

Guidance Document: Immunizations by Pharmacists and Pharmacy Interns

Updated 11-18-2017

Section 4729.41 of the Ohio Revised Code and rule 4729-5-38 of the Administrative Code authorizes a pharmacist or pharmacy intern working under the direct supervision of a pharmacist to administer the following immunizations:

- Any immunization recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) and any immunization specified in rules adopted by the Ohio State Board of Pharmacy (OSBP) to individuals 13 years old or older without a prescription.
- Any immunization recommended by the Advisory Committee on Immunization Practices of the CDC and any immunization specified in rules adopted by the OSBP to individuals between the ages of seven through 12 if there is a prescription for the immunization.
- Flu shots to individuals starting at seven years old without a prescription.

Please 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 family physician or, if the individual has no family physician, 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.

For questions regarding immunization administration by pharmacists and pharmacy interns, please review the following guidance document. 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 has been approved by the OSBP. Course requirements must adhere to section $\frac{4729.41}{1}$ of the Ohio Revised Code and rule $\frac{4729-5-36}{1}$ of the Ohio Administrative Code. See Q3 for more information on approved courses.
- (2) 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 or American Heart Association. See Q17 for more information on this requirement.

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(3) Practice in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician and approved by the OSBP. Protocols are considered approved if they meet the requirements set forth in rule 4729-5-37 of the Ohio Administrative Code.

Q2) Where can I access a list of immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention?

The CDC publishes its recommendations on its web site, which can be accessed here: http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

Q3) Where can I access a list of a Board approved immunization courses?

The Board has recently updated its policy on the approval of immunization courses that no longer requires courses to receive prior approval from the Board.

Board Resolution: Approval of Immunization Courses

Approved 11/14/2017

The Board hereby approves all immunization coursework that meets the requirements set forth in rule 4729-5-36 of the Ohio Administrative Code and waives the submission process set forth in paragraph (B) of the rule. However, the Board does reserve the right to revoke this approval status.

Any coursework requested for review by the Board must be submitted with ten days of the receipt of a written request. Failure to do so, will result in the immediate revocation the course's approval status.

For reference, a list of previously approved courses is still available here: www.pharmacy.ohio.gov/immunizations

Q4) What is the age at which a pharmacist or pharmacy intern may administer the shingles (herpes zoster) vaccination?

The shingles vaccine is recommended by the Advisory Committee on Immunization Practices to reduce the risk of shingles and its associated pain in people 60 years old or older. **HOWEVER**, rule 4729-5-38 permits the administration of the vaccine according to the age criteria specified by the FDA (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm136941.htm).

Q5) 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 rule 4729-5-36.

Q6) The training course I completed did not include all of the immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. What do I need to do prior to administering these additional immunizations?

To address this issue, the Board adopted the following resolution:

Board Resolution: New Immunizations Recommended by ACIP

Approved 11/14/2017

Pharmacists and pharmacy interns seeking to administer any new immunization recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention that was not covered by their initial immunization certification 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:

- (1) Disease states associated with the immunization;
- (2) Type or nature of activity of the immunization;
- (3) Appropriate administration schedules;
- (4) Appropriate routes of administration;
- (5) Appropriate injection sites;
- (6) Appropriate dosages;
- (7) Appropriate monitoring and treatment of the patient for adverse reactions;
- (8) Appropriate patient populations;
- (9) Precautions and contraindications; and
- (10) Proper storage requirements for the immunization.

Failure to adhere to the appropriate standard of care for administration of an immunization may result disciplinary action by the Board.

REMEMBER: EVEN IF YOU ARE TRAINED ON A PARTICULAR IMMUNIZATION, YOU CANNOT ADMINISTER IMMUNIZATIONS THAT ARE NOT ON YOUR PHYSICIAN-ESTABLISHED PROTOCOL.

Q7) Can I administer ACIP recommended immunizations, including those recommended for travel?

Yes. Effective 10/5/2015, OAC 4729-5-38 permits a pharmacist or pharmacy intern to administer <u>any</u> immunization or vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) if administered in accordance with the recommendations adopted by the committee. Please refer to OAC 4729-5-38 for additional information.

Q8) Can I administer the rabies vaccine?

Yes. Effective 10/5/2015, OAC 4729-5-38 authorizes a pharmacist or pharmacy intern to administer the rabies vaccine in accordance with a physician approved protocol under the following conditions:

For Post-Exposure

- 1. A pharmacist or pharmacy intern <u>cannot</u> provide the initial dose of the rabies post-exposure vaccine.
- 2. Follow-up doses shall be administered by the pharmacist or pharmacy intern pursuant to a prescription issued by a prescriber.
- 3. 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.

For Pre-Exposure

The pre-exposure vaccine can be administered by a pharmacist or pharmacy intern in accordance with the recommendations adopted by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

REMEMBER: EVEN IF ACIP RECOMMENDED, YOU CANNOT ADMINISTER IMMUNIZATIONS THAT ARE NOT ON YOUR PHYSICIAN-ESTABLISHED PROTOCOL.

Q9) 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.

Q10) 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.

Q11) How does a pharmacist or pharmacy intern document informed consent from a parent or guardian prior to the administration of an immunization?

Rule 4729-5-27 of the Ohio Administrative Code requires a pharmacist or pharmacy intern to obtain positive identification (such as a wet-ink signature) of the parent or legal guardian of the patient who gives informed consent prior to the administration of an immunization to an individual younger than eighteen years of age. Additional methods of positive identification are defined in rule 4729-5-01 of the Ohio Administrative Code.

Q12) What are the requirements for a Board approved physician established protocol?

The requirements for a Board approved physician-established protocol are listed in rule 4729-5-37 of the Ohio Administrative Code.

Q13) What are the Board's recordkeeping requirements for immunization administration by a pharmacist or pharmacy intern?

The Board's record keeping requirements for immunization administration are listed in paragraph (O) of <u>rule</u> 4729-5-27 of the Ohio Administrative Code.

Q14) 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.

Q15) The ACIP schedule was recently updated to include new vaccines and/or age recommendations. Am I able to administer these vaccinations?

This issue was recently addressed by the Board in the following resolution that was adopted on May 6, 2015:

Section 4729.41 of the Ohio Revised Code authorizes a pharmacist or pharmacy intern to administer any immunization that is included in either the Birth¹-18 Years or Adult Immunization schedules recommended by the Center for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). This section of code only incorporates those immunizations that were listed by the ACIP on the date the law became effective (March 19, 2015).

The Board also has the authority to adopt rules that change the immunizations authorized to reflect changes in the recommendations of the ACIP. It is the intention of the Board that it will update these rules as necessary to incorporate any change to the ACIP recommendations.

The Board recognizes that, due to the nature of the administrative rules process, there will be a delay between a change in the recommended schedules from ACIP and when rule 4729-5-38 of the Ohio Administrative Code is amended to reflect such changes. In an effort to provide clarity and ensure patient access to the recommended immunizations, the Board hereby authorizes pharmacists and pharmacy interns who meet all of the required criteria in law and rule to utilize the most recent version of the two ACIP recommended schedules (Birth-18 Years / Adult).

Licensees should be aware that any failure to meet the necessary requirements for administration of immunizations (physician approved protocols, training, age restrictions, etc.) will be grounds for disciplinary action by the Board. Further, the Board reserves the right to restrict its licensees from

¹ Please note ORC 4729.41 includes the following age restrictions on immunization administration by pharmacists and pharmacy interns: Individuals 13 years old or older without a prescription; individuals between the ages of seven and 12 if there is a prescription for the immunization; and flu shots to individuals starting at seven years old without a prescription.

any ACIP recommendations that it feels may not be appropriate for administration by a pharmacist or pharmacy intern.

Q16) Can I administer immunizations for individuals that do not meet the ACIP age criteria if I have a prescription from a physician?

No. The law and its corresponding rules only permit a pharmacist or pharmacy intern to administer an immunization or vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) if administered *in accordance with the recommendations adopted by the committee*. The only exception to this provision is the zoster vaccine which may be provided in accordance with the age criteria specified in the F.D.A. approved labeling. *Please note ORC 4729.41 includes the following age restrictions on immunization administration by pharmacists and pharmacy interns: Individuals 13 years old or older without a prescription; individuals between the ages of seven and 12 if there is a prescription for the immunization; and flu shots to individuals starting at seven years old without a prescription.*

Q17) 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.

Please 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.