#### 11/13/20

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

#### Amend:

- 4729:3-1-01 Definition section for the division of the OAC pertaining to the registration of pharmacy technicians. The rule has been amended to update references to other rules and to clarify what tasks support personnel may perform.
- 4729:3-2-01 Establishes procedure for those seeking registration as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician. The rule is amended to add in additional documentation the Board will accept to comply with the educational requirements. The rule is amended to permit reciprocity for registered and certified technicians.
- 4729:3-2-02 Establishes criminal records check requirements for those seeking registration as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician. The rule is amended to include reciprocity and to extend valid fingerprint impressions from one year to two years. The rule deletes language that is no longer applicable because it exceeds the date referenced.
- 4729:3-2-03 Establishes renewal procedure for registered pharmacy technicians and certified pharmacy technicians. The rule is amended to correct cross reference and waive the fees when a registered pharmacy technician applies to be a certified pharmacy technician in the same renewal application period. The rule is amended to mirror the language used in eLicense.
- 4729:3-3-02 Establishes standards for pharmacy technician training programs. The rule is amended to include the completion of a Doctor of Pharmacy (PharmD) program within five years or holding an active pharmacist or pharmacy intern license as an approved pharmacy technician training program.
- 4729:3-3-03 Establishes the activities registered pharmacy technicians may perform. The rule is amended to include stocking and engage in remote order entry as an activity a registered pharmacy technician may perform.
- 4729:3-3-04 Establishes the activities certified pharmacy technicians may perform. The rule is amended to clarify that a technician can enter data directly into computerized record keeping system and adds remote order entry as an activity a certified pharmacy technician may perform.

#### New:

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- 4729:3-2-06 The rule outlines the process for a terminal distributor of dangerous drugs to verify the registration and certification of pharmacy technicians prior to employment and at least every 24 months.
- 4729:3-2-07 Establishes that a person may not hold a license as a pharmacist, pharmacy intern concurrently with a pharmacy technician license unless otherwise approved by the Board.
- 4729:5-5-25 Establishes the process for remote prescription entry by a technician for an outpatient pharmacy.
- 4729:5-9-02.15 Establishes the process for remote prescription entry by a technician for an inpatient pharmacy.

### No Change:

- 4729:3-2-04 Establishes reporting requirements for those with a change of name, contact information or place of employment.
- 4729:3-2-05 Establishes minimum scores for completion of the Test of English as a Foreign Language, Internet-based test.
- 4729:3-3-01 Establishes the activities pharmacy technician trainees may perform.
- 4729:3-5-01 Establishes continuing education requirements for registered pharmacy technicians and certified pharmacy technicians seeking to renew their certificate of registration.
- 4729:3-5-02 Establishes continuing education requirements for registered pharmacy technicians and certified pharmacy technicians seeking to renew their certificate of registration.
- 4729:3-5-03 Grants extension periods and waivers for the completion of continuing education requirements for active duty veteran members and their spouses.

Comments on the proposed rules will be accepted until **close of business on December 1, 2020**. Please send all comments to the following email address: <u>RuleComments@pharmacy.ohio.gov</u>

In addition, please copy your comments to: <u>CSIPublicComments@governor.ohio.gov</u>

## 77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117



Mike DeWine, Governor Jon Husted, Lt. Governor

## Common Sense Initiative

Carrie Kuruc, Director

### **Business Impact Analysis**

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy	
Rule Contact Name and Contact Information: <u>Cameron McNamee</u> <u>Cameron.mcnamee@pharmacy.ohio.gov</u>	
Regulation/Package Title (a general description of the rules' substantive content):	
Pharmacy Technicians	
Rule Number(s): 4729:3-1-01, 4729:3-2-01, 4729:3-2-02, 4729:3-2-03, 4729:3-2-04,	
4729:3-2-05, 4729:3-2-06, 4729:3-2-07, 4729:3-3-01, 4729:3-3-02, 4729:3-3-03, 4729:3-3-	
04, 4729:3-5-01, 4729:3-5-02, 4729:3-5-03, 4729:5-5-25, 4729:5-9-02.15	
Date of Submission for CSI Review: <u>11/13/20</u>	
Public Comment Period End Date: <u>12/1/20</u>	
Rule Type/Number of Rules:	
New/_4_rules	No Change/_6 rules (FYR? _Y)
Amended/ <u>7</u> rules (FYR? <u>Y</u> )	Rescinded/ rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness,

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predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

### **Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

### The rule(s):

- a. 🛛 Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
  - 4729:3-2-01, 4729:3-2-03 Requires a registration by the Board of Pharmacy.
  - 4729:3-3-02, 4729:3-3-03, 4729:3-3-04 Requires completion of compounding training before engaging in drug compounding. Requires completion of hazardous drug handling training before handling hazardous drugs. This is unchanged from the current rule's requirements.
  - 4729:5-5-25, 4729:5-9-02.15 Requires licensure by the Board of Pharmacy.

## **b.** Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.

4729:3-1-01, 4729:3-2-01, 4729:3-2-02, 4729:3-2-03, 4729:3-2-04, 4729:3-2-06, 4729:3-3-01, 4729:3-3-02, 4729:3-3-03, 4729:3-3-04, 4729:3-5-02, 4729:5-5-25, 4729:5-9-02.15 – Violation of the rule may result in administrative licensure discipline for a pharmacy technician. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation of a license.

#### c. 🛛 Requires specific expenditures or the report of information as a condition of compliance.

4729:3-2-01: The cost of registration is \$25 dollars for pharmacy technician trainees and \$50 for certified and registered pharmacy technicians. The rule also requires the applicant to submit to a criminal records check. The cost of a criminal records check (BCI&I/FBI) includes the following fees: BCI&I - \$22, FBI - \$24, and some agencies may charge a processing fee (e.g. 77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

\$5-\$40). Furthermore, the rule requires certified technicians to submit documentation that they are nationally certified. National certification costs between \$115 - \$129 for the initial certification examination. The rule also requires foreign students to take the TOEFL IBT. The cost of this test varies by country but can cost up to \$180. This is unchanged from the current rule's requirements.

- 4729:3-2-02: Requires submission of criminal records checks for applicants. The cost of a criminal records check (BCI&I/FBI) includes the following fees: BCI&I \$22, FBI \$24, and some agencies may charge a processing fee (e.g. \$5-\$40). This is unchanged from the current rule's requirements.
- 4729:3-2-03: The cost of renewal (two-year license) is \$50 for certified pharmacy technicians and registered pharmacy technicians. This is unchanged from the current rule's requirements.
- 4729:3-2-04: There is no monetary cost to submit a change of contact information to the Board. However, the process will require the submission of a form that may take an estimated five minutes to complete. This is unchanged from the current rule's requirements.
- 4729:3-2-05: This rule provides minimum scores and does not have a cost of compliance. This is unchanged from the current rule's requirements.
- 4729:3-3-01: The rule restricts the number of technician trainees that can be supervised by a pharmacist at one time. Thus, a pharmacy that has more than two technician trainees may incur additional costs to ensure another pharmacist is on-site to provide supervision. This is unchanged from the current rule's requirements.
- 4729:3-3-02: A pharmacy technician trainee may incur a cost of attending an American Society of Health-System Pharmacists/Accreditation Council for Pharmacy Education certified training program. Employers that choose to develop a training program will also incur costs associated with developing, implementing and assessing the program. This is unchanged from the current rule's requirements.
- 4729:3-3-03: An employer that engages in non-sterile compounding will have to provide additional training for registered technicians prior to engaging in non-sterile compounding. This is unchanged from the current rule's requirements.
- 4729:3-3-04: An employer that engages in sterile and non-sterile compounding will have to provide additional training for certified technicians prior to engaging in non-sterile compounding. This is unchanged from the current rule's requirements.
- 4729:3-3-05: This will require notification to the Board if a technician observes a violation specified in the rule. Notification can be performed online and will take approximately 10-20 minutes to complete. This is unchanged from the current rule's requirements.
- 4729:3-5-01: Registered pharmacy technicians will have to obtain 10 hours of CE every two years. The cost of this rule will be the cost incurred by the technician to obtain CE. While CE

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cost varies, the Board and other providers do offer no-cost CEs to licensees. This is unchanged from the current rule's requirements.

- 4729:3-5-02 Requires reporting of continuing education to a national or state register.
- 4729:3-5-03 Pharmacy technicians to which this rule applies must submit proper documentation to renew their registration, which can take approximately 30 minutes to complete.
- 4729:5-5-25 Establishes the process for remote prescription entry for an outpatient pharmacy. There may be administrative costs associated for compliance for those entities choosing to utilize remote prescription entry.
- 4729:5-9-02.15 Establishes the process for remote prescription entry for an inpatient pharmacy. There may be administrative costs associated for compliance for those entities choosing to utilize remote prescription entry.
- d. 🖂 Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

### **Regulatory Intent**

## 2. Please briefly describe the draft regulation in plain language. Please include the key provisions of the regulation as well as any proposed amendments.

#### Amend:

- 4729:3-1-01 Definition section for the division of the OAC pertaining to the registration of pharmacy technicians. The rule has been amended to update references to other rules and to clarify what tasks support personnel may perform.
- 4729:3-2-01 Establishes procedure for those seeking registration as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician. The rule is amended to add in additional documentation the Board will accept to comply with the educational requirements. The rule is amended to permit reciprocity for registered and certified technicians.
- 4729:3-2-02 Establishes criminal records check requirements for those seeking registration as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician. The rule is amended to include reciprocity and to extend valid fingerprint impressions from one year to two years. The rule deletes language that is no longer applicable because it exceeds the date referenced.
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registered pharmacy technician applies to be a certified pharmacy technician in the same renewal application period. The rule is amended to mirror the language used in eLicense.

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- 4729:3-3-04 Establishes the activities certified pharmacy technicians may perform. The rule is amended to clarify that a technician can enter data directly into computerized record keeping system and adds remote order entry as an activity a certified pharmacy technician may perform.

### New:

- 4729:3-2-06 The rule outlines the process for a terminal distributor of dangerous drugs to verify the registration and certification of pharmacy technicians prior to employment and at least every 24 months.
- 4729:3-2-07 Establishes that a person may not hold a license as a pharmacist, pharmacy intern concurrently with a pharmacy technician license unless otherwise approved by the Board.
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### No Change:

- 4729:3-2-04 Establishes reporting requirements for those with a change of name, contact information or place of employment.
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- 4729:3-5-01 Establishes continuing education requirements for registered pharmacy technicians and certified pharmacy technicians seeking to renew their certificate of registration.
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- 4729:3-5-03 Grants extension periods and waivers for the completion of continuing education requirements for active duty veteran members and their spouses.

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## **3.** Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rules are authorized by sections 4729.26, 4729.94, and 4776.03. The statutes the rules amplifies or implements are 4729.90, 4729.96, 4729.95, 4729.94, 4729.93, 4729.921, 4729.92, 4729.91, and 4729.901.

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.

If yes, picuse or lefty explain the source and subsumee of the feachai

These rules do not implement a federal requirement.

5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule package exceeds federal requirements because the regulation of the practice of pharmacy has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice includes valid requirements for licensure as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 4729.94 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules governing registration of registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.

Section 4776.03 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing administrative and procedural requirements for criminal records checks.

### 7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of the regulations will be measured by having rules written in plain language, registrant compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

## 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

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If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

## **Development of the Regulation**

## 9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

## If applicable, please include the date and medium by which the stakeholders were initially contacted.

The rules in this package were reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all new rules and rules prior to their legislatively mandated five-year review date. Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

## 10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Committee recommended the following additions that were incorporated into the rule package:

- The incorporation of additional methods to prove English language proficiency (OAC 4729:3-2-01)
- Added holding a valid pharmacist or pharmacy intern license from another state as additional method for showing competency to practice as a pharmacy technician (OAC 4729:3-3-02)
- Clarification of registered pharmacy technician duties as it relates to stocking automated drug systems (OAC 4729:3-3-02)
- Committee requested removal of audio/visual requirements for remote processing rules and extended review of policies to every three years (OAC 4729:5-5-25 and 4729:5-9-02.15)

## 11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review this rule.

# 12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for licensure and practice of pharmacy technician trainees, registered pharmacy technicians, and certified pharmacy technicians, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives. However, the Board has amended the rules to add more avenues for pharmacy technicians to obtain the

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required training necessary to obtain registration as a registered or certified technician (including reciprocity).

## 13. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance-based regulations.

## 14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

# 15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

### **Adverse Impact to Business**

## 16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

### a. Identify the scope of the impacted business community; and

The rule package impacts the following:

- Registered pharmacy technicians;
- Certified pharmacy technicians;
- Pharmacy technician trainees;

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- Pharmacists; and
- Terminal distributor of dangerous drugs.

## b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Violation of these rules may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, required coursework, monetary fine and/or revocation of a license.

### c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

#### Amend:

- 4729:3-1-01 Definition section for the division of the OAC pertaining to the registration of pharmacy technicians. The rule has been amended to update references to other rules and to clarify what tasks support personnel may perform. As this is a definitional section, there should be no adverse impact.
- 4729:3-2-01 Establishes procedure for those seeking registration as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician. The rule is amended to permit reciprocity for registered and certified technicians. The cost of registration is \$25 dollars for pharmacy technician trainees and \$50 for certified and registered pharmacy technicians. The rule also requires the applicant to submit to a criminal records check. The cost of a criminal records check (BCI&I/FBI) includes the following fees: BCI&I \$22, FBI \$24, and some agencies may charge a processing fee (e.g. \$5-\$40). Furthermore, the rule requires certified technicians to submit documentation that they are nationally certified. National certification costs between \$115 \$129 for the initial certification examination. The rule also requires foreign students to take the TOEFL IBT. The cost of this test varies by country but can cost up to \$180.
- 4729:3-2-02 Establishes criminal records check requirements for those seeking registration as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician. The rule is amended to include reciprocity and to extend valid fingerprint impressions from one year to two years. The rule deletes language that is no longer applicable because it exceeds the date referenced. The cost of a criminal records check (BCI&I/FBI) includes the following fees: BCI&I \$22, FBI \$24, and some agencies may charge a processing fee (e.g. \$5-\$40).
- 4729:3-2-03 Establishes renewal procedure for registered pharmacy technicians and certified pharmacy technicians. The rule is amended to correct cross reference and waive the fees when a 77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

registered pharmacy technician applies to be a certified pharmacy technician in the same renewal application period. The cost of renewal (two-year license) is \$50 for certified and registered pharmacy technicians.

- 4729:3-3-02 Establishes standards for pharmacy technician training programs. The rule is amended to include the completion of a Doctor of Pharmacy (PharmD) program within five years or holding an active pharmacist or pharmacy intern license as an approved pharmacy technician training program. A pharmacy technician trainee may incur a cost of attending an American Society of Health-System Pharmacists/Accreditation Council for Pharmacy Education certified training program. Employers that choose to develop a training program will also incur costs associated with developing, implementing, and assessing the program. However, as program standards are not changing, those with training programs should not experience any additional costs.
- 4729:3-3-03 Establishes the activities registered pharmacy technicians may perform. The rule is amended to include stocking and engage in remote order entry as an activity a registered pharmacy technician may perform. An employer that engages in non-sterile compounding will have to provide additional training for registered technicians prior to engaging in non-sterile compounding.
- 4729:3-3-04 4729:3-3-04 Establishes the activities certified pharmacy technicians may
  perform. The rule is amended to clarify that a technician can enter data directly into computerized
  record keeping system and adds remote order entry as an activity a certified pharmacy technician
  may perform. An employer that engages in non-sterile compounding will have to provide
  additional training for registered technicians prior to engaging in non-sterile compounding.

### New:

- 4729:3-2-06 The rule outlines the process for a terminal distributor of dangerous drugs to verify the registration and certification of pharmacy technicians prior to employment and at least every 24 months. There will be administrative costs associated with compliance, however, this process ensures a licensee is not in violation of section 4729.95 of the Revised Code.
- 4729:3-2-07 Establishes that a person may not hold a license as a pharmacist, pharmacy intern concurrently with a pharmacy technician license unless otherwise approved by the Board. There are not costs associated with compliance.
- 4729:5-5-25 Establishes the process for remote prescription entry for an outpatient pharmacy. There may be administrative costs associated for compliance for those entities choosing to utilize remote prescription entry. The cost of compliance is the cost of developing a contract and training on the responsibilities associated with remote entry by off-site technicians and ensuring that remote technicians have access to the pharmacy's electronic patient information system. Additionally,

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out-of-state pharmacies conducting remote entry will have to obtain licensure as a terminal distributor of dangerous drugs (biennial cost of \$320).

 4729:5-9-02.15 – Establishes the process for remote prescription entry for an inpatient pharmacy. There may be administrative costs associated for compliance for those entities choosing to utilize remote prescription entry. The cost of compliance is the cost of developing a contract and training on the responsibilities associated with remote entry by off-site technicians and ensuring that remote technicians have access to the pharmacy's electronic patient information system. Additionally, out-of-state pharmacies conducting remote entry will have to obtain licensure as a terminal distributor of dangerous drugs (biennial cost of \$320).

### No Change:

- 4729:3-2-04 Establishes reporting requirements for those with a change of name, contact information or place of employment. There is no cost to submit a change of contact information to the Board. However, the process will require the submission of a form that may take an estimated five minutes to complete.
- 4729:3-2-05 Establishes minimum scores for completion of the Test of English as a Foreign Language, Internet-based test. The rule provides minimum scores but does not have a cost of compliance.
- 4729:3-3-01 Establishes the activities pharmacy technician trainees may perform. The rule
  restricts the number of technician trainees that can be supervised by a pharmacist at one time. Thus,
  a pharmacy that has more than two technician trainees may incur additional costs to ensure another
  pharmacist is on-site to provide supervision. It should be noted that during the COVID-19
  pandemic, this provision can be waived in the event of documented staffing shortages.
- 4729:3-5-01 Establishes continuing education requirements for registered pharmacy technicians and certified pharmacy technicians seeking to renew their certificate of registration. The cost of this rule will be the cost incurred by the technician to obtain CE. While CE cost varies, the Board and other providers do offer no-cost CEs to licensees.
- 4729:3-5-02 Establishes continuing education requirements for registered pharmacy technicians and certified pharmacy technicians seeking to renew their certificate of registration. The cost of this rule will be the cost incurred by the technician to obtain CE. While CE cost varies, the Board and other providers do offer no-cost CEs to licensees.
- 4729:3-5-03 Grants extension periods and waivers for the completion of continuing education requirements for active duty veteran members and their spouses. There is no cost to submit a waiver or extension request. However, the process will require the submission of a form that may take an estimated five minutes to complete.

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## 17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform licensing and training standards of pharmacy technicians.

#### **Regulatory Flexibility**

## **18.** Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

## **19.** How will the agency apply Ohio Revised Code section **119.14** (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

#### 20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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#### Chapter 4729:3-1 Pharmacy Technicians

#### 4729:3-1-01 Definitions - pharmacy technicians.

As used in this division:

(A) "Abandoned application" means an application for a registration pursuant to this division where the applicant fails to complete all application requirements within thirty days after being notified by the board. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for registration, submit the required fee\_ and comply with the registration requirements in effect at the time of reapplication.

(B) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.

(C) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section <u>3719.011</u> of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(D) "Board of pharmacy" or "board" means the state board of pharmacy established under Chapter 4729. of the Revised Code.

(E) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(F) "Certified pharmacy technician" means a person who:

(1) Has completed an approved training program pursuant to rule <u>4729:3-3-02</u> of the Administrative Code<u>or has complied with the reciprocity requirements of 4729:3-2-01 of the Administrative Code</u>;

(2) Is registered with the state board of pharmacy;

(3) Practices in this state in accordance with rule  $\underline{4729:3-3-04}$  of the Administrative Code; and

(4) Maintains a current pharmacy technician certification from an organization that has been recognized by the board.

(G) "Compounding" has the same meaning as defined in section <u>4729.01</u> of the Revised Code and agency 4729 of the Administrative Code.

(H) "Controlled substance" has the same meaning as in section  $\underline{3719.01}$  of the Revised Code.

(1) "Current pharmacy technician certification from an organization that has been recognized by the board" pursuant to division (B)(2)(d) of section <u>4729.90</u> of the Revised Code means either:

(1) The ExCPT certification provided by the national healthcareer association; or

(2) The pharmacy technician certification board (PTCB) certification.

(J) "Dangerous drug" has the same meaning as in section <u>4729.01</u> of the Revised Code.

(K) "Disciplinary action," unless otherwise stated in this division, means any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

(1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification;

(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;

(3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation;

(4) An action to reprimand or place the license, registration, or certification holder on probation;

(5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender;

(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender or other relinquishment of a license, registration or certification in lieu of a formal sanction against a person's license, registration, or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future;

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(L) "Direct supervision" or "personal supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, to provide personal review and approval of all professional activities. The pharmacist providing personal supervision of a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician shall:

(1) Be readily available to answer questions of the technician or trainee;

(2) Make appropriate in-process and end-process verifications of the activities of the technician or trainee; and

(3) Be fully responsible for the practice of the technician or trainee.

(M) "Entering information into and retrieving information from a database or patient profile" as used in section 4729.91 of the Revised Code means to enter new or refill prescription information into a database or patient profile.

(N) "Good moral character" pursuant to section <u>4729.90</u> of the Revised Code means those virtues of a person which are generally recognized as beneficial to the public health, safety and welfare, or a pattern of behavior conforming to a profession's ethical standards and showing an absence of moral turpitude, including conduct consistent with justice, honesty, or morality.

(0) "In good standing" means a pharmacist to which all the following apply:

(1) Has not been denied the privilege of supervising <u>pharmacy</u> interns, <u>certified</u> pharmacy technicians, <u>registered pharmacy technicians</u> or <u>pharmacy</u> technician trainees by the board;

(2) Has not been denied a license, registration or certificate by any public agency or licensing agency; and

(3) Does not have a license, registration or certificate limited, suspended, currently on probation, or revoked by any public agency or licensing agency.

(P) "Pharmacist" means an individual who holds a valid pharmacist license in accordance with Chapter 4729. of the Revised Code.

(Q) "Pharmacy technician trainee" means a person who:

(1) Intends to enroll or is enrolled in an approved training program pursuant to rule <u>4729:3-</u><u>3-02</u> of the Administrative Code to obtain a registration as a registered or certified pharmacy technician;

(2) Is registered as a pharmacy technician trainee with the state board of pharmacy; and

(3) Practices in this state in accordance with rule <u>4729:3-3-01</u> of the Administrative Code.

(R) "Place on probation" means to take action against a license or registration, for a period of time determined by the board, which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee or registrant may engage.

(S)

(1) "Positive identification" means a method of identifying a person that does not rely solely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

- (a) A manual signature on a hard copy record;
- (b) A magnetic card reader;
- (c) A bar code reader;
- (d) A biometric method;
- (e) A proximity badge reader;
- (f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(T) "Refill authorization" means authorization from a prescriber or prescriber's agent for a new non-controlled substance prescription renewal, provided that the prescription remains unchanged.

(U) "Refuse to grant or renew" means to deny original or continued licensure or registration for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed or registered by the board or a person seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license or registration. A person that seeks to attain such status by licensure or registration, whose license or registration the state board of pharmacy has refused to grant or renew, must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(V) "Registered pharmacy technician" means a person who:

(1) Has completed an approved training program pursuant to rule <u>4729:3-3-02</u> of the Administrative Code<u>or has complied with the reciprocity requirements of 4729:3-2-01 of the Administrative Code</u>;

(2) Is registered with the state board of pharmacy; and

(3) Practices in this state in accordance with rule <u>4729:3-3-03</u> of the Administrative Code.

(W) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code .

(X) "Revoke" means to take action against a license or registration rendering such license or registration void and such license or registration shall not be reissued. Revoke is an action that is permanent against the licensee or registrant.

(Y) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(Z)

(1) "Support personnel" means the following:

(a) An individual employed or performing contracted services at a location licensed as a terminal distributor of dangerous drugs, trained to perform clerical duties associated with the practice of pharmacy, including pricing, cashiering, drug purchasing, delivering, scheduling deliveries, answering non-professional telephone inquiries, transportation of dispensed medications within a hospital, documenting and processing third-party billing information for reimbursement, or any other activity as determined by the board.

(b) An individual contracted by a terminal distributor of dangerous drugs to perform drug inventories.

(2) Except for those responsible for the delivery of dangerous drugs, support personnel shall not have unsupervised access to dangerous drugs.

(3) Except as provided in paragraphs (X)(4) and (X)(5) of this rule or as otherwise authorized by the board in agency 4729 of the Administrative Code, support personnel shall not perform the tasks of a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(4) Support personnel may have access to or retrieve information from patient records, including a database or patient profile to perform clerical duties associated with the practice of pharmacy. Support personnel shall not enter prescription information into a patient profile.

(5) Support personnel may perform the following:

(a) Transporting dangerous drugs from a loading dock, warehouse or other area that receives shipments from a licensed wholesaler or other person licensed in accordance with section 4729.52 of the Revised Code; and.

(b) Stocking and retrieving from inventory non-controlled dangerous drugs that are not dispensed by the pharmacy.

(c) Stocking of automated drug dispensing units and floor stock with intravenous fluids that are non-controlled dangerous drugs and are not dispensed by an institutional pharmacy.

(d) Overwrapping or placing in plastic dangerous drugs that have been compounded or dispensed and appropriately labeled by a terminal distributor of dangerous drugs.

(e) Entering demographic and insurance information into an electronic system to process prescription claims.

(f) Place dangerous drugs dispensed by a pharmacist into shipping containers or packages for delivery if the terminal distributor of dangerous drugs complies with all the following:

(i) Uses barcode scanning and patient order information to ensure the accuracy of the drugs placed into shipping containers or packaging.

(ii) Develops and implements a quality assurance program to track the accuracy of the support personnel packaging the dangerous drugs.

(6) The terminal distributor of dangerous drugs shall be responsible for ensuring all support personnel comply with state and federal requirements to ensure the confidentiality of patient health records.

(7) Support personnel shall not serve as a pharmacist's delegate pursuant to section <u>4729.80</u> of the Revised Code.

(8) Support personnel are not required to obtain licensure or registration under Chapter 4729. of the Revised Code.

(AA) "Suspend" means to take action against a license or registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy.

(BB) "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section <u>3719.121</u> of the Revised Code. The board may suspend a license or registration issued pursuant to Chapter 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(CC) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the armed forces, including the national guard and reserve.

#### 4729:3-2-01 Registration procedures.

(A) An applicant for registration as a pharmacy technician trainee shall:

(1) Comply with all requirements set forth in section <u>4729.92</u> of the Revised Code.

(2) Comply with the criminal records check requirements pursuant to rule 4729:3-2-02 of the Administrative Code.

(3) Submit a complete application for registration, in a manner determined by the board, that includes:

(a) The required application fee of twenty-five dollars.

(b) Documentation, as specified by the board, that the applicant meets the following requirements:

(i) Has a high school diploma, a certificate of high school equivalence, a foreign school diploma that is equivalent to a U.S. high school diploma or has been employed continuously since prior to April 8, 2009, as a pharmacy technician without a high school diploma or certificate of high school equivalence;

(ii) Is at least eighteen years of age; and

(iii) If the applicant has a foreign school diploma that is equivalent to a U.S. high school diploma, the applicant shall submit evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule <u>4729:3-2-05</u> of the Administrative Code.

(c) Paragraph (A)(1)(a)(iii) of this rule shall not apply if the applicant complies with any of the following:

(i) Submits a diploma or transcript demonstrating completion of an associate degree or higher from an accredited college, junior college, community college or university in the United States.

(ii) Submits verification of active professional license or registration issued under the following chapters of the Revised Code: 4715., 4723., 4725., 4729., 4730., 4731., 4732., 4734., 4741., 4744., 4753., 4755., 4757., 4759., 4760., 4761., 4762., 4774., 4778., 4779., 4783.

(iii) Submits verification of an active professional license or registration from another state that permits the applicant to engage in the same profession, occupation, or occupational activity as any license or registration issued by an agency listed in paragraph (A)(3)(c)(ii) of this rule.

**Commented [MC1]:** NOTE: This covers the following healthcare boards:

o State of Ohio Board of Pharmacy (ORC 4729, 3796) o Ohio Board of Nursing (ORC 4723) o Ohio State Dental Board (ORC 4715) o State Medical Board of Ohio – (ORC 4730, 4731, 4759, 4760, 4761, 4762, 4774, 4778) o Ohio Speech and Hearing Professionals Board (ORC 4744, 4753) o Ohio Veterinary Medical Licensing Board (ORC 4741) o Occupational Therapy, Physical Therapy, and Athletic Trainers Board (ORC 4755, 4779) o Counselors, Social Workers, and Marriage & Family Therapist Board (ORC 4757)

o Ohio Board of Psychology (ORC 4732, 4783)

o Ohio Chiropractic Board (ORC 4734)

o Ohio Vision Professionals Board (ORC 4725)

(iv) Submits documentation of any other board approved method for demonstrating english language proficiency.

(ed) Any additional information or documentation as determined by the board.

(B) An applicant for registration as a registered pharmacy technician shall:

(1) Comply with all requirements set forth in section 4729.90 of the Revised Code.

(2) Complete Comply with either of the following:

(a) an Have completed an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code; or the education and training requirements set forth in division (E)(1) of section 4729:90 of the Revised Code.

(b) Hold a pharmacy technician registration or license issued by another state and have actively worked as a pharmacy technician for at least one year within the previous three years of application.

(3) Comply with the criminal records check requirements pursuant to rule 4729:3-2-02 of the Administrative Code.

(4) Submit a complete application for registration, in a manner determined by the board, that includes:

(a) The required application fee of fifty dollars;

(b) Except for applicants currently registered as pharmacy technician trainees, documentation, as specified by the board, that the applicant meets the following requirements:

(i) Has a high school diploma, a certificate of high school equivalence, a foreign school diploma that is equivalent to a U.S. high school diploma or has been employed continuously since prior to April 8, 2009, as a pharmacy technician without a high school diploma or certificate of high school equivalence;

(ii) Is at least eighteen years of age; and

(iii) If the applicant has a foreign school diploma that is equivalent to a U.S. high school diploma, the applicant shall submit evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule <u>4729:3-2-05</u> of the Administrative Code.

(c) Paragraph (B)(4)(b)(iii) of this rule shall not apply if the applicant complies with any of the following:

**Commented [MC2]:** NOTE: Would permit reciprocity for registered technicians. Certified reciprocity is addressed later in the rule.

(i) Submits a diploma or transcript demonstrating completion of an associate degree or higher from an accredited college, junior college, community college or university in the United States.

(ii) Submits verification of active professional license or registration issued under the following chapters of the Revised Code: 4715., 4723., 4725., 4729., 4730., 4731., 4732., 4734., 4741., 4744., 4753., 4755., 4757., 4759., 4760., 4761., 4762., 4774., 4778., 4779., 4783.

(iii) Submits verification of an active professional license or registration from another state that permits the applicant to engage in the same profession, occupation, or occupational activity as any license or registration issued by an agency listed in paragraph (B)(4)(c)(ii) of this rule.

(iv) Submits documentation of any other board approved method for demonstrating english language proficiency.

(ed) Any of the following documentation:

(i) An attestation signed by the pharmacy's responsible person where the applicant was educated and trained that the applicant has successfully completed the education and training requirements set forth in division (E)(1) of section 4729.90 of the Revised Code.

A responsible person shall not be required to attest to the applicant's education and training in non-sterile compounding. Training and education for non-sterile compounding shall be completed by registered technicians that perform non-sterile compounding in accordance with rule <u>4729:3-3-03</u> of the Administrative Code.

(iii) An attestation or certificate of completion signed by the program director that the applicant has successfully completed an approved training program in accordance with paragraph (A)(1), or (A)(2), or (A)(4) of rule 4729:3-3-02 of the Administrative Code.

(iiiii) A record of training and education pursuant to paragraph (B)(3) of rule 4729:3-3-02 of the Administrative Code signed by the program director and responsible person where the applicant received training that the applicant has successfully completed an approved training program in accordance with paragraph (A)(3) of rule 4729:3-3-02 of the Administrative Code.

(iii) Documentation, as determined by the board, demonstrating compliance with the reciprocity requirements of paragraph (B)(2)(b) of this rule.

(e) Any additional information or documentation as determined by the board.

(C) An applicant for registration as a certified pharmacy technician shall:

(1) Comply with all requirements set forth in section <u>4729.90</u> of the Revised Code.

**Commented** [MC3]: *NOTE: This covers the following healthcare boards:* 

o State of Ohio Board of Pharmacy (ORC 4729, 3796)

o Ohio Board of Nursing (ORC 4723)

o Ohio State Dental Board (ORC 4715)

o State Medical Board of Ohio – (ORC 4730, 4731, 4759, 4760, 4761, 4762, 4774, 4778)

- o Ohio Speech and Hearing Professionals Board (ORC 4744, 4753)
- o Ohio Veterinary Medical Licensing Board (ORC 4741)
- o Occupational Therapy, Physical Therapy, and Athletic Trainers Board (ORC 4755, 4779)
- o Counselors, Social Workers, and Marriage & Family
- Therapist Board (ORC 4757) o Ohio Board of Psychology (ORC 4732, 4783)
- o Ohio Chiropractic Board (ORC 4734)
- o Ohio Vision Professionals Board (ORC 4725)

(2) Comply with either of the following:

(a) Have completed an approved training program pursuant to rule 4729:3-3-02 of the Administrative Code: or

(b) Hold a pharmacy technician registration or license issued by another state and have actively worked as a pharmacy technician for at least one year within the previous three years of application.

-Complete an approved training program pursuant to rule <u>4729:3-3-02</u> of the Administrative Code or the education and training requirements set forth in division (E)(2) of section <u>4729:90</u> of the Revised Code.

(3) Comply with the criminal records check requirements pursuant to rule  $\frac{4729:3-2-02}{4729:3-2-02}$  of the Administrative Code.

(4) Submit a complete application for registration, in a manner determined by the board, that includes:

(a) The required application fee of fifty dollars, except as provided in rule 4729:3-2-03 of the Administrative Code.÷

(b) Documentation, as specified by the board, that the applicant has a current pharmacy technician certification from an organization that has been recognized by the board.

(c) Except for applicants currently registered as pharmacy technician trainees, documentation, as specified by the board, that the applicant meets the following requirements:

(i) Has a high school diploma, a certificate of high school equivalence or a foreign school diploma that is equivalent to a U.S. high school diploma;

(ii) Is at least eighteen years of age; and

(iii) If the applicant has a foreign school diploma that is equivalent to a U.S. high school diploma, the applicant shall submit evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule <u>4729:3-2-05</u> of the Administrative Code.

(d) Paragraph (C)(4)(c)(iii) of this rule shall not apply if the applicant complies with either of the following:

(i) Submits a diploma or transcript demonstrating completion of an associate degree or higher from an accredited college, junior college, community college or university in the United States.

**Commented** [MC4]: NOTE: Certified technician reciprocity.

(ii) Submits verification of active professional license or registration issued under the following chapters of the Revised Code: 4715., 4723., 4725., 4729., 4730., 4731., 4732., 4734., 4741., 4744., 4753., 4755., 4757., 4759., 4760., 4761., 4762., 4774., 4778., 4779., 4783.

(iii) Submits verification of an active professional license or registration from another state that permits the applicant to engage in the same profession, occupation, or occupational activity as any license or registration issued by an agency listed in paragraph (C)(4)(d)(ii) of this rule.

(iv) Submits documentation of any other board approved method for demonstrating english language proficiency.

(de) Any of the following documentation:

(i) An attestation signed by the pharmacy's responsible person where the applicant was educated and trained that the applicant has successfully completed the education and training requirements set forth in division (E)(2) of section 4729.90 of the Revised Code.

A responsible person shall not be required to attest to the applicant's education and training in non-sterile compounding and sterile compounding, including the preparation and mixing of intravenous drugs to be injected into a human being. Training and education for non-sterile compounding and sterile compounding shall be completed by certified pharmacy technicians that perform non-sterile compounding and sterile compounding and sterile compounding with rule <u>4729:3-3-04</u> of the Administrative Code.

(ii) An attestation or certificate of completion signed by the program director that the applicant has successfully completed an approved training program in accordance with paragraph (A)(1), or (A)(2), or (A)(4) of rule 4729:3-3-02 of the Administrative Code.

(iii) A record of training and education pursuant to paragraph (B)(3) of rule 4729:3-3-02 of the Administrative Code signed by the program director and responsible person where the applicant received training that the applicant has successfully completed an approved training program in accordance with paragraph (A)(3) of rule 4729:3-3-02 of the Administrative Code.

(iii) Documentation, as determined by the board, demonstrating compliance with the reciprocity requirements of paragraph (C)(2)(b) of this rule.

(e) Any additional information or documentation as determined by the board.

(D) A registration for a pharmacy technician trainee is valid for one year from the date of registration <u>but may be extended up to an additional eighteen months by the board or the board's executive director or the director's designee for good cause shown</u>. Registration is not renewable, but an individual may reapply for registration if the individual's previous registration has lapsed for more than five years or the board grants its approval. An individual that is permitted to reapply for registration as a pharmacy technician trainee shall

**Commented [MC5]:** *NOTE: This covers the following healthcare boards:* 

- o State of Ohio Board of Pharmacy (ORC 4729, 3796)
- o Ohio Board of Nursing (ORC 4723) o Ohio State Dental Board (ORC 4715)
- o State Medical Board of Ohio (ORC 4730, 4731, 4759,
- 4760, 4761, 4762, 4774, 4778)
- o Ohio Speech and Hearing Professionals Board (ORC 4744, 4753)
- o Ohio Veterinary Medical Licensing Board (ORC 4741) o Occupational Therapy, Physical Therapy, and Athletic
- Trainers Board (ORC 4755, 4779) o Counselors, Social Workers, and Marriage & Family
- Therapist Board (ORC 4757)
- o Ohio Board of Psychology (ORC 4732, 4783)
- o Ohio Chiropractic Board (ORC 4734)
- o Ohio Vision Professionals Board (ORC 4725)

comply with the criminal records check requirements pursuant to rule <u>4729:3-2-02</u> of the Administrative Code, unless otherwise determined by the board.

A registration for a pharmacy technician trainee is no longer valid if an individual receives a registration to practice as a registered pharmacy technician or certified pharmacy technician.

(E) An initial registration for a registered pharmacy technician and certified pharmacy technician is valid until the renewal date set forth in rule 4729:3-2-03 of the Administrative Code.

(F) Failure to complete all application requirements within thirty days after being notified by the board may result in the application being deemed abandoned as defined in rule <u>4729:3-1-01</u> of the Administrative Code.

(G) Registration fees for veterans shall be waived upon submission of the appropriate documentation. Documentation required to obtain a fee waiver will be published on the state board of pharmacy's web site: <u>www.pharmacy.ohio.gov</u>.

**Commented [MC6]:** *NOTE: This ensures individuals are not practicing under different registration types.* 

#### 4729:3-2-02 Criminal records checks.

(A) An applicant seeking an initial registration, including registration by reciprocity, as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician must first submit fingerprint impressions to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check.

(B) Pursuant to section <u>4776.02</u> of the Revised Code, the criminal records check performed by BCI&I shall consist of both a BCI&I criminal records check and a federal bureau of investigation (FBI) criminal records check. BCI&I shall send the results of the BCI&I and FBI criminal records checks directly to the state board of pharmacy.

(C) The state board of pharmacy requires that the criminal records check+

(1) <u>Be be</u> based on electronic fingerprint impressions that are submitted directly to BCI&I from a WebCheck provider agency or ink impressions. The state board of pharmacy may accept the results of a criminal records check based on ink impressions only in the following circumstances:

(a1) Readable electronic fingerprint impressions cannot be obtained or are rejected by either BCI&I or FBI;

(b2) The applicant is from out-of-state; or

(e3) The applicant's home address is seventy-five miles or more from the nearest WebCheck location.

(D) Except as provided in paragraph (E) of this rule, results <u>Results</u> will only be considered valid if the fingerprint impressions were obtained within <u>one twenty-four year months of</u> the date the application is received by the board.

**Commented [MC7]:** NOTE: This mirrors a current resolution. Ensures that trainees who become registered do not have to submit to another background check.

(E) Until April 6, 2019, an applicant for registration as a registered pharmacy technician or certified pharmacy technician who met the previous requirements to be a qualified pharmacy technician under section <u>4729.42</u> of the Revised Code, may satisfy the criminal records check requirements set forth in section <u>4729.90</u> of the Revised Code by either:

(1) Authorizing the superintendent of the bureau of criminal identification and investigation to make the results of a criminal records check of the applicant available to the state board of pharmacy. To meet the requirement, the criminal records check must have been conducted no earlier than twenty-four months prior to the date the application for registration is received by the board; or

(2) Submitting a copy of the results of the applicant's criminal records check that was performed by the applicant's employer to be a qualified pharmacy technician under section <u>4729.42</u> of the Revised Code to the state board of pharmacy. To meet the requirement, the criminal records check must have been conducted no earlier than twentyfour months prior to the date the application for registration is received by the board.

**Commented [MC8]:** NOTE: This verbiage is from the statute but is no longer applicable because it exceeds the date referenced.

#### 4729:3-2-03 Renewal procedures.

(A) A registered pharmacy technician shall submit a renewal application, in a manner determined by the board, that includes all the following:

(1) An attestation that the technician has completed the specified continuing education requirements pursuant to rule 4729:3-5-01 of the Administrative Code.

(2) The required biennial fee of fifty dollars, except as provided in paragraph (A) (3) of this rule.

(3) A registered pharmacy technician may apply to be a certified pharmacy technician at no cost if the registered technician applies for a certified pharmacy technician registration during the renewal application period established in paragraph (C) of this rule.

(34) Any additional information or documentation as determined by the board.

(B) A certified pharmacy technician shall submit a renewal application, in a manner determined by the board, that includes all the following:

(1) An attestation that technician has valid technician certification number from an organization that has been recognized by the board and has complied with the continuing education requirements of that organization.

(2) The required biennial fee of fifty dollars.

(3) Any additional information or documentation as determined by the board.

(C) A renewal application for registered pharmacy technicians shall be submitted no later than the thirty first of March of each even-numbered year. Renewal applications shall be accepted no earlier than January of each even-numbered year on a date determined by the board's director of licensing.

An initial registration issued by the state board of pharmacy on or after the first of January December of every evenodd-numbered year in accordance with Chapter 4729. of the Revised Code entitles the individual to whom it is issued to practice as a registered pharmacy technician until the renewal date immediately following the next required renewal date.

(D) A renewal application for certified pharmacy technicians shall be submitted no later than the thirtieth of September of each even-numbered year. Renewal applications shall be accepted no earlier than July of each even-numbered year on a date determined by the board's director of licensing.

An initial registration issued by the state board of pharmacy on or after the first of June of every even-numbered year in accordance with Chapter 4729. of the Revised Code entitles

Commented [MC9]: Corrected incorrect cross reference.

**Commented [MC10]:** Provides same window of time as certified technicians (see paragraph D).

the individual to whom it is issued to practice as a certified pharmacy technician until the renewal date immediately following the next required renewal date.

(E) A registered pharmacy technician or certified pharmacy technician who fails to renew a registration in accordance with this rule is prohibited from engaging in the activities authorized by section 4729.91 of the Revised Code and rules 4729:3-3-03 and 4729:3-3-04 of the Administrative Code.

(F) A registered pharmacy technician or certified pharmacy technician who fails to renew a registration in accordance with this rule, but has not lapsed for more than ninety days, may be reinstated renewed if the applicant complies with the following:

(1) Submits a renewal application in accordance with this rule;

(2) Pays the renewal fee and a late fee of fifty dollars.

(G) A registrant that fails to renew for more than ninety days may not renew a registration and the registration shall be considered <u>lapsed expired</u> and cannot be <u>reinstatedrenewed</u>. An individual may <u>reapply to reinstate</u> for a registration in accordance with rule 4729:3-2-01 of this rule.

(H)

(1) In accordance with section 5903.10 of the Revised Code, a holder of an expired registration shall be granted a renewal of the registration by the state board of pharmacy at the usual cost without penalty and without need to meet the requirements set forth in rule 4729: 3-2-01 of the Administrative Code if not otherwise disqualified because of mental or physical disability and if either of the following applies:

(a) The registration was not renewed because of the holder's service in the armed forces of the United States or a reserve component of the armed forces.

(b) The registration was not renewed because the holder's spouse served in the armed forces of the United States or a reserve component of the armed forces.

(2) A registered or certified pharmacy technician shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain a renewal pursuant to paragraph (H)(1) of this rule will be published on the state board of pharmacy's web site: <u>www.pharmacy.ohio.gov</u>.

(I) Renewal fees for veterans shall be waived upon submission of the appropriate documentation. Documentation required to obtain a fee waiver will be published on the state board of pharmacy's web site: <u>www.pharmacy.ohio.gov</u>.

Commented [MC11]: Uses same terminology from eLicense.

#### 4729:3-2-04 Change of name, contact information and place of employment.

(A) An individual registered pursuant to this division who has a legal change of name, shall notify the board of pharmacy within thirty days from the effective date of such change. Such notification of a name change shall be accompanied by one of the following:

(1) A notarized affidavit;

(2) A certified copy of a court record; or

(3) A certified copy of a marriage certificate.

(B) An individual registered pursuant to this division who changes their mailing or email address shall notify the board of pharmacy of the new address within thirty days after the effective date of such change.

(C) An individual registered pursuant to this division who changes their place of employment shall notify the board of pharmacy of the address of the principal place where they practice as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician within thirty days after they have commenced employment.

## 4729:3-2-05 Successful completion of the "Test of English as a Foreign Language Internet-based Test".

Successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) shall be the following minimum scores or higher:

(A) Writing: twenty-four;

(B) Speaking: twenty-six;

(C) Listening: twenty-one; and

(D) Reading: twenty-two.

#### 4729:3-2-06 - Verification of registration and certification. (NEW)

(A) In accordance with section 4729.95 of the Revised Code, a terminal distributor of dangerous drugs shall develop and implement a policy to ensure persons holding a technician trainee, registered technician, or certified pharmacy technician registration hold an active registration in accordance with this division of the Administrative Code. The policy shall require, at a minimum, the following:

(1) <u>Documented Vv</u>erification of a technician trainee, registered technician, or certified pharmacy technician registration prior to commencing employment with the terminal distributor of dangerous drugs;

(2) <u>Documented Vv</u>erification of registration, to be conducted at least every twenty-four months, of every technician trainee, registered technician, and certified pharmacy technician employed by the terminal distributor of dangerous drugs; and

(3) <u>Documented Vv</u>erification, to be conducted at least every twenty-four months, of pharmacy technician certification from an organization that has been recognized by the board for all certified pharmacy technicians employed by the terminal distributor of dangerous drugs.

(B) Documented verifications shall be maintained for a period of three years from the date of verification.

#### 4729:3-2-07 - Holding multiple registrations and licenses. (NEW)

(A) Unless otherwise approved by the board or the board's executive director:

(1) A person holding a license as a pharmacist or licensed pharmacy intern shall not hold a concurrent license as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician.

(2) Upon receiving an initial license to practice as a pharmacist or pharmacy intern, the person's registration to practice as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician shall be inactivated.

(3) Nothing in this rule prohibits a licensed pharmacy intern or pharmacist from performing the activities of a certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

#### 4729:3-3-01 Pharmacy technician trainees.

(A) A pharmacy technician trainee shall wear a name tag or badge which contains the designation "Pharmacy Technician Trainee." The required designation may be added to an existing name tag or badge. The name tag or badge and the required designation shall contain lettering of a legible size.

(B) A pharmacy technician trainee may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment:

(1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent but shall not include verbal orders;

(2) Entering information into and retrieving information from a database or patient profile;

(3) Preparing and affixing labels;

(4) Stocking dangerous drugs and retrieving those drugs from inventory;

(5) Counting and pouring dangerous drugs into containers;

(6) Placing dangerous drugs into containers prior to dispensing by a pharmacist;

(7) Non-sterile drug compounding following the completion of site-specific training pursuant to rule <u>4729:3-3-02</u> of the Administrative Code;

(8) Sterile drug compounding following the completion of a site-specific training pursuant to rule <u>4729:3-3-02</u> of the Administrative Code;

(9) Packaging and selling a dangerous drug to a patient or patient representative; and

(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner.

(C) A pharmacist is not permitted to supervise more than three pharmacy technician trainees engaging in the activities pursuant to paragraph (B) of this rule at any time, unless otherwise approved by the board.

(D) The number of pharmacy technician trainees supervised by a pharmacist does not limit the number of pharmacy interns that can be supervised by a pharmacist in accordance with rule  $\frac{4729:2-1-01}{100}$  of the Administrative Code.

#### 4729:3-3-02 Approved pharmacy technician training programs.

The purpose of this rule is to set standards for pharmacy technician training programs to ensure that graduates of the programs have the basic knowledge and experience in general pharmacy to practice in most pharmacy settings.

(A) The state board of pharmacy hereby approves the following pharmacy technician training programs:

(1) A pharmacy technician training program that holds a current accreditation from the American society of health-system pharmacists/accreditation council for pharmacy education.

(2) A program of training for pharmaceutical technicians conducted by a branch of the Armed Forces of the United States, the Indian health service of the United States department of health and human services or the United States department of veterans affairs.

(3) An employer-based training program that meets the requirements in paragraph (B) of this rule.

(4) A pharmacy technician training program offered by an Ohio public high school as part of a career-technical education program approved by the

Ohio department of education pursuant to section <u>3317.161</u> of the Revised Code. Each career-technical education program shall require approval by the state board of pharmacy in accordance with standards adopted by the board. Instructions for obtaining board approval will be made available on the board's website: <u>www.pharmacy.ohio.gov</u>.

(5) Successful completion of a doctor of pharmacy (PharmD) program from an approved school of pharmacy in accordance with rule 4729-5-01 of the Administrative Code if the applicant's graduation date is within five years of an application for registration.

**6** Held an active pharmacist or pharmacy intern license or registration in good standing from a licensing agency of any state or jurisdiction for at least one year within five years of an application for registration.

(B) An employer-based training program shall comply with all the following:

(1) The program shall have a program director. The program director and the employer licensed as a terminal distributor of dangerous drugs shall be accountable for the overall quality of the employer-based training program.

The program director shall be a licensed pharmacist in this or any other state that is in good standing.

(2) The program shall consist of didactic and practical experience training, as follows:
(a) A didactic training component that includes, at a minimum, instruction in all of the following:

(i) Mathematical calculations essential to the duties of a pharmacy technician;

(ii) Federal and state laws, rules and regulations that affect pharmacy practice, including specific laws, rules and regulations which address the use of technicians;

(iii) Medical and pharmaceutical terminology, symbols and abbreviations used in the practice of pharmacy and components of a prescription;

(iv) Preparation, packaging, labeling and proper storage of dangerous drugs;

(v) Knowledge and skills in areas of science relevant to the pharmacy technician's role, including pharmacology;

(vi) Medication safety and error prevention;

(vii) Maintaining confidentiality of patient information, including the Patient Rights and Health Insurance Portability and Accountability Act (HIPAA);

(viii) Ethical and professional standards of practice;

(ix) Recordkeeping and inventory control; and

(x) Patient and caregiver communication, including communicating with diverse populations.

(b) Didactic training may include self-directed learning experiences, including but not limited to home study, computer programs, internet or web-based courses, or any other coursework approved by the program director.

(c) The program shall ensure the required didactic training evaluates a participant's knowledge of the topics listed in paragraph (B)(2)(a) of this rule. The evaluation must include an examination consisting of a minimum of ninety questions in accordance with testing guidelines adopted by the board. The employer shall have procedures that ensure the security and integrity of the examination materials, describe the testing format, and define the successful completion of an examination, which must be at least seventy-five per cent. The examination shall consist primarily of multiple choice, essay, or short answer questions. The questions on the examination shall not be given to the examinee prior to taking the examination. The answers to the examination must not be given to the examinee prior to or during the examination. The examinee shall agree in writing not to share the questions or answers to the examination with any other person.

(d) The didactic training requirements in paragraph (B)(2)(a) of this rule are waived if the trainee has a current pharmacy technician certification from an organization that has been recognized by the board.

(e) Three hundred hours of practical experience in a pharmacy under the direct supervision of a licensed pharmacist that directly relates to the activities permitted in paragraph (B) of rule <u>4729:3-3-01</u> of the Administrative Code.

(3) A written or electronic record of training and education shall be maintained as part of the training program that documents the completion of the training requirements, including the number of practical experience hours completed. This documentation must include an attestation by the program director and the terminal distributor's responsible person where the technician is employed that the technician trainee has successfully completed the training program pursuant to this rule. A copy of the documentation shall be provided to each participant who successfully completes the program.

(4) The program director must ensure that regular and ongoing assessments of program effectiveness are conducted and use the evaluations for continuous improvement of the program. Measures shall include, but are not limited to, the following:

(a) Program completion; and

(b) Program participant satisfaction.

(5) The program shall maintain the following records for a minimum of three years and shall be furnished to the state board of pharmacy within three business days of receipt of a request from the board:

(a) All technician training records and evaluations;

(b) Program assessments conducted in accordance with this rule.

(6) Employer-based training programs may be subject to audit to ensure compliance with the requirements of this rule.

(a) An employer-based training program subject to audit shall provide all requested documentation demonstrating compliance with this rule within thirty days of a request by the board.

(b) Unless an extension is granted, failure to provide the requested documentation within thirty days of a request by the board may result in the suspension of the approval status of the training program.

(c) After reviewing the training program, the board may return it to the employer for revision. Failure to make the necessary revisions may result in the suspension of the approval status of the training program.

(d) The approval status of a training program may be reinstated only after the employer meets the requirements of this rule and any additional requirements as determined by the board.

(C) In order to perform non-sterile drug compounding, a pharmacy technician trainee shall complete the following training requirements prior to compounding non-sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <795>.

(2) Non-sterile drug compounding training shall be obtained through completion of a sitespecific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this paragraph.

(4) Ensuring pharmacy technician trainees are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(6) The training required pursuant to this paragraph may be used to meet the practical experience hours required in paragraph (B)(2)(e) of this rule.

(D) In order to perform sterile drug compounding, a pharmacy technician trainee shall complete the following training requirements prior to compounding sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <797>.

(2) Sterile drug compounding training shall be obtained through completion of a sitespecific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this paragraph.

(4) Ensuring pharmacy technician trainees are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(6) The training required pursuant to this paragraph may be used to meet the practical experience hours required in paragraph (B)(2)(e) of this rule.

(E) A terminal distributor of dangerous drugs and the licensee's responsible person shall be responsible for the implementation of additional training that is of appropriate breadth and depth to clearly address the competencies for a technician trainee to safely and effectively work in a specific practice setting.

(F) Unless otherwise approved by the board, a board approved training program is only valid for application as a registered pharmacy technician or certified pharmacy technician in accordance with rule <u>4729:3-2-01</u> of the Administrative Code if the program was completed within five years of an application for registration.

(G) Paragraph (F) of this rule does not apply in the following circumstances:

(1) An applicant for registration has been actively practicing as a pharmacy technician in this or another state within one year of application to the board; or

(2) An applicant has maintained a current pharmacy technician certification from an organization that has been recognized by the board.

(H) An individual may sit for an examination to obtain a pharmacy technician certification from an organization that has been recognized by the board at any time.

#### 4729:3-3-03 Registered pharmacy technicians.

(A) A registered pharmacy technician shall wear a name tag or badge which contains the designation "Registered Pharmacy Technician." The required designation may be added to an existing name tag or badge. The name tag or badge and the required designation shall contain lettering of a legible size.

(B) A registered pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment:

(1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent but shall not include verbal orders;

(2) Requesting refill authorizations for dangerous drugs from a prescriber or prescriber's agent, so long as there is no change from the original prescription;

(3) Entering information into and retrieving information from a database or patient profile;

(4) Preparing and affixing labels;

(5) Stocking dangerous drugs and retrieving those drugs from inventory;

(6) Counting and pouring dangerous drugs into containers;

(7) Placing dangerous drugs into containers prior to dispensing by a pharmacist;

(8) Non-sterile drug compounding in accordance with the required training in paragraph (C) of this rule;

(9) Packaging and selling a dangerous drug to a patient or patient representative; and

(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner- $\frac{1}{2}$ 

(11) Stocking automated drug storage systems, floor stock, and crash carts at a location licensed as a terminal distributor of dangerous drugs if either of the following applies:

(a) The terminal distributor utilizes barcode administration for restocking the drugs and develops and implements a quality assurance program to ensure the accuracy of the personnel stocking the dangerous drugs; or

(b) For restocking automated drug storage systems only: a pharmacist verifies the final dispensing of a dangerous drug removed from the automated drug storage system.

(C) A registered pharmacy technician may:

(1) Engage in remote entry of prescriptions in accordance rule 4729:5-5-25 of the Administrative Code; or

(2) Engage in remote entry of medication orders in accordance with rule 4729:5-9-02.15 of the Administrative Code.

(CD) In order to perform non-sterile drug compounding, a registered pharmacy technician shall complete the following training requirements prior to compounding non-sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <795>.

(2) Non-sterile drug compounding training shall be obtained through completion of a sitespecific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

(4) Ensuring registered pharmacy technicians are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(DE) A terminal distributor of dangerous drugs and the licensee's responsible person shall be responsible for the implementation of policies and procedures for additional training appropriate to duties and responsibilities performed by a registered pharmacy technician as well as an ongoing quality assurance plan to ensure competency.

#### 4729:3-3-04 Certified pharmacy technicians.

(A) As used in this rule, "positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(B) A certified pharmacy technician shall wear a name tag or badge which contains the designation "Certified Pharmacy Technician." The required designation may be added to an existing name tag or badge. The name tag or badge and the required designation shall contain lettering of a legible size.

(C) A certified pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment:

(1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent. New verbal prescription orders from a prescriber or a prescriber's agent for non-controlled drugs may be accepted pursuant to paragraph (C)(13) of this rule.

(2) Entering information into and retrieving information from a database or patient profile.

(3) Preparing and affixing labels.

(4) Stocking dangerous drugs and retrieving those drugs from inventory.

(5) Counting and pouring dangerous drugs into containers.

(6) Placing dangerous drugs into containers prior to dispensing by a pharmacist.

(7) Non-sterile drug compounding in accordance with the required training in paragraph (D) of this rule.

(8) Sterile drug compounding in accordance with the required training in paragraph (E) of this rule.

(9) Packaging and selling a dangerous drug to a patient or patient representative.

(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner.

(11) Stocking automated drug storage systems, floor stock, and crash carts at a location licensed as a terminal distributor of dangerous drugs.

(a) Notwithstanding the definition of direct supervision in rule <u>4729:3-1-01</u> of the Administrative Code, a certified pharmacy technician may stock automated drug storage systems, crash carts, and floor stock at a location licensed as a terminal distributor of

dangerous drugs if a pharmacist is not physically present at the licensed location and all of the following apply:

(i) A pharmacist is readily available to answer questions of the certified pharmacy technician;

(ii) A pharmacist is responsible for conducting routine verifications of the activities of the certified pharmacy technician to prevent the diversion of dangerous drugs;

(iii) A pharmacist is fully responsible for all activities conducted by the certified pharmacy technician at the licensed location.

(12) Requesting refill authorizations for dangerous drugs from a prescriber or prescriber's agent, so long as there is no change from the original prescription;

(13) Accepting new verbal prescription orders, including refill authorizations, for noncontrolled drugs from a prescriber or a prescriber's agent pursuant to all of the following:

(a) The pharmacist on duty who is supervising the activity of the certified pharmacy technician will determine if the technician is competent to receive a verbal order.

(b) The pharmacist on duty who is supervising the activity of the certified pharmacy technician is responsible for the accuracy of a prescription order received by a technician.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription order received by a certified pharmacy technician.

(d) The certified pharmacy technician may not receive a prescription order for a controlled substance.

(e) If applicable, the certified pharmacy technician receiving a prescription order must document the full name of the prescriber's agent.

(f) The receiving certified pharmacy technician shall immediately reduce the prescription order to writing, which may include entering the information directly into a computerized record keeping system, and shall review the prescription with the pharmacist on duty.

(g) Prior to dispensing, positive identification of the receiving certified pharmacy technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the prescription.

(h) The certified pharmacy technician and the pharmacist on duty must meet all other applicable rules for the receipt of new verbal prescription orders pursuant to agency 4729 of the Administrative Code.

(14) Send or receive copies of non-controlled prescriptions pursuant to all of the following:

**Commented [MC12]:** Makes it clear that the technician can enter into computer.

(a) The pharmacist on duty who is supervising the activity of the certified pharmacy technician will determine if the technician is competent to send or receive a prescription copy.

(b) The pharmacist on duty who is supervising the activity of the certified pharmacy technician is responsible for the accuracy of a prescription copy that is sent or received by a technician.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription copy that is sent or received by a certified pharmacy technician.

(d) The certified pharmacy technician may not send or receive a prescription copy for a controlled substance.

(e) The pharmacist or certified pharmacy technician receiving a prescription copy from a certified pharmacy technician must document the full names of the sending technician and the technician's supervising pharmacist. The receiving technician shall immediately reduce the prescription copy to writing, which may include entering the information directly into a computerized record keeping system, and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the certified pharmacy technician and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the copy.

(f) The pharmacist or certified pharmacy technician sending a prescription copy to a certified technician must document the full names of the receiving technician and the technician's supervising pharmacist.

(g) The certified technician and the pharmacist on duty must meet all other applicable rules for the transfer of a prescription copy pursuant agency 4729 of the Administrative Code.

(15) Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment.

(16) Performing diagnostic laboratory testing pursuant to agency 4729 of the Administrative Code.

(D) A certified pharmacy technician may:

(1) Engage in remote entry of prescriptions in accordance rule 4729:5-5-25 of the Administrative Code; or

(2) Engage in remote entry of medication orders in accordance with rule 4729:5-9-02.15 of the Administrative Code.

 $(\underline{\textbf{PE}})$  In order to perform non-sterile drug compounding, a certified pharmacy technician shall complete the following training requirements prior to compounding non-sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <795>.

(2) Non-sterile drug compounding training shall be obtained through completion of a sitespecific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

(4) Ensuring certified pharmacy technicians are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(EE) In order to perform sterile drug compounding, a certified pharmacy technician shall complete the following training requirements prior to compounding sterile preparations:

(1) Training shall comply with the requirements set forth in the United States pharmacopeia chapter <797>.

(2) Sterile drug compounding training shall be obtained through completion of a sitespecific, structured on-the-job didactic and experiential training program and shall not be transferable to another practice site, except between practice sites under common ownership and control.

(3) When the responsible person or a pharmacist designated by the responsible person is satisfied with the employee's knowledge and proficiency, the responsible person or the responsible person's designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

(4) Ensuring certified pharmacy technicians are properly trained shall be the responsibility of the terminal distributor of dangerous drugs and the licensee's responsible person.

(5) All training requirements set forth in this paragraph shall be appropriately documented and made readily retrievable for immediate inspection by an agent of the state board of pharmacy. Documentation shall be maintained by the terminal distributor of dangerous drugs for a minimum of three years.

(FG) A terminal distributor of dangerous drugs and the licensee's responsible person shall be responsible for the implementation of policies and procedures for additional training

appropriate to duties and responsibilities performed by a certified pharmacy technician as well as an ongoing quality assurance plan to ensure competency.

#### 4729:5-5-25 - Remote Prescription Entry (NEW)

(A) As used in this rule:

(1) "Direct supervision" and "personal supervision" has the same meaning as in rule 4729:3-1-01 of the Administrative Code.

(2) "Remote prescription entry" means the entry of prescriptions for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs by a remote technician under the direct supervision or remote supervision of a pharmacist. Remote prescription entry does not include dispensing, interpreting, evaluating, or approval of prescriptions or any other activities not permitted by state or federal laws, rules, and regulations. Remote prescription entry may include clarifying prescriptions and other data entry, including the and processing of insurance coverage. The requirements of this rule shall be limited to the entry of prescriptions dispensed in or into this state.

(3) "Remote pharmacy" means either:

(a) A pharmacy licensed as a terminal distributor of dangerous drugs that dispenses dangerous drugs; or

(b) A pharmacy licensed as a limited category II terminal distributor of dangerous drugs which does not stock, own, or dispense any dangerous drugs, and whose sole business consists of entry, review, and/ or verification of prescriber orders and consulting services under contract for outpatient pharmacies in this state.

(4) "Remote supervision" means that a pharmacist directs and controls the actions of remote technicians through the use<u>of</u> of audio and visual technology that ensures a supervising pharmacist can meet the requirements listed in this paragraph. A pharmacist providing remote supervision shall:

(a) Be readily available to answer questions of a remote technician; and

(b) Be fully responsible for the practice and accuracy of the remote technician.

(5) "Remote technician" means any of the following:

(a) If performing remote prescription entry in this state: an Ohio registered certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee, either employed or a contract employee of an outpatient pharmacy or remote pharmacy, who either conducts prescription entry from a remote site, which may include the technician's residence or other location where the technician and the outpatient or remote pharmacy can ensure the confidentiality and integrity of patient information, or on the premises of a remote pharmacy or outpatient pharmacy; or

(b) If performing remote prescription entry outside of this state: a pharmacy technician licensed or registered in the state where the remote prescription entry is occurring, either

employed or a contract employee of an outpatient pharmacy or remote pharmacy, who either conducts prescription entry from a remote site, which may include the technician's residence or other location where the technician and the outpatient or remote pharmacy can ensure the confidentiality and integrity of patient information, or on the premises of a remote pharmacy or outpatient pharmacy.

If the technician performs remote order entry in a state that does not license or register pharmacy technicians, the technician shall hold an appropriate registration with the board of pharmacy in accordance with chapter 4729. of the Revised Code and this division of the Administrative Code.

(B) An outpatient pharmacy may outsource prescription entry to a remote pharmacy provided the pharmacies are under common ownership or control or the outpatient pharmacy has entered into a written contract or agreement with a pharmacy that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.

(C) The outpatient pharmacy and remote pharmacy must maintain a copy of the contract or agreement in a readily retrievable manner for inspection and review by an agent, inspector, or employee of the board.

(D) An outpatient pharmacy utilizing remote prescription entry shall ensure that all remote technicians providing such services have been trained on the outpatient pharmacy's policies and procedures relating to prescription entry.

(1) The training of each remote technician shall be documented. The outpatient pharmacy and the remote pharmacy shall jointly develop a procedure to communicate changes in policies and procedures related to prescription entry.

(2) A terminal distributor of dangerous drugs may utilize one training program for all outpatient pharmacies under the terminal distributor's common ownership and control.

(E) An outpatient pharmacy utilizing remote technicians shall maintain or have access to a record of the name and address of each technician, evidence of current licensure or registration, and the address of each location where the technician will be providing remote prescription entry services.

(F) The outpatient pharmacy shall ensure that any remote technician shall have secure electronic access to the outpatient pharmacy's patient information system and to other electronic systems that an on-site technician has access to when the pharmacy is open.

(G) Each remote entry record must comply with all recordkeeping requirements for outpatient pharmacies, including capturing the positive identification of the remote technician involved in the entry of the prescription.

(H) An outpatient pharmacy utilizing remote prescription entry is responsible for maintaining records of all prescriptions entered into their information system, including prescriptions entered by a remote technician.

(I) An outpatient pharmacy utilizing remote prescription entry services shall develop and implement a policy and procedure manual. A remote pharmacy shall maintain a copy of those portions of the policy and procedure manual that relate to the remote pharmacy's operations. Each manual shall include all the following:

(1) Outline the responsibilities of the outpatient pharmacy and the remote pharmacy;

(2) Include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies and remote technicians involved in remote prescription entry; and

(3) Include policies and procedures for:

(a) Protecting the confidentiality and integrity of patient information;

(b) Ensuring that no patient information is duplicated, downloaded, or removed from the outpatient pharmacy's patient information system;

(c) Maintaining appropriate records of each technician involved in prescription entry;

(d) Complying with federal and state statutes and regulations; and

(e) <u>Annually reviewing Reviewing the</u> written policies and procedures <u>at least every three</u> <u>years or upon the implementation of a significant change of written policies and procedures</u> and documentation of the <del>annual</del> review.

(J) A pharmacy intern that is licensed in this or any other state may engage in remote prescription entry pursuant to the requirements of this rule.

#### 4729:5-9-02.15 - Remote Order Entry (NEW)

(A) As used in this rule:

(1) "Direct supervision" and "personal supervision" has the same meaning as in rule 4729:3-1-01 of the Administrative Code.

(2) "Remote order entry" means the entry of medication orders for an inpatient pharmacy licensed as a terminal distributor of dangerous drugs by a remote technician under the direct supervision or remote supervision of a pharmacist. Remote order entry does not include dispensing, interpreting, evaluating, or approval of medication orders or any other activities not permitted by state or federal laws, rules, and regulations. Remote prescription order entry may include clarifying orders and other data entry, including andthe processing of insurance coverage. The requirements of this rule shall be limited to the entry of prescriptions orders.

(3) "Remote pharmacy" means either:

(a) A pharmacy licensed as a terminal distributor of dangerous drugs that dispenses dangerous drugs; or

(b) A pharmacy licensed as a limited category II terminal distributor of dangerous drugs which does not stock, own, or dispense any dangerous drugs, and whose sole business consists of entry, review, and/ or verification of prescriber orders and consulting services under contract for institutional pharmacies in this state.

(4) "Remote supervision" means that a pharmacist directs and controls the actions of remote technicians through the use of audio and visual technology that ensures a supervising pharmacist can meet the requirements listed in this paragraph. A pharmacist providing remote supervision shall:

(a) Be readily available to answer questions of a remote technician; and

(b) Be fully responsible for the practice and accuracy of the remote technician.

(5) "Remote technician" means any of the following:

(a) If performing remote order entry in this state: an Ohio registered certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee, either employed or a contract employee of an inpatient pharmacy or remote pharmacy, who either conducts <u>prescription\_order\_entry</u> from a remote site, <u>which may include the technician's</u> residence or other location where the technician and the outpatient or remote pharmacy can ensure the confidentiality and integrity of patient information, or on the premises of a remote pharmacy or institutional pharmacy; or

(b) If performing remote order entry outside of this state: a pharmacy technician licensed or registered in the state where the remote order entry is occurring, either employed or a

contract employee of an institutional pharmacy or remote pharmacy, who either conducts prescription order entry from a remote site, which may include the technician's residence or other location where the technician and the outpatient or remote pharmacy can ensure the confidentiality and integrity of patient information, or on the premises of a remote pharmacy or institutional pharmacy.

If the technician performs remote order entry in a state that does not license or register pharmacy technicians, the technician shall hold an appropriate registration with the board of pharmacy in accordance with chapter 4729. of the Revised Code and this division of the Administrative Code.

(B) An institutional pharmacy may outsource <u>prescription order</u> entry to a remote pharmacy provided the pharmacies are under common ownership or control or the institutional pharmacy has entered into a written contract or agreement with a pharmacy that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.

(C) The inpatient pharmacy and remote pharmacy must maintain a copy of the contract or agreement in a readily retrievable manner for inspection and review by an agent, inspector, or employee of the board.

(D) An inpatient pharmacy utilizing remote <u>prescription\_order</u> entry shall ensure that all remote technicians providing such services have been trained on the inpatient pharmacy's policies and procedures relating to <u>prescription\_order</u> entry.

(1) The training of each remote technician shall be documented. The inpatient pharmacy and the remote pharmacy shall jointly develop a procedure to communicate changes in policies and procedures related to <u>prescription order</u> entry.

(2) A terminal distributor of dangerous drugs may utilize one training program for all inpatient pharmacies under the terminal distributor's common ownership and control.

(E) An inpatient pharmacy utilizing remote technicians shall maintain or have access to a record of the name and address of each technician, evidence of current licensure or registration, and the address of each location where the technician will be providing remote order entry services.

(F) The inpatient pharmacy shall ensure that any remote technician shall have secure electronic access to the inpatient pharmacy's patient information system and to other electronic systems that an on-site technician has access to when the pharmacy is open.

(G) Each remote entry record must comply with all recordkeeping requirements for inpatient pharmacies, including capturing the positive identification of the remote technician involved in the entry of the medication order.

**Commented [MC13]:** Comment for Board Consideration: There may be limitations for this requirement. Suggest an alternative approach.

(H) An inpatient pharmacy utilizing remote order entry is responsible for maintaining records of all <u>prescriptions\_orders</u>\_entered into their information system, including <u>prescriptions\_orders</u>\_entered by a remote technician.

(I) An inpatient pharmacy utilizing remote order entry services shall develop and implement a policy and procedure manual. A remote pharmacy shall maintain a copy of those portions of the policy and procedure manual that relate to the remote pharmacy's operations. Each manual shall include all the following:

(1) Outline the responsibilities of the inpatient pharmacy and the remote pharmacy;

(2) Include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies and remote technicians involved in remote order entry; and

(3) Include policies and procedures for:

(a) Protecting the confidentiality and integrity of patient information;

(b) Ensuring that no patient information is duplicated, downloaded, or removed from the inpatient pharmacy's patient information system;

(c) Maintaining appropriate records of each technician involved in prescription order entry;

(d) Complying with federal and state statutes and regulations; and

(e) Reviewing written policies and procedures at least every three years or upon the implementation of a significant change of written policies and procedures and documentation of the review.

(c) Annually reviewing the written policies and procedures and documentation of the annual review.

(J) A pharmacy intern that is licensed in this or any other state may engage in remote order entry pursuant to the requirements of this rule.

#### 4729:3-5-01 Continuing education - definitions.

As used in Chapter 4729:3-5 of the Administrative Code.

(A) "A.C.P.E." means the accreditation council for pharmacy education.

(B) "Continuing education unit" or "C.E.U." means ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.

(C) "Continuing pharmacy education" or "continuing education", as required in section <u>4729.12</u> of the Revised Code, means post-registration pharmacy education undertaken to maintain professional competency to practice as a pharmacy technician, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare. Continuing pharmacy education may be obtained from any of the following providers:

(1) A pharmacy jurisprudence program pursuant to paragraph (D) of this rule;

(2) An approved in-state provider of volunteer healthcare services in accordance with section <u>4745.04</u> of the Revised Code and agency 4729 of the Administrative Code;

(3) An A.C.P.E. accredited continuing education provider.

(D) "One-third of a licensee's continuing education requirement" as used in division (C) of section <u>4745.04</u> of the Revised Code and paragraph (C) of rule <u>4729:3-5-02</u> of the Administrative Code, means the total number of required C.E.U.s for licensure renewal divided by three and rounded down to the nearest whole number.

(E) "Pharmacy jurisprudence" means continuing education the includes any of the following:

(1) An A.C.P.E. law program as identified by A.C.P.E numbering convention "03";

(2) A board of pharmacy approved continuing education program provided by an in-state approved jurisprudence provider pursuant to agency 4729 of the Administrative Code that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy; or

(3) A program presented by the state board of pharmacy that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy.

(F) "Patient or medication safety" means an A.C.P.E. continuing education program identified by the A.C.P.E. numbering convention "05" that deals with the prevention of healthcare errors and the elimination or mitigation of patient injury caused by healthcare errors.

(G) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the armed forces, including the national guard and reserve.

# 4729:3-5-02 Continuing education requirements for registered and certified technicians.

(A) As a condition for the renewal of a registration as a registered pharmacy technician, the registrant shall complete a total of ten contact hours (1.0 C.E.Us) of continuing pharmacy education during the twenty-four months preceding the expiration date of the technician's registration. The continuing pharmacy education shall be in pharmacy technician-specific subject matter and shall include, at a minimum, the following:

(1) Two contact hours (0.2 C.E.Us) of continuing pharmacy education shall be in the subject of pharmacy jurisprudence (law).

(2) Two contact hours (0.2 C.E.Us) of continuing pharmacy education shall be in the subject of patient or medication safety.

(B) Paragraph (A) of this rule does not apply to registered pharmacy technicians that obtain an initial registration within six months of the expiration date of the registration.

(C) A registered pharmacy technician may satisfy up to one-third of the technician's continuing education requirements by providing health care services as a volunteer in accordance with section <u>4745.04</u> of the Revised Code. The location where health care services are provided shall be an approved in-state provider of volunteer healthcare services in accordance with agency 4729 of the Administrative Code.

(D) Registered pharmacy technicians shall keep all certificates and other documented evidence of participation which have been issued by a non-A.C.P.E. accredited provider for which the pharmacy technician has claimed continuing education units towards renewal of the technician's registration for a period of one year following the year in which evidence was required for renewal.

(1) Documentation, as determined by the state board of pharmacy, shall be submitted only when requested by the board.

(2) The board shall monitor compliance by conducting an audit of registrants.

(3) The board shall require the reporting of continuing education units to a national and/or state register.

(E) As a condition for the renewal of a registration as a certified pharmacy technician, the registrant shall complete all continuing education requirements necessary to maintain the registrant's pharmacy technician certification from an organization that has been recognized by the board.

# 4729:3-5-03 Veteran and military family provisions related to continuing education.

(A) Extension of continuing education requirements.

(1) In accordance with section <u>5903.12</u> of the Revised Code, the state board of pharmacy shall grant extension periods and waivers for the completion of continuing education requirements for active duty veteran members and the spouses of active duty veterans. If a registered pharmacy technician or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the technician or the technician's spouse was on active duty.

(2) Upon receiving the application and proper documentation, the board's director of licensing shall extend the continuing education reporting period by an amount of time equal to the total number of months that the registrant or their spouse spent on active duty during the current reporting period. For purposes of this division, any portion of a month served on active duty shall be considered one full month.

(3) The registrant shall submit proper documentation certifying the active duty service and the length of that active duty service. Documentation required to obtain an extension or waiver pursuant to paragraph (A)(1) of this rule will be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(B) Determining fulfillment of continuing education.

(1) If a registered pharmacy technician is a veteran, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the registration holder no more than two years prior to the thirty first of march of the year in which a technician's registration must be renewed when determining the fulfillment of any continuing education requirements.

(2) For the board to consider relevant education, training, or service completed by a registered technician, the registrant shall submit a request for consideration and evidence or documentation of the education, training, or service to the director of licensing at least thirty days prior to the required continuing education reporting period pursuant to rule <u>4729:3-5-02</u> of the Administrative Code.