

8/8/2017

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.

New

- 4729:2-4-02: Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules.
- 4729:2-4-01: Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns.
- 4729:2-2-08: Establishes the requirements for when and how a pharmacy intern should notify the Board of Pharmacy of a change to their license.
- 4729:2-2-09: Establishes the process by which a pharmacy intern shall renew their license with the Board of Pharmacy.
- 4729:2-2-10: Allows for pharmacy interns with an expired license to be granted renewal contingent upon their service, or the service of a spouse, in the armed forces.

Rescinded

- 4729-5-04: Establishes the violations that may lead to the denial or discipline of a pharmacist or intern license.

Comments on the proposed rules will be accepted until close of business on August 28, 2017.

Please send all comments to the following email address:

Cameron.mcnamee@pharmacy.ohio.gov

In addition, please copy your comments to:

CSIPublicComments@governor.ohio.gov

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Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Pharmacy interns

Rule Number(s): New: 4729:2-4-02; 4729:2-4-01; 4729:2-2-08; 4729:2-2-09; 4729:2-2-10

Rescinded: 4729-5-04

Date: 8/8/2017

Rule Type:

New

5-Year Review

Amended

Rescinded

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.

New

- 4729:2-4-02: Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules.
- 4729:2-4-01: Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns.
- 4729:2-2-08: Establishes the requirements for when and how a pharmacy intern should notify the Board of Pharmacy of a change to their license.

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- 4729:2-2-09: Establishes the process by which a pharmacy intern shall renew their license with the Board of Pharmacy.
- 4729:2-2-10: Allows for pharmacy interns with an expired license to be granted renewal contingent upon their service, or the service of a spouse, in the armed forces.

Rescinded

- 4729-5-04: Establishes the violations that may lead to the denial or discipline of a pharmacist or intern license. <http://codes.ohio.gov/oac/4729-5-04v1>

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

The proposed rules are authorized by sections 4729.26 and 4729.10 of the Ohio Revised Code.

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?

These 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 the practice of pharmacy has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice of pharmacy includes the adoption of licensing standards for pharmacy interns.

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 Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 4729.10 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules requiring a licensee or registrant to report to the board a violation of state or federal law.

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 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 various 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?

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

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

- Pharmacy interns.

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

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

c. Quantify the expected adverse impact from the regulation.

New

- 4729:2-4-02: Establishes the requirements for when and how pharmacy interns should notify the Board of Pharmacy of violations of Ohio laws and rules. This rule will require the reporting of suspected violations to the Board. The suspected violations may be reported using the Board's online compliant form, which takes approximately 10-15 minutes per submission.
- 4729:2-4-01: Establishes the scope of disciplinary actions the Board of Pharmacy may impose on pharmacy interns. Disciplinary action may result in a fine of up to \$500 per violation as well as other actions listed in question 14b of this rule.
- 4729:2-2-08: Establishes the requirements for when and how a pharmacy intern should notify the Board of Pharmacy of a change to their license. The regulation includes a reporting requirement. This requirement takes approximately 5-10 minutes to submit the necessary one-page form.
- 4729:2-2-09: Establishes the process by which a pharmacy intern shall renew their license with the Board of Pharmacy. Pharmacy interns must pay \$22.50 to renew their license (fee in statute) and submit a renewal application that takes approximately 30 minutes to complete.
- 4729:2-2-10: Allows for pharmacy interns with an expired license to be granted renewal contingent upon their service, or the service of a spouse, in the armed forces. Pharmacy interns to which this rule applies must submit proper documentation to renew their license, which can take approximately 30 minutes to complete.

Rescinded

- 4729-5-04: Establishes the violations that may lead to the denial of a pharmacist or intern license. This rule is being replaced by rule 4729:2-4-01. The regulation should have no adverse impact as it is being rescinded.

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 protect and promote public safety by ensuring uniform licensing, reporting and discipline standards for pharmacy interns.

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 to renew a license, report a suspected violation or comply with state laws and rules by a pharmacy intern 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, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:2-4-02 – Duty to Report

(A) As used in this rule:

(1) “Error in dispensing” or “prescription error” means an act or omission of clinical significance relating to the dispensing of a drug. An error in dispensing is considered a violation of division (A)(2) of section 3715.52 and section 3715.64 of the Revised Code.

(B) Pursuant to section 4729.10 of the Revised Code, a pharmacy intern who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the Board.

(C) The following shall be reported to the Board:

(1) Except as provided in paragraph (C)(1)(a) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacy intern shall not be required to report in accordance with this rule if the intern becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The intern’s treatment of the individual for the condition; or

(ii) The intern having access to the individual’s protected health information.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate or aid and abet in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925. and 2913. of the Revised Code, or any rule adopted by the board under those provisions by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule 4729:2-4-01 of the Administrative Code.

(D)

(1) Pursuant to section 4729.23 of the Revised Code, the identity of the pharmacist making a report under paragraph (C) of this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (C)(1) of this rule, a pharmacist may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing they were the reporting individual.

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(E) Reporting required in accordance with paragraph (C) this rule shall be made in writing, either by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

- (1) The name of the licensee or registrant or other individual in violation;
- (2) The violation which is believed to have occurred; and
- (3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacy intern shall notify the board of any of the following:

- (1) Any criminal conviction within ten days after the date of conviction, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light and failure to use a turn signal or expired vehicle registration.
- (2) Convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.
- (3) Granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.
- (4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacy intern shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) An error in dispensing shall not be required to be reported to the board in accordance with this rule.

(I) Pursuant to rule 4729.10 of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with paragraph (C) of this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

4729:2-4-01 – Disciplinary Actions

(A) As used in this rule:

(1) “Dishonesty” means any action by a licensee or registrant to include, but is not limited to, making any statement intended to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) “Unprofessional conduct” means conduct unbecoming of a licensee or registrant, or conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual advances, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacy intern if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacist:

(a) Has been convicted of a felony, or a crime of moral turpitude, as defined in section [4776.10](#) of the Revised Code;

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy;

(c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist or pharmacy intern unfit to practice pharmacy;

(d) Has been convicted of a misdemeanor related to, or committed in, the practice of pharmacy;

- (e) Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections [3715.52](#) to [3715.72](#) of the Revised Code, Chapter 2925., 3796. or 3719. of the Revised Code, or any rule adopted by the board under those provisions;
- (f) Knowingly lent the pharmacy intern's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy;
- (g) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home;
- (h) Committed fraud, misrepresentation, or deception in applying for or securing a license by the board under this chapter or under Chapter 3715. or 3719. of the Revised Code;
- (i) Failed to comply with an order of the board or a settlement agreement;
- (j) Committed acts that constitute moral turpitude as defined in section [4776.10](#) of the Revised Code or gross immorality;
- (k) Violated any state or federal law, regulation or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration;
- (l) Has been disciplined by the Ohio state board of pharmacy pursuant to section [4729.16](#) of the Revised Code;
- (m) Has been disciplined by any professional licensing board; or
- (n) Failed to conform to prevailing standards of care of similar pharmacy interns under the same or similar circumstances, whether or not actual injury to a patient is established.

(NOTE: RESCIND 4729-5-04): <http://codes.ohio.gov/oac/4729-5-04v1>

4729:2-2-08 Pharmacy intern change of name, address or employment.

(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.

(B) Requests for a duplicate wall certificate shall be issued in the 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 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.

4729:2-2-09 – Pharmacy intern licensure and renewal.

(A) Upon the effective date of this rule:

(1) 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 pharmacist until the next annual renewal date.

(2) A pharmacy intern license shall be renewed annually on the fifteenth day of September.

(3) An individual who fails to renew the pharmacy intern's license by the fifteenth day of September shall not engage in the practice of pharmacy until a valid license is issued by the board.

(4) In accordance with section 4729.15 of the Revised Code, the annual renewal fee shall be twenty-two dollars and fifty cents.

(B) Effective May 1, 2019:

(1) Except as provided in paragraph (B)(2) 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.

(2) 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.

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

(4) An individual who fails to renew the pharmacy intern's license by the fifteenth day of September of every odd-numbered year shall not practice as a pharmacy intern until a valid license is issued by the board.

(5) In accordance with section 4729.15 of the Revised Code, the renewal fee shall be forty-five dollars.

(C) Paragraph (A) of this rule is no longer applicable effective May 1, 2019.

(D) A license of a pharmacy intern that has graduated from an approved school of pharmacy may only be renewed once.

(1) The license shall only be valid for one year.

(2) The one-year license fee shall be twenty-two dollars and fifty cents.

4729:2-2-10 – Veteran and military family provisions related to pharmacy intern licensure.

(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 the length of that 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) Upon receipt of all required documentation and when applicable, a pharmacy intern license shall be issued no later than three business days of the applicant's eligibility for licensure, to each applicant who is a veteran, spouse or surviving spouse of a veteran.

(C) 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.