

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Pharmacy Interns / Continuing Education

Rule Number(s): Amended: 4729-3-03; 4729-7-02; 4729-7-03;

No Change: 4729-7-07; 4729-7-08

Date: 2/6/2014

Rule Type:

New
✓ Amended

✓ 5-Year Review
Rescinded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.

This rule package pertains to application requirements for pharmacy interns as well as continuing education requirements for pharmacists and education providers.

Proposed Rule Changes

- **4729-3-03:** Removes the requirement that a pharmacy intern submit an original transcript when applying for a license.

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- **4729-7-02:** Changes the submission date for pharmacist continuing education requirements from March 1st to September 15th.
- **4729-7-03:** Removes the requirement that a pharmacist submit original continuing education documentation.

No Change Rules

- **4729-7-07:** Permits the Board of Pharmacy to revoke or suspend the status of a continuing education provider.
- **4729-7-08:** Allows a pharmacist to demonstrate the completion of continuing education requirements by presenting evidence of pharmacy practice specialty certification.

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

The proposed rule is authorized by section 4729.26 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.08, 4729.11, 4729.12 and 4729.13.

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 rule does 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 pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice, including admission to practice, standards of practice, continuing education requirements and the discipline of pharmacists and pharmacy interns. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy traditionally has been left to state boards.

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)?

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Section 4729.26 of the Ohio Revised Codes authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy. The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of the Ohio Revised Code to promote the public's safety. In the absence of these rules, there would be no uniform criteria for application as a pharmacy intern or submission of continuing education for registered pharmacists. In addition, this section of rule is necessary to provide the Board of Pharmacy the authority to revoke or suspend the status of a continuing education provider to ensure quality continuing education for pharmacists.

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 were reviewed and approved by the Ohio State Board of Pharmacy's Rules Review Committee. The committee comprised a broad array of stakeholders including:

- OhioHealth
- Trumbull Memorial Hospital
- Kroger
- Hock's Pharmacy
- Northeast Ohio Medical University
- Nationwide Children's Hospital
- Giant Eagle
- Absolute Pharmacy
- St Ann's Hospital
- Akron General
- Cedarville University, School of Pharmacy

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

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For the proposed rule changes (4729-3-03; 4729-7-02; 4729-7-03), the Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback from the committee was incorporated into the rule package.

For the no change rules (4729-7-07; 4729-7-08), the Ohio State Board of Pharmacy Rules Review Committee reviewed the current regulations as part of the mandated 5-year rule review process. No additional changes to the rules were recommended.

Following the approval of the package by the Rules Review Committee, the Ohio State Board of Pharmacy formally approved the rules.

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. However, input was solicited from registered pharmacists through the Board's Rules Review Committee representing health systems, hospitals and retail practice.

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 pharmacists and pharmacy interns adhere to uniform regulations, the Ohio State 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 for intern applications and continuing education requirements. At this juncture, it was the determination of the Board's Rule 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?

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The Board of Pharmacy's Director of Legal Affairs reviewed the Ohio Administrative Code to ensure that these regulations do not duplicate an existing Ohio 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 rule 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 quarterly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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 rules primarily impact pharmacists, pharmacy interns and continuing education providers.

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

Discipline might include reprimand, imposition of a fine, and suspension of a license and/or revocation of a license. Additional adverse impacts include fees for individuals seeking licensure as pharmacy interns, costs to obtain continuing education credits, and lost revenue for revocation of provider status for continuing education.

c. Quantify the expected adverse impact from the regulation.

The rules have the following adverse impact:

4729-3-03: Removes the requirement that a pharmacy intern submit an original transcript when applying for a license. This will result in a cost savings to the pharmacy intern, as they will not be required to mail original documentation. The cost of registering as a

pharmacy intern in Ohio is \$22.50. In addition, this rule requires an application which could take between 30 – 60 minutes to complete.

4729-7-02: Changes the submission date for pharmacist continuing education units from March 1st to September 15th. This change could result in some efficiency gains for registered pharmacists as they will only be required to submit information to the board on one date rather than two dates.

The rule in general requires pharmacists to submit an annual licensure fee of \$97.50 for renewal. The average time to complete the renewal application is 20 minutes.

4729-7-03: Removes the requirement that a pharmacist submit original continuing education documentation. This will result in a cost savings to registered pharmacists, as they will not be required to mail original documentation.

The rule in general requires pharmacists to submit evidence of 60 hours of continuing education every three years. While low cost and no-cost credit is available, one source cites \$30 as the average cost per continuing education credit.

4729-7-07: Permits the Board of Pharmacy to revoke or suspend the status of a continuing education provider. This is a continuation of an existing rule. If a continuing education provider's approval is revoked, it could result in a loss of revenue to that provider.

4729-7-08: Allows a pharmacist to demonstrate the completion of continuing education requirements by presenting evidence of pharmacy practice specialty certification. This is a continuation of an existing rule. This allows a pharmacist the flexibility to obtain specialty certification (for example, Board Certified Pharmacotherapy Specialist) to meet their continuing education requirements. The cost of a BCPS certification is \$600 for an initial exam and \$100 for annual recertification.¹ However, pharmacists can obtain low-cost or no-cost continuing education units from approved providers throughout Ohio, including the Ohio State Board of Pharmacy.

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

The Ohio State Board of Pharmacy is committed to ensuring that pharmacists obtain continuing education in order to adhere to standards that protect the health and safety of all Ohioans. In

¹ <https://www.bpsweb.org/apply/fees.cfm>

addition, the Board is moving towards compliance methods that minimize paper records in favor of electronic systems.

Regulatory Flexibility

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

This rule package does not provide any exemptions or alternative means of compliance for small businesses. The law applies to all pharmacists, pharmacy interns and continuing education providers who wish to practice pharmacy or provide continuing education in the state of 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 Ohio State 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 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 staff members are available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek an update 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.

**4729-3-03 APPLICATION FOR REGISTRATION AS A PHARMACY INTERN
(PROPOSED CHANGE)**

- (A) Every person desiring to register as a pharmacy intern for the purpose of obtaining the practical experience required for examination and registration as a pharmacist shall submit the following to the state board of pharmacy:
- (1) A completed application form as provided by the board;
 - (2) A head and shoulders photograph taken within the previous six months;
 - (3) Fee;
 - (4) ~~An original transcript certifying~~ **Documentation, as determined by the state board of pharmacy,** that the applicant has in fact successfully completed a minimum of sixty semester or ninety quarter hours of college work; and
 - (5) A certificate of enrollment from a school of pharmacy certifying that the person is 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 4729-5-34 of the Administrative Code.
- (B) The state board of pharmacy may register 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 4729-5-04 of the Administrative Code, deny the issuance of a certificate of registration or an identification card to practice as a pharmacy intern.

4729-7-02 REQUIREMENTS FOR RENEWAL OF A PHARMACIST IDENTIFICATION CARD (PROPOSED CHANGE)

- (A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of six C.E.U.s of approved continuing education shall be submitted by the date indicated on the continuing pharmacy education report form and at intervals. At least 0.3 C.E.U.s of the total required

C.E.U.s must be obtained from Ohio state board of pharmacy approved programs in jurisprudence.

(B) Documentation of the required C.E.U.s shall be submitted on forms provided by the state board of pharmacy.

(C) The C.E.U.s must be obtained ~~on or after March first of the year that is within a period of time that is no more than~~ three years prior to ~~May~~ September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. A pharmacist shall be subject to further action of the board if the continuing pharmacy education report forms are not filed by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete. If reporting continuing 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.

(D) C.E.U.s obtained in excess of the required C.E.U.s at the time the continuing education is required for identification card renewal, may not be transferred and applied to future requirements.

(E) For the first three C.E.U. reporting years following the adoption of this rule, the board may accept C.E.U.s within a period of time from March first, three years prior to September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal.

(E E) A pharmacist whose identification card has lapsed or has been suspended may renew his/her identification card, if he/she qualifies for renewal pursuant to section 4729.12 or section 4729.13 of the revised Code, by paying the required fee, completing the application for renewal, and, if he/she would have been required to report continuing pharmacy education during the period of lapse or suspension, by providing evidence of having obtained the number of C.E.U.s required at the time of renewal by submitting the certificates of participation obtained during the three-year period immediately preceding the date of applying for renewal.

(F) Ohio-registered 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 do not practice pharmacy in Ohio, may renew their identification card by paying the required fee, completing the application for renewal, and submitting the following signed statement on their continuing pharmacy education report form:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, number (insert license number), in the state of (insert name of state), that I have met the continuing pharmacy education requirements of this state and I do not presently practice pharmacy in the state of Ohio. I hereby agree to immediately notify the Ohio state board of pharmacy if I return and commence the practice of pharmacy in the state of Ohio."

(G) The state board of pharmacy may grant extension periods and waivers for the completion of license renewal and continuing education requirements for active military

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service members and their spouses. 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. A pharmacist seeking an extension period or waiver must provide documentation to the board demonstrating active-duty service.

(H) If a pharmacist is a member of the armed forces, reserves, the Ohio National Guard, the Ohio military reserve, or the Ohio naval militia, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder when determining the fulfillment of any continuing education requirements.

4729-7-03 EVIDENCE OF CONTINUING PHARMACY EDUCATION EXPERIENCES **(PROPOSED CHANGE & 5-YEAR RULE REVIEW)**

- (A) Registered pharmacists shall keep all certificates and other documented evidence of participation which have been issued for approved C.E.U.s for which the pharmacist has claimed continuing education units towards renewal of his/her Ohio registered pharmacist identification card for a period of one year following the year in which evidence was required for renewal.
- (B) ~~The original certificates or documents~~ Documentation, as determined by the state board of pharmacy, shall be submitted to the state board of pharmacy only when requested by the board.
- (C) The board will monitor compliance by auditing a random sample of registrants each reporting period.

4729-7-07 PROBATION OR REVOCATION OF APPROVAL AS A PROVIDER (5-YEAR RULE REVIEW)

The board of pharmacy, upon receipt of evidence that any approved provider is presenting experiences not conforming to the requirements developed pursuant to rule 4729-7-06 of the Administrative Code, may place a provider on probationary status or revoke such approval.

4729-7-08 ALTERNATIVE METHODS OF PROVING CONTINUING COMPETENCY (5-YEAR RULE REVIEW)

- (A) As an alternative to providing evidence of all of the required C.E.U.S of approved continuing education as required by rule 4729-7-02 of the Administrative Code except for the 0.3 C.E.U.S of Ohio state board of pharmacy approved jurisprudence, a pharmacist may satisfy the continuing pharmacy education requirements by providing evidence at the time of renewal that he/she has met the requirements of and is currently certified by a board approved pharmacy practice specific specialty certification program. At a minimum, such pharmacy practice specific specialty certification programs shall consist of:

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- (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) Pharmacists who choose to meet their continuing pharmacy education requirements in the manner described in paragraph (A) of this rule are still required to provide evidence of having completed at least 0.3 C.E.U.S of Ohio state board of pharmacy approved pharmacy jurisprudence related continuing education.