ACTION: Original

Rule Summary and Fiscal Analysis Part A - General Questions

Rule Number: 4729:5-2-05

Rule Type: New

Rule Title/Tagline: Notification of Accessible Services.

Agency Name: State Board of Pharmacy

Division: Terminal Distributors of Dangerous Drugs

Address: 77 Sough High Street 17th Floor Columbus OH 43215

Contact: Summer Corson Phone: 6144664143

Email: summer.corson@pharmacy.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? 3719.28, 4729.26
- 5. What statute(s) does the rule implement or amplify? 4729.55
- 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?

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

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Without this regulation, the Board of Pharmacy would not be able to provide Ohio patients with access to information on what accessible services are available in their area.

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

Requires every outpatient pharmacy in the state of Ohio to report to the Board the type of language translation services (for example, translated prescription labels) available for patients whose first language is not English, as well as report to the Board on the types of services available for patients who are hard of hearing or patients who have low vision. The outpatient pharmacy must submit this information as part of the licensure and renewal process and must also notify the Board of any change to their accessible services as listed above within thirty days of the change. The outpatient pharmacy shall be required to provide the services they report to offer to their patients upon request, unless there is a temporary software or equipment failure of the service offered.

An additional 3-5 minutes would be required for an employee of an outpatient pharmacy to fill out an online form describing the accessible services their pharmacy provides.

- 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 Administrative Code. The O.A.C. is 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.

Not Applicable

II. Fiscal Analysis

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

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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?

An additional 3-5 minutes would be required for an employee of an outpatient pharmacy to fill out an online form describing the accessible services their pharmacy provides.

- 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? 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 the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

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

The proposed rule requires every outpatient pharmacy to report information on the accessible services provided by the pharmacy.

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

An additional 3-5 minutes would be required for an employee of an outpatient pharmacy to fill out an online form describing the accessible services their pharmacy provides.

- 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