



Rules for Stakeholder Comment – Immunizations

Issue Date: 8/21/2024

Comments Due: 9/18/2024

These rules are being proposed to align with the requirements set by [substitute Senate Bill 144](#) of the 135th Ohio General Assembly. In accordance with Chapter 119. of the Revised Code, the Ohio Board of Pharmacy proposes the adoption of the following rules:

Rule Number / Title	Type of Rule Change
Rule 4729:1-3-02 Immunization administration by pharmacists.	Amend
Rule 4729:2-3-03 Immunization administration by pharmacy interns.	Amend
Rule 4729:3-3-06 Immunization administration by certified and registered pharmacy technicians.	Amend

Comments on the proposed rules will be accepted until close of business on **September 18, 2024.**

Please send all comments to the following email address:
isabella.blankenship@pharmacy.ohio.gov.

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;
 - (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.

Amendment Summary: 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 offered by ASHI as a Board-approved program.

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.

Amendment Summary: *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 ASHI as a Board-approved program.*

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 **(6/28/2024)**~~**(8/5/2022)**~~:

(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.

Amendment Summary: *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 ASHI as a Board-approved program.*