

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

Agency Name

Division

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4729-11-09

Rule Number

NO CHANGE

TYPE of rule filing

Rule Title/Tag Line

**Sale of schedule V controlled substance products without a
prescription.****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: **3719.28 , 4729.26**

5. Statute(s) the rule, as filed, amplifies or implements: **3719.05 , 4729.28 ,
4729.51**

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

Section 4729.26 of the Ohio Revised Codes authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy, including the prescribing and dispensing of dangerous drugs. The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of the Ohio Revised Code to promote the public's safety.

Without these regulations, there would be no uniform regulations for the sale of schedule V substances that contain opium or stimulants. These substances, such as codeine cough syrup, are widely abused and non-prescription sales should be regulated in the interest of public safety.

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:

Permits, under certain conditions, the sale of schedule V controlled substance products, which is not a prescription drug, by a pharmacist without a prescription. Restrictions include limits on the amount of schedule V controlled substances that contain opium or stimulants, identification requirements as well as the product must be sold at retail.

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. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. 119.032 Rule Review Date: 3/17/2014 and 03/17/2019

(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

No net impact on the agency's budget.

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:

Board staff pharmacists estimate that this rule could result in an additional 1-3 minutes for dispensing schedule V products containing opium or stimulants if the patient does not have a prescription from a licensed health care provider. It should also be noted that a limited number of pharmacies offer these products without a prescription, as many have changed their policies due to the abuse potential of these medications.

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**

Violation of the rules may result in administrative licensure discipline for the pharmacist and/or the location licensed as a terminal distributor of dangerous drugs (TDDD). Discipline might include reprimand, fines, suspension of the license, required course work, and/or revocation of the license.

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **No**