Rule Summary and Fiscal Analysis
Part A - General Questions

Rule Number: 1301:18-1-01

Rule Type: New

Rule Title/Tagline: Definitions.

Agency Name: Department of Commerce

Division: Division of Cannabis Control

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I. Rule Summary

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

    A. **What is the rule's five year review date?**

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?** 3780.03, 3796.03

5. **What statute(s) does the rule implement or amplify?** 3780.03, 3780.07, 3780.08, 3780.10, 3780.11, 3796.03, 3796.09, 3796.10, 3796.13, 3796.30

6. **Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires?** No

    A. **If so, what is the citation to the federal law or rule?** Not Applicable

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

    To adopt definitions for terms used throughout OAC 1301:18.

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

The rule includes definitions of words or terms used throughout the Division's other rules in OAC 1301:18. The changes in this amended rule are to adopt additional definitions related to new rules the Division is also filing to provide clarity around cannabis-specific terms, medical marijuana patient registration, advertising, and licensing.

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

10. **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

11. **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

12. **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.

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

    There are no expected costs directly associated with this rule.

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

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

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

Not Applicable.

III. Common Sense Initiative (CSI) Questions

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

18. Does this rule have an adverse impact on business? No

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

Not directly, but it does define licensing terms, such as provisional license and the restrictions associated with that license.

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? No

Not directly, but it does define complete registration for the purposes of medical marijuana patient registration and the information that must be reported.

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? No

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? Yes

A. How many new regulatory restrictions do you propose adding to this rule? 14

1 (A) For purposes of these rules, the following definitions shall apply:

2 (A) (1) Abandoned application means an application submitted pursuant to division 1301:18 of the Administrative Code which does not meet the minimum

eligibility requirements for review, or is otherwise deemed abandoned pursuant to these rules, and is removed from the application process.

3 (A)(8) Cannabis container: a sealed, hard or soft-bodied receptacle in which cannabis or cannabis products are directly placed. (1) A cannabis container that is not subsequently placed into any secondary package as defined by this rule, shall adhere to all packaging and labeling requirements outlined under rule 1301:18-4-20 of the Administrative Code.

4 (A) (8) Cannabis container: a sealed, hard or soft-bodied receptacle in which cannabis or cannabis products are directly placed. (1) A cannabis container that is not subsequently placed into any secondary package as defined by this rule, shall adhere to all packaging and labeling requirements outlined under rule 1301:18-4-20 of the Administrative Code.

5 (A)(14) Date order written, which shall be the date the written recommendation was issued.

6 (A)(16) Cultivation Area means the boundaries of the enclosed areas in which adult use cannabis is cultivated during the vegetative stage and flowering stage of the cultivation process. For purposes of calculating the cultivation area square footage, enclosed areas used solely for the storage and maintenance of mother plants, clones, or seedlings shall not be included.

7 (A)(18)(d) Notwithstanding paragraph (1) or (2) of this definition, no misdemeanor offense, including misdemeanors of the first degree, related to cannabis possession, cannabis trafficking, illegal cultivation of cannabis, illegal use or possession of drug paraphernalia or cannabis drug paraphernalia, or other cannabis related crimes shall be considered a disqualifying offense.

8 (A)(21) Final Form means the form of cannabis as manicured, trimmed, manufactured, or processed and intended for customer sale. The intended form of cannabis immediately prior to submission to a testing laboratory licensed pursuant to 1301:18 of the Administrative Code for all state-required testing. For purposes of submission of final form cannabis for any state-required testing, final form cannabis may, but is not mandated to be, placed in a container or package.

9 (A)(21) Final Form means the form of cannabis as manicured, trimmed, manufactured, or processed and intended for customer sale. The intended form

of cannabis immediately prior to submission to a testing laboratory licensed pursuant to 1301:18 of the Administrative Code for all state-required testing. For purposes of submission of final form cannabis for any state-required testing, final form cannabis may, but is not mandated to be, placed in a container or package.

10 (A)(31) Packaging intended for Direct Customer Sale: the final cannabis packaging as presented, displayed, and sold to customers at a licensed dispensary. Packaging for direct customer sale, may include a cannabis container and secondary packaging, depending on the product type. All packaging for direct customer shall adhere to all mandates outlined for rule 1301:18-4-20 of the Administrative Code.

11 (A)(35) Prohibited facility means a school, church, public library, public playground, or public park, as defined by this rule.

12 (A)(36) Provisional license means a temporary license issued to a license applicant that establishes certain conditions that must be met by the provisional licensee before it may be issued a cultivator, processor, testing laboratory, or dispensary certificate of operation and engage in any authorized activity outlined under division 1301:18 of the Administrative Code.

13 (A)(41) Raw single serving unit means a unit that is packed with dried cannabis plant material (such as trim, shake or ground flower) and wrapped in rolling paper. A raw single serving unit contains only dried cannabis plant material. A batch of raw single serving units must be wrapped in rolling paper prior to all state-required testing.

14 (A)(47) Test Sample Collector: means an individual who is a registered employee pursuant to rule 1301:18-3-09 of the Administrative Code who retrieves test samples from a licensed entity, conducts all required test sample collection, and adheres to all mandates pertaining to test sample collection on behalf of a testing laboratory licensed pursuant to division 1301:18 of the Administrative Code.

B. How many existing regulatory restrictions do you propose removing from this rule? 28

1 OAC 3796:3-2-01 (A) A processor shall establish, maintain, and comply with the policies and procedures contained in the operations plan submitted by the processor as part of the application that was approved by the department.

2 OAC 3796:3-2-01 (A) The operations plan shall include policies and procedures for the production, storage, inventory, and transportation of plant material, medical marijuana extract, and medical marijuana products.

3 OAC 3796:3-2-01 (A) At a minimum, a facility's operations plan shall accomplish the following:

4 OAC 3796:3-2-01 (B) A processor shall acquire plant material from a cultivator or dispensary licensed under Chapter 3796. of the Revised Code. Plant material may only be acquired from a dispensary under the following conditions:

5 OAC 3796:3-2-01(B)(1) The plant material has reached or exceeded the expiration date listed on the label;

6 OAC 3796:3-2-01(B)(2) The plant material shall be processed into medical marijuana extract for use in the manufacture of medical marijuana products;

7 OAC 3796:3-2-01(B)(3) The plant material acquired from the dispensary shall not be combined with other batches of plant material during processing;

8 OAC 3796:3-2-01(B)(4) The medical marijuana products manufactured using the plant material shall not be identified as or associated with the brand, cultivator, or processor that originally packaged and sold the plant material to the dispensary

9 OAC 3796:3-2-01(B)(5) The medical marijuana products manufactured using the plant material shall be subject to laboratory testing pursuant to rule 3796:3-2-06 of the Administrative Code.

10 OAC 3796:3-2-01(C)(6)(a) The non-marijuana ingredients must be obtained from licensed and regulated sources that comply with the requirements of federal and state laws and regulations;

11 OAC 3796:3-2-01(C)(7) A processor shall comply with all applicable OSHA regulations as well as comply with and pass inspection for any applicable fire, safety, and building codes pertaining to the use and storage of the equipment and solvents used in the manufacture of medical marijuana products.

12 OAC 3796:3-2-01 (D) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods shall designate at least one individual to train and supervise employees in the use of extraction equipment and associated

solvents who has earned, at minimum, a Bachelor's Degree in engineering or physical sciences from an accredited university, or who has at least three years of experience in the operation of the equipment being used in the facility or similar equipment.

13 OAC 3796:3-2-01 (E) A processor shall submit, as part of the application process, and maintain an operations plan and quality control plan for the processing of medical marijuana in its facility. The purpose of these plans is to ensure a safe, consistent product supply and minimize the deviation in quality of the production lots of medical marijuana products

14 OAC 3796:3-2-01(E)(1) A processor shall submit to the department any proposed changes to its plans approved as part of its application submitted under rule 3796:3-1-02 of the Administrative Code.

15 OAC 3796:3-2-01(E)(2) The department shall review and approve or reject the proposed changes before the proposed changes can be made.

16 OAC 3796:3-2-01(F) A processor shall maintain a facility in the following manner:

17 OAC 3796:3-2-01(F)(1) A processor shall keep all floors and benches free of debris, dust, and any other potential contaminants, and shall control rodents and other pests.

18 OAC 3796:3-2-01(F)(1) A processor shall keep all floors and benches free of debris, dust, and any other potential contaminants, and shall control rodents and other pests.

19 OAC 3796:3-2-01(F)(2) A processor shall use chemicals, cleaning solutions, and other sanitizing agents approved for use around vegetables, fruit, medicinal plants, or food contact surfaces, and shall store them in a manner that protects against contamination.

20 OAC 3796:3-2-01(F)(2) A processor shall use chemicals, cleaning solutions, and other sanitizing agents approved for use around vegetables, fruit, medicinal plants, or food contact surfaces, and shall store them in a manner that protects against contamination.

21 OAC 3796:3-2-01(F)(3) A processor shall keep its equipment in a clean environment and maintain a cleaning and equipment maintenance log at the facility.

22 OAC 3796:3-2-01(F)(4) The processor shall have its scales, balances, or other weight and/or mass measuring devices routinely calibrated using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least once

23 OAC 3796:3-2-01(F)(5) The water supply shall be derived from a source that is compliant with rule 901:3-1-05 of the Administrative Code.

24 OAC 3796:3-2-01(F)(6) A processor shall implement policies and procedures related to receiving, inspecting, transporting, segregating, preparing, packaging, and storing plant material, medical marijuana extract, and medical marijuana products in accordance with adequate sanitation principles.

25 OAC 3796:3-3-01(E)(4)(c) If the corrective measures meet the department's satisfaction, the department SHALL indicate such on the inspection report and conclude the inspection.

26 OAC 3796:3-3-01(E)(4)(c) If the corrective measures do not meet the REQUIREments of the written plan of correction, the department SHALL take action in accordance with rule#3796:5-6-01#of the Administrative Code.

27 OAC 3796:3-3-01(E)(4)(c) If the corrective measures do not meet the REQUIREments of the written plan of correction, the department SHALL take action in accordance with rule#3796:5-6-01#of the Administrative Code.

28 OAC 3796:3-3-01(F) If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, risk to public health, or the occurrence of a PROHITBITed activities under rule#3796:5-6-02#of the Administrative Code, the department may take immediate action authorized under rule#3796:5-6-01#of the Administrative Code.

C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.

28 regulatory restrictions removed
24 from OAC 3796:3-2-01
4 from OAC 3796:3-3-01

D. Please justify the adoption of the new regulatory restriction(s).

The Division is required by OAC 3780 and 3796 to establish rules to regulate by medical and non-medical cannabis. When promulgating rules, it is necessary

to define terms used throughout the rules to provide clarity. The regulatory restrictions included in the definitions are necessary to ensure appropriate manufacture and testing of cannabis, as well as defining licensee authorizations.