Rule Summary and Fiscal Analysis
Part A - General Questions

Rule Number: 3796:2-2-02

Rule Type: Amendment

Rule Title/Tagline: Cultivator and plant-only processor packaging and labeling.

Agency Name: Medical Marijuana Control Program

Division: Medical Marijuana Cultivators

Address: 77 S. High St., 23rd Floor Columbus OH 43215

Contact: Andrew Makoski **Phone:** 614-728-7636

Email: andrew.makoski@com.ohio.gov

I. Rule Summary

1. **Is this a five year rule review?** No

   A. **What is the rule's five year review date?** 12/6/2021

2. **Is this rule the result of recent legislation?** No

3. **What statute is this rule being promulgated under?** 119.03

4. **What statute(s) grant rule writing authority?** ORC 3796.03

5. **What statute(s) does the rule implement or amplify?** ORC 3796.03, ORC 3796.06(D)(1), ORC 3796.06(D)(2), ORC 3796.19(B)(2)

6. **What are the reasons for proposing the rule?**

   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. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

   This rule adds a definition of THC to the existing MMCP definitions.

   It also amends the definition of THC content as well as the packaging and labeling rules to align with the new definition of THC.

8. **Does the rule incorporate material by reference?** No

9. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

   Not Applicable

10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

    Not Applicable

II. Fiscal Analysis

11. **Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

    This will have no impact on revenues or expenditures.

    N/A

    Not Applicable

12. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

    Not Applicable

13. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B).** No

14. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C).** No

15. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

    There is not a new fee associated with this rule update.

III. Common Sense Initiative (CSI) Questions

16. **Was this rule filed with the Common Sense Initiative Office?** Yes

17. **Does this rule have an adverse impact on business?** Yes

    A. **Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business?** No

    B. **Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms?** No

    C. **Does this rule require specific expenditures or the report of information as a condition of compliance?** Yes

    The rule requires Licensees to report additional information on the packaging and labeling of medical marijuana products, as well as additional reporting requirements into the state inventory tracking system.

    D. **Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies?** Yes

    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.

IV. Regulatory Restrictions (This section only applies to agencies indicated in R.C. 121.95 (A))

18. **Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95?** No

A. How many new regulatory restrictions do you propose adding?

Not Applicable

B. How many existing regulatory restrictions do you propose removing?

Not Applicable