

Rule Summary and Fiscal Analysis (Part A)**Medical Marijuana Control Program**

Agency Name

Testing Laboratories

Division

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3796:4-2-01

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

Testing laboratory operations.**RULE SUMMARY**1. Is the rule being filed for five year review (FYR)? **No**2. Are you proposing this rule as a result of recent legislation? **Yes**Bill Number: **HB523**General Assembly: **131**Sponsor: **Huffman, S.**3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**4. Statute(s) authorizing agency to adopt the rule: **R.C. 3796.03**5. Statute(s) the rule, as filed, amplifies or implements: **R.C. 3796.03, R.C. 3796.09**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

Department of Commerce must promulgate rules for the Medical Marijuana Control Program pursuant to Chapter 3796 of the Revised Code.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE,

then summarize the content of the rule:

Rule 3796:4-2-01 details testing laboratory operations and establishes standards with which testing laboratories must comply to ensure testing consistency and safety. This rule also contains rules on equipment cleanliness, facility sanitation and other quality assurance considerations. This rule requires the employment of a scientific director and indicates which methods of analysis are permitted.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

ISO/IEC 17034 is a document that persons affected by this rule would readily be able to locate due to it being an industry standard. Similarly "Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control" is one of the few testing laboratory standards directly applicable to medical marijuana testing laboratories specifically. As such, people affected by this rule and qualified to operate a testing laboratory would readily be able to obtain this document.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

The texts are too large to file.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Minor language changes were made for the purpose of clarity, and the equipment maintenance log provision was expanded to include maintenance performed by equipment manufacturers or contracted third-parties. Additionally, laboratories are now required to segregate incoming samples from those being analyzed in order to

prevent cross-contamination.

12. Five Year Review (FYR) Date:

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

0

none

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

n/a

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

This rule requires testing laboratories to submit operations plans, which will entail costs that cannot be estimated at this time. Costs will be highly variable based on facility specifications and analytical methods and equipment.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component

dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

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? **Yes**

Failure to comply may result in actions being taken pursuant to 3796:5-6-01.

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

The entity must develop and maintain an operations plan.