



# Common Sense Initiative

Mike DeWine, Governor  
Jon Husted, Lt. Governor

Joseph Baker, Director

Comments on the proposed rules will be accepted until close of business on November 1, 2024. Please send all comments to the following email address:

[RuleComments@pharmacy.ohio.gov](mailto:RuleComments@pharmacy.ohio.gov)

In addition, please copy your comments to: [CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

## Business Impact Analysis

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

Rule Contact Name and Contact Information: Bella Blankenship  
[Isabella.blankenship@pharmacy.ohio.gov](mailto:Isabella.blankenship@pharmacy.ohio.gov)

Regulation/Package Title (a general description of the rules' substantive content):  
Immunization by Pharmacy Personnel

Rule Number(s): 4729:1-3-02, 4729:2-3-03, 4729:3-3-06

Date of Submission for CSI Review: 10/23/2024

Public Comment Period End Date: 11/8/2024

**Rule Type/Number of Rules:**

New/\_\_\_ rules

No Change/\_\_\_ rules (FYR? \_\_\_)

Amended/ 3 rules (FYR? Yes )

Rescinded/\_\_\_ rules (FYR?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

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

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

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

### **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.*

**Rule 4729:1-3-02 | Immunization administration:** Updated the rule to reflect upcoming changes to the statute that permit pharmacists to administer any vaccine to patients 5 years and older. Includes requirement that the importance of well-child visits must be emphasized for any vaccine administered to a patient 18 years and younger as is required by law. Adds BLS training program as offered by the American Safety and Health Institute as a Board-approved program.

**Rule 4729:2-3-03 | Immunization administration by pharmacy interns:** Includes requirement that the importance of well-child visits must be emphasized for any vaccine administered to a patient 18 years and younger as is required by law. Adds BLS training

program offered by the American Safety and Health Institute as a Board-approved program.

**Rule 4729:3-3-06 | Immunization administration:** Updated the rule to reflect upcoming changes to the statute that permit a certified or registered pharmacy technician to administer any vaccine to patients 5 years and older. Includes requirement that the importance of well-child visits must be emphasized for any vaccine administered to a patient 18 years and younger as required by statute. Adds BLS training program offered by the American Safety and Health Institute as a Board-approved program.

**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.*

N/A.

**5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

N/A these proposed regulations do not implement a federal requirement.

**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)?**

These rules are being proposed in response to the passage of Senate Bill 144 as passed by the 135<sup>th</sup> Ohio General Assembly.

**7. 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/registrant 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.*

N/A.

### **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.*

Prior to filing with CSI, these rules were distributed for public comment and were also reviewed and approved by the Board of Pharmacy.

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

Input was received with regards to concern that pharmacists, pharmacy interns, and certified/registered pharmacy technicians are able to administer immunizations, as well as provide caregivers with information on the importance of well-child visits. This input did not affect the draft regulation as these provisions are requirements of ORC 47291.41 (effective 10/24/24) and the Board of Pharmacy has a statutory requirement to incorporate such provisions into the rules.

**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 were not used to develop or review the rules.

**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?**

*Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the administration of immunizations by pharmacy personnel, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

**13. 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 other Ohio Board of Pharmacy regulations.

**14. 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 website, 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 from the Director of Policy and Communications, and feedback from the Board’s legal department for every citation submitted.

**Adverse Impact to Business**

**15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

- a. Identify the scope of the impacted business community, and**  
Pharmacies, pharmacists, pharmacy interns, and pharmacy technicians engaging in administration of immunizations.
  
- b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**  
*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.*

Provisions of the rules include several changes to the ability of pharmacy personnel to administer immunizations. When a patient under the age of 18 years old receives an immunization at a pharmacy, it is now required for the immunizer to inform their caregiver of the importance of well-child visits. This new requirement may marginally increase the amount of time spent with each patient and may result in some additional administrative costs but is not expected to impact pharmacy operations in any significant manner.

**16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve**

*readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

The Board now recognizes the basic life support (BLS) certification program offered by the American Health and Safety Institute (ASHI) as a Board-approved program that meets the requirement for pharmacy personnel to be able to administer immunizations.

**17. 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 regulation protects and promotes public safety by ensuring uniform administration of immunizations to protect the public's health.

**Regulatory Flexibility**

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

This rule package does not provide any exemptions or alternative means of compliance for small businesses when it comes to the handling or destruction of controlled substance medications. 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 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 pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

**20. What resources are available to assist small businesses with compliance of the regulation?**

Board of Pharmacy staff are 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.

**Rule 4729:1-3-02 | Immunization administration by pharmacists. (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 recommended by the **advisory** committee on immunization practices of centers for disease control and prevention in the United States department of health and human services ~~(8/5/2022)~~ **(6/28/2024)** 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;

**77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117**

**CSIPublicComments@governor.ohio.gov**

- (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) 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:
    - (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 a~~ pharmacy intern, **certified pharmacy technician or registered pharmacy technician** 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, **certified pharmacy technician or registered pharmacy technician** 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 primary care provider 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, **certified pharmacy technician or registered pharmacy technician** 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 administer to an individual who is seven five 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.~~**

**(G) A pharmacist, in accordance with section [4729.41](#) of the Revised code and this rule, may administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.**

(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) 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 primary care provider or, if the individual has no 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;
- (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) For each immunization administered by a pharmacist to an individual who is younger than eighteen years of age, the pharmacist shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.**

~~(L)~~ **(M)** 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, **American safety and health institute**, 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 or electronic hands-on training component.

~~(M)~~ **(N)** 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)~~ **(O)** 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)~~ **(P)** 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, **American safety and health institute**, 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 or electronic hands-on 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) 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.

(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) 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 primary care provider or, if the individual has no 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;
- (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.

**(G) For each immunization administered by a pharmacy intern to an individual who is younger than eighteen years of age, the pharmacy intern shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.**

~~(G)~~ (H) 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.

**Rule 4729:3-3-06 | Immunization administration by certified and registered pharmacy technicians. (AMEND)**

~~(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02, may do any of the following:~~

~~(1) In the case of administer to an individual who is seven five 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.~~

**(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02 of the Administrative Code, may:**

**(1) Administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.**

~~(3) (2)~~ The pharmacist on duty who is supervising the technician may prohibit, limit, or restrict the type of immunizations administered, including the age of the patient, by the technician.

(B) For a certified or registered pharmacy technician to be authorized to engage in the administration of immunizations, comply with all the following requirements:

(1) Complete a practical training program that meets the requirements set forth in paragraph (C) of this rule.

(2) Administer immunizations authorized by a physician-established protocol that meets the requirements of rule 4729:1-3-02 of the Administrative Code.



(3) Be authorized by the supervising pharmacist to administer immunizations. The supervising pharmacist may restrict the type of immunizations provided by a certified or registered technician.

(4) 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, **American safety and health institute**, 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 or electronic hands-on training component.

(5) The pharmacist on duty who is supervising the technician shall be on-site to administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the registered or certified pharmacy technician.

(6) The pharmacist on duty who is supervising the technician determines if the technician is competent to administer immunizations.

(C) A course in the administration of immunizations developed pursuant paragraph (B) of this rule 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 six hours in length and include, at a minimum, the following topic areas:

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

(b) A review of each immunization 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 ~~(8/5/2022)~~ **(6/28/2024)**:

- (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;
  - (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.
- (D) 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.
- (E) The pharmacy employing the technician shall ensure informed consent is obtained pursuant to rule 4729:5-5-04 of the Administrative Code prior to the administration of an immunization.
- (F) The pharmacy employing the technician shall ensure the technician maintains the competency and skills necessary to safely administer immunizations. The pharmacy shall

ensure the technician has initial and annual documented assessment of competency in immunization administration.

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

(H) The pharmacy where a technician is administering immunizations in accordance with this rule shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(I) For each immunization administered to an individual by a certified or registered pharmacy technician, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy employing the technician shall be responsible for ensuring the notification of the individual's primary care provider or, if the individual has no 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) Reporting to the state's immunization registry;
- (7) Documented verbal communication; or
- (8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

**(J) For each immunization administered by a certified pharmacy technician or registered pharmacy technician to an individual who is younger than eighteen years of age, the certified pharmacy technician or registered pharmacy technician shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.**

~~(J)~~ **(K)** The pharmacy employing a certified or registered technician authorized to provide immunizations in accordance with this rule, shall maintain, or have immediate access to, the following records on file at the location(s) where the pharmacy technician administers immunizations in accordance with this rule:

- (1) Proof of successful completion of a training course specified in paragraph (C) of this rule;
- (2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(4) of this rule; and
- (3) Proof of competency assessments as required in paragraph (F) of this rule.

~~(K)~~ **(L)** A pharmacist practicing within an outpatient pharmacy shall not supervise more than three pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.

~~(L)~~ **(M)** A pharmacist supervising an immunization clinic outside of an outpatient pharmacy shall not supervise more than six pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.