

## Rule Summary and Fiscal Analysis

### Part A - General Questions

**Rule Number:** 4729-9-12

**Rule Type:** Rescission

**Rule Title/Tagline:** Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.

**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? 3719.04, 4729.60, 4729.541, 4729.54, 4729.51
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The rule is being rescinded and being moved to a new division that will contain all of the drug distributor rules.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 the requirements to verify licensure prior to the sale or purchase of dangerous drugs.

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. The O.R.C. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule.
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?**

The estimated time to complete an initial application is approximately 1-2 hours. A renewal application takes approximately 30 minutes to complete. If the applicant is a virtual wholesaler or third-party logistics provider and is not licensed in their home state, the rule requires the entity to obtain and maintain Verified-Accredited Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy. VAWD accreditation is \$5,500 in the first year and \$7,500 every three years.

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 the rule may result in administrative licensure discipline for a location licensed as or applying to be a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation/denial of a license.

C. Does this rule require specific expenditures or the report of information as a condition of compliance? No