



Rules for Stakeholder Feedback – Pharmacy Technician Vaccine Administration (Proposed Rule)

ISSUE DATE: 9/13/2022

The Board proposes the following rule as a **new** rule:

- Rule 4729:3-3-06 – Immunization administration.

Comments on the proposed rule will be accepted until close of business on **October 14, 2022**. Please send all comments to the following email address:

RuleComments@pharmacy.ohio.gov.



Rule 4729:3-3-06 – Immunization administration.

(A) A certified and 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 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; or

(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.

(3) 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 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.

(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 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):

(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) 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 competency assessments as required in paragraph (F) of this rule.

(K) Unless otherwise approved by the Board, a pharmacist shall not supervise more than three pharmacy technicians engaged in the administration of immunizations pursuant to this rule.