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.**

    Paragraph (C)(3): Added "and conduct"
    Paragraph (A)(2): Replaces language regarding entry into the system and instead requires compliance with the rule.

    03/18/2019 Paragraph (A)(2): Added phrase "does so"
    Paragraph (A)(3): Removed the word "that"
    Paragraph (A)(3)(h)(i): Removed "whom" and changed to "performing"
    Paragraph (D) and (F): Deleted. Then consolidated rule language into new paragraph (E).

    03/14/2019 Removed typo (i..e incomplete sentence) from paragraph (C)(1). Added language specifying responsible person or designee is needed for controlled substance inventory to match existing language for other location-based rules currently filed with JCARR.

    03/14/2019 Paragraph C: Adds "registered" to the list of individuals who may conduct and witness the disposal of controlled substances. Permits veterinarians to use of animal aides to witness disposal.

    03/13/2019 Removed paragraph (A)(3)(i): That added a requirement to produce lot numbers and expiration dates for batched compounded drugs.

    Updated language in paragraph (A)(3).

    Paragraph (A)(3)(c): changed "Quantity of drug(s) added to each container" to "Name and quantity of each ingredient". This means the same thing but provides greater clarity and matches terminology used nationally.

03/08/2019 Paragraph (A)(2): Removed requirement for double-sided scanned electronic documents.
Paragraph (A)(3): Removed requirement for maufacturer lot number, distributor control number and expiration date. Also specified that discarded controlled substances must be documented.
Paragraph (A)(3): Added a requirement to produce lot numbers and expiration dates for batched compounded drugs.

02/25/2019 Update RSFA #16(C) per JCARR's request. There were no changes to the actual rule.

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? Yes

This rule requires any facility that wishes to keep drug records off-site to notify the state board of pharmacy as a condition of compliance.