Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

Immunizations by Pharmacists and Pharmacy Interns

Updated 6/16/2023

For COVID-19 specific information, please review the following guidance documents:

- Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic
- Administration of COVID-19 Vaccines during the COVID-19 Pandemic

Section 4729.41 of the Ohio Revised Code and rules 4729:1-3-02 & 4729:2-3-03 of the Administrative Code authorize a pharmacist or pharmacy intern working under the direct supervision of a pharmacist to administer, subject to a physician protocol, the following immunizations:

- Any immunization for any disease to individuals 13 years old or older without a prescription.
- Any immunization for any disease to individuals ages 7-12 if there is a prescription for the immunization (except as provided below for COVID-19 vaccines and flu shots).
- FDA-authorized COVID-19 vaccines and flu shots to individuals starting at seven years old without a prescription.

REMEMBER: YOU CANNOT ADMINISTER IMMUNIZATIONS THAT ARE NOT ON YOUR PHYSICIAN-ESTABLISHED PROTOCOL.

NOTE: For each immunization administered, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist or 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. The notice shall be given not later than thirty days after the immunization is administered.

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For questions regarding immunization administration by pharmacists and pharmacy interns, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) How does an Ohio pharmacist or pharmacy intern become authorized to administer immunizations?

A pharmacist or pharmacy intern is required to do all of the following to be authorized to administer immunizations pursuant to Ohio law:

- (1) Successfully complete a course in the administration of immunizations that meets the requirements established in rules by the Board of Pharmacy. Course requirements are listed in paragraph (A) of rule <u>4729:1-3-02</u> of the Ohio Administrative Code.
- (2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course that is certified by the American Red Cross or American Heart Association or approved by the State Board of Pharmacy. See Q9 for more information on this requirement.
- (3) Practice in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician that meets the requirements set forth in rule by the Board of Pharmacy.

Requirements for immunization protocols can be found in paragraph (D) of rule <u>4729:1-3-02</u> of the Ohio Administrative Code.

Q2) Some pharmacy journals include continuing education on vaccines. May I take one of those courses to fulfill my obligations for immunization training?

All training programs must comply with the requirements of paragraph (A) of rule <u>4729:1-3-02</u> of the Ohio Administrative Code.

Q3) Can I administer the rabies vaccine?

Yes, if it is administered in accordance with the physician-authorized protocol.

Q4) Can I administer B12 injections or allergy shots?

The administration of allergy shots by a pharmacist or pharmacy intern is not permitted by law. The administration of B12 injections is permissible. For more information on B12 injections, please visit: www.pharmacy.ohio.gov/injections.

Q5) Am I required to obtain consent from a minor's parent or guardian prior to the administration of an immunization?

Yes. For each immunization administered by a pharmacist or pharmacy intern to an individual younger than eighteen years of age, the pharmacist or a pharmacy intern shall obtain permission from the individual's parent or legal guardian. Informed consent must be obtained pursuant to rule <u>4729:5-5-04</u> of the Administrative Code to administer an immunization.

Q6) What are the record keeping requirements for pharmacist administering immunizations?

Rule <u>4729:5-5-04</u> (I) states that all immunization records must be maintained for three years and shall include the following information:

- (1) Full name and address of the patient;
- (2) Patient's date of birth or age;
- (3) Patient's applicable allergy information;
- (4) Date of administration;
- (5) Name, strength, and dose of the immunization administered;
- (6) Lot number and expiration date of the immunization;
- (7) Route of administration;
- (8) Location of the injection site;

- (9) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;
- (10) Identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer the immunization.

Q7) What are the requirements for a physician-established protocol?

Per rule <u>4729:1-3-02</u> (D), a physician-established protocol for the administration of immunizations shall include the following:

- (1) For each immunization:
- (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 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 under the direct supervision of a pharmacist may engage in the administration of immunizations.

Q8) Can a pharmacy intern that has completed the required immunization training administer immunizations under the direct supervision of a pharmacist who has not completed the required immunization training?

No. A pharmacy intern cannot practice outside of the scope of their supervising pharmacist.

Q9) What basic life-support training courses certified by the American Red Cross or American Heart Association satisfy the requirements of the law?

The Board has determined that a pharmacist or intern may satisfy this training requirement by completing a certified course that either provides CPR & AED training for lay persons or a more advanced basic life-support training course for healthcare providers.

For the American Red Cross: This includes either <u>CPR/AED</u> (note First Aid is not required) or the more advanced <u>Basic Life Support for Healthcare Providers (BLS)</u>.

For the American Heart Association: This includes either <u>Heartsaver® CPR AED</u> or the more advanced <u>Basic Life Support (BLS) for Healthcare Providers</u>.

As a reminder, pharmacists and interns are also required to maintain such certification in order to legally administer immunizations pursuant to the law.

NOTE: A course that offers a blended learning model (offering in-person training and self-directed learning) meets the requirements of the law.

In addition, the Board adopted the following resolution on April 3, 2017:

Recognition of Additional Basic Life Support Training for Immunization Administration (ORC 4729.41) & Administration of Other Injectable Drugs (ORC 4729.45)

The Board hereby recognizes that CPR/AED or Basic Life Support certification provided by American Safety and Health Institute (ASHI) meets the basic-life support training requirements pursuant to sections 4729.41 and 4729.45 of the Revised Code.

Q10) Am I required to follow the Advisory Committee on Immunization Practices (ACIP) recommendations under Ohio law?

While generally encouraged, updates to section 4729.41 (effective 5/13/2021) have removed requirements to adhere to ACIP recommendations. Pharmacists and interns must still comply with the requirements set forth in their physician-established protocol.

REMEMBER: YOU CANNOT ADMINISTER IMMUNIZATIONS THAT ARE NOT ON YOUR PHYSICIAN-ESTABLISHED PROTOCOL.

Q11) Are there any notification requirements?

Yes. For each immunization administered, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist or 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. 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.