

## Rule Summary and Fiscal Analysis

### Part A - General Questions

**Rule Number:** 4729:6-11-01

**Rule Type:** New

**Rule Title/Tagline:** Third Party Logistics Providers - General Operations.

**Agency Name:** State Board of Pharmacy

**Division:**

**Address:** 77 South High St. 17th floor Columbus OH 43215

**Contact:** Alexandra Simon

**Email:** Alexandra.Simon@pharmacy.ohio.gov **Phone:** 614-502-7161

#### 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? 4729.53

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.

Provides for the general operations of 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, United States Pharmacopeia, and the Ohio Administrative Code. The O.R.C., U.S.P., 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.

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, except to correct the title of 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.

0

Not applicable.

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

Requires third-party logistics providers to adhere to physical security requirements to prevent diversion and repacking in accordance with federal standards. It should be noted that the security requirements have not changed from current rules, and current licensees should not experience any additional costs.

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**

Provides for the general operations of a third-party logistics provider. Requires third party logistics providers to adhere to physical security requirements to prevent diversion. This may result in the need for additional investments to ensure they meet Board standards. It should be noted that the security requirements have not changed from rule 4729-9-29 and current licensees should not experience any additional costs.