3/11/15

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 Ohio State 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New & Rescinded Rules

- **4729-5-23:** Provides clarification for a law change regarding diabetic shoe fitting by pharmacists (4779.02).
- **4729-5-38:** Rule addresses upcoming changes to the requirements of section 4729.41 of the Ohio Revised Code by: 1) specifying the types of immunizations that a pharmacist or pharmacist intern can administer; 2) outlines informed consent requirements; and 3) ensures compliance with federal law. These changes will take effect on 3/19/2015. The current rule will be rescinded.

Amended Rules

- **4729-5-36:** Updates the rule on physician adopted protocols for immunization administration to reflect upcoming changes to the requirements of section 4729.41 and includes a reference to the new OAC 4729-5-38. These changes will take effect on 3/19/2015.
- **4729-5-37:** Updates the rule on required training for pharmacist and pharmacy interns to administer immunizations to reflect upcoming changes to the requirements of section 4729.41 and includes a reference to the new OAC 4729-5-38. These changes will take effect on 3/19/2015.
- **4729-9-19:** Updates the rule to clarify that the Board may deny a license to an entity based upon an owner or employee's criminal record or any discipline from a professional licensing board.

Comments on the proposed rules will be accepted until close of business on March 27, 2015. Please send all comments to the following email address:
Cameron.mcnamee@bop.ohio.gov

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Pharmacists – Administrative Provisions & Violations as Evidence for Denial of License

Rule Number(s): New: 4729-5-23; 4729-5-38

Amended: 4729-5-36; 4729-5-37; 4729-9-19

Rescinded: 4729-5-38

Date: 03/11/2015

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Amended — Rescinded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.

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- **4729-5-37:** Updates the rule on required training for pharmacist and pharmacy interns to administer immunizations to reflect upcoming changes to the requirements of section 4729.41 and includes a reference to the new OAC 4729-5-38. These changes will take effect on 3/19/2015.
- **4729-9-19:** Updates the rule to clarify that the Board may deny a license to an entity based upon an owner or employee's criminal record or any discipline from a professional licensing board.

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

The proposed rules are authorized by sections 4729.26 and 4729.41 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.51 and 4779.02.

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 a pharmacist/pharmacy intern's scope of

practice and licensure of sites where dangerous drugs are stored. 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)?

Section 4729.26 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy, which includes a pharmacist's scope of practice and the regulation of entities that store dangerous drugs.

Section 4729.41 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules pertaining to the administration of immunizations by pharmacy professionals, including the types of immunizations that can be provided.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapters 4729 of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide uniform standards for the administration of immunizations by pharmacists and pharmacy interns.
- Ensure that pharmacists/pharmacy interns are able to provide the most up-to-date CDC ACIP recommended immunizations.
- Permit the Board to deny the license of a location that stores dangerous drugs, including controlled substances, based upon criminal actions of owners and employees.
- Ensure that pharmacists who fit diabetic shoes do so within their scope of practice.

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 of dangerous drugs 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 on February 20, 2015. The committee is comprised of a broad array of stakeholders including:

- Select Specialty Hospital – Akron
- Berger Health System
- The Kroger Company
- Meijer
- Nationwide Children's Hospital
- Fort Hamilton Hospital
- Central Ohio Compounding Pharmacy
- Healthspan Physicians and Integrated Care
- Cedarville University School of Pharmacy
- Fairview Hospital – Cleveland Clinic
- OhioHealth
- Wal-Mart
- Pharmacy Systems, Inc.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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 Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback from the committee 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 the 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 rules for immunization administration, diabetic shoe fitting and entities storing dangerous drugs, 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 Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Legal Affairs and Pharmacist Compliance Supervisor reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio State 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. 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 monthly 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 rule package impacts the following:

- Ohio licensed Pharmacists and Pharmacy Interns;
- Locations licensed as Terminal Distributors of Dangerous Drugs; and
- Locations licensed as Wholesale Distributors of Dangerous Drugs.

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, wholesale distributor of dangerous drugs or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- **4729-5-23:** Provides clarification for a law change regarding diabetic shoe fitting by pharmacists (4779.02). This should not have any adverse impact on pharmacist or pharmacy interns as it is a clarification of an upcoming change in the Ohio Revised Code.
- **4729-5-38:** Rule addresses upcoming changes to the requirements of section 4729.41 of the Ohio Revised Code by: 1) specifying the types of immunizations that a pharmacist or pharmacist intern can administer; 2) outlines informed consent requirements; and 3) ensures compliance with federal law. This rule is an update to an existing rule regarding pharmacist and pharmacy intern immunizations. Compliance with this rule may result in administrative and record keeping costs to pharmacies that provide immunizations to patients.
- **4729-5-36:** Updates the rule on physician adopted protocols for immunization administration to reflect upcoming changes to the requirements of section 4729.41 and includes a reference to the new OAC 4729-5-38. These changes will take effect on 3/19/2015. This rule is an update to an existing rule regarding pharmacist and pharmacy intern immunization administration. Compliance with this rule may result in administrative costs to pharmacies as they will need to update their protocols to reflect the addition of new immunizations that can be administered by pharmacists and pharmacy interns.
- **4729-5-37:** Updates the rule on required training for pharmacist and pharmacy interns to administer immunizations to reflect upcoming changes to the requirements of section

4729.41 and includes a reference to the new OAC 4729-5-38. These changes will take effect on 3/19/2015. The typical cost of an immunization course ranges from $229 - $349.

- **4729-9-19:** Updates the rule to clarify that the Board may deny a license to an entity based upon an owner or employee's criminal record or any discipline from a professional licensing board. This is a clarification of an existing rule and the amendment should not have any adverse impact on a regulated entity. However, the rule itself does allow the Board to deny a license to terminal or wholesale distributor of dangerous drug based upon criminal activity or professional licensure discipline, which would prevent the entity from conducting business in the state of Ohio.

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 believes that the regulatory intent of the proposed rules is necessary in order to protect the health and safety of all Ohioans by providing uniform regulations to ensure the following:

- Consistent standards for immunizations provided by pharmacists and pharmacy interns, as required by law;
- Clarity for pharmacist and pharmacy interns fitting diabetic shoes; and
- Clear standards for the denial of a terminal or wholesale distributor license for criminal or other administrative sanctions.

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 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 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.

4729-9-19 Violations as evidence for denial of terminal, wholesale, or manufacturer license.

(A) The state board of pharmacy may consider as evidence of a person not meeting the requirements provided in sections 4729.53 and 4729.55 of the Revised Code, and may deny a person registration as a wholesale distributor of dangerous drugs or licensure as a terminal distributor of dangerous drugs in Ohio if such person:

(1) Has been convicted of a felony;

(2) Has been convicted of violating any state or federal pharmacy or drug law;

(3) Is not of good moral character and habits;

(4) Is addicted to or abusing ~~liquor~~ alcohol or drugs;

(5) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or

(6) Has been disciplined by any professional licensing board.

(B) When a request for licensure as a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or as a wholesaler or manufacturer of controlled substances is made, the state board of pharmacy may consider as evidence of the facility not meeting the requirements for licensure as provided in Chapters 3719. and 4729. of the Revised Code, or may deny issuance of such licensure, if:

(1) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing board to the spouse or other family member;

(2) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing board to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed;

(3) The facility knowingly employs a person ~~if such an employee:~~ who: ~~has been denied the right to work in such a facility by the state board of pharmacy as part of an official order of the board;~~

(a) Has been denied the right to work in such a facility by the state board of pharmacy as part of an official order of the board;

(b) Has been denied the right to work in such a facility by another professional licensing board as part of an official order of that board;

(c) Has been convicted of a felony;

(d) Has been convicted of violating any state or federal pharmacy or drug law;

(e) Is not of good moral character and habits;

(f) Is addicted to or abusing alcohol or drugs;

(g) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or

(h) Has been disciplined by any professional licensing board.

(C) "Person" has the same meaning as in 4729.01(S) of the revised code and also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

4729-5-36 Protocols for the administration of immunizations.

(A) To be considered an approved protocol pursuant to division (B)(3) of section 4729.41 of the Revised Code, the physician-established protocol for the administration of immunizations must include at least the following:

(1) For each medication listed in division (A)(3) of section 4729.41 of the Revised Code and each immunization pursuant to rule 4729-5-38 of the Administrative Code:

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Appropriate dosage;

(e) Appropriate administration schedules;

(f) Appropriate routes of administration;

(g) Appropriate injection sites;

(2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation.

(3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(4) A method to notify an individual's physician or the applicable board of health within thirty days after administering medication, except for influenza immunizations administered to individuals eighteen years of age and older.

(5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations.

(B) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the administering pharmacist. The pharmacist must renew the protocol annually with the physician.

(C) Upon the request of the state board of pharmacy, a pharmacist shall immediately provide the protocols for immunizations pursuant to division (B)(3) of section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative Code. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it. The state board of pharmacy may review the protocols with the state medical board and the board of nursing, as appropriate.

4729-5-37 Course requirements in the administration of immunizations.

(A) A course in the administration of immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet at least the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.

(3) The course must be a minimum of five hours in length and include at least the following:

(a) A review of immunology that includes a discussion of the body's immune system reaction to the immunizations.

(b) A review of each medication listed in division (A)(3) of section 4729.41 of the Revised Code and each immunization pursuant in rule 4729-5-38 of the Administrative Code that includes the following:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Appropriate administration schedules;

(iv) Appropriate routes of administration;

(v) Appropriate injection sites;

(vi) Appropriate dosages;

(vii) Appropriate monitoring and treatment of the patient for adverse reactions, including the use of diphenhydramine and epinephrine;

(viii) Appropriate patient populations;

(ix) Precautions and contraindications;

(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(4) The course must provide a method to evaluate the successful mastery of the content.

(B) All courses in immunizations must be submitted to the state board of pharmacy for approval. The courses may be reviewed with the state medical board and the board of nursing, as appropriate. Any subsequent revisions to the course, after the initial approval, must be submitted to the state board of pharmacy for approval.

(C) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist who has not successfully completed a course in immunization administration that meets the requirements set forth in this rule, must complete a course that meets the requirements in this rule prior to the administration of any immunization listed in rule 4729-5-38 of the Administrative Code.

4729-5-38 Immunization administration.

Rescind current rule and replace with the following:

(A) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist may administer in accordance with section 4729.41 of the Revised Code the following:

(1) Any immunization that is included in either of the following immunization schedules (3/1/2015) recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services:

(a) The recommended immunization schedule for persons aged zero through eighteen years;

(b) The recommended adult immunization schedule.

(B) In addition to the immunizations listed in paragraph (A) of this rule, a pharmacist or pharmacy intern in accordance with section 4729.41 of the Revised Code, may administer the zoster vaccine according to the age criteria specified in the F.D.A. approved labeling.

(C) A pharmacist or pharmacy intern shall obtain informed consent to administer an immunization pursuant to paragraph (O) of rule 4729-5-27 of the Administrative Code.

(D) A pharmacist or pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 U.S.C. § 300aa-26 (3/1/2015).

(E) A pharmacist or pharmacy intern who engages in the administration of immunizations shall do so in accordance with rules 4729-5-36 and 4729-5-37 of the Administrative Code.

4729-5-23 Therapeutic Diabetic Shoes

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacist or pharmacy intern acting under the direct supervision of a pharmacist, may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist shall not provide any other services that are authorized under chapter 4779 of the Revised Code.