

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:6-11-01

Rule Type: Amendment

Rule Title/Tagline: Third party logistics providers - general operations.

Agency Name: State Board of Pharmacy

Division: Distributors of Dangerous Drugs

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I. Rule Summary

1. Is this a five year rule review? Yes
 - A. What is the rule's five year review date? 3/19/2024
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, 3719.28
5. What statute(s) does the rule implement or amplify? 4729.53
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.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be

kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Section 3719.13 of the Ohio Revised Code authorizes employees of the Board of Pharmacy to inspect prescriptions, orders, records, and stocks of dangerous drugs and controlled substances.

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

Provides for the general operations of a third-party logistics provider. Requires outsourcing to adhere to physical security requirements to prevent diversion and to prepare compounded drugs in accordance with federal standards. In addition to minor grammatical amendments, the rule also requires outsourcing facilities to maintain records for five years in accordance with ORC 3719.07.

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 and the Ohio Administrative Code. The O.R.C. and O.A.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.

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.

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?**

Drug distributors may experience an increase in costs due to the extension of the recordkeeping requirements from three to five years. Licensees would generally experience compliance costs to ensure records are stored in compliance with the rule.

- 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 this rule may result in administrative discipline for a licensee/registrant. Discipline might include reprimand, denial of a license, suspension of a license, required course work (pharmacists/interns/technicians), 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**

Requires notification of new drug storage areas.

- 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**

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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