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.

Amend

- 4729:3-2-02: Establishes criminal records check requirements for those seeking registration as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician.

Comments on the proposed rules will be accepted until close of business on July 26, 2019. Please send all comments to the following email address: Ali.Simon@pharmacy.ohio.gov

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

Agency Name: State of Ohio Board of Pharmacy
Agency Contact Info: Ali Simon (ali.simon@pharmacy.ohio.gov)
Regulation/Packet Title: Pharmacy Technicians
Rule Number(s): 4729:3-2-02

Date: 7/11/2019

Rule Type:
- [X] Amended
- [ ] New
- [ ] 5-Year Review
- [ ] Rescinded

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. 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. 
   Please include the key provisions of the regulation as well as any proposed amendments.

**Amend**
- 4729:3-2-02: Establishes criminal records check requirements for those seeking registration as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician. The rule is being amended to remove grandfathering provisions that are no longer applicable and to extend when a criminal records check is valid from 12 months to 24 months.

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

   The rule is authorized by sections 4729.26, 4729.94 and 4776.03 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? If yes, please briefly explain the source and substance of the federal requirement.

   This rule does not implement a federal requirement nor is it required to obtain/maintain federal approval.

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 pharmacy technician trainee, registered pharmacy technician, or certified 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 Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 4729.94 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules governing registration of registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.
Section 4776.03 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing administrative and procedural requirements for criminal records checks.

Without this regulation, the Board would not be able to provide uniform criminal records check requirements for pharmacy technician applicants.

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

The success of the regulation 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.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The Board posted the amended rule to its website for public comment on 5/17/2019. The rule was also distributed to the Board’s CSI stakeholder distribution list.

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

The Board did not receive any comments from stakeholders on the amended rule.

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 package.

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 rule is essential to protecting the public’s safety by ensuring uniform standards for pharmacy technician background checks, 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 registration processes for pharmacy technicians. At this juncture, it was the determination of the Board that the rule 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 regulation does 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 Board of Pharmacy’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. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board’s compliance staff 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, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy 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;
      Applicants for a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician registration.

   b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and
      Violation of this rule may result in the refusal to grant an applicant a pharmacy technician license. Additionally, the rule requires an applicant (or an applicant’s employer) to cover the cost of a BCI&I/FBI criminal records check. It should be noted that the extension of the timeframe to obtain a valid background check from 12 months to 24 months will reduce the overall adverse impact on those who must obtain a background check for a trainee registration and then apply for a registered/certified technician registration once they have completed their training.

   c. Quantify the expected adverse impact from the regulation.
      *The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

      Requires submission of criminal records checks for applicants. The cost of a criminal records check (BCI&I/FBI) includes the following fees: BCI&I - $22, FBI - $25.25, and some agencies may charge a processing fee (e.g. $5-$40).

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

   The Board believes that the regulatory intent of the proposed rule is necessary to protect the health and safety of all Ohioans by ensuring uniform rules for pharmacy technician applicants to obtain criminal records checks.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.
The 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 regulations are 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, failure to obtain a criminal records check in accordance with the rule (and as required by law) will prevent the issuance of a pharmacy technician registration.

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 and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations. The Board also posts information on compliance with all pharmacy technician registration requirements to its licensing website:

https://www.pharmacy.ohio.gov/Licensing/PTech.aspx
4729:3-2-02 Criminal records checks. (AMEND)

(A) An applicant seeking an initial registration as a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician must first submit fingerprint impressions to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check.

(B) Pursuant to section 4776.02 of the Revised Code, the criminal records check performed by BCI&I shall consist of both a BCI&I criminal records check and a federal bureau of investigation (FBI) criminal records check. BCI&I shall send the results of the BCI&I and FBI criminal records checks directly to the state board of pharmacy.

(C) The state board of pharmacy requires that the criminal records check:

(1) Be based on electronic fingerprint impressions that are submitted directly to BCI&I from a WebCheck provider agency or ink impressions. The state board of pharmacy may accept the results of a criminal records check based on ink impressions only in the following circumstances:

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

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

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

(D) Except as provided in paragraph (E) of this rule, results will only be considered valid if the fingerprint impressions were obtained within one year twenty-four months of the date the application is received by the board.

(E) Until April 6, 2019, an applicant for registration as a registered pharmacy technician or certified pharmacy technician who met the previous requirements to be a qualified pharmacy technician under section 4729.42 of the Revised Code, may satisfy the criminal records check requirements set forth in section 4729.90 of the Revised Code by either:

- Authorizing the superintendent of the bureau of criminal identification and investigation to make the results of a criminal records check of the applicant available to the state board of pharmacy. To meet the requirement, the criminal records check must have been conducted no earlier than twenty-four months prior to the date the application for registration is received by the board; or

- Submitting a copy of the results of the applicant's criminal records check that was performed by the applicant's employer to be a qualified pharmacy technician under section 4729.42 of the Revised Code to the state board of pharmacy. To meet the requirement, the criminal records check must have been conducted no earlier than twenty-four months prior to the date the application for registration is received by the board.