

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-2-04

Rule Type: New

Rule Title/Tagline: Procedure for discontinuing business as a terminal distributor of dangerous drugs.

Agency Name: State Board of Pharmacy

Division: Terminal Distributors of Dangerous Drugs

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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? 4729.54, 3719.07, 4729.37, 4729.55
6. What are the reasons for proposing the rule?

Provide uniform procedures for discontinuing business and the transfer or disposal of drug stock.
7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

Specifies the procedure for discontinuing as a terminal distributor which requires the distributor to file a notice with the board. The terminal distributor will need to complete an inventory of all controlled substances being transferred or disposed of.

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 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.

10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Paragraph (A)(3): removed phrase dispensed and replaced with sale. Removed reference to ORC 4729.37.

Paragraph (B)(1): Added comma and removed the word "of" from the end of the paragraph.

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 a terminal distributor of dangerous drugs to notify the board of discontinuation of business. A discontinuation of business form is two pages and takes approximately 10 minutes to complete. The licensee must also submit a complete inventory of all controlled substances being transferred or disposed of and keep records of purchase and dispensing for three years. The inventory may take several

hours to complete depending on the size of the controlled substance stock. It should be noted that maintaining records pertaining to controlled substances for three years is required by the Ohio Revised Code (3719.07).

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

The rule requires that records pertaining to controlled substances for three years which is a requirement of ORC.