

4729:1-3-02**Immunization administration.**

(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 pursuant to paragraph (G) of this rule 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 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) 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.
- (L) 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 or, if the individual has no family physician, 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) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.
- (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 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.
- (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.
- (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.

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CERTIFIED ELECTRONICALLY

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Certification

09/10/2020

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Date

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