

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-2-04

Rule Type: Amendment

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? Yes
 - A. What is the rule's five year review date? 4/24/2024
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. Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires? No
 - A. If so, what is the citation to the federal law or rule? Not Applicable
7. What are the reasons for proposing the rule?

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

- 8. 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 a licensee 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. The rule is being amended to require notice within 30 days of closure rather than 30 days prior.

- 9. Does the rule incorporate material by reference? Yes**
- 10. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

This rule references the Ohio Administrative Code. The O.A.C. is 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.

- 11. 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

- 12. Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

This will have no impact on revenues or expenditures.

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Not Applicable.

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

In general, violation of these rules may result in administrative licensure discipline for a licensee. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license. Pharmacies that are closing may also experience increased administrative costs to meet the patient notification requirements.

14. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No**
15. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No**
16. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

Not Applicable.

III. Common Sense Initiative (CSI) Questions

17. **Was this rule filed with the Common Sense Initiative Office? Yes**
18. **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**

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- C. **Does this rule require specific expenditures or the report of information as a condition of compliance? Yes**

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. The terminal distributor is also required to notify their patients who have been dispensed a prescription in the last six months that the location is shutting down, contacting them either by email, direct mail, or text message. The time to complete this requirement depends on the number of patients were receiving their medications at that location.

- D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? No

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? No

- A. How many new regulatory restrictions do you propose adding to this rule?

Not Applicable

- B. How many existing regulatory restrictions do you propose removing from this rule?

Not Applicable

- C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.

Not Applicable

- D. Please justify the adoption of the new regulatory restriction(s).

Not Applicable