ACTION: Final

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Ohio | Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Department of Commerce, Medical Marijuana Control Program

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Tetrahydrocannabinol (THC) definition, packaging, labeling and testing update

Rule Number(s): 3796: 1-1-01; 3796: 2-2-02; 3796:2-2-06; 3796:3-2-02; 3796:3-2-04; 3796:3-2-06; 3796:4-2-04; 3796:4-2-05

Date of Submission for CSI Review: 7/14/2021

Public Comment Period End Date: 7/28/2021

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__8_ rules (FYR? ___)

Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

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

   This regulation adds a definition of Tetrahydrocannabinol (THC) and updates the definition of THC content to specifically include Delta-8 THC and other isomers of THC. The regulation also updates the packaging, labeling and testing rules to be in line with the definition.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Ohio Revised Code: 3796.03; 3796.06; 3796.07; 3796.14

4. **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.

   The Regulation does not implement a federal requirement.

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

   Marijuana is a schedule I controlled substance at the federal level, so the Medical Marijuana Control Program and the rules promulgated for it are necessarily outside the scope of federal rules.

6. **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)?**

   The Department has an interest in maintaining patient safety over the contents of medical marijuana products, and to ensure that there is transparency in packaging, labeling and testing of medical marijuana products. This update provides patients with that transparency and allows the Department to better track which THC isomers are being used in medical marijuana products in Ohio.

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

   The Department will monitor which THC isomers are being tested and used in medical marijuana products in Ohio via the inventory tracking system. The Department will monitor patient feedback on the packaging and labeling rules via surveys. The Department will consider proper testing and labeling of the THC content of medical marijuana products as a success.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   N/A

Development of the Regulation

9. **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.

   The Department received input on a potential rules package in a conference call with the Ohio Medical Cannabis Industry Association on May 27, 2021. Further written feedback was provided by the Ohio Medical Cannabis Industry Association on May 28, 2021. The Department has also had discussions with other licensed medical marijuana entities both before and after the Department's guidance on Delta-8 THC issued on June 15, 2021. Although these changes does not impact patients as business entities, patient feedback on the

current rules requested stronger requirements for labeling of what isomers of THC are included in the THC content on labels.

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

    Patients made comments requesting additional transparency with regards to labeling of THC isomers in medical marijuana products, specifically regarding Delta-8 THC. The Ohio Medical Cannabis Industry Association made comments on how the Department could use the existing rules to require ingredients to be listed on labels. The Department considered the input from the Ohio Medical Cannabis Industry Association when formulating the new rules package, however in order to avoid "rule-making by policy" the Department felt a rules update and comment period was the most appropriate way to provide for stakeholder feedback.

11. **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?**

    As marijuana is a schedule I substance at the federal level, there is little data available on how different isomers affect patients. However, the Department reviewed how other States are approaching the question of THC isomers. The regulation pulls from these sources to determine which practices are most effective for the Ohio medical marijuana industry.

12. **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?**

    The Department considered working within the already existing language contained in 3796:2-2, 3796:3-2 and 3796:4-2, but felt that a rules update would provide more clarity and allow for stakeholder and public input into the rules.

13. **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 regulation is already performance based with regards to THC content caps as they are required in the Revised code. With regards to the testing, packaging and labeling rules, the Department requires consistency in reporting, both in form and in substance, in order to properly monitor and track medical marijuana products, so a performance based regulation is not appropriate for this purpose.

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

The Medical Marijuana Control Program has exclusive authority over medical marijuana entities in Ohio. As these regulations are updates to existing rules, there are no additional regulations that could be duplicated.

15. **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 will track which isomers are being tested, packaged and labeled through the inventory tracking system, and will work with the vendor to ensure that the rules are being effectively implemented by the system. All medical marijuana entities are required to use the inventory tracking system and adhere to the packaging and labeling requirements. The Department will work with testing laboratories to ensure consistent testing results for the required testing and reporting regulations.

Adverse Impact to Business

16. **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; and**
       This regulation affects all medical marijuana cultivators, processors and testing laboratories in Ohio.
    b. **Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**
       The cultivators and processors will be required to pay for any additional costs associated with new testing, packaging and labeling requirements. Cultivators and processors may be required to modify existing product lines in order to bring them into compliance. Non-compliance with these regulations could result in civil penalties being assessed in accordance the Department's enforcement authority. In extreme cases, product recalls may be required in the event that non-compliant products are produced and distributed, however the risk of recalls is always present within the medical marijuana industry, and these regulations do not increase the likelihood of a recall being required.
    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 cost to update packaging and labeling requirements varies from producer to producer, and some will not incur any additional cost as their products are not impacted by the regulation. Some producers may be required to modify existing product lines in response to this rule update. An initial expenditure of time to update Standard Operating

Procedures will be required, estimated to be 1-2 hours of Department training for any new reporting requirements. This may then require additional time for licensees to then train their employees. These estimates are based on consultation with the Department's compliance agents.

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

Patient feedback indicates that transparency in which THC isomers are contained in medical marijuana products was a high priority. As with any pharmaceutical or food product, the ingredients contained in a product that is meant to be ingested, particularly for medical purposes, are of great importance to consumers. The cost to update procedures and labels for medical marijuana products are outweighed by the Department's interest in preserving patient safety as consumers of these products.

Regulatory Flexibility

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

There are no exemptions for small businesses as consistent compliance with testing, packaging, labeling and reporting is required in the medical marijuana industry. Exemptions would be inappropriate under these circumstances.

19. 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?

The Department will consider all relevant factors when determining if any civil penalties will be applied on a case by case basis, and if Ohio Revised Code 119.14 can be appropriately applied to any given situation.

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

The Department will assign a member of the compliance team to interface directly with each entity, whether small or large, who will act as a point of contact with any rules and regulatory compliance questions. The Department will conduct regular inspections and may provide opportunities to correct any deficiencies that may be discovered.