

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

NEW

TYPE of rule filing

Rule Title/Tag Line

Immunization & Vaccine Administration.**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: **HB394**General Assembly: **130**Sponsor: **Smith, Antonio**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:

The rule proposed under this statutory authority is necessary to facilitate compliance with the provisions in Chapters 4729 of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

-Provide uniform standards for the administration of immunizations by pharmacists and pharmacy interns; and

-Ensure that pharmacists/pharmacy interns are able to provide the most up-to-date CDC ACIP recommended immunizations.

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 addresses recent changes to the requirements of section 4729.41 of the Ohio Revised Code by: 1) specifying the types of immunizations that a pharmacist or pharmacy intern can administer; 2) outlines informed consent requirements; and 3) ensures compliance with federal law.

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, Ohio Administrative Code, the United States Code (U.S.C.) and the Advisory Committee on Immunization Practices (ACIP). The O.R.C., O.A.C., U.S.C. and ACIP are generally available 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 exempts 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:

The rule is modified to allow for the administration of vaccinations/immunizations that are recommended by the Centers for Disease Control and Prevention and are not listed on the immunization schedules but are approved for administration in certain situations (i.e. travel). The rule also specifies the age restrictions and the notification requirements required in the Ohio Revised Code.

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.

\$0.00

no impact.

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:

This rule is an update to an existing rule regarding immunizations. Compliance with this rule may result in administrative and record keeping costs to pharmacies that provide immunizations to patients.

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 these rules may result in administrative licensure discipline for a pharmacist or pharmacy intern. Discipline might include reprimand, suspension of a license, required course work, monetary fine and/or revocation of a license.

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

The rule requires notification of a family physician or local health department for any immunization/vaccine administered by a pharmacist or pharmacy intern.