9/29/22

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:

- **4729:1-3-02:** Immunization administration.
- **4729:2-3-03:** Immunization administration by pharmacy interns.

Comments on the proposed rules will be accepted until close of business on October 21, 2022. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Kylynne Johnson
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Regulation/Package Title (a general description of the rules' substantive content):

Pharmacist and Intern Immunization Administration

Rule Number(s): 4729:1-3-02 (amend), 4729:2-3-03 (amend)

Date of Submission for CSI Review: 9/29/22

Public Comment Period End Date: 10/21/22

Rule Type/Number of Rules:

New/__rules
Amended/__2__rules (FYR? __)
No Change/___ rules (FYR? __)
Rescinded/____ rules (FYR? ___)

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 regulations that have an adverse impact on business 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.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   4729:1-3-02- Establishes the training requirements for a pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements. A course for vaccine administration costs up to $425.

   4729:2-3-03- Establishes the required training for a pharmacy intern under the direct supervision of a pharmacist to administer immunizations and outlines informed consent requirements. A course for vaccine administration costs up to $425.

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   Violation of these rules may result in administrative licensure discipline for a pharmacist and pharmacy intern. Discipline might include reprimand, continuing education, suspension of a license, monetary fine and/or revocation of a license.

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Pharmacies may experience administrative costs to ensure compliance with these rules.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

Amend:

- 4729:1-3-02: Establishes the training requirements for a pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements. Language is updated to reflect a recent change in the Ohio Revised Code (HB 6 – 134th General Assembly).
- 4729:2-3-03: Establishes the required training for a pharmacy intern under the direct supervision of a pharmacist to administer immunizations and outlines informed consent requirements. Language is updated to reflect a recent change in the Ohio Revised Code (HB 6 – 134th General Assembly).

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

The proposed rule is authorized by sections 4729.26 and 4729.41 of the Ohio Revised Code.

4. 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.

These rules do not implement a federal requirement.

5. 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, including interns, has traditionally been done at the state level by legislatively created state boards of pharmacy. Additionally, section 4729.41 of the Revised Code requires the Board to adopt rules regarding administration of vaccinations by pharmacists and pharmacy interns.

6. **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 4729.41 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the administration of immunizations by pharmacy professionals.

Without these regulations, the Board of Pharmacy would not be able to ensure uniform standards for pharmacists and pharmacy interns performing immunization administration.

7. **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.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **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.

This package was published on the Board's website for public comment.

10. **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 comments from its public stakeholder posting.

11. **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.

12. 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 the practice of pharmacy and distribution of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. 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 practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance - based regulations.

14. 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.

15. 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

16. 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; and

The rule package impacts the following:

- Pharmacists;
- Pharmacy Interns.

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

Violation of this rule may result in administrative licensure discipline for a pharmacist or pharmacy intern. Discipline might include reprimand, suspension of a license, continuing education, monetary fine and/or revocation of a license.

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.

Amend:

4729:1-3-02: Establishes the training requirements for a pharmacist to administer immunizations, allows a pharmacist to administer specific immunizations under a physician approved protocol, and outlines informed consent requirements. Language is updated to reflect a recent change in the Ohio Revised Code (HB 6 – 134th General Assembly). A course for vaccine administration costs up to $425. Additionally, pharmacists may incur costs relating to maintain their basic life support training.

4729:2-3-03: Establishes the required training for a pharmacy intern under the direct supervision of a pharmacist to administer immunizations and outlines informed consent requirements. Language is updated to reflect a recent change in the Ohio Revised Code (HB 6 – 134th General Assembly). A course for vaccine administration costs up to $425. Additionally, pharmacists may incur costs relating to maintain their basic life support training.

17. 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 rules is necessary to protect the health and safety of all Ohioans by providing uniform regulations for immunization administration.

Regulatory Flexibility

18. 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.

19. 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 distribution of dangerous drugs is not considered a paperwork error but a direct danger to the public health or safety.

20. 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.

Rule 4729:1-3-02 | Immunization administration. (AMEND)

(A) A course in the administration of immunizations developed pursuant to division (B)(1) of section 4729.41 of the Revised Code shall meet 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 shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

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

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

(b) A review of each immunization ~~authorized~~ **recommended by the committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (8/5/2022)** that includes the following:

(i) Disease states associated with the immunization;

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

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

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

(viii) Patient populations;

(ix) Precautions and contraindications; and

(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.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the participant has successfully completed the course.

(B) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(C)

~~(1) Pharmacists seeking to administer any immunization listed in paragraph (G) of this rule that was added after the completion of an initial immunization course shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:~~

~~(a) Disease states associated with the immunization;~~

~~(b) Type or nature of activity of the immunization;~~

~~(c) Administration schedules;~~

~~(d) Routes of administration;~~

~~(e) Injection sites;~~

~~(f) Dosages;~~

~~(g) Monitoring and treatment of the patient for adverse reactions;~~

~~(h) Patient populations;~~

~~(i) Precautions and contraindications; and~~

~~(j) Proper storage requirements for the immunization.~~

~~(2)~~ Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacist to discipline in accordance with rule 4729:1-4-01 of the Administrative Code.

(D) Pursuant to section 4729.41 of the Revised Code, a physician-established protocol for the administration of immunizations shall include the following:

(1) For each **immunization authorized:** ~~dangerous drug listed in paragraph (G) of this rule:~~

(a) Name and strength;

(b) Precautions and contraindications;

(c) Intended audience or patient population;

(d) Dosage;

(e) Administration schedules;

(f) Routes of administration; and

(g) 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 an immunization, 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.

(E) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.

(F) Upon the request of the state board of pharmacy, a pharmacist or terminal distributor of dangerous drugs shall immediately provide the protocols for immunizations. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist or terminal distributor for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has granted approval.

(G) A pharmacist may administer the following immunizations in accordance with section 4729.41 of the Revised Code and this rule:

(1) In the case of an individual who is seven years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:

(a) Influenza;

(b) COVID-19;

(c) Any other disease, but only pursuant to a prescription.

(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.

~~(1) Any immunization or vaccine that is included in either of the following schedules and is administered according to those schedules:~~

~~(a) The immunization schedule for persons aged zero through eighteen years 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 (1/15/2020).~~

~~(b) Except as listed in paragraph (G)(2) of this rule, the adult immunization schedule 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 (1/15/2020).~~

~~(2) The herpes zoster vaccine according to the age criteria specified in the United States food and drug administration's approved labeling.~~

~~(3) Except as provided in paragraphs (G)(4) and (G)(5) of this rule, any other immunization or vaccine 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 if administered in accordance with the recommendations adopted by the committee.~~

~~(4) The rabies vaccine for post exposure, if all the following are met:~~

~~(a) A pharmacist does not provide the initial dose of the rabies post exposure vaccine;~~

~~(b) Follow-up doses are administered pursuant to a prescription issued by a prescriber; and~~

~~(c) The follow-up doses are administered in accordance with recommendations adopted 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 (1/15/2020).~~

~~(5) The requirements listed in paragraph (G)(4) of this rule do not apply to the rabies vaccine for preexposure if administered in accordance with recommendations adopted 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 (1/15/2020).~~

~~(6) Any immunization to an individual eighteen years of age or older pursuant to a prescription if all the following apply:~~

~~(a) The pharmacist is authorized to administer the immunization pursuant to a physician-approved protocol established in paragraph (D) of this rule; and~~

~~(b) The pharmacist has the required training in accordance with this rule to administer the immunization.~~

~~(7) Any immunization approved by the United States food and drug administration for the prevention of COVID-19 in accordance with the limitations set forth in section 4729.41 of the Revised Code.~~

(H) A pharmacist shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(I) Immunization records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(J) A pharmacist shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

~~**(K) An immunization or vaccine specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:**~~

~~**(1) The immunization for influenza is administered to individuals who are seven years of age or older; or**~~

~~**(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.**~~

(**K**) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist shall notify the individual's ~~family physician~~ **primary care provider** or, if the individual has no ~~family physician~~ **primary care provider,** the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication; ~~or~~

(7) Reporting to the state's immunization registry; or

(**8**) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(L) A pharmacist administering immunizations in accordance with this rule shall receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(M) A pharmacist who completed a course in the administration of immunizations that complied with the training requirements in effect immediately prior to the adoption of this rule shall be deemed in compliance with division (B)(1) of section 4729.41 of the Revised Code.

(N) A pharmacist shall maintain the following records on file at the location(s) where the pharmacist administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (M) of this rule.

(O) As part of engaging in the administration of immunizations or supervising an individual authorized to administer immunizations, a pharmacist may administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the pharmacist or other authorized individuals under the supervision of the pharmacist.

Rule 4729:2-3-03 | Immunization administration by pharmacy interns. (AMEND)

(A) Pharmacy interns working under the direct supervision of a pharmacist may administer immunizations listed in paragraph (C) of this rule if an intern complies with the following:

(1) Successfully completes a course in the administration of immunizations that meets the requirements set forth in rule 4729:1-3-02 of the Administrative Code.

(2) Practices in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician that complies with the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Receives and maintains certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in-person or, at a minimum, offer an in-person training component.

(4) The supervising pharmacist has completed all of the training necessary to administer immunizations in accordance with rule 4729:1-3-02 of the Administrative Code.

(B)

~~(1) Pharmacy interns working under the direct supervision of a pharmacist seeking to administer any immunization listed in paragraph (C) of this rule that was added after the completion of an initial immunization course approved pursuant to rule 4729:1-3-02 of the Administrative Code shall, at a minimum, conduct a review of appropriate clinical resources to familiarize themselves with all the following prior to the administration of the immunization:~~

~~(a) Disease states associated with the immunization;~~

~~(b) Type or nature of activity of the immunization;~~

~~(c) Administration schedules;~~

~~(d) Routes of administration;~~

~~(e) Injection sites;~~

~~(f) Dosages;~~

~~(g) Monitoring and treatment of the patient for adverse reactions;~~

~~(h) Patient populations;~~

~~(i) Precautions and contraindications; and~~

~~(j) Proper storage requirements for the immunization.~~

~~(2)~~ Failure to adhere to the standard of care for administration of an immunization shall be considered a violation of this rule and may subject a pharmacy intern to discipline in accordance with rule 4729:2-4-01 of the Administrative Code.

(C) A pharmacy intern working under the direct supervision of a pharmacist may administer the same immunizations authorized for pharmacist administration **as authorized by section 4729.41 of the Revised Code and rule 4729:1-3-02 of the Administrative Code.** ~~listed in paragraph (G) of rule 4729:1-3-02 of the Administrative Code.~~

(D) A pharmacy intern shall obtain informed consent pursuant to rule 4729:5-5-04 of the Administrative Code to administer an immunization.

(E) A pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

~~(F) An immunization specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:~~

~~(1) The immunization for influenza is administered to individuals who are seven years of age or older; or~~

~~(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.~~

(~~G~~ **F**) For each immunization administered to an individual by a pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy intern shall notify the individual's ~~family physician~~**primary care provider** or, if the individual has no ~~family physician~~**primary care provider**, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication; ~~or~~

(7) Reporting to the state's immunization registry; or

(**8**) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(~~H~~ **G**) A pharmacy intern shall maintain the following records on file at the location(s) where the pharmacy intern administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (A)(1) of this rule; and

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (A)(3) of this rule.