

**9/6/2017**

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**

- 4729:3-5-03: Grants extension periods and waivers for the completion of continuing education requirements for active duty veteran members and their spouses.

Comments on the proposed rules will be accepted until close of business on September 22, 2017. Please send all comments to the following email address:

[Cameron.mcnamee@pharmacy.ohio.gov](mailto:Cameron.mcnamee@pharmacy.ohio.gov)

In addition, please copy your comments to:

[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

## Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Pharmacy Technician Continuing Education

Rule Number(s): New: 4729:3-5-03

Date: 9/6/2017

**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Rescinded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.

**New**

- 4729:3-5-03: Grants extension periods and waivers for the completion of continuing education requirements for active duty veteran members and their spouses.

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

The proposed rules are authorized by section 4729.26 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?**

This 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 practice of pharmacy has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice includes valid requirements for licensure as a registered pharmacy technician.

**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 5903.12 of the Ohio Revised Code requires the extension of continuing education reporting periods for licensees called to active duty military service.

**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 rule.

**Development of the Regulation**

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

The rule in this package was 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 rule was 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 rule, 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 licensure of registered pharmacy technicians, 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 rule 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 rule 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 rule.

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 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 rule package impacts the following:

- Pharmacy technicians.
- Spouses of pharmacy technicians.

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

This rule has an information reporting requirement if seeking an extension or requesting military training to meet continuing education requirements.

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

### **New**

- 4729:3-5-03: Grants extension periods and waivers for the completion of continuing education requirements for active duty veteran members and their spouses. Registered pharmacy technicians to which this rule applies must submit proper documentation to renew their license, which can take approximately 30 minutes to complete.

**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 the registered entity because documentation is necessary in order to prevent this exemption from being utilized inappropriately.

## **Regulatory Flexibility**

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

The rule does 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 complete continuing education requirements for a registered pharmacy technician 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.

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

(A) Extension of continuing education requirements.

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

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

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

(B) Determining fulfillment of continuing education.

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

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