

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

Agency Name

Division

Cameron McNamee

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4729-5-38

Rule Number

AMENDMENT

TYPE of rule filing

Rule Title/Tag Line

Immunization administration.**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: **4729.26, 4729.41**

5. Statute(s) the rule, as filed, amplifies or implements: **4729.41**

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

Section 4729.26 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy. Section 4729.41 of the Ohio Revised Code requires the state board of pharmacy to adopt rules regarding the administration of vaccines by pharmacists to individuals eighteen years of age or older. 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 this regulation, the Ohio State Board of

Pharmacy would not be able to ensure that all pharmacists providing the zoster vaccine check that the patient meets the age criteria specified in the F.D.A. approved labeling and that the pharmacist has met the training approved by 4729-5-36. The intent of this rule is to increase the zoster immunization rates for older adults. According to the CDC, in 2011, 15.8% of adults aged ≥60 years reported receiving the zoster vaccination to prevent shingles, similar to the estimate for 2010. Whites aged ≥60 years had higher zoster vaccination coverage (17.6%) compared with blacks (7.9%), Hispanics (8.0%), and Asians (14.0%).

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:

Removes the requirement that an individual obtain a prescription prior to the administration of the zoster (shingles) vaccine by a pharmacist. This rule would still require that all pharmacists check to ensure that the patient meets the age criteria specified in the F.D.A. approved labeling for the vaccine and that the pharmacist has met the training approved by the rule in another section of the code.

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 rule references the Ohio Revised Code and Administrative Code. The O.R.C. and the O.A.C. are generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule.

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:

Ohio Revised Code Sections 121.75 and 121.76 exempt these texts from inclusion in this filing.

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: **3/7/2014**

(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

This does not impact 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:

The proposed rule removes a requirement that a prescription be issued prior to the administration of the zoster vaccination by a pharmacist. The removal of this restriction should not impose any additional cost, as pharmacies already offering

the vaccination must comply with existing vaccination requirements. Such requirements include training courses that range from \$45 to \$65.

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? **Yes**

Prior to the administration of any vaccination, OAC 4729-5-37 requires a physician-established protocol for the administration of immunizations.

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, 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? **Yes**

This rule requires pharmacists who administer the zoster vaccination must meet the training criteria for vaccination courses. Such requirements include training courses that range from \$45 to \$65.