

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:1-3-02
Rule Type: Amendment
Rule Title/Tagline: Immunization administration.
Agency Name: State Board of Pharmacy
Division: Pharmacists
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I. Rule Summary

1. **Is this a five year rule review?** No
 - A. **What is the rule's five year review date?** 12/1/2025
2. **Is this rule the result of recent legislation?** Yes
 - A. **If so, what is the bill number, General Assembly and Sponsor?** HB 6 - 134 - Rep. Roemer
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. **Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires?** No
 - A. **If so, what is the citation to the federal law or rule?** Not Applicable
7. **What are the reasons for proposing the rule?**

Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for pharmacists.

- 8. 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. Language is updated to reflect a recent change in the Ohio Revised Code (HB 6 â 134th General Assembly).

- 9. Does the rule incorporate material by reference? Yes**
- 10. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, 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.

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

Updated "physician" to "primary care provider" in paragraph (D)(4).

II. Fiscal Analysis

- 12. Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

This will have no impact on revenues or expenditures.

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Not applicable.

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

A course for vaccine administration costs up to \$425.

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

15. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No
16. If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.

Not applicable.

III. Common Sense Initiative (CSI) Questions

17. Was this rule filed with the Common Sense Initiative Office? Yes
18. 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

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. A course for vaccine administration costs up to \$425.

- 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. Discipline might include reprimand, continuing education, suspension of a license, 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

- D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? Yes

Pharmacies may experience administrative costs to ensure compliance with these rules.

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? No

A. How many new regulatory restrictions do you propose adding to this rule?

Not Applicable

B. How many existing regulatory restrictions do you propose removing from this rule?

Not Applicable

C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.

Not Applicable

D. Please justify the adoption of the new regulatory restriction(s).

Not Applicable