#### 1/19/2017

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

#### Amended

- 4729-5-22: Adds dosage strength and frequency to scope of patient counseling, removes drug therapy distinction for supplemental counseling, and adds definition of personal supervision.
- 4729-5-33: Replaces registration with licensure, specifies passport photograph and dimensions, and removes specific language with regards to supervised practical experience hours.
- 4729-5-31: Replaces jurisprudence examination compiled by the board with the Multistate Pharmacy Jurisprudence Examination, specifies that unfulfilled applications will be deemed abandoned, and limits attempts to pass examinations to five, with one additional attempt in extraordinary circumstances.
- 4729-3-01: Specifies that a preceptor must have a license to practice pharmacy and at least one year of practice experience as an Ohio licensed pharmacist, and adds conditions to the definition of good standing.
- 4729-3-02: Replaces mentions of registration with licensure.
- 4729-3-03: Replaces mentions of registration with licensure and specifies passport photograph dimensions.
- 4729-3-04: Adds rule 4729-3-09, adds seventy-two hour deadline for notification to the state board of pharmacy and current employers of end of enrollment in a school of pharmacy, and adds ten day deadline for returning intern certificate to state board of pharmacy.
- 4729-3-05: Changes documented supervised practical experience hours requirement to the national accreditation standard of seven hundred and forty.
- 4729-3-06: Adds a thirty-day deadline for submitting a change of internship site and/or preceptor form.
- 4729-5-32: Elaborates on requirements for applicants seeking licensure as a pharmacist by reciprocity in Ohio. Removes requirement to get in-state finger prints for the required criminal records check.

#### **Rescinded**

• 4729-3-09: Added to rule 4729-3-04.

Comments on the proposed rules will be accepted until close of business on February 3, 2017. Please send all comments to the following email address: <u>Cameron.mcnamee@pharmacy.ohio.gov</u>

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov



# **Business Impact Analysis**

Agency Name: <u>State of Ohio Board of Pharmacy</u>	
Regulation/Package Title: Pharmacists and Pharmacy Interns	
Rule Number(s): <u>Amend: 4729-5-22; 5-33; 5-31; 3-01; 3-02; 3-03; 3-04; 3-05; 3-06; 5-32</u>	
<u>Rescind: 4729-3-09</u>	
Date: <u>1/18/2017</u>	
Rule Type:	
New	<mark>5-Year Review</mark>
Amended	<b>Rescinded</b>

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

## **Regulatory Intent**

### 1. Please briefly describe the draft regulation in plain language.

### **Amended**

- 4729-5-22: Adds dosage strength and frequency to scope of patient counseling, removes drug therapy distinction for supplemental counseling, and adds definition of personal supervision.
- 4729-5-33: Replaces registration with licensure, specifies passport photograph and dimensions, and removes specific language with regards to supervised practical experience hours.

- 4729-5-31: Replaces jurisprudence examination compiled by the board with the Multistate Pharmacy Jurisprudence Examination, specifies that unfulfilled applications will be deemed abandoned, and limits attempts to pass examinations to five, with one additional attempt in extraordinary circumstances. This limitation is a national standard adopted by the test administrator, the National Association of Boards of Pharmacy.
- 4729-3-01: Specifies that a preceptor must have a license to practice pharmacy and at least one year of practice experience as an Ohio licensed pharmacist, and adds conditions to the definition of good standing.
- 4729-3-02: Replaces mentions of registration with licensure.
- 4729-3-03: Replaces mentions of registration with licensure and specifies passport photograph dimensions.
- 4729-3-04: Adds rule 4729-3-09, adds seventy-two hour deadline for notification to the state board of pharmacy and current employers of end of enrollment in a school of pharmacy, and adds ten day deadline for returning intern certificate to state board of pharmacy.
- 4729-3-05: Changes documented supervised practical experience hours requirement to the national accreditation standard of seven hundred and forty.
- 4729-3-06: Adds a thirty-day deadline for submitting a change of internship site and/or preceptor form.
- 4729-5-32: Elaborates on requirements for applicants seeking licensure as a pharmacist by reciprocity in Ohio. Removes requirement to get in-state finger prints for the required criminal records check.

## **Rescinded**

• 4729-3-09: Added to rule 4729-3-04.

## 2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The proposed rules are authorized by sections 4729.26 and 4776.03 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.07, 4729.08, 4729.13, and 4729.071.

# **3.** Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

The proposed rules do not implement a federal requirement.

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

This rule package exceeds federal requirements because the regulation of pharmacists and pharmacy interns has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board of Pharmacy.

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

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

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

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the above referenced chapters of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Ensure uniform standards for the licensure of pharmacists and pharmacy interns.
- Require the offer of patient counseling prior to the dispensing of prescription medications.

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

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

# **Development of the Regulation**

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

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

Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

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

The rules review committee made the following modifications to the initially proposed rules:

- 4729-5-22: Requested updated definition for personal supervision to provide greater flexibility to pharmacy interns to conduct patient counseling.
- 4729-3-01: Changed the requirements of a preceptor from the proposed two-years of licensure to one-year of licensure.

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

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

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

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

As the regulations are essential to protecting the public's health and safety by ensuring uniform regulations related to the licensure of pharmacy professionals and patient counseling, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

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

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

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

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

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

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

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

## **Adverse Impact to Business**

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

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

The rule package impacts the following:

- Pharmacists;
- Pharmacy interns.

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

Violation of these rules may result in administrative licensure discipline for a pharmacist or pharmacy intern. Discipline might include reprimand, suspension of a license, continuing education, monetary fine and/or revocation of a license.

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

### Amended

- 4729-5-22: Overall the rule requires the offer of patient counseling prior to the dispensing
  of prescription medications. However, the rule does permit pharmacy interns to provide
  such counseling if the pharmacist is present on-site as opposed to the current requirement
  of direct supervision. This flexibility may reduce overall demand on pharmacists.
- 4729-5-33: The application to take the examinations for licensure as a pharmacist requires completing the application, which takes approximately one hour to complete. Additionally, a fee of \$110.00 is required, along with a certificate of education from an approved school of pharmacy.
- 4729-5-31: The registration fee for the NAPLEX is \$575.00 per examination, while the fee for the MPJE is \$250.00 per examination. For those who fail to take both exams within twelve months of the board receiving the application, the cost of an additional application is \$110.00. For those who fail to achieve a passing score, additional examinations will incur additional fees.
- 4729-3-01: Specifies that a preceptor must have a license to practice pharmacy and at least one year of practice experience as an Ohio licensed pharmacist. This rule should only impact those wishing to perform preceptor responsibilities who do not meet the requirements set forth in rule.
- 4729-3-02: Replaces mentions of registration with licensure. Applicants must be enrolled in a school of pharmacy or received a professional degree in pharmacy. The application for licensure as a pharmacy intern includes a fee of \$22.50, and requires completing the application which takes approximately thirty minutes to complete.
- 4729-3-03: Replaces mentions of registration with licensure and specifies passport
  photograph dimensions. Applicants must be enrolled in a school of pharmacy or received
  a professional degree in pharmacy. The application for licensure as a pharmacy intern
  includes a fee of \$22.50, and requires completing the application which takes
  approximately thirty minutes to complete.
- 4729-3-04: Adds rule 4729-3-09, adds seventy-two hour deadline for notification to the state board of pharmacy and current employers of end of enrollment in a school of pharmacy, and adds ten day deadline for returning intern certificate to state board of pharmacy. The pharmacy intern must return their certificate to the board in the allotted time.
- 4729-3-05: Increases documented supervised practical experience hours requirement to seven hundred and forty. The additional two hundred and forty hours should not have an adverse impact because all nationally accredited pharmacy schools recognized by the Board require students to meet this requirement.
- 4729-3-06: Adds a thirty-day deadline for submitting a change of internship site and/or preceptor form. The deadline means the intern must take the time to fill out the statement of preceptor, approximately 15 minutes, before the thirty day deadline.
- 4729-5-32: Elaborates on requirements for applicants seeking licensure as a pharmacist by reciprocity in Ohio. The rule matches the requirements listed on the application so 77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117 CSIOhio@governor.ohio.gov

there should be no adverse impact. The rule also removes the requirement to submit electronic fingerprints for a criminal records check by allowing a candidate to also submit ink fingerprints to BCI&I. This means that candidates will no longer have to travel to Ohio to submit electronic fingerprints and can have fingerprints rolled in their state.

### **Rescinded**

 4729-3-09: Added to rule 4729-3-04. The rule is being rescinded should have no adverse impact.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. In particular, they ensure uniform regulations that allow for:

- Standards for the licensure of pharmacists and pharmacy interns;
- Patient counseling requirements.

### **Regulatory Flexibility**

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

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

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

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

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

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

#### 4729-5-22 Patient counseling.

(A) A pharmacist or the pharmacist's designee shall personally offer to provide the service of counseling pursuant to paragraph (B) of this rule to the patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. In this situation, when counseling is refused, the pharmacist shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

(B) A pharmacist, or an intern under the personal supervision of a pharmacist, shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:

(1) The name and description of the drug;

(2) The dosage form, dose, <u>strength</u>, <u>frequency</u>, route of administration, and duration of drug therapy;

(3) The intended use of the drug and the expected action;

(4) Special directions and precautions for preparation, administration, and use by the patient;

(5) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(6) Techniques for self-monitoring drug therapy;

(7) Proper storage;

(8) Prescription refill information;

(9) Action to be taken in the event of a missed dose; and

(10) The pharmacist's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.

(C) Other forms of <del>drug therapy</del> information may be used when appropriate to supplement the counseling by the pharmacist. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictogram labels, and video programs.

(D) Patient counseling shall not be required for inpatients of an institutional facility as defined in rule 4729-17-01 of the Administrative Code.

(E) Notwithstanding, rule 4729-5-01 of the Administrative Code, "personal supervision" as used in paragraph (B) of this rule, means that a pharmacist is on the premises at all times and is fully aware of all activities performed by the pharmacy intern. A pharmacist who has accepted responsibility for the supervision and training of a pharmacy intern is responsible for all acts performed by the pharmacy intern working under their supervision.

### 4729-5-33 Examination application for registration licensure as pharmacist.

(A) Every person desiring to apply to take the examinations for registration <u>licensure</u> as a pharmacist shall submit the required application materials and fees to the national association of boards of pharmacy 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 (2x2 inches) taken within the previous six months;

(3) Required fee;

(4) A certificate of education completed and certified by an approved school of pharmacy pursuant to rule  $\underline{4729-5-07}$  of the Administrative Code documenting the successful graduation of the applicant with a doctor of pharmacy degree obtained after December 31, 2006; or

(5) All items in paragraphs (A)(1) to (A)(3) of this rule, one thousand five hundred the required hours of supervised practical experience pursuant to paragraph (A)(2) of rule 4729-3-05 of the Administrative Code; and

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

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule <u>4729-5-34</u> of the Administrative Code.

(B) The state board of pharmacy may make an applicant eligible to take the examinations as soon as the board receives all the required items set forth in paragraphs (A)(1) to (A)(3) and paragraph (A)(4) or (A)(5) of this rule.

(C) The state board of pharmacy may, pursuant to rule  $\frac{4729-5-04}{4729-5-04}$  of the Administrative Code, deny admission to the licensure examination.

### 4729-5-31 Criteria for licensure by examination.

(A) Pursuant to sections 4729.07 and 4729.13 of the Revised Code regarding pharmacist licensure by examination:

(1) The examination shall consist of the "North American Pharmacist Licensure Examination (NAPLEX)" and the Multistate Pharmacy Jurisprudence Examination (MPJE). a jurisprudence examination compiled by the state board of pharmacy or the "National Association of Boards of Pharmacy (NABP)."

(2) The minimum passing score is seventy-five on each exam.

(a) Any candidate who fails to receive a 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 score of seventy-five on the <u>MPJE jurisprudence</u> 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 <u>his/her</u> <u>the candidate's</u> 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 <u>4729.08</u> of the Revised Code regarding graduates of unapproved schools or colleges of pharmacy located outside the United States and who are using an approved examination to establish equivalency of their education, the candidate shall:

(1) Obtain a score 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 <u>4729-5-34</u> of the Administrative Code.

(D) Any examination candidate who fails to take both of the required examinations <u>pursuant to</u> <u>paragraph (A) of this rule</u> 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 state board of pharmacy, as the original application shall be deemed abandoned pursuant to rule 4729-9-01 of the Administrative Code.

(E) The record of the passing score for an examination candidate who takes both of the required examinations <u>pursuant to paragraph (A) of this rule</u>, 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 Ohio jurisprudence examination <u>MPJE</u> within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.

(G) Pursuant to section <u>4729.071</u> of the Revised Code and rule <u>4729-5-12</u> of the Administrative Code a candidate must submit electronic <u>or ink</u> fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. An examination candidate must submit fingerprint impressions no later than twelve months after the date the board receives the application materials or the scores obtained on <u>the NAPLEX and/or MPJE</u> will be denied. After twelve months, a candidate must submit a new application, the required fee, fingerprint impressions, and new examination scores.

(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 pursuant to this rule.

#### 4729-3-01 Definitions.

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

(A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

(B) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of an internship program.

(1) A "preceptor" is a pharmacist who holds a current identification card license to practice <u>pharmacy</u> which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship licensing pursuant to paragraph (C) of rule <u>4729-3-05</u> of the Administrative Code. <u>A preceptor shall have at least one year of practice experience as an Ohio licensed pharmacist.</u>

(2) A person may serve as the preceptor for more than one intern.

 $(\underline{3})$  The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty unless otherwise approved by the board.

(<u>4</u>) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship licensing.

(C) "Director of internship" has the same meaning as provided in section <u>4729.11</u> of the Revised Code.

(C) "In good standing" means that the preceptor has not been denied the privilege of supervising interns by the board, is in compliance with all applicable federal, state, and local regulations, is not the subject of an investigation or disciplinary action by any agency of the federal, state, or local government and has not been denied a license, registration or certificate or has a license, registration or certificate limited, suspended, or revoked by any public agency or licensing agency.

(D) "Statement of Preceptor" is a form provided by the state board of pharmacy that identifies the preceptor and internship site for a pharmacy intern.

(E) "Practical Experience Affidavit" is a form provided by the state board of pharmacy used to submit evidence of practical experience for internship credit pursuant to rule 4729-3-06 of the Administrative Code.

(F) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy <u>pursuant to rule 4729-5-07 of the Administrative Code</u>.

#### 4729-3-02 Registration Licensure as a pharmacy intern.

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

(B) If a person is actively working towards the requirements for licensure as a pharmacist and desires to work as a pharmacy intern in Ohio, <u>the person he/she-must</u>:

(1)

(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; or

(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 Spoken English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule <u>4729-5-34</u> of the Administrative Code.

(2) Submit electronic fingerprint <u>or ink</u> impressions for a criminal records check pursuant to section  $\frac{4729.071}{1000}$  of the Revised Code and rule  $\frac{4729-5-12}{1000}$  of the Administrative Code.

(3) Apply to the state board of pharmacy for <u>licensure registration</u> as a pharmacy intern.

#### 4729-3-03 Application for registration licensure as a pharmacy intern.

(A) Every person desiring to register seeking a license as a pharmacy intern for the purpose of obtaining the practical experience required for examination and registration 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 <u>http://www.pharmacy.ohio.gov;</u>

(2) A head and shoulders <u>passport size</u> photograph  $(2 \times 2 \text{ inches})$  taken within the previous six months;

(3) Fee;

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

(5) Documentation, in a manner prescribed by the board, from a school of pharmacy certifying that the person is <u>currently</u> enrolled in a school of pharmacy and has begun taking professional classes directly related to the practice of pharmacy; or

(6) All items listed in paragraphs (A)(1) to (A)(3) of this rule and:

(a) 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

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule <u>4729-5-34</u> of the Administrative Code.

(B) The state board of pharmacy may register <u>license</u> an applicant as a pharmacy intern as soon as the state board of pharmacy receives all the required items set forth in paragraphs (A)(1) to (A)(5) or paragraph (A)(6) of this rule.

(C) The state board of pharmacy may, pursuant to rule  $\frac{4729-5-04}{1000}$  of the Administrative Code, deny the issuance of a certificate of registration or an identification card license to practice as a pharmacy intern.

#### 4729-3-04 Pharmacy intern identification card-license renewal and expiration.

A pharmacy intern may renew <u>their his/her identification card license</u> each year provided <u>he/she</u> is <u>they are</u> actively working toward the requirements for licensure as a pharmacist and otherwise meets the requirements and rules of the state board of pharmacy. The state board of pharmacy may, pursuant to rule <u>4729-5-04</u> of the Administrative Code, deny the issuance of <u>a</u> an identification card license to practice pharmacy as an intern.

(A) An intern shall be considered to be actively working towards licensure as a pharmacist if he/she they have has complied with all of the statutes and rules regarding internship since registration licensure as a pharmacy intern, and:

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

(2) He/she The intern is is a member of the armed forces and can provide evidence that he/she they have has been accepted for enrollment in a school of pharmacy upon his/her their release from the armed forces; or

(B) 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 <u>his/her\_their</u> license only once. In the event of extraordinary circumstances and when due to no fault of the intern, the board may approve additional renewals.

#### ADD RULE 4729-3-09:

(C) When a candidate Upon receives receiving an initial license his/her first identification card to practice as a pharmacist, his/her the candidate's license registration as a pharmacy intern terminates.

(D) A pharmacy intern, other than a graduate pharmacist intern, must immediately notify his/her the state board of pharmacy, their current employer and any subsequent employer where practicing as a pharmacy intern within seventy-two hours if he/she they are is-no longer enrolled in a school of pharmacy. The person should shall immediately return his/her their pharmacy intern certificate and pocket identification card to the state board of pharmacy within ten days of notifying the board.

RESCIND 4729-3-09

#### 4729-3-05 Internship credit.

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

(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 <u>pursuant to rule 4729-5-07 of the Administrative Code</u>; or

(2) Obtained a total of at least one thousand five hundred 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  $\frac{4729-3-06}{6}$  of the Administrative Code; or

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

(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 Spoken English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule <u>4729-5-34</u> 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 internship licensing for approval prior to beginning the experience in these areas. The request shall include a detailed description of the contemplated 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 4729-3-06 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 rule 4729-5-04 of the Administrative Code. to be guilty of violation(s) pursuant to section  $\frac{4729.16}{Code}$  of the Revised Code.

#### 4729-3-06 Statement of preceptor and practical experience affidavit.

(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 occurrence 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) If an intern has graduated after December 31, 2006 without obtaining 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, the intern must obtain one thousand five hundred hours of supervised practical experience, pursuant to paragraphs (A)(2), (B), and (C) of rule <u>4729-3-05</u> of the Administrative Code, to satisfy the requirement to take the examinations. The intern is responsible for submitting the following required forms to certify the hours hour and supervision requirements pursuant to rule 4729-3-05 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 <u>an</u> 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 <u>he/she</u> <u>the intern</u> changes internship sites and/or preceptors. <u>The form must be submitted within thirty days of a change of internship site and/or preceptor.</u>

(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 reasonable notice.

(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 the board office or postmarked no later than the first day of March of the following year.

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

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

### 4729-5-32 Criteria for licensure by reciprocity.

(A) Pursuant to section <u>4729.09</u> of the Revised Code:

(1) Certification that the credentials of an applicant for registration without examination, filed with the board of the state with which he/she holds a certificate of good standing, are at least the equivalent of those then required by the Ohio board, shall be filed on forms provided by the "National Association of Boards of Pharmacy" or similar forms recognized and approved by the board of pharmacy.

(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) Be of good moral character and habit.

(3) Obtained a degree in pharmacy from a school of pharmacy approved by the state board of pharmacy pursuant to rule 4729-5-07 of the Administrative Code;

(4) 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 pursuant to rule 4729-5-07 of the Administrative Code; 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.

(5) 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 by the National Association of Boards of Pharmacy (NABP) or similar forms recognized and approved by the board of pharmacy.

(<u>B</u>) An applicant who has met the requirements of the state <u>or jurisdiction</u> with which <u>he/she the</u> <u>applicant holds</u> 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 <del>Spoken</del>

English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729-5-34 of the Administrative Code.

(<u>C</u>) 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, <u>as the original application shall be deemed abandoned pursuant to rule 4729-9-01 of the Administrative Code.</u>

(D) Pursuant to section 4729.071 of the Revised Code and rule 4729-5-12 of the Administrative Code a candidate must submit electronic <u>or ink</u> 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 months after the date the board receives the application materials. After twelve months, a candidate must submit a new application, the required fee, fingerprint impressions, and again personally appear before the board as described in this paragraph (C) of this rule.