

## Rule Summary and Fiscal Analysis

### Part A - General Questions

**Rule Number:** 4729:7-3-06

**Rule Type:** New

**Rule Title/Tagline:** Record Keeping.

**Agency Name:** State Board of Pharmacy

**Division:** Drug Compounding

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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?** 4729.01, 4729.51, 4729.53, 4729.54, 4729.541 and 4729.55
6. **What are the reasons for proposing the rule?**

This rule is being proposed because all sections of OAC relating to drug compounding are being consolidated into 4729:7 of the OAC. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for drug compounding.
7. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

Sets forth the record keeping standards for compounding of dangerous drugs that shall be maintained by the responsible person. All records must be readily retrievable and uniformly maintained at the place where the dangerous drugs are located.

8. **Does the rule incorporate material by reference? No**
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.**

*Not Applicable*

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?**

Prescribers will experience increased administrative costs to document activities pertaining to drug compounding as part of this recordkeeping rule.

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 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**