Rule Summary and Fiscal Analysis
Part A - General Questions

Rule Number: 4729:3-3-04

Rule Type: Amendment

Rule Title/Tagline: Certified pharmacy technicians.

Agency Name: State Board of Pharmacy

Division:

Address: 77 South High St. 17th floor Columbus OH 43215

Contact: Alexandra Simon

Email: Alexandra.Simon@pharmacy.ohio.gov **Phone:** 614-502-7161

I. Rule Summary

1. **Is this a five year rule review?** No
    A. **What is the rule's five year review date?** 12/4/2022
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?** 4729.94, 4729.26
5. **What statute(s) does the rule implement or amplify?** 4729.90, 4729.901, 4729.91, 4729.92, 4729.921, 4729.93, 4729.94, 4729.95, 4729.96
6. **What are the reasons for proposing the rule?**

    This rule is being proposed to amend pharmacy technician standards. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for pharmacy technicians.
7. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

Establishes the activities certified pharmacy technicians may perform. Amended to include stocking automated drug dispensing units and adds certain requirements for verbal refill authorizations

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 United States Pharmacopeia (U.S.P.), which is a generally accepted industry standard for compounding drugs. The U.S.P. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule. U.S.P. is also a required reference for compounding pharmacies.

10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

    Paragraph (A): Added definition of positive identification.
    Paragraph (B): Shifted previous paragraph A.
    Paragraph (C): Updated cross reference in paragraphs (C)(1), (7) and (8).
    Paragraph (C)(11)(a)(iv): Removed paragraph.

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?**

    An employer that engages in non-sterile compounding will have to provide additional training for certified technicians prior to engaging in non-sterile compounding.

An employer that engages in sterile compounding will have to provide additional training for certified technicians prior to engaging in sterile compounding.
An employer that works with hazardous drugs will have to provide additional training for certified technicians prior to engaging in the handling of those drugs.
If not already developed, pharmacies will incur added costs to develop these trainings.

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?** Yes

    Requires completion of compounding training before engaging in drug compounding. Requires completion of hazardous drug handling training before handling hazardous drugs.

    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