

7/5/2017

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

- 4729:2-2-03: Establishes criminal records check requirements for applicants seeking to become a pharmacy intern.
- 4729:1-2-05: Establishes criminal records check requirements for applicants seeking to become a pharmacist by examination or reciprocity.
- 4729-17-11: Creates guidelines for hospitals to own and operate a self-service kiosk for the pickup of new or refill prescriptions for hospital employees and their family members.

Rescinded

- 4729-5-12: Establishes criminal records check requirements for applicants seeking to become pharmacists by examination or reciprocity and pharmacy interns.

Comments on the proposed rules will be accepted until close of business on July 19, 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

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Criminal records check; prescription kiosks

Rule Number(s): New: 4729:2-2-03; 4729:1-2-05; 4729-17-11

Rescinded: 4729-5-12

Date: 7/5/2017

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Rescinded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

- 4729:2-2-03: Establishes criminal records check requirements for applicants seeking to become a pharmacy intern.
- 4729:1-2-05: Establishes criminal records check requirements for applicants seeking to become a pharmacist by examination or reciprocity.

- 4729-17-11: Creates guidelines for hospitals to own and operate a self-service kiosk for the pickup of new or refill prescriptions only for hospital employees and their family members.

Rescinded

- 4729-5-12: Establishes criminal records check requirements for applicants seeking to become pharmacists by examination or reciprocity and pharmacy interns.

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

The proposed rules are authorized by sections 4729.26, 4776.03 and 3719.28 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 includes valid requirements for licensure as a pharmacist or a pharmacy intern, and for dispensing dangerous drugs.

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 4776.03 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing administrative and procedural requirements for criminal records checks.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules regarding the form and content of records to be kept by persons authorized to manufacture,

distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

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?

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.

The committee provided the following input on rule 4729-17-11 of the Administrative Code, which was incorporated into the rule:

- Clarifying the definition of hazardous drugs.
- Removal of regular monitoring by hospital security staff.
- Reduction of the number of days' security footage must be maintained.

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 pharmacists and pharmacy interns as well as ensuring consistent dispensing of dangerous drugs, 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, 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;

The rule package impacts the following:

- Pharmacists;
- Pharmacy interns;
- Hospitals licensed as terminal distributors of dangerous drugs; and
- Terminal distributors of dangerous drugs owned by a hospital.

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, pharmacy intern or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New

- 4729:2-2-03: This regulation is identical to a regulation being rescinded. However, the rule requires FBI and Ohio Bureau of Criminal Identification and Investigation (BCI&I) background checks for pharmacy interns. The cost of this regulation includes the following fees: BCI&I - \$22, FBI - \$24, and some agencies may charge a processing fee (e.g. \$5-\$40).
- 4729:1-2-05: This regulation is identical to a regulation being rescinded. However, the rule requires FBI and Ohio Bureau of Criminal Identification and Investigation (BCI&I) background checks pharmacists. The cost of this regulation includes the following fees: BCI&I - \$22, FBI - \$24, and some agencies may charge a processing fee (e.g. \$5-\$40).
- 4729-17-11: This regulation allows for a new machine for dispensing, but does not require a license holder to add one to their facility. Those that choose to install a kiosk will have to ensure the kiosk has the proper security requirements, including video cameras. Furthermore, it requires any kiosk not on a hospital campus to be separately

licensed as a terminal distributor of dangerous drugs. The cost of the license ranges from \$112.50 to \$150.00 per year based upon the type of drugs contained in the kiosk.

Rescinded

- 4729-5-12: This regulation is being rescinded. Therefore, there will be 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 protect and promote public safety by ensuring uniform licensing standards. In addition, they support efforts to securely distribute dangerous drugs by automated kiosks.

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 drug destruction or the reporting of theft or significant loss 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.

4729:2-2-03 - Criminal records check for pharmacy interns.

(A) Pursuant to section [4729.071](#) of the Revised Code, an applicant seeking an initial license as a pharmacy intern 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 from a WebCheck provider agency only in the following circumstances:

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

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

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

(2) Results will only be considered valid if the fingerprint impressions were obtained within six months of the date the application is received by the board.

(D) If a pharmacy intern's license has lapsed for more than three years, the applicant shall submit to a criminal records check that meets the criteria prescribed in this rule.

4729:1-2-05 - Criminal records check for pharmacists

(A) Pursuant to section [4729.071](#) of the Revised Code, an applicant seeking an initial license as a pharmacist by examination or reciprocity 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 from a WebCheck provider agency only in the following circumstances:

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

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

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

(2) Results will only be considered valid if the fingerprint impressions were obtained within six months of the date the application is received by the board.

(D) If a pharmacist's license has lapsed for more than three years after the expiration of the card, the applicant shall submit to a criminal records check that meets the criteria prescribed in this rule.

RESCIND: 4729-5-12 Criminal records check for pharmacists and pharmacy interns.

4729-17-11 – Hospital Self-Service Employee Prescription Kiosks (NEW)

(A) As used in this rule:

(1) Hazardous drug means any dangerous drugs identified by at least one of the following criteria:

- (a) Carcinogenicity, teratogenicity, or developmental toxicity;
- (b) Reproductive toxicity in humans;
- (c) Organ toxicity at low dose in humans or animals;
- (d) Genotoxicity or new drugs that mimic existing HDs in structure or toxicity.

(2) “Self-service employee prescription kiosk” or “kiosk” means a self-service kiosk for the pickup of new or refill prescriptions only for hospital employees and their family members.

(B) A self-service employee prescription kiosk shall meet all the security requirements of this rule and be located either:

(1) On the campus of a hospital licensed as a terminal distributor of dangerous drugs and located in the immediate proximity of a pharmacy; or

(2) At a location that is licensed as a terminal distributor of dangerous drugs and owned by a hospital.

(C) Only a dangerous drug prescription dispensed by a hospital-owned pharmacy may be provided to the patient or employee representative of the patient via a self-service kiosk. A kiosk shall not provide any of the following:

(1) Any drug that must be refrigerated; or

(2) Any hazardous drug.

(D) A kiosk located in accordance with paragraph (B)(1) of this rule shall be placed either:

(1) In an area that is not in the proximity of any location where emergency or urgent care is provided; or

(2) An area that is restricted to hospital employees only that is secured by both a physical barrier with suitable locks and an electronic barrier to detect unauthorized entry.

(E) A kiosk located in accordance with paragraph (B)(2) of this rule shall be placed in an area that is restricted to hospital employees and is secured by both a physical barrier with suitable locks and an electronic barrier to detect unauthorized entry.

(F) All kiosks shall be continuously monitored by one or more video cameras that possess the capability of having its picture recorded. The video camera(s) shall provide 100 percent video coverage of the kiosk. Camera recordings shall be maintained for at least ninety days and shall be made available to an agent of the state board of pharmacy immediately upon request. The kiosk location must have adequate lighting to produce clear digitally recorded and still picture production.

(G) A kiosk located in accordance with paragraph (B)(1) of this rule shall only be stocked by a hospital employed pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician or qualified pharmacy technician.

(H) A kiosk located in accordance with paragraph (B)(2) of this rule shall only be stocked or under the direct supervision of the hospital employed pharmacist.

(I) A dispensing pharmacy described in paragraph (C) of this rule shall maintain an appropriate recordkeeping system in place that will provide accountability for proper receipt, delivery, disposal and return of all prescriptions provided to a patient or employee representative of the patient via a self-service kiosk.

(J) A kiosk shall employ a method of positive identification, as defined in rule 4729-5-01, other than a manual signature to identify a patient or employee representative of the patient such that a finished prescription is delivered from a kiosk only to its intended recipient.

(K) A kiosk must prominently display notification that patient counseling is available pursuant to rule 4729-5-22 of the Administrative Code. Counseling may be provided by a pharmacist reachable at a toll-free telephone number who has access to the patient profile. Instructions on how to contact a pharmacist via toll-free telephone must be displayed by the kiosk and must also be printed on the customer receipt or included with patient instructions.

(L) A self-service employee prescription kiosk shall meet all of the following:

- (1) Electronically protected against unauthorized access;
- (2) Be bolted to the floor or installed in a wall;
- (3) Be constructed in such manner as to prevent tampering, break-in and theft of inventory; and
- (4) Able to sound an alarm if break-in is attempted.

(M) Prior to the deployment of a kiosk, the responsible person at the location licensed as a terminal distributor of dangerous drugs shall test the kiosk to ensure that it releases drugs properly. The responsible person shall monitor performance of the kiosk on an ongoing basis and test the kiosk for accuracy whenever any change or upgrade is made.

(N) All drugs and devices in a kiosk shall be stored shall be dry, well-ventilated, and maintained in a clean and orderly condition. Kiosks shall be maintained at temperatures which will ensure the integrity of the drugs as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(O) Dangerous drugs stored in a kiosk that are not picked up by a patient may be returned to stock shelves in accordance with rule 4729-9-04 of the Administrative Code.

(P) Prior to the approval of a kiosk, the board shall receive a request from the responsible person on the terminal distributor of dangerous drugs license. Upon notification, the board shall conduct an inspection of the system to determine if it meets the requirements of this rule.

(Q) If an inspection does not result in the approval of a kiosk, the responsible person named on the terminal distributor of dangerous drugs may request an in-person meeting with the board to appeal the denial.