, so the

proposed amendments delete this provision to avoid duplication and potential conflict.

- 3796:5-6-04 (New): As written, the Department's rules regarding medical marijuana facilities are very specific and in many places, very prescriptive. While this is appropriate for this new industry, the rules sometimes prevent the Department from allowing common-sense solutions to challenges that arise for licensees. For example, one licensee had its local government impose a moratorium after it had been awarded its provisional license. Because the rules don't allow changes of location during the provisional license period, the licensee is currently unable to move forward toward operation in a new location. The proposed new rule would provide the Director flexibility to grant variances in instances where the rules are unnecessarily burdensome and a variance would be in the public interest and not inconsistent with statute. The proposed language is similar to authority already adopted for the Pharmacy Board relevant to its licensees under the MMCP.

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

   Ohio Revised Code 3796.02, 3796.03, 3796.09, 3796.13, and 3796.14

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?**
   If yes, please briefly explain the source and substance of the federal requirement.

   This regulation does 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.**

   Federal law classifies marijuana as a schedule I controlled substance, making it illegal at the federal level. Ohio's Medical Marijuana Control Program is entirely a state-level regulatory program, so all associated rules pertain only to authority from the Ohio Revised Code.

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)?**

   Medical marijuana is a product that will be purchased and consumed by Ohio residents, including children. Proper regulation is necessary to protect the public by preventing diversion and to ensure patient safety through appropriate growing, processing, and testing protocols. Ohio Revised Code chapter 3796 established the Medical Marijuana Control Program to create a licensing framework for the businesses operating in the medical marijuana industry, and to assure patients that the medical marijuana they are consuming has been subject to regulations that help ensure its safety.

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

   There are a number of electronic systems – under both the Department of Commerce and the Ohio Board of Pharmacy – that track data related to the medical marijuana industry, including complete seed-to-sale tracking of medical marijuana inventory; numbers of licensees, patients, caregivers, and doctors in the state; and amount and category of product sold in Ohio. Ultimately, these metrics are utilized to help ensure public health and safety relative to medical marijuana, to create a framework for the successful operation of businesses under the program, and to promote a better public understanding of this new industry.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   There are two primary stakeholder associations representing the businesses operating in Ohio's medical marijuana industry – the Ohio Medical Marijuana License Holder Coalition and the National Cannabis Industry Association of Ohio. The Department met with representatives of both groups – on November 29, 2018 and December 4, 2018, respectively – to share the proposals and seek feedback on these and other issues. A copy of the proposed rules and draft Business Impact Analysis was sent for review on February 27 to the Medical Marijuana Advisory Committee, which represents a broad array of stakeholders in Ohio's new medical marijuana space.

   The Department has also met on a number of occasions with a specific cultivator licensee impacted by a decision by its local government to impose a moratorium after the cultivation provisional licenses had been awarded. Because the rules don't allow changes of location during the provisional license period, the licensee is currently unable to move forward toward operation in a new location. The proposed new rule 3796:5-6-04 was developed in part to address the situation raised by this business owner and others.

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

   As mentioned above, the feedback from licensees was the primary factor in the proposed new rule 3796:5-6-04. The business stakeholder groups were supportive of both the new rule and the proposed amended rules as they reduce the impact to licensees in the MMCP. The

proposed change eliminating the requirement that only Type 1 Key Employees dispose of waste product was requested by the business stakeholders.

The stakeholder groups have identified other rule updates they would like the Department to pursue as well, and it was communicated that Commerce would consider those in a separate rule filing at a later date that would address issues that are less time-sensitive.

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?**

   While there are a number of elements of the Medical Marijuana Control Program that are based on science and data, the specific changes proposed in this rule package are based on the operational experiences through the first phase of this program and are targeted to address specific challenges and/or risks identified from those experiences.

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?**

    Although the proposed rules in this package operate within the context of the broader framework of the existing Medical Marijuana Control Program, many of these proposals are intended to promote alternative regulations based on the Department's experiences implementing the program. For example, the proposed rules:

    - Reduce the amount of information prospective licensed employees are required to submit because the information has been determined to be unnecessary or can be obtained through other avenues less burdensome to the licensees; and
    - Provide flexibility to the Department to consider unforeseen circumstances where the rules could create a barrier to business operations without providing additional protection for public health and safety.

11. **Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

    The statutory framework for the Medical Marijuana Control Program requires the Department to limit the number of cultivator, processor, and testing lab licensees operating in Ohio, and to impose strict regulations on how those facilities are to operate. However, licenses were awarded based on a competitive application process in which applicants were able to demonstrate their capabilities to successfully operate in this industry and protect the public health and safety. The result of this licensing process is a number of qualified licensees who operate under the laws and rules, but who are able to implement their own business models, take their own approaches to compliance, and grow and manufacture the products that they choose within this market.

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

The Ohio Department of Commerce is given the exclusive authority to regulate the cultivation, processing, and testing of medical marijuana in the State of Ohio. However, in ancillary areas where other state agencies have the expertise and jurisdiction – such as building and fire codes, food safety, local regulations, and environmental controls – Commerce coordinates with and defers to the agency with the expertise and jurisdiction.

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 is continuously engaged with stakeholders and licensees in the program to communicate expectations and ensure understanding of regulatory requirements. In addition, the MMCP regularly sends electronic communications to share important messages, including rule updates. Finally, the MMCP compliance division has participated in the development of these proposed rules and will be able to communicate them directly to licensees as they work together to ensure compliance.

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;**
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
    c. **Quantify the expected adverse impact from the regulation.**
    The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

The impacted business community consists of the licensees under the Medical Marijuana Control Program – currently 29 cultivators, 40 processors, and five testing laboratories. Under the broader regulatory program, licensees incur licensing fees (outlined in OAC 3796:5-1-01), compliance time, and potential sanctions for failure to comply (outlined in OAC 3796:5-6). The MMCP was designed to be a strict regulatory program to ensure the protection of the public safety and welfare, as well as the health of patients. As a result, there are a number of elements such as security, tracking of product from seed-to-sale, and requirements around transporting product where regulatory compliance is a fundamental aspect of the licensee's day-to-day business.

Most of the impacts to business inherent in the overall MMCP are not a part of the specific rules in this package. However, the requirements around destruction of plant material (3796:2-2-03) are very specific and require the licensee to expend time to ensure the destruction is carried out according to rule, including being in view of surveillance cameras and being properly recorded in the seed-to-sale inventory tracking system. Compliance with building and fire codes also impact businesses through specific compliance costs including fire suppression and building inspections. While difficult to quantify due to differences in building layout and offsets from reduced insurance and other expenses, code compliance can potentially add several thousand dollars to construction costs.

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

    The proposed rules identify and correct specific challenges and risks from implementation of the first phase of the Medical Marijuana Control Program, and are necessary to avoid negative outcomes for licensees and for patients under the program. In most cases, the impacts of the proposed changes are either neutral or benefit the regulated business community by providing additional flexibility.

    Existing regulatory requirements already dictate that medical marijuana facilities be sophisticated facilities, and construction expenses are already significant. The requirement that cultivation facilities comply with the applicable building and fire codes is essential to ensuring the safety of the employees in these facilities and the communities in which they are located. Likewise, the specific procedures required for destruction of plant material is necessary to ensure that marijuana product is not diverted from facilities and that the ability to track marijuana plants through their entire lifecycle is protected.

Regulatory Flexibility

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

    The regulatory framework for the Medical Marijuana Control Program does create alternative options for small businesses, most notably a separate cultivator license for smaller operators. However, none of these elements are part of the proposed rules in this package.

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?**

    There are no elements of the proposed rules that address enforcement actions under the MMCP, including paperwork requirements.

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

The Department is continuously engaged with stakeholders and licensees in the program to communicate expectations, answer questions, and ensure understanding of regulatory requirements. In addition, the MMCP regularly sends electronic communications to share important messages, including rule updates. Finally, the MMCP compliance division works directly with licensees on a daily basis to ensure compliance.