Rule Summary and Fiscal Analysis
Part A - General Questions

Rule Number: 4729:7-3-03

Rule Type: New

Rule Title/Tagline: Non-Hazardous Drugs Compounded by a Prescriber.

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 prescriber drug compounding.

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

Provides the requirements for non-hazardous drugs compounded by a prescriber and the requirements if the prescriber is a veterinarian. Further defines the responsibilities for the responsible person on the terminal distributor license. With some exceptions, requires the adherence to United States Pharmacopeia (USP) Chapters 795 and 797 when compounding drugs.

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, US Code, and the Ohio Administrative Code. The O.R.C., U.S.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 also references the United States Code (U.S.C) and the United States Pharmacopeia (U.S.P.), which is a generally accepted industry standard for compounding drugs. The U.S.C. and U.S.P. are 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 cross reference in paragraph (H) from (G) to (G)(2). This still requires the prescriber to review and approval
    of the compounding process (i.e. master formulas, etc.). However, the rule still permits the final check to be conducted by nurses.

    03/18/2019 Paragraphs (A) and (B): Removed "the"
    Paragraph (E)(2): Changed division to rule
    Paragraph (E)(9): Specified that aseptic technique is only required for sterile compounded drugs
    Paragraph (I): Added last name as an example that may be used for verification
    Paragraph (L)(2): Updated labeling requirements for veterinarians - removed beyond-use date

    03/08/2019 Paragraph (C): Specifies that immediate-use drugs may also be compounded in accordance with USP 797 in addition to rule 4729:7-3-04.

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?

Overall this rule will result in increased costs to prescribers that prepare compounded drugs that are not for immediate use. The major cost incurred is the purchase of an ISO 5 hood, which can cost up to $6,000. Additional costs include equipment to maintain an aseptic environment such as gloves, masks, gowns, head and shoe covers. Additional costs also include staff time for training personnel in proper compounding techniques, cleaning and disinfecting compounding areas and ensuring compliance with the 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 this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, 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?** No