Rules for Public Comment - Spring 2023

The following rules are being reviewed as part of the five-year review process required by Ohio law:

Continuing Education

- 4729-6-01 - Continuing Education Providers - Definitions. (AMEND)
- 4729-6-02 - Criteria for in-state approved providers of pharmacy jurisprudence continuing education. (AMEND)
- 4729-6-03 - Criteria for in-state approved providers of continuing pharmacy education for providing volunteer health care services. (NO CHANGE)

Pharmacists

- 4729:1-2-01 - Criteria for licensure by examination. (AMEND)
- 4729:1-2-02 - Criteria for licensure by reciprocity. (AMEND)
- 4729:1-2-03 - Examination application for licensure as a pharmacist. (AMEND)
- 4729:1-2-04 - Successful completion of the Test of English as a Foreign Language, Internet-based Test. (NO CHANGE)
- 4729:1-2-05 - Criminal records check for pharmacists. (NO CHANGE)
- 4729:1-2-06 - Pharmacist change of name, address or employment. (AMEND)
- 4729:1-2-07 - Pharmacist licensure and renewal. (RESCIND AND NEW)
- 4729:1-2-08 - Veteran and military family provisions related to pharmacist licensure. (NO CHANGE)
- 4729:1-5-01 - Pharmacist Continuing Education - Definitions. (AMEND)
- 4729:1-5-02 - Continuing education requirements for pharmacists. (AMEND)
- 4729:1-5-03 - Veteran and military family provisions related to continuing education. (AMEND)

Pharmacy Interns

- 4729:2-2-01 - Licensure as a pharmacy intern. (AMEND)
- 4729:2-2-02 - Application for licensure as a pharmacy intern. (AMEND)
- 4729:2-2-03 - Criminal records check for pharmacy interns. (NO CHANGE)
- 4729:2-2-04 - Pharmacy intern license renewal and expiration. (AMEND) [RESCIND 4729:2-2-09]
- 4729:2-2-05 - Internship credit. (NO CHANGE)
- 4729:2-2-06 - Statement of preceptor and practical experience affidavit. (AMEND)
- 4729:2-2-07 - Successful completion of the Test of English as a Foreign Language, Internet-based Test. (NO CHANGE)

- 4729:2-2-08 - Pharmacy intern change of name, address or employment. (AMEND)
- 4729:2-2-10 - Veteran and military family provisions related to pharmacy intern licensure. (NO CHANGE)

Pharmacy Technicians

- 4729:3-2-01 - Registration procedures. (AMEND)
- 4729:3-3-02 - Approved pharmacy technician training programs. (AMEND)
- 4729:3-3-03 - Registered pharmacy technicians. (AMEND)

Terminal Distributors of Dangerous Drugs

- 4729:5-2-02 - Terminal distributor of dangerous drugs licensing and renewal. (RESCIND & NEW)

Drug Distributors

- 4729:6-2-02 – Distributor of dangerous drugs licensing and renewal. (RECIND and NEW)
- 4729:6-2-03 – Criminal Records Checks. (AMEND)
- 4729:6-2-04 – Drug Distributor Applications. (AMEND)
- 4729:6-2-06 – Procedure for discontinuing business as a distributor of dangerous drugs. (NO CHANGE)

Pharmacy Compounding

- 4729:7-2-03 - Drugs compounded in a pharmacy. (AMEND)*

**This rule is not up for its 5-year review. However, proposed modifications allowing for registered pharmacy technicians to perform sterile compounding require an amendment to this rule.*

Comments on the proposed rules should be submitted using the following form: https://www.surveymonkey.com/r/SpringRules23.

Comments on the rules are due by May 31, 2023.

Rule 4729-6-01 | Continuing Education Providers - Definitions. (AMEND)

(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 a provider listed in paragraph (C) of this rule.

(C) "Continuing pharmacy education" or "continuing education", as required in section 4729.12 of the Revised Code, is defined as post-licensure pharmacy education undertaken to maintain professional competency to practice pharmacy, 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 (E) of this rule;

(2) An approved in-state provider of volunteer healthcare services in accordance rule 4729-6-03 of the Administrative Code;

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

(D) "In-state provider" means an Ohio provider approved by the state board of pharmacy to provide the following continuing pharmacy education:

(1) Board approved pharmacy jurisprudence in accordance with paragraph (E)(2) of this rule; or

(2) Volunteer healthcare services in accordance with paragraph (C)(2) of this rule.

(E) "Pharmacy jurisprudence" continuing education shall include 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 in accordance with rule 4729-6-02 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) All C.E.U.s obtained from an approved in-state provider prior to the effective date of this rule shall be deemed valid for pharmacist continuing education requirements pursuant to Chapter 4729:1-5 of the Administrative Code.**~~

Rule 4729-6-02 | Criteria for in-state approved providers of pharmacy jurisprudence continuing education. (AMEND)

In-state providers of pharmacy jurisprudence continuing education who seek approval by the state board of pharmacy must demonstrate ability and willingness to offer quality pharmacy jurisprudence continuing education in a responsible manner and shall submit evidence of this on applications developed by the board. The minimum criteria shall include:

(A) There shall be a program director charged with the administration of the continuing pharmacy education program that serves as a liaison to the board. Unless otherwise approved by the board, the program director shall be a pharmacist licensed to practice pharmacy in Ohio.

(B) Providers shall award pharmacy jurisprudence continuing education credit to successful participants in units consisting of C.E.U.s.

(C) Providers shall maintain a list of successful program or experience participants and the participants' Ohio license or registration numbers for a **four-year** ~~**five-year**~~ period to be made available to the board upon request.

(D) Providers shall award a certificate to each successful participant containing at least the following information:

(1) The name of the provider;

(2) The completion date of the experience;

(3) The name of the participant;

(4) The title of the experience;

(5) The number of C.E.U.s the experience has been assigned;

(6) The program or experience identification number according to the numbering system designated by the board;

(7) The manual signature, including a scanned image, or the electronic signature of the program director listed in paragraph (A) of this rule.

(E) Ohio jurisprudence program providers shall submit, in a manner determined by the board, a provider program notice and list of successful participants and the participants' license or registration numbers to the board no later than sixty days after a program is presented.

(F) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education experiences with the goal of continual improvement.

(G) Providers should utilize an evaluation mechanism to allow each participant to assess the achievement of personal objectives.

(H) All programs offered by an approved pharmacy jurisprudence provider shall be no less than one contact hour of participation (0.1 C.E.U.). ~~**Programs offered after the effective date of this rule that are less than 0.1 C.E.U. will not be accepted by the board for licensure or registration renewal.**~~

(I) Jurisprudence continuing education programs shall also meet the following requirements:

(1) Contain accurate information on current laws, rules, and regulations;

(2) Consist of information relevant to the practice of pharmacy in Ohio;

(3) Be presented in an unbiased manner; and

(4) Shall not be utilized for more than two years from the date the program was approved by the state board of pharmacy.

(J) If an initial jurisprudence program submission is denied by the state board of pharmacy, the approved pharmacy jurisprudence continuing education provider may resubmit that program to address the problem areas outlined by the board during the review process. If the resubmitted program is not approved by the board, the provider shall not submit a program covering the same topic for a period of one year from the date of the denial.

(K)

(1) Once approved as an in-state provider of pharmacy jurisprudence continuing education, the provider shall maintain or update the providers contact information, at a minimum, biennially, in accordance with a schedule adopted by the board. Contact information shall be updated using a form approved by the board.

(2) Providers who have not complied with paragraph (K)(1) of this rule shall no longer be deemed as an approved in-state provider of pharmacy jurisprudence continuing education. The provider shall have to resubmit an application for approval in accordance with this rule.

(L) The board of pharmacy, upon receipt of evidence that any approved provider is presenting experiences not conforming to the requirements of this rule, may place a provider on probationary status or revoke such approval.

Rule 4729-6-03 | Criteria for in-state approved providers of continuing pharmacy education for providing volunteer health care services. (NO CHANGE)

In-state providers seeking approval by the state board of pharmacy must demonstrate ability and willingness to monitor and report volunteer services for continuing pharmacy education provided in accordance with section 4745.04 of the Revised Code in a responsible manner and shall submit evidence of this on applications developed by the board. The minimum criteria shall include:

(A) There shall be a program director charged with the administration of the continuing pharmacy education program that serves as a liaison to the board. The program director shall be a designated representative of the entity that provides health care services.

(B) Providers shall award continuing pharmacy education credit to successful participants in units consisting of C.E.U.s and in accordance with the requirements of section 4745.04 of the Revised Code.

(C) Providers shall maintain a list of the number and date of volunteer hours of participants and the participants' Ohio license or registration numbers for a five-year period to be made available to the board upon request.

(D) Providers shall award a certificate to each successful participant containing at least the following information:

(1) The name of the provider;

(2) The completion date of the experience;

(3) The name of the participant;

(4) The title of the experience;

(5) The number of C.E.U.s the experience has been assigned;

(6) The program or experience identification number according to the numbering system designated by the board;

(7) The manual signature, including a scanned image, or the electronic signature of the program director listed in paragraph (A) of this rule.

(E) All in-state providers shall provide, in a manner determined by the board, a provider program notice and list of successful participants and the participants' license or registration numbers to the board no later than sixty days after the date of volunteer service is completed.

(F) The board of pharmacy, upon receipt of evidence that any approved provider is presenting experiences not conforming to the requirements pursuant to this rule, may place a provider on probationary status or revoke such approval.

(G) All C.E.U.s shall be awarded in half hour increments at the rate of 0.05 C.E.U.s for each thirty minutes spent providing health care services as a volunteer.

(H) Once approved as an in-state provider of continuing pharmacy education for providing volunteer health care services, the provider shall maintain or update the provider's contact information, at a minimum, biennially, in accordance with a schedule adopted by the board. Contact information shall be updated using a form approved by the board. Providers who have not complied with this paragraph shall no longer be deemed as an approved in-state provider. The provider shall have to resubmit an application for approval in accordance with this rule.

Rule 4729:1-2-01 | Criteria for licensure by examination. (AMEND)

(A) Pursuant to sections 4729.07 and 4729.13 of the Revised Code, pharmacist licensure by examination shall consist of the "North American Pharmacist Licensure Examination" (NAPLEX) and the "Multistate Pharmacy Jurisprudence Examination" (MPJE) **administered by the national association of boards of pharmacy (NABP).**

(1) **Unless otherwise approved by the board, t**he minimum passing score on each examination ~~**is seventy-five**~~ **shall be determined by NABP**.

(a) Any candidate who fails to receive a **passing** score ~~**of seventy-five**~~ on the NAPLEX examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

(b) Any candidate who fails to receive a **passing** score ~~**of seventy-five**~~ on the MPJE jurisprudence examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

(B) A candidate may use the NABP process to transfer the candidate's NAPLEX score to Ohio only after the candidate has met all of the requirements set by the board for examination and licensure in Ohio.

(C) Pursuant to section 4729.08 of the Revised Code, graduates of unapproved schools or colleges of pharmacy located outside the United States who are using an approved examination to establish equivalency of their education shall:

(1) Obtain a **passing** score**, as determined by NABP,** ~~**no lower than seventy-five**~~ on the "Foreign Pharmacy Graduate Equivalency Examination (FPGEE)"; and

(2) Show oral proficiency in English by successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:1-2-04 of the Administrative Code.

(D) Any examination candidate who fails to take both of the required examinations pursuant to paragraph (A) of this rule within twelve months from the date the board receives the application materials shall submit a new application for the required examination or examinations and remit the fee established by the board, as the original application shall be deemed abandoned.

(E) The record of the passing score for an examination candidate who takes both of the required examinations pursuant to paragraph (A) of this rule, but successfully only completes one examination will:

(1) Be maintained up to three years if no more than twelve months has elapsed between attempts to successfully complete the remaining examination.

(2) Not be maintained if more than twelve months has elapsed between attempts to successfully complete the remaining examination. It will then be necessary for the examination candidate to repeat both examinations for Ohio licensure.

(F) Any candidate who has requested to transfer their NAPLEX score to Ohio must take the MPJE within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.

(G) Pursuant to section 4729.071 of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving **approval to take the required examinations** ~~**an initial license to practice as a pharmacist**~~. An examination candidate must submit fingerprint impressions no later than ~~**twelve months**~~ **sixty days** after the date the board receives the application materials ~~**or the scores obtained on the NAPLEX and/or MPJE will be denied**~~. After ~~**twelve months**~~ **sixty days** a candidate must submit a new application, the required fee, **and** fingerprint impressions, **as the original application shall be deemed abandoned**.

(H) Candidates shall be limited to a total of five attempts to pass the NAPLEX and the MPJE. The board may grant one additional attempt to pass the NAPLEX and the MPJE in the event of extraordinary circumstances. A candidate that exceeds the limits set forth in this paragraph is no longer eligible to obtain licensure as a pharmacist **by examination** pursuant to this rule.

(I) Pursuant to section 4729.16 of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.

Rule 4729:1-2-02 | Criteria for licensure by reciprocity. (AMEND)

(A) An applicant seeking licensure as a pharmacist by reciprocity shall comply with all the following:

(1) Be at least eighteen years of age.

(2) Obtain a degree in pharmacy from a school of pharmacy approved by the state board of pharmacy.

(3) Have met the applicable practical experience requirements by either:

(a) Successfully graduating after December 31, 2006 with a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the state board of pharmacy; or

(b) Obtaining a total of at least one thousand seven hundred and forty hours of documented supervised practical experience in Ohio or any other state or jurisdiction in which the credentials are at least the equivalent of those required by this state at the time the experience was obtained. If the reciprocating state or jurisdiction requires less than the required hours, the board may grant internship credit for practice as a pharmacist.

(4) Hold an active license or registration to practice pharmacy, which is in good standing, in a state or jurisdiction in which the credentials are at least the equivalent of those required by this state. Certification of these credentials shall be **~~filed on forms provided~~** **conducted** by the national association of boards of pharmacy (NABP)**~~ or similar forms recognized and approved by the board~~**.

(B) An applicant who has met the requirements of the state or jurisdiction with which the applicant holds a certificate of good standing pursuant to a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate shall be required to establish proficiency in spoken English by providing evidence of the successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:1-2-04 of the Administrative Code.

~~(C) Candidates who qualify for licensure by reciprocity shall personally appear before the full board within six months of the date that the application is filed with the board. Candidates who do not appear before the board within the six-month period must file a new application and fee for licensure by reciprocity, as the original application shall be deemed abandoned.~~

(C) Except as provided in rule 4729:1-2-09 of the Administrative Code, candidates who qualify for licensure by reciprocity shall successfully complete a course developed by the board, that includes a scored evaluation component, on Ohio's law and rules governing the practice of pharmacy.

(1) Candidates who do not successfully complete this course within six months following the submission of a completed application shall file a new application and required fee for licensure by reciprocity, as the original application shall be deemed abandoned.

(2) The Board may require an applicant to complete the "Multistate Pharmacy Jurisprudence Examination" (MPJE) in lieu of completing the course if the applicant has never obtained a passing score on the MPJE for any state or jurisdiction.

(D) Pursuant to section 4729.071 of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. A reciprocity candidate must submit fingerprint impressions no later than **~~twelve~~** **six** months after the date the board receives the application materials. After **~~twelve~~** **six** months, a candidate must submit a new application, the required fee, **and** fingerprint impressions**~~., and again personally appear before the board as described in this paragraph (C) of this rule.~~**

(E) Pursuant to division (B)(2) of section 4796.03 of the Revised Code, the board hereby waives the requirements set forth in division (B)(1) of section 4796.03 of the Revised Code.

(F) Pursuant to division (F)(3) of section 4796.03 of the Revised Code, the required fee for reciprocity shall be three-hundred and thirty-seven dollars and fifty cents and any transaction fee as required by section 125.18 of the Revised Code.

(G) Pursuant to section 4729.16 of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.

Rule 4729:1-2-03 | Examination application for licensure as a pharmacist. (AMEND)

(A) Each person seeking to apply to take the examinations for licensure as a pharmacist shall submit the required application materials and fees to the national association of boards of pharmacy (NABP) and the following to the state board of pharmacy:

(1) A completed application form as provided by the board;

~~**(2) A head and shoulders passport photograph (two by two inches) taken within the previous six months;**~~

(**2**) ~~**(3)**~~ Required fee, **including any transaction fee as required by section 125.18 of the Revised Code**; ~~**and**~~

(**3**) ~~**(4)**~~ Either of the following:

(a) A certificate of education completed and certified by an approved school of pharmacy documenting the successful graduation of the applicant with a doctor of pharmacy degree obtained after December 31, 2006; or

(b) The required hours of supervised practical experience pursuant to rule 4729:2-2-05 of the Administrative Code, and either:

(i) A certificate of education completed and certified by an approved school of pharmacy documenting the successful graduation of the applicant; or

(ii) Certification **provided by the national association of boards of pharmacy documenting the applicant has** ~~**of having**~~ established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission" (FPGEC) certificate and evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule 4729:1-2-04 of the Administrative Code.

(5) Any other information or documentation as determined by the board.

(B) The state board of pharmacy may make an applicant eligible to take the required examinations as soon as the board receives all the items set forth in paragraph (A) of this rule and the results of a criminal records check pursuant to section 4729.071 of the Revised Code.

(C) The state board of pharmacy may deny admission to the licensure examination.

Rule 4729:1-2-04 | Successful completion of the Test of English as a Foreign Language, Internet-based Test. (NO CHANGE)

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.

Rule 4729:1-2-05 | Criminal records check for pharmacists. (NO CHANGE)

(A) Pursuant to section 4729.071 of the Revised Code, an applicant seeking an initial license as a pharmacist by examination or reciprocity 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 4776.02 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) Be 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:

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

(b) The applicant is from out-of-state;

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

(2) Results will only be considered valid if the fingerprint impressions were obtained within one year of the date the application is received by the board.

Rule 4729:1-2-06 | Pharmacist change of name, address or employment. (AMEND)

(A) A pharmacist, who has a legal change of name, shall notify the board of pharmacy, in a manner determined by the board, 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**;**

(4) A government-issued identification card which reflects the pharmacist's name change; or

(5) Any other documentation as approved by the board.

~~**(B) Requests for a duplicate wall certificate shall be issued in the new name of the pharmacist and shall be accompanied by the following:**~~

~~**(1) The wall certificate issued in the original name; and**~~

~~**(2) The required fee.**~~

(B) Requests for a duplicate wall certificate shall be issued in the new name of the pharmacist and shall be accompanied by the required fee. The pharmacist shall promptly destroy the wall certificate that no longer reflects their legal name.

(C) Upon receipt of the required documents and fee pursuant to paragraphs (A) and (B) of this rule, the board will forward the duplicate wall certificate issued in the pharmacist's new name.

(D) A pharmacist who changes their mailing or email address shall notify the board of pharmacy, in a manner determined by the board, of the new address within thirty days after the effective date of such change.

(E) A pharmacist who changes their place of employment shall notify the board of pharmacy, in a manner determined by the board, of the address of the principal place where they practice, including pharmacist placement services, within thirty days after they have commenced such practice.

(F) The board shall only issue a duplicate wall certificate to a pharmacist who has lost, misplaced, or damaged their original wall certificate. A pharmacist seeking a duplicate wall certificate in accordance with this paragraph shall submit a request for a duplicate wall certificate in manner determined by the board and shall pay the required fee.

Rule 4729:1-2-07 | Pharmacist licensure and renewal. (RESCIND AND NEW)

NOTE: This proposed rule is intended to replace current rule OAC 4729:1-2-07.

(A) Except as provided in paragraph (B) of this rule, a pharmacist license issued by the state board of pharmacy in accordance with Chapter 4729. of the Revised Code entitles the individual to whom it is issued to practice as a pharmacist until the next renewal date.

(B) An initial pharmacist license issued by the state board of pharmacy on or after the first of May of every odd-numbered year in accordance with Chapter 4729. of the Revised Code entitles the individual to whom it is issued to practice as a pharmacist until the renewal date immediately following the next required renewal date.

(C) A pharmacist license shall be renewed on the fifteenth day of September of every odd-numbered year.

(D) An individual who fails to renew their license by the fifteenth day of September of every odd-numbered year shall not engage in the practice of pharmacy until a valid license is issued by the board.

(E) In accordance with section 4729.15 of the Revised Code, the renewal fee shall be two hundred fifty dollars and any transaction fee as required by section 125.18 of the Revised Code.

(F) In accordance with section 4729.15 of the Revised Code, a pharmacist renewing a license that expired less than three years shall pay the renewal fee plus a penalty of thirty-seven dollars and fifty cents.

Rule 4729:1-2-08 | Veteran and military family provisions related to pharmacist licensure. (NO CHANGE)

(A) Renewal of an expired license.

(1) In accordance with section 5903.10 of the Revised Code, a holder of an expired license shall be granted a renewal of the license by the state board of pharmacy at the usual cost without penalty and without re-examination if not otherwise disqualified because of mental or physical disability and if either of the following applies:

(a) The license was not renewed because of the holder's service in the armed forces.

(b) The license 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 and the service resulted in the holder's absence from this state.

(2) A pharmacist shall submit proper documentation certifying the active duty service and length of active duty service. Documentation required to obtain a renewal pursuant to paragraph (A)(1) of this rule will be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(B) The state board of pharmacy may implement fee waivers for licensure. If implemented, fee waivers will be published on the state board of pharmacy's web site: www.pharmacy.ohio.gov.

(C) Substantially equivalent education.

In accordance with section 5903.03 of the Revised Code, there are no military programs of training or military primary specialties which are substantially equivalent to the education requirements for licensure as a pharmacist.

Rule 4729:1-5-01 | Pharmacist Continuing Education - Definitions. (AMEND)

As used in Chapter 4729:1-5 of the Administrative Code:

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

~~**(B) "Board approved pharmacy practice-specific specialty certification program" means a practice-specific specialty certification program approved by the state board of pharmacy. The board shall adopt a resolution of the approved programs and make a list of the approved programs available on its website (www.pharmacy.ohio.gov). At a minimum, such pharmacy practice-specific specialty certification programs shall consist of:**~~

~~**(1) Periodic recertification examinations;**~~

~~**(2) Documentation by the certification program that the pharmacist is currently certified by the program;**~~

~~**(3) Other requirements as determined by the board.**~~

(B) "Board approved pharmacy practice-specific specialty certification program" means a practice-specific specialty certification program that meets one of the following:

(1) The program is offered by the board of pharmacy specialties (BPS); or

(2) The program is offered by the specialty pharmacy certification board (SPCB); or

(3) A program approved by the board that consist of the following:

(a) Periodic recertification examinations;

(b) Documentation by the certification program that the pharmacist is currently certified by the program; and

(c) Other requirements as determined by the board.

(C) "Continuing education unit" or "C.E.U." means ten contact hours of participation in an organized continuing pharmacy education experience presented by a provider listed in paragraph (D) of this rule.

(D) "Continuing pharmacy education" or "continuing education", as required in section 4729.12 of the Revised Code, means post-licensure pharmacy education undertaken to maintain professional competency to practice pharmacy, 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 (F) of this rule;

(2) An approved in-state provider of volunteer healthcare services in accordance with section 4745.04 of the Revised Code and rule 4729-6-03 of the Administrative Code;

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

(E) "One-third of a licensee's continuing education requirement" as used in division (C) of section 4745.04 of the Revised Code and paragraph (H) of rule 4729:1-5-02 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.

(F) "Pharmacy jurisprudence" continuing education shall include 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 rule 4729-6-02 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.

(G) "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.

(H) "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.

Rule 4729:1-5-02 | Continuing education requirements for pharmacists. (AMEND)

(A)

(1) Except as provided in paragraph~~s~~ (A)(2) ~~**and (A)(3)**~~ of this rule, ~~**four**~~ **three** C.E.U.s (~~**forty**~~ **thirty** contact hours) of approved continuing education shall be completed by a pharmacist licensed in accordance with Chapter 4729. of the Revised Code prior to the renewal of the pharmacist's license. At least 0.2 C.E.U.s of the total required C.E.U.s must be obtained in pharmacy jurisprudence and at least 0.2 C.E.U.s of the total required C.E.U.s must be obtained in patient or medication safety. **The C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.**

~~**(2) A pharmacist who obtains an initial license by reciprocity or examination during an even-numbered year shall complete two C.E.U.s (twenty contact hours) of approved continuing education to be completed prior to the renewal of the pharmacist's license. At least 0.1 C.E.U. of the total required C.E.U.s must be obtained in pharmacy jurisprudence and at least 0.1 C.E.U of the total required C.E.U.s must be obtained in patient or medication safety.**~~

~~**(3) A pharmacist who obtains an initial license by reciprocity or examination prior to May first in an odd-numbered year shall complete two C.E.U.s (twenty contact hours) of approved continuing education to be completed prior to the renewal of the pharmacist's license. At least 0.1 C.E.U. of the total required C.E.U.s must be obtained in pharmacy jurisprudence and at least 0.1 C.E.U of the total required C.E.U.s must be obtained in patient or medication safety.**~~

(2) A pharmacist who obtains initial licensure by reciprocity or examination shall not have to complete the continuing education requirements for the initial licensure period prior to the renewal of that pharmacist's license.

(B)

(1) A pharmacist may satisfy the continuing pharmacy education requirements in accordance with paragraph (A) of this rule by providing evidence at the time of renewal that the pharmacist has met the requirements of and is currently certified by a board approved pharmacy practice-specific specialty certification program.

(2) Except as provided in paragraph (B)(3) of this rule, a pharmacist who meets the requirements of paragraph (B)(1) of this rule shall be required to complete at least 0.2 C.E.U.s in pharmacy jurisprudence and 0.2 C.E.U.s in patient or medication safety. The C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.

(3) A pharmacist who obtains initial licensure by reciprocity or examination shall not have to complete the continuing education requirements for the initial licensure period prior to the renewal of that pharmacist's license.

~~**(2) Pharmacists who meet the requirements of paragraph (B)(1) of this rule shall be required to complete either of the following prior to renewal:**~~

~~**(a) At least 0.2 C.E.U.s in pharmacy jurisprudence and 0.2 C.E.U.s in patient or medication safety. The C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.**~~

~~**(b) If the pharmacist obtains initial licensure in accordance with paragraphs (A)(2) and (A)(3) of this rule, at least 0.1 C.E.U. in pharmacy jurisprudence and 0.1 C.E.U. in patient or medication safety. The C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.**~~

(C)

~~**(1) Except as provided in paragraph (C)(2) of this rule,**~~ C.E.U.s must be obtained within a period that is no more than two years prior to September fifteenth of the year in which a pharmacist's license must be renewed.

~~**(2) A pharmacist obtaining initial licensure by reciprocity or examination may apply C.E.U.s obtained during the pharmacist's initial period of licensure to meet the continuing education requirements set forth in this rule.**~~

(D) Except as provided in paragraph (F) of this rule, a pharmacist whose license has lapsed or is being renewed after board action shall obtain three C.E.U.s of continuing education during the two-year period immediately preceding the date the renewal application is filed with the board.

(1) At least 0.2 C.E.Us must be in pharmacy jurisprudence and 0.2 C.E.U.s must be in patient or medication safety.

(2) Any additional continuing education requirements ordered pursuant to a board order or settlement agreement shall not be counted for the purposes of meeting this requirement.

~~**(D) If continuing pharmacy education is required after a pharmacist's license has lapsed or where the license is being renewed after board action, continuing education must be obtained during the three-year period immediately preceding the date the renewal application is filed with the board office. A pharmacist shall obtain two C.E.U.s for each year the pharmacist's license has lapsed or is subject to board action.**~~

(E) C.E.U.s obtained that exceed the required C.E.U.s at the time continuing education is required for licensure renewal may not be transferred and applied to future requirements.

(F) Ohio-licensed pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who have not practiced pharmacy in Ohio at any time during the two years prior to the renewal date in which a pharmacist's license must be renewed, may renew their license in accordance with the provisions of Chapter 4729. of the Revised Code without having to comply with the requirements of this rule.

(G) A pharmacist may satisfy up to one-third of the pharmacist's continuing education requirements by providing health care services as a volunteer in accordance with section 4745.04 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 rule 4729-6-03 of the Administrative Code.

(H) Pharmacists shall keep all certificates and other documented evidence of participation that have been issued by non-A.C.P.E. accredited providers for approved C.E.U.s for which the pharmacist has claimed continuing education units towards licensure renewal for a period of one year following the year in which continuing education was required for renewal.

(I) The board may request a pharmacist submit documentation demonstrating compliance with the continuing education requirements of this rule. A pharmacist shall have thirty days to submit such documentation upon receipt of a request by the board.

(J) The board shall monitor compliance by conducting an audit of licensees**, as determined by the board**.

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

Rule 4729:1-5-03 | Veteran and military family provisions related to continuing education. (AMEND)

(A) Extension of continuing education requirements.

(1) In accordance with section 5903.12 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 current pharmacist 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 pharmacist or the pharmacist'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 licensee 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 licensee 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 pharmacist is a veteran, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder no more than two years prior to September fifteenth of the year in which a ~~**pharmacists**~~ **pharmacist's** license 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 pharmacist, the licensee shall submit a request for consideration and evidence or documentation of the education, training, or service to the director of licensing at least sixty days prior to the required continuing education reporting period pursuant to rule 4729:1-5-02 of the Administrative Code.

Rule 4729:2-2-01 | Licensure as a pharmacy intern. (AMEND)

(A) A license as a pharmacy intern shall only be issued for the purpose of allowing those individuals who intend to become licensed pharmacists the opportunity to obtain the practical experience required for examination and licensure as a pharmacist.

(B) If a person is actively working towards the requirements for licensure as a pharmacist and **seeks** ~~**desires**~~ to work as a pharmacy intern in Ohio, the person shall:

(1) Comply with at least one of the following:

(a) Have successfully completed at least sixty semester or ninety quarter hours of college, be enrolled in a school of pharmacy, and has begun taking professional classes directly related to the practice of pharmacy;

(b) Have obtained a first professional degree in pharmacy from a program which has been recognized and approved by the state board of pharmacy; or

(c) Have established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and have established proficiency in spoken English by successfully completing the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:2-2-06 of the Administrative Code.

(2) Submit electronic fingerprint or ink impressions for a criminal records check pursuant to section 4729.071 of the Revised Code.

(3) Apply to the state board of pharmacy for licensure as a pharmacy intern.

Rule 4729:2-2-02 | Application for licensure as a pharmacy intern. (AMEND)

(A) Each person seeking a license as a pharmacy intern for the purpose of obtaining the practical experience required for examination and licensure as a pharmacist shall submit the following to the state board of pharmacy:

(1) A completed application form as provided by the board, which can be accessed by visiting http://www.pharmacy.ohio.gov.

~~**(2) A head and shoulders passport size photograph (two by two inches) taken within the previous six months;**~~

(2) ~~**(3)**~~ **Required fee** ~~**Fee**~~.

(3) ~~**(4)**~~ Documentation, in a manner determined by the board, that the applicant has successfully completed a minimum of sixty semester or ninety quarter hours of college work~~**; and**~~**.**

(4) ~~**(5)**~~

(a) Documentation, in a manner determined by the board, from a school of pharmacy that has been recognized and approved by the board certifying that the person is currently enrolled in a school of pharmacy and has begun taking professional classes directly related to the practice of pharmacy; or

(b) Either of the following:

(i) Certification of having obtained a first professional degree in pharmacy from a program that has been recognized and approved by the state board of pharmacy; or

(ii) Certification **provided by the national association of boards of pharmacy documenting the applicant has** ~~**of having**~~ established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729:2-2-06 of the Administrative Code.

(5) Any other information or documentation as determined by the board.

(B) The state board of pharmacy may license an applicant as a pharmacy intern as soon as the state board of pharmacy receives all the required items set forth in paragraph (A) of this rule **and the results of a criminal records check pursuant to section 4729.071 of the Revised Code.**

(C) The state board of pharmacy may deny the issuance of a license to practice as a pharmacy intern.

(D) A pharmacy intern licensed in another state may apply for licensure by reciprocity by complying with the requirements listed in this rule.

(E) Pursuant to division (B)(2) of section 4796.03 of the Revised Code, the board hereby waives the requirements set forth in division (B)(1) of section 4796.03 of the Revised Code.

(F) In accordance with section 4729.15 of the Revised Code, the required fee for licensure as a pharmacy intern shall be thirty dollars and any transaction fee as required by section 125.18 of the Revised Code.

(G) Pursuant to section 4729.16 of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.

Rule 4729:2-2-03 | Criminal records check for pharmacy interns. (NO CHANGE)

(A) Pursuant to section 4729.071 of the Revised Code, an applicant seeking an initial license as a pharmacy intern 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 4776.02 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) Be 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:

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

(b) The applicant is from out-of-state;

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

(2) Results will only be considered valid if the fingerprint impressions were obtained within one year of the date the application is received by the board.

Rule 4729:2-2-04 | Pharmacy intern license renewal and expiration. (AMEND) [RESCIND 4729:2-2-09]

(A) Except as provided in paragraph (B) of this rule, a pharmacy intern license issued by the state board of pharmacy in accordance with Chapter 4729. of the Revised Code entitles the individual to whom it is issued to practice as a pharmacy intern until the next renewal date.

(B) An initial pharmacy intern license issued by the state board of pharmacy on or after the first of May of every odd-numbered year in accordance with Chapter 4729. of the Revised Code entitles the individual to whom it is issued to practice as a pharmacy intern until the renewal date immediately following the next required renewal date.

(C) A pharmacy intern license shall be renewed on the fifteenth day of September of every odd-numbered year.

(D) An individual who fails to renew their license by the fifteenth day of September of every odd-numbered year shall not engage in the practice of pharmacy until a valid license is issued by the board.

(E) A pharmacy intern shall submit the renewal fee as specified in section 4729.15 of the Revised Code and any transaction fee as required by section 125.18 of the Revised Code.

(~~A~~ **F**) A pharmacy intern may renew ~~the intern's~~ **their** license each year provided they are actively working toward the requirements for licensure as a pharmacist and otherwise meet the requirements and rules of the state board of pharmacy. The state board of pharmacy may refuse to grant or renew license to practice pharmacy as an intern.

(~~B~~ **G**) An intern shall be considered to be actively working towards licensure as a pharmacist if the intern has complied with all of the statutes and rules regarding internship since licensure as a pharmacy intern, and:

(1) The intern is currently enrolled in a school of pharmacy and is taking professional classes directly related to the practice of pharmacy; or

(2) The intern is a member of the armed forces and can provide evidence that the intern has ~~has~~ been accepted for enrollment in a school of pharmacy upon their release from the armed forces.

(~~C~~ **H**) An intern who has obtained a first professional degree in pharmacy from a school of pharmacy, or who has established equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission" (FPGEC) certificate, may renew the intern's license only once. In the event of extraordinary circumstances and when due to no fault of the intern, the board may approve additional renewals **or license extensions**.

(~~D~~ **I**) Upon receiving an initial license to practice as a pharmacist, the intern's license to practice as a pharmacy intern terminates.

(~~E~~ **J**) A pharmacy intern, other than a graduate pharmacist intern, must notify the state board of pharmacy, the intern's current employer and any subsequent employer where practicing as a pharmacy intern within ~~seventy-two hours~~ **three business days** if they are no longer enrolled in a school of pharmacy. ~~The person shall return their pharmacy intern certificate to the state board of pharmacy within ten days of notifying the board.~~ **Upon notification that an intern is no longer enrolled in a school of pharmacy, the Board shall inactivate the intern license and the intern shall no longer be permitted to practice as a pharmacy intern in this state.**

Rule 4729:2-2-05 | Internship credit. (NO CHANGE)

(A) The pharmacy internship credit requirement for the licensure examinations shall be deemed satisfactorily completed when the intern has either:

(1) Successfully graduated after December 31, 2006 with a doctor of pharmacy degree ("Pharm.D.") from a school of pharmacy approved by the "Accreditation Council for Pharmacy Education" (A.C.P.E.) and the state board of pharmacy; or

(2) Obtained a total of at least one thousand seven hundred and forty hours of documented supervised practical experience accepted by the state board of pharmacy which may include any hours:

(a) Documented on a practical experience affidavit pursuant to rule 4729:2-2-06 of the Administrative Code; or

(b) Worked in another state where the appropriate licensing agency submits to the board an official verification of the actual practical experience contact hours completed that meets the requirements in paragraph (A)(2) of this rule.

(B) No internship credit shall be granted by the board for practical experience until a foreign pharmacy graduate has established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission" (FPGEC) certificate, and has established proficiency in spoken English by successfully completing the "Test of English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule 4729:2-2-07 of the Administrative Code.

(C) Practical experience obtained pursuant to paragraph (A)(2)(a) of this rule may include up to five hundred hours of internship credit at a site other than a pharmacy licensed as a terminal distributor of dangerous drugs (e.g., manufacturing, research, consulting, drug information, and drug utilization review). To receive credit for such experience, a formal request must be submitted to the director of licensing for approval prior to beginning the experience in these areas. The request shall include a detailed description of the internship with respect to time, place, duties, responsibilities, professional supervision, and the person supervising the experience. The request must be signed by both the intern and the person supervising the experience and returned with a completed statement of preceptor form. If approved by the board, the hours must be documented using a practical experience affidavit pursuant to rule 4729:2-2-06 of the Administrative Code.

(D) Internship credit may be denied for the practical experience accumulated when an intern is found in violation of section 4729.16 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:2-2-06 | Statement of preceptor and practical experience affidavit. (AMEND)

(A) At the beginning of internship, or if there is a change in preceptor or employment site, the intern must submit a completed statement of preceptor form within thirty days of the change to the state board of pharmacy. The filing of a statement of preceptor form is not required for a change of preceptor or internship site related to a school of pharmacy academic program.

(B) The intern is responsible for submitting the following required forms to certify the hour and supervision requirements pursuant to rule 4729:2-2-05 of the Administrative Code:

(1) A statement of preceptor form must be received by the state board of pharmacy for each pharmacy intern within thirty days of beginning an internship under a preceptor's supervision.

(a) No credit will be given for practical experience obtained prior to thirty days of the date that the statement of preceptor form is received by the board office; except, in the event of extraordinary circumstances and when due to no fault of the intern, the board may accept a retroactive date of filing for the statement of preceptor.

(b) The intern must file a statement of preceptor form whenever the intern changes internship sites and/or preceptors. The form must be submitted within thirty days of a change of internship site and/or preceptor.

(2) A practical experience affidavit form must be used to submit evidence of practical experience for internship credit.

(a) Practical experience reported on the affidavit shall be the total number of actual clock hours worked during the reported time period rounded to the nearest hour. The hours reported must be able to be documented by payroll or other records which may be examined by the state board of pharmacy upon request.

(b) Practical experience affidavits must be signed by the preceptor and submitted to the state board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit.

(c) Practical experience affidavits for a calendar year may be submitted at any time, except that they must be **~~received in~~** **submitted to** the board **~~office or postmarked~~** no later than **~~the first day of March of the following year~~** **one year after the credit is earned**.

(d) No internship credit shall be granted by the board for practical experience obtained before licensure as an intern or during a period when the intern's license has lapsed.

(e) No internship credit shall be granted by the board for practical experience obtained for the purposes of the intern's school of pharmacy academic program.

~~(C) Statement of preceptor and practical experience affidavit forms may also be used to document any additional hours completed by the intern.~~

Rule 4729:2-2-07 | Successful completion of the Test of English as a Foreign Language, Internet-based Test. (NO CHANGE)

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.

Rule 4729:2-2-08 | Pharmacy intern change of name, address or employment. (AMEND)

(A) A pharmacy intern, who has a legal change of name, shall notify the board of pharmacy, in a manner determined by the board, 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~~.~~**;**

(4) A government-issued identification card which reflects the pharmacist's name change; or

(5) Any other documentation as approved by the board.

(B) Requests for a duplicate wall certificate shall be issued in the intern's new name and shall be accompanied by the following:

(1) The wall certificate issued in the original name; and

(2) The required fee.

(C) Upon receipt of the required documents and fee in paragraphs (A) and (B) of this rule, the board will forward the duplicate wall certificate issued in the intern's new name.

(D) A pharmacy intern who changes their mailing or email address shall notify the board of pharmacy, in a manner determined by the board, of the new address within thirty days after the effective date of such change.

(E) A pharmacy intern who changes their place of employment shall notify the board of pharmacy, in a manner determined by the board, of the address of the principal place where they practice within thirty days after they have commenced such practice.

Rule 4729:2-2-10 | Veteran and military family provisions related to pharmacy intern licensure. (NO CHANGE)

(A) Renewal of an expired license.

(1) In accordance with section 5903.10 of the Revised Code, a holder of an expired license shall be granted a renewal of the license by the state board of pharmacy at the usual cost without penalty if not otherwise disqualified because of mental or physical disability and if either of the following applies:

(a) The license was not renewed because of the holder's service in the armed forces.

(b) The license 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 and the service resulted in the holder's absence from this state.

(2) A pharmacy intern shall submit proper documentation certifying the active duty service and length of active duty service. Documentation required to obtain a renewal pursuant to paragraph (A)(1) of this rule will be published on the state board of pharmacy's website: www.pharmacy.ohio.gov.

(B) The state board of pharmacy may implement fee waivers for licensure. If implemented, fee waivers will be published on the state board of pharmacy's web site: www.pharmacy.ohio.gov.

Rule 4729:3-2-01 | Registration procedures. (AMEND)

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

(1) Comply with all requirements set forth in section 4729.92 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, **including any transaction fee as required by section 125.18 of the Revised Code**.

(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.

(c) Notwithstanding the requirements of paragraph (A)(3)(b)**(ii)** of this rule, the board may register as a pharmacy technician trainee an applicant who is seventeen or eighteen years of age and does not possess a high school diploma or certificate of high school equivalence if the applicant is enrolled in a career-technical school program that is approved by the board and conducted by a city, exempted village, local, or joint vocational school district.

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

(4) A pharmacy technician trainee licensed or registered in another state may apply for registration by reciprocity by complying with the requirements listed in paragraphs (A)(1) through (A)(3) of this rule.

(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) 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~~ **five** 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, **including any transaction fee as required by section 125.18 of the Revised Code**;

(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 4729:3-2-05 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:

(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 an attestation signed by the responsible person**, or the equivalent in the state where the technician is registered,** of the pharmacy where the technician is actively employed or was employed in the ~~three~~ **five** years prior to the date of submission of an application. The responsible person must complete the required attestation form provided by the board and attest to their personal observation that the technician applicant demonstrates the required proficiency (reading, listening, speaking, and writing) in the english language to practice safely and effectively as a registered pharmacy technician.

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

(d) Any of the following documentation:

(i) An attestation**,** ~~or~~ certificate of completion**, or other board approved documentation** submitted by the terminal distributor of dangerous drugs that the applicant has successfully completed an approved training program in accordance with paragraph (A)(1), (A)(2), or (A)(4) of rule 4729:3-3-02 of the Administrative Code. **It shall be the responsibility of the terminal distributor of dangerous drugs to ensure that the documentation submitted to the board accurately reflects the completion of an approved training program.**

~~**(ii) A record of training and education pursuant to paragraph (B)(3) of rule 4729:3-3-02 of the Administrative Code signed by the 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~~ **ii**) 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 4729.90 of the Revised Code.

(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~~ **five** years of application~~.~~**; or**

(c) Holds a current pharmacy technician certification from an organization that has been recognized by the board for at least two years immediately preceding the date the application is submitted and has been actively practicing as a pharmacy technician in a state that does not issue a pharmacy technician license or registration for at least two of the five years immediately preceding the date the application is submitted.

(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, **including any transaction fee as required by section 125.18 of the Revised Code**, 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 4729:3-2-05 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.

(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 an attestation signed by the responsible person**, or the equivalent in the state where the technician is registered,** of the pharmacy where the technician is actively employed or was employed in the ~~**three**~~ **five** years prior to the date of submission of an application. The responsible person must complete the required attestation form provided by the board and attest to their personal observation that the technician applicant demonstrates the required proficiency (reading, listening, speaking, and writing) in the english language to practice safely and effectively as a certified pharmacy technician.

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

(e) Any of the following documentation:

(i) An attestation**,** ~~**or**~~ certificate of completion**, or other board approved documentation** submitted by the terminal distributor of dangerous drugs that the applicant has successfully completed an approved training program in accordance ~~**with paragraph (A)(1), (A)(2), or (A)(4) of**~~ rule 4729:3-3-02 of the Administrative Code.

~~**(ii) A record of training and education pursuant to paragraph (B)(3) of rule 4729:3-3-02 of the Administrative Code signed by the 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**~~ **ii**) Documentation, as determined by the board, demonstrating compliance with the reciprocity requirements of paragraph**s** (C)(2)(b) **and (C)(2)(c)** of this rule.

(f) 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 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. 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 comply with the criminal records check requirements pursuant to rule 4729:3-2-02 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.**~~

(D) Pursuant to section 4729.921 of the Revised Code, the registration for a pharmacy technician trainee is eighteen months.

(E) A pharmacy technician trainee that fails to meet the education and training requirements during the trainee's initial registration period, may apply for reinstatement of their registration by submitting an application and required fee as required by paragraph (A) of this rule.

(F) Pursuant to section 4729.96 of the Revised Code, a limited or restricted registration may be issued to an applicant upon the determination of the board.

(G) ~~**(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.

(H) ~~**(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 4729:3-1-01 of the Administrative Code.

(I) ~~**(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: www.pharmacy.ohio.gov.

Rule 4729:3-3-02 | Approved pharmacy technician training programs. (AMEND)

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 3317.161 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: www.pharmacy.ohio.gov.

(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 4729:3-3-01 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.

(4) It shall be the responsibility of the terminal distributor of dangerous drugs providing employer-based training to ensure that the documentation provided to pharmacy technician trainees accurately reflects the completion of an approved training program. Failure on the part of the terminal distributor of dangerous drugs to ensure the accuracy of training documentation shall be considered a violation of rule 4729:5-4-01 of the Administrative Code.

~~**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 and certifies the competency of each technician trainee completing the training program pursuant to this rule.**~~ A copy of the documentation shall be provided to each participant who successfully completes the program.

(5) A terminal distributor of dangerous drugs providing employer-based training at more than one licensed location in this state shall develop and implement written policies and procedures detailing how each location shall comply with the requirements of this rule.

(**6** ~~**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.

(**7** ~~**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.

(**8** ~~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>**, as defined in rule 4729:7-1-01 of the Administrative Code**.

(2) If preparing non-sterile hazardous compounded drugs in accordance with rule 4729:7-2-03 of the Administrative Code, the training shall also comply with the applicable requirements set forth in United States pharmacopeia chapter <800>, as defined in rule 4729:7-1-01 of the Administrative Code.

(**3** 2) Non-sterile drug compounding training shall be obtained through completion of a site-specific, 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.

(**4** 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.

(**5** 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.

(**6** 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.

(**7** ~~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>**, as defined in rule 4729:7-1-01 of the Administrative Code**.

(2) If preparing sterile hazardous compounded drugs in accordance with rule 4729:7-2-03 of the Administrative Code, the training shall also comply with the applicable requirements set forth in United States pharmacopeia chapter <800>, as defined in rule 4729:7-1-01 of the Administrative Code.

(**3** ~~2~~) Sterile drug compounding training shall be obtained through completion of a site-specific, 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.

(**4** ~~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.

(**5** ~~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.

(**6** ~~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.

(**7** ~~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 4729:3-2-01 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.

Rule 4729:3-3-03 | Registered pharmacy technicians. (AMEND)

(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~~ **D**) of this rule;

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

(**10** ~~9~~) Packaging and selling a dangerous drug to a patient or patient representative;

(**11** ~~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;

(**12** ~~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.

(D) 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>**, as defined in rule 4729:7-1-01 of the Administrative Code**.

(2) If preparing non-sterile hazardous compounded drugs in accordance with rule 4729:7-2-03 of the Administrative Code, the training shall also comply with the applicable requirements set forth in United States pharmacopeia chapter <800>, as defined in rule 4729:7-1-01 of the Administrative Code.

(**3** ~~**2**~~) Non-sterile drug compounding training shall be obtained through completion of a site-specific, 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.

(**4** ~~**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 persons designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

(**5** ~~**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.

(**6** ~~**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.

(E) In order to perform sterile drug compounding, a registered 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>, as defined in rule 4729:7-1-01 of the Administrative Code.

(2) If preparing sterile hazardous compounded drugs in accordance with rule 4729:7-2-03 of the Administrative Code, the training shall also comply with the applicable requirements set forth in United States pharmacopeia chapter <800>, as defined in rule 4729:7-1-01 of the Administrative Code.

(3) Sterile drug compounding training shall be obtained through completion of a site-specific, 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.

(4) 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 persons designee will sign the documentation records to show that the employee was appropriately trained in accordance with this rule.

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

(6) 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.

(~~**E**~~ **F**) 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.

Rule 4729:5-2-02 | Terminal distributor of dangerous drugs licensing and renewal. (RESCIND & NEW)

NOTE: This proposed rule is intended to replace current rule OAC 4729:5-2-02.

(A) A terminal distributor of dangerous drugs license issued pursuant to Chapter 4729. of the Revised Code shall expire on the thirty-first day of March of every odd-numbered year. A license shall be renewed biennially, according to the provisions of section 4729.55 of the Revised Code, and the standard renewal procedure of Chapter 4745. of the Revised Code.

(B) An initial terminal distributor of dangerous drugs license issued on or after the thirtieth day of January of every odd-numbered year shall receive an expiration date of the thirty-first day of March of the next odd-numbered year.

(C) A terminal distributor of dangerous drugs who seeks to renew a license shall submit an application for renewal and pay the required fee in accordance with section 4729.55 of the Revised Code and this division of the Administrative Coder on or before the license expiration date.

(D) A terminal distributor of dangerous drugs who has experienced a change in responsible person pursuant to section 4729:5-2-01 of the Administrative Code and has not yet reported such change to the board, shall submit the required notification prior to submitting a renewal application.

(E) A terminal distributor of dangerous drugs who has experienced a change in description pursuant to section 4729:5-2-03 of the Administrative Code and has not yet reported such change to the board, shall submit the required application and fee in lieu of a renewal application.

An application and fee submitted pursuant to section 4729:5-2-03 of the Administrative Code during the renewal period will qualify as a renewal application and be awarded an expiration date in accordance with paragraph (A) of this rule.

(F) The required fees for initial licensure and biennial renewal of a terminal distributor of dangerous drugs license shall be in accordance with sections 4729.55 and 125.18 of the Revised Code.

(G) Licensure pursuant to section 4729.54 of the Revised Code is not applicable to any facility owned or operated by the following:

(1) The United States department of defense;

(2) The United States department of veterans affairs; or

(3) Any other federal agency.

(H) A terminal distributor of dangerous drugs licensed pursuant section 4729.54 of the Revised Code that fails to renew a license in accordance with this division of the Administrative Code is prohibited from engaging in any authorized activity of a terminal distributor until a valid license is issued by the board.

(I) A terminal distributor of dangerous drugs that fails to renew its license by the expiration date is considered lapsed and may be reinstated upon receipt of a renewal application, fee, and penalty as specified in section 4729.55 of the Revised Code.

(J) A terminal distributor of dangerous drugs that has lapsed for more than sixty days after the expiration date is considered expired and may be reinstated upon receipt of a reinstatement application and fee as specified in section 4729.55. A terminal distributor filing a reinstatement application must meet the requirements of this chapter and section 4729.54 of the Revised Code.

(K) Paragraphs (D) and (E) of this rule do not limit the board from taking disciplinary action pursuant to rule 4729:5-4-01 of the Administrative Code against a licensee for failure to comply with the requirements of Chapter 4729:5-2 of the Administrative Code.

4729:6-2-02 – Distributor of dangerous drugs licensing and renewal. (RECIND and NEW)

NOTE: This proposed rule is intended to replace current rule OAC 4729:6-2-02.

(A) All drug distributor licenses issued pursuant to section 4729.52 of the Revised Code shall expire on the thirtieth day of June of every odd-numbered year. A license shall be renewed biennially, according to the provisions of sections 4729.52 and 4729.53 of the Revised Code and the standard renewal procedure of Chapter 4745. of the Revised Code.

(B) An initial drug distributor license issued on or after the first day of May of every odd-numbered year shall receive an expiration date of the thirtieth day of June of the next odd-numbered year.

(C) A drug distributor who seeks to renew a license shall submit an application for renewal and pay the required fee in accordance with section 4729.52 of the Revised Code on or before the license expiration date.

(D) A drug distributor who has experienced a change in responsible person pursuant to section 4729:6-2-01 of the Administrative Code and has not yet reported such change to the board, shall submit the required notification prior to submitting a renewal application.

(E) A drug distributor who has experienced a change in description pursuant to section 4729:6-2-05 of the Administrative Code and has not yet reported such change to the board, shall submit the required application and fee in lieu of a renewal application.

An application and fee submitted pursuant to section 4729:6-2-05 of the Administrative Code during the renewal period will qualify as a renewal application and be awarded an expiration date in accordance with paragraph (A) of this rule.

(F) The required fees for initial licensure and biennial renewal of a distributor of dangerous drug licensure shall be in accordance with sections 4729.52 and 125.18 of the Revised Code.

(G) Licensure pursuant to section 4729.52 of the Revised Code is not applicable to any facility owned or operated by the following:

(1) The United States department of defense;

(2) The United States department of veterans affairs; or

(3) Any other federal agency.

(H) A drug distributor licensed pursuant section 4729.52 of the Revised Code that fails to renew a license in accordance with this division of the Administrative Code is prohibited from engaging in any authorized activity of a drug distributor until a valid license is issued by the board.

(I) A drug distributor that fails to renew its license by the expiration date is considered lapsed and may be reinstated upon receipt of a renewal application, fee, and penalty as specified in sections 4729.55 and 125.18 of the Revised Code.

(J) A drug distributor that has lapsed for more than sixty days after the expiration date is considered expired and may be reinstated upon receipt of a reinstatement application and fee as specified in section 4729.55 and 125.18 of the Revised Code. A drug distributor filing a reinstatement application must meet the requirements of this chapter and section 4729.52 of the Revised Code.

4729:6-2-03 – Criminal Records Checks. (AMEND)

(A) **Unless otherwise approved by the board, a** new distributor of dangerous drug license will not be issued until the following persons submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check in accordance with paragraph (C) of this rule:

(1) The responsible person on the application for licensure; and

(2) The following persons based upon the drug distributor's business type:

(a) All partners of a partnership.

(b) The sole proprietor of a sole proprietorship.

(c) All members of a limited-liability company.

(**e d**) Except as provided in paragraph (A)(3) of this rule, the president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and, if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation.

If the director or the director's designee determines other person(s) in the organizational structure have substantial control, such as the power to influence management and operational decision-making over the distribution of dangerous drugs, the director or designee may require a criminal records check of those with substantial control in addition to or in place of those persons set forth in this paragraph.

(**e** ~~**d**~~) The agency director of a government agency.

(f) The executive director or any equivalent position of a nonprofit organization.

(3) For publicly traded corporations, the board's executive director or the ~~**directors**~~ **director's** designee may waive the criminal records checks required in paragraph (A)(2)(c) of this rule under the following circumstances:

(a) The public traded corporation submits a request to the executive director and includes the organizational structure of the corporation, including all corporate officer positions responsible for directing the distribution of dangerous drugs. The director or the ~~**directors**~~ **director's** designee may request additional information about the corporation's organizational structure.

(b) The executive director or the director's designee approves an alternate list of corporate officers that are required to submit a criminal records check. If approval is not provided, the publicly traded corporation shall comply with paragraph (A)(2)(c) of this rule.

(B) The persons listed in paragraph (A)(2) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to a criminal records check in accordance with this rule.

(C) All criminal records checks conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI) and shall comply with the following:

(1) Be 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:

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

(b) The person or persons listed in paragraph (A) of this rule reside outside of the state of Ohio; or

(c) The person or persons listed in paragraph (A) of this rule have a home address that is seventy-five miles or more from the nearest WebCheck location.

(2) Results will only be considered valid if the fingerprint impressions were obtained within one year of the date the application is received by the board.

(3) The results of the criminal records check must be sent directly to the state board of pharmacy from BCI&I.

(D) Only new persons listed in paragraphs (A)(1) and (A)(2) of this rule shall be required to submit to a criminal records check for a new application resulting from a change in the description of a distributor of dangerous drugs pursuant to rule 4729:6-2-05 of the Administrative Code.

4729:6-2-04 – Drug Distributor Applications. (AMEND)

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a distributor of dangerous drugs:

(1) The name, full physical business address (not a post office box), and telephone number.

(2) All trade, fictitious, or business names used by the licensee (e.g. "doing business as" or "formerly known as"). ~~**Trade or business names shall not be identical to the name used by another, unrelated drug distributor permitted to purchase or sell drugs in this state.**~~

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs located in this state or used to distribute drugs into this state.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, **limited liability company,** corporation, ~~**or**~~ government agency**, or nonprofit organization**).

(5) The following information for the owner(s) and/or operator(s) of the drug distributor:

(a) For a partnership:

(i) The full name, business address, social security number, and date of birth of each partner. If the partner is not a natural person, each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(ii) The name of the partnership.

(iii) The partnership's federal employer identification number.

(b) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.

(c) For a limited lability company: the full name, business address, social security number, and date of birth of each member. If the member(s) is not a nature person, each business entity that is a member having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(~~**b**~~ **d**) For a corporation:

(i) The full name, business address, social security number and date of birth of the corporation's president, vice-president, secretary, treasurer and chief executive officer, or any equivalent position. For a publicly traded corporation that obtains a criminal records check waiver pursuant to paragraph (A)(3) of rule 4729:6-2-03 of the Administrative Code, the full name, business address, social security number and date of birth of the corporate officers subject to a criminal records check as determined by the boards executive director or directors designee.

(ii) The name or names of the corporation.

(iii) The state of incorporation.

(iv) The corporation's federal employer identification number.

(v) The name of the parent company, if applicable.

(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.

~~**(c) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.**~~

(~~**d**~~ **e**) For a government agency: the full name, business address, social security number, and date of birth of the agency director.

(f) For a nonprofit organization: the full name, business address, social security number, and date of birth of the executive director or any equivalent position.

(6) If the entity submitting an application for a distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, the licensing process shall include an inquiry to the licensing authority of the state or jurisdiction to determine if the entity possesses a current and valid license **or registration** to distribute dangerous drugs in that state or jurisdiction and any disciplinary action, including actions pending, the licensing authority is taking or may have taken against the entity. This information may be used to determine if the business entity should be granted a license by the state board of pharmacy. An entity located outside the boundaries of the state of Ohio that is making application for licensure as a third-party logistics provider or virtual wholesaler shall maintain **a drug distributor** ~~**verified-accredited wholesale distributors (VAWD)**~~ accreditation from the national association of boards of pharmacy if the state where the entity resides does not license such entities.

(7) If applicable, proof of the ~~**entitys**~~ **entity's** valid registration with the United States food and drug administration and/or the United States drug enforcement administration.

(8) Any information required on the application as determined by the board.

(9) Any follow-up information as deemed necessary by the board's executive director or the director's designee upon receipt of the application materials.

(B) Prior to the end of the licensing period established in rule 4729:6-2-02 of the Administrative Code, a renewal application requesting such information as the state board of pharmacy may require will be sent to the email or physical address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the date established in rule 4729:6-2-02 of the Administrative Code.

4729:6-2-06 – Procedure for discontinuing business as a distributor of dangerous drugs. (NO CHANGE)

(A) A distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the state board of pharmacy. The notice shall be submitted, in a manner determined by the board, at least thirty days in advance of the proposed date of discontinuing business, unless waived by the board's executive director or the director's designee due to extraordinary circumstances beyond the licensee's control. This notice shall include the following information:

(1) The name, address, and license number of the drug distributor discontinuing business.

(2) If applicable, the name, address, and license number of the drug distributor or other authorized entity where the dangerous drugs will be transferred.

(3) The name and address of the secured location where the records required to be maintained in accordance with this division will be stored.

(4) The proposed date of discontinuing business.

(B) Unless the licensee is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the licensee discontinuing business may transfer the dangerous drugs and records in accordance with the following:

(1) On the date of discontinuing business, a complete inventory of all controlled substances being transferred, or disposed pursuant to rule 4729:6-3-01 of the Administrative Code, shall be made. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred or disposed.

(2) This inventory shall serve as the final inventory of the licensee discontinuing business and the initial inventory of the licensee to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer.

4729:7-2-03 | Drugs compounded in a pharmacy. (AMEND)

(A) For all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>. This paragraph does not apply to non-sterile compounded preparations exempted from the requirements of this chapter in accordance with paragraph (C) of rule 4729:7-2-01 of the Administrative Code.

(B) For all sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <797>. This paragraph does not apply to sterile compounded drugs exempted from the requirements of this chapter in accordance with rule 4729:7-2-02 of the Administrative Code.

(C) For all antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code, the pharmacy shall comply with United States pharmacopeia chapter <800>.

(D) For all non-antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code and for all compounded hazardous drug preparations listed in table two or three on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code, the pharmacy shall comply with either:

(1) United States pharmacopeia chapter <800>; or

(2) All the following:

(a) Conduct a risk assessment for any hazardous drug preparations listed in paragraph (D) of this rule to determine if any additional containment strategies, work practices, and/or training is required to minimize occupational exposure. Risk assessments shall be made readily retrievable for review by an agent, inspector or employee of the state board of pharmacy. The risk assessment must be reviewed at least every twelve months and the review documented. If a risk assessment is not performed, the compounded drug preparations shall be prepared in accordance with paragraph (D)(1) of this rule. The risk assessment must, at a minimum, consider the following:

(i) Type of hazardous drug (e.g., non-antineoplastic or reproductive risk only);

(ii) Dosage form;

(iii) Risk of exposure;

(iv) Packaging; and

(v) Manipulation.

(b) Ensure that any employees of reproductive capability confirm in writing that they understand the potential risks of handling drugs listed in paragraph (D) of this rule.

(E) Comply with Title 21 U.S. Code section 353a (11/27/2013).

(F) Only the following may engage in compounding at a pharmacy:

(1) A pharmacist;

(2) A pharmacy intern under the personal supervision of a pharmacist;

(3) A certified pharmacy technician**, registered pharmacy technician,** or pharmacy technician trainee under the personal supervision of a pharmacist~~; and~~**.**

~~**(4) A registered pharmacy technician under the personal supervision of a pharmacist, but only with respect to non-sterile drug compounding.**~~

(G) For all compounded drug preparations, a pharmacist shall:

(1) Conduct the final check of the compounded drug preparation; and

(2) Be responsible for the dispensing of a compounded drug preparation.

(H) For all compounded drug preparations, a pharmacist shall be responsible for the following:

(1) All compounding records pursuant to rule 4729:7-2-04 of the Administrative Code;
(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(I) A drug shall be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(J) In addition to the requirements of this rule, compounded drug preparations dispensed to an outpatient shall comply with the following requirements:

(1) Be labeled according to rule 4729:5-5-06 of the Administrative Code; and
(2) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(K) In addition to the requirements of this rule, compounded drug preparations dispensed to an inpatient shall be labeled according to the inpatient labeling requirements in agency 4729 of the Administrative Code; and

(L) Labels for a compounded drug that is prepared in anticipation of a patient-specific prescription shall also contain the following:

(1) The name, strength, and quantity of each active ingredient used in the compounded drug preparation;

(2) Pharmacy control number;

(3) The assigned beyond-use date;

(4) The identification of the repackager or outsourcing facility by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier;

(5) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(M) A prescription for a schedule II controlled substance narcotic to be compounded for the direct administration to a patient may be transmitted to a pharmacy by facsimile. The prescription shall comply with the requirements of 21 CFR 1306.11 (3/31/2010).

(N) The pharmacy shall maintain a system for the safe disposal of drug waste in accordance with all state and federal laws, rules and regulations.

(O) The pharmacy shall comply with the drug database reporting requirements pursuant to division 4729:8 of the Administrative Code.

(P) A pharmacy shall report to the state board of pharmacy within seventy-two hours upon discovery, and in a manner determined by the board, any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy.

(1) As used in this paragraph, a product quality issue means any of the following:

(a) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

(b) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

(c) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

(2) A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

(Q) A pharmacy shall report to the state board of pharmacy within seventy-two hours of issuance or receipt, and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.