

## Rule Summary and Fiscal Analysis

### Part A - General Questions

**Rule Number:** 4729:5-3-02

**Rule Type:** Amendment

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

**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? 7/26/2021
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 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 drugs immediately by phone and complete a form within thirty days. The rule is amended to update the rule's references to 21 C.F.R. 1307.76 and DEA Form 222.

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. 121.75, 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.**

*Not Applicable*

## **II. Fiscal Analysis**

11. **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.

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 but it may take additional time to gather the information necessary to complete the form.

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
15. 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**

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

- 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 Restrictions (This section only applies to agencies indicated in R.C. 121.95 (A))**

18. 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?

Not Applicable

**B. How many existing regulatory restrictions do you propose removing?**

Not Applicable