

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? **No**

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:

Central Ohio is currently experiencing a mumps outbreak that has reached 390 cases, as reported by the Ohio Department of Health (5/27/14). Nationally, there were 438 known mumps cases in 39 states last year, according to the Centers for Disease Control and Prevention.

In addition, a measles outbreak now has infected 155 people in six counties: Ashland, Coshocton, Holmes, Knox, Richland and Wayne (5/27/14).

In response to these outbreaks, ODH and local health departments are encouraging residents to get vaccinated with the Measles-Mumps-Rubella (MMR) vaccine.

The spread of these two preventable diseases is largely attributed to unvaccinated populations.

The Ohio State Board of Pharmacy is committed to ensuring that pharmacists and pharmacies adhere to standards that protect the health and safety of all Ohioans. The recent outbreaks indicate the need to maximize the availability of the vaccine.

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:

Authorizes a licensed pharmacist to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older.

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: **5/22/2019**

(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

This will have no impact on revenues or expenditures.

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 authorizes a licensed pharmacist to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older. The rule will require pharmacies offering the vaccine to update their protocols pursuant to OAC 4729-5-37, which may result in a negligible one-time cost.

This rule also requires pharmacists who administer the listed vaccinations to meet the training criteria for vaccination courses. Such requirements include training

courses that can cost up to \$349 (source: Ohio Pharmacists Association).

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**

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