

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729-9-29

Rule Type: Rescission

Rule Title/Tagline: Licensure as a third party logistics provider.

Agency Name: State Board of Pharmacy

Division:

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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? 8/17/2018
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?

The rule is being rescinded and being moved to a new division that will contain all of the drug distributor rules. This new rule division would allow the Board 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.**

Not Applicable

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?**

Requires third-party logistics providers to adhere to physical security requirements to prevent diversion and repacking in accordance with federal standards.

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? No

- 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 licensure discipline for a pharmacist, pharmacy intern, pharmacy technician (including trainee) and terminal/wholesale distributors of dangerous drugs. Discipline might include reprimand, denial of a license, suspension of a license, required course work (pharmacists/interns), 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**