

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:1-3-02

Rule Type: New

Rule Title/Tagline: Immunization administration.

Agency Name: State Board of Pharmacy

Division: Pharmacists

Address: 77 South High Street Room 1702 Columbus OH 43215-6126

Contact: Cameron McNamee **Phone:** 614-466-7322

Email: cameron.mcnamee@bop.ohio.gov

I. Rule Summary

1. **Is this a five year rule review?** No
 - A. **What is the rule's five year review date?**
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.**

Establishes the training requirements for a pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements.

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, the Ohio Administrative Code, and United States Code (U.S.C). The O.R.C., O.A.C., and U.S.C. are generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule. Ohio Revised Code Sections 121.75 and 121.76 exempts these texts from inclusion in this filing.

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

Updated incorrect cross reference in paragraph (G)(5). Also updated the incorporation by reference dates. Permits the administration of COVID-19 vaccines.

05/08/2019 Updated paragraph (O) to require maintain proof of maintenance of basic life support training.

*04/29/2019 Paragraph (B): Removed board approval requirement.
Added paragraph (O).*

II. Fiscal Analysis

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.

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Not applicable.

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

Pharmacists will have to complete an ACPE-accredited course meeting the requirements specified in the rule. A course for vaccine administration costs up to \$390.

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

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? Yes**

Pharmacists will have to complete an ACPE-accredited course meeting the requirements specified in the rule. A course for vaccine administration costs up to \$390.

- 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 this rule may result in administrative licensure discipline for a pharmacist. Discipline might include reprimand, denial of a license, 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? No**