

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-3-02

Rule Type: New

Rule Title/Tagline: Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.

Agency Name: State Board of Pharmacy

Division:

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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? 3719.28, 4729.26
5. What statute(s) does the rule implement or amplify? 3719.07, 4729.55
6. What are the reasons for proposing the rule?

This rule is necessary to promote the public's safety and uniformity of care throughout Ohio. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for reporting the theft or significant loss of dangerous drugs.

7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

Provides the requirements for reporting the theft or loss of dangerous drugs by a terminal distributor of dangerous drugs. A licensee must report theft or significant loss of a dangerous drug immediately by phone and complete a form within thirty days.

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/or 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.

This rule references the U.S. Code of Federal Regulations. The C.F.R 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.**

Updated to correct typo in MOR to CSI.

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 theft or significant loss form can take about 30 minutes to complete.

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 this rule may result in administrative discipline for a licensee/registrant. Discipline might include reprimand, denial of a license, suspension of a license, required course work (pharmacists/interns/technicians), 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? Yes

A licensee must report theft or significant loss of a dangerous drug immediately by phone and complete a form within thirty days.