

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:6-11-02

Rule Type: New

Rule Title/Tagline: Third Party Logistics Providers - Recordkeeping.

Agency Name: State Board of Pharmacy

Division:

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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?

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? 4729.52

6. What are the reasons for proposing the rule?

Without these regulations, the Board would not be able to ensure uniformity for drug distributors operating in Ohio.

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

Includes the requirements for all records maintained by a third-party logistics provider.

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, and the Federal Food, Drug, and Cosmetic Act. The O.R.C., O.A.C., and federal act 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.**

Revised filed to reflect updates to the RSFA responses. No changes were made to the rule.

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?**

These rules are similar to what is already required by a third-party logistics provider of dangerous drugs. The rule does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit.

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? 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 a distributor of dangerous drugs. Discipline might include reprimand, suspension/denial of a license, monetary penalty 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 does require notification for off-site storage. This is a one-page form that takes approximately 15 minutes to complete and submit.