#### **ACTION:** Original

# Rule Summary and Fiscal Analysis Part A - General Questions

**Rule Number:** 4729-5-38

Rule Type: Rescission

**Rule Title/Tagline:** Immunization and vaccine administration.

**Agency Name:** State Board of Pharmacy

**Division:** 

Address: 77 South High St. 17th floor Columbus OH 43215

**Contact:** Alexandra Simon

Email: Alexandra.Simon@pharmacy.ohio.goPhone: 614-502-7161

#### I. Rule Summary

- 1. Is this a five year rule review? Yes
  - A. What is the rule's five year review date? 3/27/2019
- 2. Is this rule the result of recent legislation? No
- 3. What statute is this rule being promulgated under? 119.03
- 4. What statute(s) grant rule writing authority? 4729.26, 4729.41
- 5. What statute(s) does the rule implement or amplify? 4729.41
- 6. What are the reasons for proposing the rule?

The content of the rule is being moved to a new division in the Administrative Code that is specific to pharmacists. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for pharmacists.

7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

The rule specifies the types of immunizations that a pharmacist or pharmacy intern can administer, outlines informed consent requirements, and ensures compliance with federal law.

Page 2 Rule Number: **4729-5-38** 

- 8. Does the rule incorporate material by reference? Yes
- 9. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.

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.

10. If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.

Not Applicable

### II. <u>Fiscal Analysis</u>

11. As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.

This will have no impact on revenues or expenditures.

0

Not applicable.

12. What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?

Compliance with this rule may result in administrative and record keeping costs to pharmacies that provide immunizations to patients.

- 13. Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No
- 14. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No

## III. Common Sense Initiative (CSI) Questions

Page 3 Rule Number: **4729-5-38** 

- 15. Was this rule filed with the Common Sense Initiative Office? Yes
- 16. Does this rule have an adverse impact on business? Yes
  - 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.