

Rule Summary and Fiscal Analysis (Part A)**State Medical Board**

Agency Name

Division

Sallie Debolt

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4731-11-03

Rule Number

AMENDMENT

TYPE of rule filing

Rule Title/Tag Line

Schedule II controlled substance stimulants.**RULE SUMMARY**

1. Is the rule being filed consistent with the requirements of the RC 119.032 review? **Yes**

2. Are you proposing this rule as a result of recent legislation? **No**

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: **4731.05**

5. Statute(s) the rule, as filed, amplifies or implements: **4731.22**

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

To clarify permissible uses of Schedule II controlled substance stimulants.

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:

The proposed amendments deletes from a permissible use that the patient in is in the terminal states of a disease that is accompanied by severe pain and add intractable pain and closed head injuries. The proposed amendments also delete the

provision requiring Medical Board approval of an written protocol for the clinical investigation of the effects of such drugs.

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:

This response left blank because filer specified online that the rule does not incorporate a text or other material by reference.

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:

This response left blank because filer specified online that the rule does not incorporate a text or other material by reference.

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 If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation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

The revision expands the legitimate uses for Schedule II controlled substances as they relate to sleep disorders to include situations that go beyond narcolepsy. The changes allow Schedule II drugs to be used in treating idiopathic hypersomnia and hypersomnias due to medical conditions known to cause excessive sleepiness.

12. 119.032 Rule Review Date: **6/6/2008**

(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.

0.00

Not applicable.

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

Not applicable.

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:

None.

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**